

**Consultation-based Reassurance for Patients with
Musculoskeletal Lower Back Pain Consulting
Orthopaedic Spine Teams**



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‘I’ve learned that people will forget what you said, people will forget what you did, but people will never forget how you made them feel.’

Maya Angelou

DECLARATION OF AUTHORSHIP

I, Kathrin Braeuninger–Weimer, hereby declare that this thesis submission is my own work, and to the best of my knowledge does not represent the work of others, published or unpublished. Where I have consulted the work of others, this is always clearly indicated.

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Date:

ABSTRACT

Research in primary care showed that consultation-based reassurance influences patient outcomes. It is strongly linked to short-term outcomes such as satisfaction, but certain types of reassurance are also associated with long-term outcomes, such as anxiety or further health care utilization. Nonetheless, there is gap in research examining the role of reassurance on people who consult in secondary care. Especially, for patients who are consulting in surgical settings, yet for whom surgery is not indicated as appropriate treatment option. There are several reasons why surgery might be ruled out as treatment, ranging from the resolution of symptoms to the exhaustion of available appropriate treatment options.

To investigate consultation-based reassurance for patients with chronic musculoskeletal lower back pain consulting with orthopaedic spinal care teams for whom surgery is not recommended, a mixed-method design was adopted. Firstly, a qualitative study was conducted with 30 patients who had consulted and been discharged from orthopaedic spinal care. One-to-one interviews were conducted to examine how patients felt about being discharged without further treatment and how they perceived reassurance in their last specialist consultation. Findings indicated that patients felt dismissed and discouraged. Especially when no active treatment was offered, they required specific behaviours from their consultants to feel sufficiently reassured and encouraged to self-manage their condition. Subsequently, a prospective-cohort study (n = 605) was conducted to test the role of consultation-based reassurance on outcomes shortly after the consultation, and at 3- months follow-up.

Findings showed that reassurance was associated with short- and long- term outcomes. Patients who were recommended surgery perceived higher levels of reassurance than those who were discharged or received other treatments. Specifically, after controlling for patients' clinical symptoms and individual differences, and adjusting for their hospital setting and type of practitioner, reassurance significantly and strongly predicted satisfaction, and significantly predicted how enabled patients felt directly after the consultation. In addition, more

perceived cognitive reassurance and (partially) higher levels of perceived generic reassurance were associated with worst outcome in the long- term. Patients who perceived less relationship- building reported more GP visits at 3- months

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CHAPTER 1: MUSCULOSKELETAL LOW BACK PAIN

Definition

Over the years different terms, such as simple-, mechanical-, non-specific-, musculoskeletal lower back pain (MSK LBP), have been used. They aimed to capture the nature of this pain experience which cannot be attributed to a specific disease, pathology, problem, or cause. Although it can be argued that the name ‘non-specific’ is suitable because it defines LBP for what it is; pain that cannot be attributed to a recognizable pathology, or, cannot be attributed to a specific cause, there has also been growing pressure to replace it with an alternative term. From a medical perspective, diagnostic investigations have no role in the management of non-specific LBP (Maher, Underwood, & Buchbinder, 2017), and ‘non-specific LBP’ is more like a label than a diagnosis. Without a diagnosis rationale for treatment is challenging. In the absence of the option of removing the cause of the pain, which remains unknown, the focus lies on symptom fighting only, which implies trying to reduce the pain experience and consequences as much as possible. In addition, the name ‘non-specific’ could be argued to increase patients sense of helplessness since it applies that practitioners have no idea what is happening. Research has shown that laypersons and health care providers alike are less inclined to help, feel less sympathy, dislike patients more, suspect deception and attribute less pain severity to patients who present with non-specific LBP (Penn, Overstreet, Trost, & Goodin, 2019). This may lead to pain-related injustice perception which in turn has been shown to be associated with increased levels of CLBP severity and disability (Penn et al., 2019) and with poorer physical and psychological well-being (De Ruddere & Craig, 2016). The problems related to the name of LBP not only evoked ongoing debates but also lead to a very recent shift in definition, whereby the term ‘non-specific LBP’ has been replaced with ‘musculoskeletal LBP’, which will be used throughout this thesis.

The authors of the Global Burden of Disease (GBD) 2010 study have raised the issue of the substantial heterogeneity in the definitions of low back pain (LBP) throughout the literature, which limits the ability to compare and pool data (Hoy et al., 2010).

With a constant change in the actual name of the terminology of low back pain as well as its case definition, the new 2016 NICE guidelines set clear terms that were to be included or excluded in the scope of the guidelines. All descriptions of LBP from people under 16 year of age, being due to a suspected serious underlying pathology, cancer, trauma, fracture, neurological disorders, adolescent scoliosis, and infection or inflammatory disease (e.g. spondyloarthritis) process, were excluded. Terms like musculoskeletal low back pain, non-specific back pain, mechanical low back pain, simple low back pain, and low back pain with or without sciatica, were included (NICE, 2016). The guidelines refer to non-specific low back pain simply as:

‘pain in the back between the bottom of the rib cage and the buttock creases’ (NICE, 2016, pp.807).

Nevertheless, it could be argued that the GBD used a more explicit case definitions in previous years, which is in line with Dionne et al. (2008) minimal LBP definition that emerged from over 51 identified articles through a consensus approach involving 28 experts in back pain research from 12 countries:

‘Activity-limiting low back pain (\pm pain referred into one or both lower limbs) that last for at least 1 day. The ‘low back’ is defined as the area on the posterior aspect of the body from the lower margin of the twelfth ribs to the lower gluteal folds’ (Hoy et al., 2010, pp. 159).

Traditionally low back pain had no reliable and valid classification system and thus it was given a duration-based classification (Koes, van Tulder, & Thomas, 2006; Carlson & Carlson, 2011), focusing on the duration of the current episode (Kongsted, Kent, Axen, Downie, & Dunn, 2016):

Acute: Low back pain with an abrupt onset lasting less than 6 weeks.

Sub-acute: Low back pain lasting between 6 and 12 weeks.

Chronic: Recurrent and often persisting low back pain lasting longer than 3 months.

However, the old classification system has been challenged due to limitation. Firstly, the ‘chronic’ category is limited in differentiating between a recent flare-up of

recurrent LBP and a recent onset episode experienced for the first time. As a result, patients reporting mild symptoms for more than three months and patients with persistent severe pain are fitted under the same hat: chronic pain. Moreover, in most cases, LBP is an episodic condition and people who have had LBP in the past are likely to have future episodes. Thus, the course of LBP experienced by an individual is not well reflected by an overall population-averaged course (Kongsted et al., 2016). The recognition that LBP is an episodic condition has emerged through a pioneering study into LBP trajectories published by Dunn and Croft in 2006, and the number of subsequent studies. The identification of specific LBP trajectories by those studies underpins the notion that differentiation between acute and chronic LBP was over simplistic and a shift in paradigm focusing on trajectories over time was required (Kongsted et al., 2016). Therefore, the new NICE (2016) guidelines have moved away from the previous duration-based classification and considers acute back pain as experiencing symptoms for less than 3 months. Furthermore, LBP is now considered to be a continuum where the importance of poor outcome is rated as more relevant than the duration of symptoms (NICE, 2016).

Epidemiology and Aetiology

Musculoskeletal LBP is a major health problem worldwide with tremendous humanitarian and financial burden on society. It affects many people and has a negative impact on their work capacity and is coupled with escalating health-care costs. This has an impact on the overall well-being of an individual by frequently resulting in impairment of physical and psychological health and a decline in the performance of social responsibilities including work and family (Manchikanti, Singh, Falco, Benyamin, & Hirsch, 2014). It has been estimated that approximately 60-80% of people will be affected by LBP throughout their lifetime (Truchon, 2001). Nationally, it is reported that around 80% of the population seek healthcare for spinal pain at some point in their lives, and about 5% develop persisting, lower musculoskeletal back pain (National Spinal Taskforce, 2013).

It is by definition, pain without a clear aetiology, hence it is of unknown origin and providing a specific identification of the exact source of pain often impossible (Koes

et al., 2006). In 85% - 95% of all MLBP there is no clear pathoanatomical cause, in which case external factors must be considered (Hoy et al., 2010; Chatterjee, Hemmings, & Laupheimer, 2016). In previous years, experimental studies suggest that LBP originates from several combinations of pathology, such as degenerative changes in the lumbar spine, ligaments, intervertebral discs or facet joints, the paravertebral musculature and fascia, blood vessels, the vertebral periosteum, the annulus fibrosis, spinal nerve roots, and/ or the muscles (Deyo & Weinstein, 2001). It has been argued that the most common cause of LBP are pathological changes in the intervertebral disc (degenerative disease, hernia). Nonetheless, other spine elements such as paraspinal structures may also change pathologically and cause pain (Klekot, Zimny, Czapiga, & Sasiadek, 2012). However, the evidence is inclusive and hence the onset of low back pain remains obscure and diagnosis extremely difficult to make (Deyo & Weinstein, 2001; Chou, Qaseem, Snow, & Casey, 2007).

It has been estimated that in about 5% - 15% LBP symptoms can be traced back to a specific cause (Deyo & Weinstein, 2001; Hoy et al., 2010; Chatterjee, Hemmings, & Laupheimer, 2016). The advance in imaging technology has hugely contributed to the early identification of obvious causes arising from neurological compromise (e.g. neoplasia or fracture) in the past years. Once an obvious cause has been identified the diagnosis of musculoskeletal LBP can be excluded. This advance could be seen as a blessing and a curse. On one side, the new developments in 3D imaging hugely facilitate the diagnosis of MLBP through enabling clear exclusion. On the other hand, it has been argued that the excessive use of imaging results in the emerging of 'overmedicalizing' LBP, with the long noted problem of excessive and rapidly increasing unnecessary use of advanced imaging (Deyo, Mirza, Turner, & Martin, 2009), (more on imaging in Chapter 2 under 'diagnostic tests'). Therefore, musculoskeletal LBP remains a major problem for diagnosis. It also remains one of the most controversial and difficult conditions to manage for clinicians, patients and policy makers (Manchikanti et al., 2014). Regardless, researchers and clinicians in the spine medicine domain perceive it as a well-recognized clinical entity (Protus, 2014), as its global impact is hard to ignore. In the year 1990, 2010 and 2013 the Global Burden of Disease (GBD) study estimated the burden disability of all MSK disorders in 187 countries and 21 regions of the world. They found, when combining

all MSK conditions, they account for 21.3% of total years lived with disability (6.7% when taking into account death) and 23.2% of all mental and behavioral problems, globally (Woolf, 2015). MLBP is the most prevalent condition out of the four (osteoarthritis, rheumatoid arthritis, osteoporosis, LBP) major musculoskeletal disorders (Woolf & Pfleger, 2003). Thus, it is the leading cause of disability in the world (Hoy et al., 2014) and is often a major cause of other mental health problems (Lim et al., 2012; Manchikanti et al., 2014).

Prevalence and incidence rates

Before discussing prevalence and incidence rates of LBP, some limitations of such research are being highlighter to raise awareness to reading and interpreting the following results. Findings such as single summary measures or mean prevalence must be interpreted with caution in the light of the following problems with prevalence research. One, variations in measurement made pooling of data difficult. Prevalence estimates vary depending on the LBP definition (Balague et al., 2012). For example, Ozguler and colleagues (2000) showed LBP risk factors and prevalence (in the previous 6 months) vary according to the definition used. The prevalence was reported as high as 45%, when defined as ‘pain lasting at least a day’, and, as low as 8%, when defined as ‘requiring sick leave’. Moreover, women were more likely to seek care than man and people with previous LBP episodes, especially with more disabling and painful ones were the most frequent care-seekers. Which in turn, may also explain why prevalence in LBP was rated higher for females than males (Hoy et al., 2012; Swain et al., 2014). Second, there are still many LBP cases that go unreported. One reason might be that research assesses a certain number of people in a population with LBP at a certain time point, hence evoking the risk of missing episodes of LBP outside this period. Another potential reason may be that people simply do not seek health care (Maher et al., 2016). A systematic review and meta-analysis of eleven studies found less than 60% of people with LBP seek health care. There may also be a problem with recall bias, especially when relying on self-report from people with chronic LBP, who may end up guessing their lifetime pain experience (Hoy et al., 2012). Third, it has been suggested that incidence (no. of new LBP cases in given time) and prevalence (no. of individuals with LBP at a given

time) should be treated separately and not be compared (Hoy et al., 2010b). Fourth, it may be difficult to pool data between countries. For example, developing countries seem to have higher occurrence rates of chronic LBP, hence when pooled and compared with prevalence data from studies conducted in the Europe, results may show skewed data (Hoy et al., (2012). Considering those methodological limitations, research making conclusions about risk factors or cost analysis, as well as records of consultations may not be relied upon to provide accurate data on the population prevalence of LBP. Regardless, conclusions must always be interpreted with some caution.

There is a wide variation in reported prevalence rates. Prevalence was found highest in Western Europe followed by North Africa/Middle East, and lowest in the Caribbean as well as central Latin America. In Western countries the reported lifetime prevalence varies from 49% to 70% and point prevalence from 12% to 30% (Koes et al., 2006), whereas studies have reported it as high as 84% (Airaksinen et al., 2006). A review of the worldwide (165 studies from 53 countries) prevalence of LBP (Hoy et al., 2012), showed it is a major problem throughout the world (Manchikanti et al., 2014). There was no reported difference in prevalence between rural and urban areas, whereas reported differences in prevalence between high-income countries (median 30.3% [IQR 16.9–46.6]), middle-income (21.4% [10.6–38.6]) and low-income (18.2% [0.8–21.7]) countries (Hoy et al., 2012). After adjusting for methodological variations, it showed a point prevalence of 11.9% \pm 2.0%, a one- month prevalence of around 23.2% \pm 2.9%, a one-year prevalence of 38.0% \pm 19.4% and the lifetime prevalence was around 39.9% \pm 24.3% (Airaksinen et al., 2006; Hoy et al., 2012; Manchikanti et al., 2014). The one-year prevalence was estimated between 15% and 45% and adult incidence 5% (Hoy et al., 2010).

A systematic review (n = 28 studies) estimated the prevalence of chronic LBP according to sex and age, reported the prevalence was 4.2% in individuals aged between 24 and 39 years old and 19.6% in those aged between 20 and 59 (Meucci et al., 2015). Other prevalence studies for chronic LBP estimated prevalence to be around 23% (Airaksinen et al., 2006; Hoy et al., 2012), although the highest rate of chronic LBP prevalence was reported in the Brazilian older population with 25.4%

(Meucci et al., 2015). Overall, the annual prevalence of chronic LBP has been estimated to range from 15% to 45%, with a point prevalence of 30% (Manchikanti et al., 2009). The annual incidence rate for chronic LBP was about 50%, whereas 40.2% of patients were reported to have persistent symptoms annually, with 36.1% showing some improvement and 14.2% suffering with an exacerbation of their symptoms. Epidemiology studies in the United Kingdom (UK) reported the lifetime incidence of LBP to be 58%-84% (Parsons, Ingram, Clarke-Cornwell, & Symmons, 2011), whereas, 16% of women and 11% of men suffer from chronic LBP (Bernstein, Malik, Carville, & Ward, 2017). In 2011, at prevalence study in Japan with data from 65,496 respondents investigated multiple factors associated with chronic disabling LBP. They reported the lifetime prevalence was 83% and 4-week prevalence was 36%. Although the majority of participants had disability-free LBP, they found lower educational level (adjusted odds ratio (aOR): 1.21; 95 % CI: 1.09, 1.34), smoking [aOR: 1.17; 95 % CI: 1.05, 1.30], history of disabling back pain among family members and/or significant others (aOR: 1.46; 95 % CI: 1.27, 1.67), traffic injury (aOR: 2.81; 95 % CI: 2.07, 3.81), occupational LBP (aOR: 1.34; 95 % CI: 1.16, 1.55), advice to rest upon back pain consultation (aOR: 3.84; 95 % CI: 3.36, 4.40), radiating pain (aOR: 4.94; 95 % CI: 4.45, 5.48), compensated work injury (aOR: 2.42; 95 % CI: 1.92, 3.05), and low back surgery (aOR: 10.69; 95 % CI: 9.02, 12.68), were associated with chronic LBP over a lifetime (Fujii & Matsudaira, 2013).

LBP is more common in countries with high-income economies (Hoy et al., 2012). However, it has been argued that socioeconomic background has not been significantly associated with CLBP prevalence (Adamson, Hunt, & Nazareth, 2011). Contradictory, findings from an epidemiology study of United States (US) adults, suggested chronic LBP was association with adjusted odds ratios ($OR_{adj} \geq 2$) included age 50–69 years, annual household income <\$20,000, less than high school education, income from disability, depression, sleep disturbances, and medical comorbidities. The authors concluded that US adults with chronic LBP are socioeconomically disadvantaged, are often covered by government-sponsored health insurance, and make frequent health care visits (OR_{adj} 3.35 [95% CI 2.40–4.67] for ≥ 10 health care visits in the past year; $P < 0.0001$) (Shmagel, Foley, & Ibrahim, 2016).

Age

Musculoskeletal low back pain affects all age groups (Balagué, Mannion, Pellisé, & Cedraschi, 2012; Dunn, Hestbaek, & Cassidy, 2013). Hoy and colleagues (2012) found the highest prevalence among women and people between the age of 40 and 80 years (Manchikanti et al., 2014). The long-held belief that LBP in childhood is rare has been dispelled through reported cases of LBP occurring in children of 8 years of age (Majid & Truumees, 2008). Swain, Henschke, Kamper & Gobina, et al. (2014) looked at LBP in 402406 adolescents from 28 countries. The research yielded approximately 37% (95% CI 36.8-37.1) reported at least one episode a month or even more frequently with an increasing prevalence with age; 27.4% (11- year olds), 37.0% (13-year olds), 46.7% (15-year olds). Furthermore, the review of 56 epidemiological studies found that the prevalence of LBP in teenagers is similar to that in adults (Jeff et al., 2007). However, in this age-group, LBP seems to have little effects on quality of life, unless pain is highly recurrent or present in other locations, or both (Balague et al., 2012). LBP is reported the most frequent activity-limiting complaint in young to middle aged people and more common in people aged 40 to 69 years than any other age groups (Maher, Underwood, & Buchbinder, 2016). Consistently, the data suggested that LBP in childhood predicted LBP in adulthood (Hoy et al., 2010; Maher et al., 2016; Dunn et al., 2013), prevalence increased with age, and peaks in older age groups (Hoy et al., 2012; Hoy et al., 2014). The estimated average age-related prevalence of persisting LBP was about 15% in adults and 27% in elderly (Dionne, Dunn, Croft., 2006). LBP is highly prevalent and invades all walks of life, but its consequences are especially grave for elderly people (Manchikanti et al., 2014). Frequency of severe and reoccurring LBP will rise sharply in the coming years, which presents an additional public health consequence of the aging population in many countries (Dionne, Dunn, Croft., 2006). Moreover, the prevalence and incidence of many musculoskeletal conditions increases with age; this, coupled with the rising retirement age, means that the impact of musculoskeletal pain on the workforce will rise further (Zheltoukhova & Bevan, 2012). Chronic LBP prevalence appears to increase linearly, from the third decade of life on, until 60 years of age and it appears to be more prevalent in women (Meucci, Fassa, & Faria, 2015). The overall prevalence has been reported to have increased 162%, among women aged 21 to 34 it is said to have increased by 320% and among men aged 45

to 54 the increase is estimated to 293%. One of the speculated causes of this rapid increase in LBP prevalence may be due to the increased symptom awareness and reporting, which is increasingly reported to the public through the media and Internet. This lead to LBP being a more prominent part of life over the past decades (Manchikanti et al., 2014).

Work

When LBP leads to loss of production due to frequent sick leave coupled with a high demand of medical services, it displays a huge economic factor. In Germany, back-related disorders are a major cause for receiving disability benefits, with an estimate total annual cost ranging between 16 and 22 billion euros. LBP ranks third, as reason for early retirement and retains the first place as cause for work disability (Schmidt & Kohlmann, 2005). Especially in high income countries, musculoskeletal LBP is the most frequent occupational problem, and reported as the leading cause for time of work absence in most of the world (Hoy et al., 2014). The findings from a study that pooled results from four different meta-analyses suggested pooled incidence of LBP was 26% for both community-based and occupational populations. Furthermore, it suggested that incidence does not differ by occupational/ community-based samples, nor if one is pain free at baseline or first-time incidence. Moreover, there was considerable convergence for these estimates to an incidence proportion of about 25% (Taylor et al., 2014). A summary report of the 2009 NICE guidelines, stated approximately 20% of people are still symptomatic (Parsons et al., 2011) and 3% remain off work a year after an episode of LBP (Bernstein et al., 2017). On average, 80% of patients who received treatment for their acute LBP were able to return to work within 1 month (Von Heymann, Schloemer, Timm, & Muehlbauer, 2013). In Norway, in 2006, almost one in three disability pensions were granted for musculoskeletal disorders (Odeen et al., 2013) and in 2008, musculoskeletal pain was reported to be cause of 35% of sick leave payments (Brage, Ihlebæk, Natvig, & Bruusgaard, 2010). In the UK, musculoskeletal disorders accounted for around 23% of sick certificates (Pincus, Woodcock, & Vogel, 2010). In 2011, LBP was reported to result in the loss of 4.1 million working days (Parsons, Ingram, Clarke-Cornwell, & Symmons, 2011). Persisting long-term MSK LBP in the UK alone is estimated to

be responsible for 11- 13.5% of all-time off work, with each person on average taking about 15.9 days off work, accounting for 3.4 million working days lost in 2015 (NICE, 2016). The Office for National Statistics reported in 2016 that sickness absence due to musculoskeletal pain, especially back pain, resulted in 30.8 million days lost (Comer, 2017).

Occupational LBP are seen in higher proportions in men (Manchikanti et al., 2014). Among those who do seek medical care it makes up 4% of the population that report time off-work due to LBP, which equates for approximately 90 million lost working days (Dunn & Croft, 2004). Per patient per year the days of absence is estimated to be ranging from 9 days in the USA, to 10 days in West Germany, 20 days in Canada and the UK, 25 days in the Netherlands, and 40 days in Sweden (Manchikanti et al., 2014). Although, pain episodes are typically short lived and a rapid improvement of pain and disability can be observed in the first month enabling the return to work, it still has been estimated that 60% to 80% of patients consulting in primary care report continuous pain and disability a year later (Itz, Geurts, van Kleef, & Nelemans, 2013). It has been estimated that persisting LBP accounts for 11–12% of the population being disabled (Airaksinen et al., 2006). About 28% of the US industrial population will experience disabling LBP at some time, 8% of the entire working population will be disabled in any given year, contributing to 40% of all lost work days (Manchikanti et al., 2014). Although there is much concern on people with disabling, chronic LBP, who are no longer able to participate in work, by far not all workers with chronic LBP become work-disabled. Many workers are able to cope with their chronic LBP at work and hence maintain their employment, without consulting a health care professional or seek multidisciplinary rehabilitation. Research focusing on predictors or associations between sick leave and work disability of people with chronic LBP, identified fear avoidance, de-conditioning, pain acceptance, catastrophizing, emotional distress, life control and self-efficacy, as factors (Vries, Reneman, Groothoff, Geertzen, & Brouwer, 2012).

Consultations

Nationally most people will seek healthcare for spinal pain at some point in their lives. It has been estimated that about one-third of the UK adult population is affected by LBP (Potier, Tims, Kilbride, & Rantell, 2015). In the UK, LBP is the second most common symptom related reason, after respiratory problems, for consulting the primary care practitioner (Deyo & Weinstein, 2001), whereas in the US, LBP is the fifth most common reason for all physician visits with approximately one quarter of adults reporting to have experienced LBP that lasts for at least one whole day in the past three months (Deyo et al., 2009). The GP's consultations for LBP per year were estimated between 8 and 12 million (Dunn & Croft, 2004) with about one-quarter (6-9%) of adults seeking consultation with their GP's annually (Dunn & Croft, 2005), which accounts for about 14% of all primary care consultations (Jordan, Kadam, Hwayward, et al., 2010). Considering, about 10% of back episodes lead to consultations with the GP, it was estimated that 90% of those patients improved at 1 month. Although patients may stop seeking care, the majority continue to be symptomatic at 1 year, suggesting only 21-25% completely recovered (pain & disability). Therefore, persistent LBP carries a fluctuating chronic symptom course with intermittent flares (Croft, Macfarlane, Papageorgiou, Thomas, & Silman, 1998).

For most people consulting their GP for an acute episode of LBP they are likely to feel better soon after, whereas patients consulting for CLBP are likely to be persistently troubled over the next months. Data shows that following the initial consultation, about 90% of patients ceased consulting within 3 months again, and most continued to experience LBP and related disability one year after the consultation. Moreover, it was argued that regardless of whether individuals seek medical attention or not, there is no substantial differences in regards to the frequency or intensity of their LBP experience (Balagué, Mannion, Pellisé, & Cedraschi, 2012). This could either mean that the consultation is not worthwhile or that patients feel that there is little help available (Axén & Leboeuf-Yde, 2013). On the other hand, patients are reliant on waiting times or schedules of appointments from their GP's, which could account for the fact that patients stop consulting their GP in the first 3 months (Whitehurst, Bryan, Lewis et al., 2015). Factors such as a

delay in treatment can further lead to chronicity and a third of patients with this condition have predominantly neuropathic pain (National Spinal Taskforce, 2013). Interestingly, data from the US Government Accountability Office in 2008 showed that the cost associated with LBP has increased substantially, whereas the proportion of physician's visits attributed to CLBP has not majorly changed (Balagué et al., 2012). However, for most people, there is no cure that can relieve the pain permanently, and higher levels of pain-related disability are strongly associated with greater usage of healthcare services (Blyth, March, Brnabic, & Cousins, 2004). Patients with persisting long-term LBP often spend many years seeking help from a variety of specialists and sometimes get stuck in a vicious circle of care seeking (Clare, Andiappan, MacNeil, Bunton, & Jarrett, 2013). Although the service provision across the UK is variable, it has been estimated that there is currently only one pain specialist available for every 32,000 people in pain (Donaldson, 2009).

Although the proportion of health-care resources used for LBP is large, only few people actually seek care (Balagué, Mannion, Pellisé, & Cedraschi, 2012; Maher et al., 2016). Research suggested that patients tend to consult later in the course of an LBP episode instead of the very beginning of its onset. A systematic review with meta-analysis, examining 11 population based studies (n= 13 486) and found a pooled prevalence of care-seeking of 58% (95% CI 32–83). Care-seeking was also found to be more common in women, individuals with previous LBP, poor general health, and with more disabling or more painful episodes. Whereas, perceived disability was more strongly associated with care-seeking than pain intensity (Ferreira et al., 2010). This may also explain why LBP has also been reported to be slightly more common in the females than males of all age groups (Hoy et al., 2012; Swain et al., 2014; Maher et al., 2016). Moreover, during pregnancy, back pain appears to be a significant problem and it often continues after delivery (Thorell & Kristiansson, 2012). A Cochrane review showed that more than two-thirds of pregnant women suffered from LBP, whilst, the mean and median prevalence of LBP during pregnancy was estimated to be 45% and 49%, retrospectively (Pennick & Young, 2007).

Cost

The burden of LBP in industrialized countries has been increasing as well as the number of treatment options available (Ferreira et al., 2010). During the second half of the 20th century LBP has become one of the biggest problems for the public health systems not only in the West but also extending worldwide. The financial burden alone includes costs for medical care, employee retraining, administrative expenses and litigation, medical care, indemnity payment and productivity loss (Hoy et al., 2010). There is a variety of sources research turns to in order to gain information about the costs associated with MLBP, such as third-party payers (e.g. health insurance providers), patient self-report, employer records, disability insurers, or government records (Dagenais, Caro, & Haldeman, 2008). However, it is important to always consider it as an estimate, since calculations for costs may originate from unreliable sources.

Recurring, persisting, disabling, long- term MSK LBP is not only of driving force in lost productivity and healthcare utilization, and hence associated with major clinical and economic problems, it is of substantial toll on the afflicted, their loved ones, and thus of detrimental cost for society in general (Croft, Blyth, & van der Windt, 2010). Around 1.6 million people in the UK develop chronic MSK LBP every year and for about half of them the pain is recurring, persisting, and disabling (Donaldson, 2009). Approximately 3-4% of the younger adult population (below 45 years old) and about 5-7% of the older adults (over 45 years old) are chronically disabled by MSK LBP (NICE, 2016). Alone LBP accounts for 11% of total disability in the UK population (NICE, 2016) and LBP was estimated to be over 20% of the UK's total health exposure (Potier et al., 2015). Persisting, disabling MLBP may lead to reduced productivity, time off work, and loss of employment. Over 100 million European citizens suffer from chronic musculoskeletal pain, especially back and upper limb, are the single biggest cause of incapacity for work, accounting for an estimated costs that exceeds 12 billion (Bevan et al., 2009). The Office for National Statistics (2014) reported that almost 31 million days of work were lost, costing the UK economy £14 billion in 2013, due to back, neck and muscle problems.

In the attempts to treat chronic pain, healthcare costs are linked to costs of investigations, primary care and secondary care referrals, interventions including the prescription of analgesics or other drugs such as antidepressants, as well as surgery. For most MLBP patients, invasive procedures are the last resort once all other conservative treatment options have failed (Carlson & Carlson, 2011). Surgery should only be an option for individuals who experience severe or progressive weakness, or when there are signs of cauda equine syndrome, or the patient had no response to adequate trials of non-surgical approaches for at least 4-6 weeks with observed significantly impaired quality of life (Chou, 2011). Indictors for surgery have been argued to be either relative, pain refractory to conservative or minimally invasive options, or absolute, referring to urgent conditions such as progressive neurologic deficits or bowel or bladder dysfunction (Carlson & Carlson, 2011). Although only a small minority of patients suffering from LBP require surgery, rates of surgical procedures are rising, especially for spinal fusion. In England, approximately 10,000 adult patients each year have elective spinal surgery, costing the Nation Health Services (NHS) £200 million per annum. Further, the NHS spends £9 million a year on injections which research evidence has shown to be mostly ineffective (NHS, 2016). The impact on NHS) resources is significant, with half a billion pounds spend annually on medication and estimated £12.3 billion per year for chronic non-malignant back pain alone (Donaldson, 2009). Overall, increasing musculoskeletal conditions are the third most expensive speciality after mental health and cardiology accounting for approximately £10 billion of the NHS's £110 billion budget making (Woolf, Pfleger, & Burden, 2013). In 2016, it was estimated to costs the UK economy 12 billion pound per year (NICE, 2016) and thus seen as NHS research priority (Donaldson, 2009).

Diagnosis

In primary care, the key step for the clinician involves the identification of possible underlying pathologies by using diagnostic classification systems (diagnostic triage). Based on a focused clinical assessment, patients are classified into three broad categories; 1.) having specific pathology, 2.) radicular syndrome (e.g. nerve root pathology including spinal canal stenosis), and 3.) MLBP. Subsequently,

management recommendations are directed according to the patients classification to one of the three categories (Bardin, King, & Maher, 2017). In essence, the MLBP diagnosis is based on the exclusion of the other two categories, specific pathologies, or non-spinal causes (Carlson & Carlson, 2011; Bardin, King, & Maher, 2017). Thus, the initial step is to recognise underlying spinal pathology problems or nerve root problems, the so called 'red flags' (e.g. tumour, infection, fracture, age of onset <20 or >55 years, trauma, unexplained weight loss or wide-spread neurological changes, etc.) (Koes et al., 2010). In primary care, LBP is occasionally the initial symptom of a number of more serious specific spinal pathologies, of which the most common is vertebral fracture. The next step is to recognise radicular syndrome, which involves a focused history and clinical examination. There are clinical features that distinguish three subsets of nerve root involvement; radicular pain (or sciatica), radiculopathy, and spinal stenosis. The source of the clinical features lies in facet joint cysts, osteophytes, disc herniations, spondylolisthesis and acquired or degenerative canal stenosis. Whereas, some severe problems demand urgent management, such as spinal tumours that may result in deterioration of radicular syndrome as well as crossover to cauda equine syndrome (Bardin et al., 2017). As soon as the first two categories are ruled out, the patient may be considered as having musculoskeletal low back pain and further imaging should only be indicated for patients with 'red flag' conditions (Koes et al., 2006; Bardin, King, & Maher, 2017).

Musculoskeletal low back pain is of unknown origin hence symptoms are defined as predominantly non-traumatic and without clear aetiology. This is supported by studies showing no strong association between anatomical abnormalities in x-ray and magnetic resonance imaging and LBP. Moreover, imaging data showed that finding abnormalities was equally common with people with no back pain as people with MLBP (Koes et al., 2006). The diagnosis of specific LBP, on the other hand, requires symptoms that are caused by a specific pathophysiological mechanism, such as rheumatoid arthritis, fracture, tumour, infections, hernia nuclei pulposi, or osteoporosis. The exclusion of a specific pathology and the differential diagnosis of radicular syndrome is complex and guidelines definitions seldom match the high variability of manifestations seen in clinical practice (Bardin et al., 2017). In 2006, it was estimated that 85% to 90% of LBP patients, were diagnosed with MLBP (Deyo & Weinstein, 2001; Koes et al., 2006). A more recent study showed more than 1%

patients are diagnosed with specific spinal pathology, around 5% to 10% patients diagnosed with radicular syndrome (e.g. nerve root pathologies) and 90% to 95% patients diagnosed with MLBP (Koes et al., 2010). Thus, the vast majority of patients, will have MLBP with no identifiable cause, which means most LBP patients do not receive a clear diagnosis for their pain. This may conflict with patients' expectations of an exact diagnosis, specific treatment, prognosis, and relief of pain. Failure to provide patients with this model may result in them believing their symptoms are doubted by the health care professionals, and hence their symptoms have not been given legitimacy (Mounce, 2002). Research findings show an uncertain aetiology discourages patients, which in turn is associated with the reoccurrence of symptoms (Carlson & Carlson, 2011). The lack of aetiology is not only highly frustrating but also affects peoples' mental and emotional wellbeing, which contributes to their physical function and overall impairment (Carlson & Carlson, 2011).

The diagnosis of persisting musculoskeletal LBP is more complicated than that. Chronic pain is of complex nature and associated with multiple different factors. Psychosocial factors are one of the most evident indicators for developing chronicity, which are classified under 'yellow flags', affecting emotional and behavioural factors (Potier et al., 2015). For example, those of psychosocial dimensions (e.g. pain behaviour, or appraisal) explain how people respond to LBP (Balague et al., 2012). The 'yellow flag' assessment tool has been developed to help assess patients who are not improving (Mounce, 2002). Beyond, the flag' system has expanded with the understanding that LBP's prognostic factors are of multiple components and origins. For example, 'yellow flags' (psychological), black flags (workplace organizational and environment), and blue flags (attitudes and perceptions of the workplace) (Hayden et al., 2010). The final diagnostic category should be based on pain behaviour, functional status or disability, clinical signs, and pain distribution (Wittenauer, Smith, & Aden, 2013).

It has been argued that the diagnosis of MLBP is complicated because there is no standardized approach by the physicians in their clinical decision making process, which leads to wide variations in care (Deyo & Weinstein, 2001). Healthcare professionals learn and practice examination skills within varying concepts of care,

which is mostly relevant to their branch of medicine or therapy. Therefore, it is not expected that they necessarily find an agreement in the clinical findings or the importance of those findings across these different paradigms of care. However, variations in inter-observer and intra-observer variability can be improved with training as well as experience (NICE, 2016). Additionally, it has been argued that clinical guidelines vary in the wealth of information they produce which potentially leads to very different recommendations and care. On the contrary, a review of clinical guidelines from 11 countries concluded that they provide generally similar recommendations regarding the diagnostic triage (MLBP, radicular syndrome, specific pathology). The most consistent features for MLBP between the guidelines was the recognition that psychological factors must be considered as risk factors for chronicity, the restricted use of imaging, and the early activation of patients whereas discouraging bed rest (Koes et al., 2010). Once serious pathology has been excluded, patients need to start participating in their recovery process by developing ways of coping with pain and impairment on a long-term basis (Mounce, 2002). Overall, the aim should be to achieve an early tenable diagnosis followed by a comprehensive (holistic & proactive) treatment for back pain, whilst it is still a sub-acute phase, which in turn may lessen a long-term negative impact and improve the patient-practitioner relationship, as well as avoid excessive costs and complications for secondary care (Froud et al., 2014).

Risk Factors for developing MLBP

MLBP is a multifactorial disorder with many possible aetiology (Manchikanti et al., 2014). It cannot definitely be traced back to physical structures in the back, hence other causes such as demographic, psychological, general characteristics, or work-related factors, which may lead to the development of LBP, are considered instead. Perceiving LBP as a multifaceted disease has emerged with the biopsychosocial model which indicates that biomedical, psychological and social factors are involved and should be considered in MLBP (Dunn et al., 2013). Consequently, to dissect this 20th-century health-care enigma and to analyse the various risk factors, epidemiologic studies have focused on occupational, non-occupational, and psychosocial risk factors (Manchikanti et al., 2014).

Primary prevention, informed by research that identifies predictive risk factors, aims to reduce first-time LBP. Longitudinal studies have been extremely helpful in informing primary care intervention programs of predictive risk factors for first-time LBP whereas cross-sectional studies looking at prevalence estimates and factors associated with prolonged pain and disability are less helpful for the design of prevention programmes. Coenen and colleagues (2014) systematically reviewed the literature of eight longitudinal studies and meta-analysed the slope of associations between lifting during work (quantified in duration, frequency or intensity) on the incidence of LBP. They found that weight of the load (OR 1.11 [95% CL 1.05–1.18] per 10kg lifted) as well as the number of lifts (OR 1.09 [95% CL 1.03–1.15] per 10 lifts per day) had increased the risk of LBP incidence, whereas they were unable to pool the data for the duration of lifting. It was concluded that compared to incidence of LBP without being exposed to lifting, lifting loads over 25kg and lifting over 25 times a day may increase the annual incidence of LBP by 4.32% and 3.50%, respectively. Thus, the intensity and frequency of lifting significantly predicted the occurrence of LBP within a working population. In terms lifestyle factors, a meta-analysis (n = 40 studies) assessed the association between LBP occurrence and smoking. They found a modest association between smoking as a significant risk factor for incidence of LBP (OR 1.30 [95% CI 1.16–1.45]). When compared to people who never smoked, prevalence and incidence of LBP was higher for both current (OR 1.31 [95% CL 1.11-1.55) and former (OR 1.32 [95% CI 0.99-1.77]) smokers (Shiri, Karppinen, & Leino-Arjas, et al., 2010a). Furthermore, a meta-analysis of 33 studies found that compared to non-overweight people, obesity (OR 1.53 [95% CL 1.22–1.92]) was associated increased incidence prevalence of LBP in the past 12-months (Shiri et al., 2010b). Lastly, a systematic review with meta-analysis (n = 19) found depressive symptoms (OR 1.59 [95% CL 1.26–2.01]) as a factor contributing to the development of LBP, whereas this was noted to become higher in patients with more severe levels of depression (Pinheiro et al., 2015).

One major problem when evaluating research is the variation in definition of LBP, making pooling data and comparison difficult. Taylor, Goode, George, and Cook (2014) studied risk factors for LBP including two different definitions: first incidence LBP or the initial transition to LBP from a pain-free state. In their systematic review and meta-analysis, they included 41 studies in 4 different

population groups (community-dwelling first-time LBP, occupational-based first-time LBP, community-dwelling recurrent LBP, and occupational-based recurrent LBP). They found that there was considerable convergence in incidence rates in the two (community & occupational) conditions, regardless of the LBP definition, with a meta-analytical estimate of about 25% in incidence proportion. Furthermore, multiple diverse psychological (e.g. mental distress and depression) and physical risk factors (e.g. frequent moving or lifting >25lbs and standing or walking >2h per day) were identified for both definitions, whereas no consistent risk factor was found for first-time LBP. For transition to LBP from a pain-free state, the previous history of LBP was the most consistent risk factor. Notwithstanding, causal links are hard to determine and findings may be limited, because considerable heterogeneity in variety of studies, research method, and sample sizes makes pooling of data ambitious.

In summary, risk factors include history of LBP injuries, physical activity (e.g. heavy lifting, repetitive lifting, twisting and vibration including driving), smoking, obesity/physical fitness, static work postures, prolonged standing or walking, road traffic accidents, and falls (Mounce, 2002). The most consistent predictor for transition to LBP from a baseline of pain-free state was the previous history of back pain (Mounce, 2002; Schmidt & Kohlmann, 2005; Taylor, Goode, George, & Cook, 2014b). A number of authors have highlighted the role of psychological distress in the development of LBP, including factors such as anxiety, depression, catastrophizing, kinesophobia referring to fear of movement, and somatization referring to the expression of distress as physical symptoms or their persistence (Hasenbring, Rusu, & Turk, 2012; Linton, 2000; Manchikanti et al., 2014; Mounce, 2002; Pincus & Mccracken, 2013; Schmidt & Kohlmann, 2005). Implementation of clinical interventions that successfully target psychological risk factors have been reported (Pincus, Burton, Vigel et al., 2002). Thus, effective early intervention programmes for LBP are key to decreasing the likelihood of developing chronicity as well as achieving a rapid and sustained recovery (Potier et al., 2015). Contradictory, it has been argued that at present there is only mixed effectiveness regarding targeting modifiable physical, occupational, and psychological risk factors for LBP (Taylor et al., 2014b).

Recurrence

Following a new episode, the pain is typically mild, short-lived, and rarely disabling with patients recover within a few weeks. For a patient experiencing an acute episode with the shortest time since LBP onset, prognosis is favourable; claiming that about 75- 90% of patients will recover within 6 weeks of seeking health care (Van Tulder et al., 2006; Grotle, Brox, Veierod, et al., 2005; Coste, Lefrancois, Guillemin, & Pouchot, 2004; Henschke et al., 2008), whereas for others the pain does not resolve within the first 4-6 weeks (Koes et al., 2010). This not only shows substantial variability in outcome, but more so the claim of 90% of acute LBP episodes resolving spontaneously in the first month is inconclusive. It might reflect reality when looking at short-term ‘recovery’ (e.g. return to work) in LBP but not when taking a long-term perspective. The rather confusing literature in this area makes it difficult to arrive at a consensus, because there is considerable variability, regarding the exact definitions of LBP (da Silva et al., 2017; Hestbaek, Leboeuf-Yde, & Manniche, 2003). Especially in regards to the outcome measures (e.g. definition of recovery or reoccurrence), they are measured through different parameters over different time periods (Pincus et al., 2002). For example, originally it was suggested that reduced activities, bed rest and days off-work are measures for ‘disability’, but later updates renamed the domain to ‘work disability’ shifting the focus more to using number of days off work, number of days cut-of work, and the overall time for return-to-work (Froud et al., 2014). However, there is evidence that reoccurrence is one of the main characteristics of MLBP, affecting millions of people (Chou, Qaseem, Owens, & Shekelle, 2011). One year after an acute episode one third of patients’ report persisting pain of at least moderate intensity 6-12 months after a consultation, and 1 out of 5 people experience substantial limitations in activity (Henschke et al., 2008).

In previous years LBP was considered to be a self-limiting condition that can be compared to a common cold. However, research in the past two decades has shown that LBP is a highly recurrent condition (Dunn, Hestbaek, & Cassidy, 2013), for most people this would mean persisting pain and associated disability for months. A systematic review of 36 articles aimed to investigate the long-term course of LBP incident and prevalent cases. It was found that approximately 62% of patients

continued to have pain a year after consultation, about 16% who were initially off work were still sick-listed after 6 months, approximately 60% experienced relapses of pain, about 33% had relapses of work absence (Hestbaek Leboeuf-Yde, & Manniche, 2003). Despite the large heterogeneity, this study shows that LBP is not a short-term condition that achieves quick and long-lasting improvements. In recent years, this has been confirmed by studies of LBP trajectory patterns (pattern of changes in pain over time). A summary of the current knowledge on LBP trajectory patterns concluded that trajectory patterns have consistently shown that the course of LBP is not optimally captured by average of the overall population. Most research uses a single time-point outcome, which in light of LBP being of episodic nature, is not an optimal measure. Whereas, some distinct trajectory patterns identified across different cohorts and setting may better reflect the individuals' course of LBP. For most patients those trajectories have clearly illustrated that LBP is not a condition from which one recovers rapidly nor develop chronic severe pain. Instead, it is a potentially life-long condition of persisting and highly fluctuating pain of low or medium intensity (Kongsted et al., 2016). In support, where the findings from a long-term (7 year) trajectories of LBP study, suggested that unlike previous notions assuming LBP has a prevailing pattern of recurrent or fluctuating pain, people tend to remain in a particular pain trajectory, with similar characteristics, when estimated in two periods at the beginning and end of the 7-year period. Widely fluctuating pain did not seem to be common, which suggests people either recover quickly and maintain very low (or no) pain, or they tend to have persistently high levels of pain. These findings suggested there are no phases or degeneration in the course of LBP over time, instead people seem to have pain patterns varying slightly around their own mean long-term pain (Dunn, Campbell, & Jordan, 2013). Furthermore, in terms of investigating the risk of recurrence, a recent systematic review aimed to examine the risk and prognostic factors for, a recurrence of LBP in patients who have recovered from a previous episode within the last year. The review included 8 studies, however, did not conduct a meta-analysis due to the small number, generally poor methodological quality, heterogeneity of existing studies. They concluded that expect in 2 included studies suggesting a history of previous episodes of LBP prior to the most recent one was the only consistent predictor, it was not possible to obtain robust estimates of the risk of LBP recurrence or prognostic for LBP recurrence at

this point in time. Authors call for a urgent need for high-quality inception cohort studies investigating risk factors of LBP recurrence (da Silva et al., 2017).

In conclusion, chronic LBP is a highly reoccurring and an extremely persisting disorder, that can be understood as a chain of related episodes that may stretch over a very long period of time. Nonetheless, it has been argued that only a small proportion of patients actually remain severely disabled (Koes et al., 2006). Therefore, LBP is now more commonly perceived as a life-long condition (Dunn, Hestbaek, & Cassidy, 2013; Axén & Leboeuf-Yde, 2013), which is comparable to diabetes instead of a self-limiting condition, like a common cold. Moreover, it can be perceived as an always present underlying ‘trait’, perhaps with different causes and modifying factors as life goes on, but certainly much more of a lifelong process than previously thought (Axén & Leboeuf-Yde, 2013). Similar to a diabetic, who experiences symptoms of either hypoglycaemia or hyperglycaemia, likewise, LBP patients experiences different episodes of pain. However, with diabetes, the cause of such complications is mostly known (imbalance of blood glucose levels), therefore preventing reoccurrence can be targeted enabling people to take self-control in effectively managing their condition. Whereas, for LBP factors that evoke another episode, or factors determining the transitioning from acute to chronic pain are unknown, and thus it is unclear how to prevent reoccurrence in LBP. In both conditions, certain procedures that help managing the situation (e.g. insulin for diabetes or physiotherapy for LBP) are well known and expanding in development, providing hope that cure may be found one day. This means that people need to accept that their condition is of life-long cause and focus on acquiring the best set of skills that helps managing it. On the other hand, research determining factors predictive of reoccurrence as well as developing and evaluating interventions that aim to prevent chronicity at an early stage, is of utmost importance in the future.

Risk for transition from acute to chronic

An overview of Cochrane reviews reasoned chronic pain is defined as pain lasting beyond the normal tissue healing time (12 weeks). It has a mean prevalence in adults of 20%, and contributes to poor quality of life, disability, sleep disturbances, anxiety,

depression, and healthcare costs (Geneen et al., 2017). It has been estimated that even after having received treatment, approximately 7% of patients develop chronic LBP, whereas, patient without treatment develop persistent and recurrent LBP in 60% (Hestbaek et al., 2003). Therefore, appropriate treatment seems to be essential to avoid chronic pain (Von Heymann et al., 2013). These small numbers of people use the majority of the financial and health-care resources, therefore, most economic and social costs can be attributed primarily with chronic LBP with prolonged disability (Mounce, 2002). Frymoyer and Cats-Baril (1991) reported LBP disability accounting for more than 75% of the costs that are associated with LBP. Thus, it is crucial to understand which factors determine the transition from acute to chronic LBP and use those which are modifiable to inform interventions and/or treatments.

Individual, psychosocial, social, biological, and occupational associated factors should be taken into consideration when trying to grasp the complex transitioning from acute to chronic low back pain (Manchikanti et al., 2014). Risk factors for chronicity may include low levels of physical activity, high levels of psychological distress in the episode, premorbid dissatisfaction with employment or work status, unemployment, and poor self-related health (Mounce, 2002). Furthermore, Hestbaek, Leboeuf-Yde, and Manniche (2003)'s review findings suggested that the mean prevalence of LBP in cases with previous episodes was approximately 56% (range 14 to 93%) compared to about 22% (range 7 to 39%) for those who had no prior history of LBP. Regardless of the high fluctuation in prevalence rates, the risk of chronic LBP was consistently about twice as high for patients with a history (at least 1 previous episode) of LBP. Nonetheless, biopsychosocial factors seem to be the biggest indicators for individuals developing chronicity (Potier et al., 2015).

In adult life, potential determinants, such as occupational factors and psychosocial factors in adulthood, have received considerable attention. However, it has been recognised that chronic pain is not simply a phenomenon that occurs in adulthood, but which is present, although less commonly, in children, adolescents, and young adults. Thus, applying risk factors occurring later in life is problematic and the role of contributing factors earlier in life must be contemplated (Mallen, Peat, Thomas, & Croft, 2006). For example, research suggested that psychological factors are more

important than mechanical factors for children with LBP (Watson, Papageorgiou, & Jones et al., 2002).

Findings from a review of prospective studies ($n = 37$) examining the relationship between psychological variables and back and neck pain, indicated stress, mood, emotions, cognitive functioning, pain behaviour, distress or anxiety were all found to be significant factors. Whereas, personality factors produced mixed results, abuse was also found to be a potentially significant factor. Authors summarised that psychological factors play a significant role not only in the transition to chronic problems but also in maintaining chronic pain (Linton, 2000). All guidelines have now consistently recognised that psychological factors are a risk factor for chronicity (Koes et al., 2010). Psychological risk factors, referred to as ‘yellow flag’, for chronic symptoms and disability have been developed as part of the assessment for patients who are not improving. Whilst not exclusive to physical risk factors, they were designed to identify people who need a different approach in preventing illness behaviour, fear avoidance behaviours and prolonged distress (Mounce, 2002). They have originally been used as prognostic factors for the development of LBP, and the identification through early screening was expected to prompt interventions to achieve secondary prevention. Nevertheless, it has been argued that the conceptualization of ‘yellow flags’ is too broad. It should be differentiated primarily to psychological risk factors and have different categories for social and environmental risk factors for transition to chronic LBP (Nicholas, Linton, Watson, & Main, 2011). Pincus, Burton, Vogel, and Field (2002) systematically reviewed ($n = 6$) the evidence of psychological factors in the transitioning from an acute to chronic LBP. Findings revealed that psychological factors, specific to depression/low mood ($d = 0.4$) had a moderate effect on the transition to chronicity compared to clinical factors. Further, distress and somatization were most associated with the progression from and acute to chronic LBP, whereas cognitive factors such as fear-avoidance and catastrophizing were not associated with chronicity. However, this was mainly due to the unacceptable quality ratings of the studies which were measuring these cognitive factors. Authors call for more prospective studies to disentangle the various psychological parameters (fear avoidance and catastrophizing) involved in the transitioning to chronic LBP. Nevertheless, the evidence presented is sufficient to justify clinical trials for interventions that address

somatization and distress as predictor variables in the prevention of transitioning to chronic pain. Evidence suggested that patients who were identified with ‘yellow flags’ and who had their psychological factors addressed, seemed to have better outcomes compared to patients who had those factors ignored (Ferreira et al., 2010). Lastly, secondary prevention programs (e.g. reassurance as intervention) should be aimed to modify risk factors predictive of the LBP onset in order to reduce reoccurring LBP, instead of exclusively focusing on the optimizing of rehabilitation techniques. The main challenge is the early identification of patients at risk for chronicity and subsequently preventing the chronicity from occurring (Koes et al., 2006).

Although prognosis studies provide guidance for understanding when LBP is likely to transition from acute to chronic, this guidance must yet be taken with great caution since determining what really happens in between the initial consultation and follow-up at a later time point is more complex and reliant on a number of different factors. Therefore, it can be argued that the prognosis of chronic LBP is yet uncertain, which might be due to the struggles of obtaining a representative cohort. One reason being that prognosis studies were based on studies with a large loss of follow-up or unrepresentative survival cohorts. Thus, it has been suggested that one option of an optimal design may be to recruit a sample from a population at risk of developing chronic LBP, followed by the identification of an inception cohort from incident cases (Costa et al., 2009). Researchers conducted an inception cohort study in Sydney with the aim to identify prognostic markers at the onset of chronicity and describe the course of chronic LBP. The study sample where a big sub-cohort (973 consecutive patients with acute LBP presented to primary care) and those whose pain persisted for three months ($n = 406$) were used to form the inception cohort. Outcome and putative predictor measures were taken at the initial presentation to primary care, onset of chronicity (study entry), and follow-up at 9 and 12 months. Recovery in this study was defined through measures of pain intensity, work status and disability. They found of the participants ($n = 259$) who had not recovered from pain related disability at study entry, 47% had recovered by 12 months. Furthermore, high levels of disability, high pain intensity, previous sick leave due to LBP, low levels of education, greater perceived risk of persisting pain and being born outside Australia were associated with delayed recovery from pain.

Considering the aforementioned difficulty with prognosis studies, future research should be conducted with repeated measures of LBP and associated disability at multiple different time points over a long period of time instead of measuring outcome at a single point in time. This may add to the understanding of the course of LBP, by gathering information about where and why the impact of factors change over time (Hayden, Dunn, van der Windt, & Shaw, 2010). This is especially important when acknowledging the shift in paradigm that regards LBP as a chain of LBP episodes with focus on its course. In the past, LBP was thought of as a single entity with an ‘end point’, hence researched measured ‘recovery’ or ‘return to work’ at a rather arbitrarily chosen point in time. However, in reality LBP patients experience very irregular pain episodes that appear and disappear with varying intensity and duration. In other words, chances are high that different studies used different ‘cut-of points’, which makes it likely that LBP was captured at different phases of the condition. Thus, it has been argued that comparisons between people and studies are potentially meaningless (Axén & Leboeuf-Yde, 2013). Looking at the huge technical advance, a more realistic solution to collect frequent data at the ‘right’ time may be achieved by using online diary systems accompanied by online surveys that have constant reminders. However, perusing into the technological direction also poses problems such as requiring respondents to constantly use and have access to the internet, which might be especially problematic for the older generations.

Risk Factors predicting poor outcome or delayed improvement

Regardless of whether it is acute or chronic LBP, it can lead to functional limitation and disability, remaining a prominent complaint for people who seek health care (Taylor et al., 20014). However, the longer people who develop chronic low back pain experience the persisting problem, the less likely is recovery (Koes et al., 2006). This shift in paradigm, recognising MLBP as an episodic condition, has directed the focus of attention away from perceiving LBP as a single entity towards acknowledging the course of it to be more complex. One frequently asked question by patients with LBP is: ‘Is my pain going to get better?’. In this context, prognosis may refer to the probable prediction of the outcome of LBP over time. Thus, research aiming to identify factors that may affect patient’s outcome use follow-up studies of

health-care seeking at a single time point (e.g. baseline consultation LBP and 1 year later).

Health professionals are faced with the challenge and frustration of assessing people with MLBP, who may not always have apparent or organic causes. It has been argued that the lack of a clear biomedical model is making it even more problematic for patients and clinicians to legitimize the pain as well as a direct initial treatment decisions (Hill et al., 2008). The most recent literature accepts the biopsychosocial nature of CMLBP and acknowledges that it is affected by a complex interplay of genetic, physical, psychological, environmental, cultural, and societal factors (Balagué et al., 2012). Psychosocial factors are associated with the risk of chronicity (Linton, 2000; Pincus, Burton, Vogel, & Field, 2002), the maintenance of it (Edwards, Dworkin, Sullivan, Turk, & Wasan, 2016) and linked to poor outcomes (Keeley et al., 2008; Pincus & Mccracken, 2013). A review of evidence of the biopsychosocial model of LBP suggesting that it is not the biopsychosocial framework that fails to explain back pain, but research and clinical practice that only restrictively understood and applied it (Pincus, Kent, et al., 2013). The NICE (2016) guidelines listed some recognized risk factors that may make patients more likely to suffer from chronic disabling LBP. These include demographic and physical factors (e.g. being female, older age and leg pain), psychological factors (e.g. negative beliefs and behaviours, passive attitude towards treatment, depression and anxiety), and social factors (e.g. poor work environment, job dissatisfaction, unhelpful social support). Psychological risk factors have been traditionally conceptualised as obstacles to recovery and have been referred to as yellow flags (Kendall, 1997; Nicholas, Linton, Watson, Main, 2011), yet they are not completely understood, nor is the transition of their use to the clinic straight forward (Linton & Shaw, 2011). Psychological factors, which include mood, related beliefs and behaviours, have an important role in the experience of MLBP (Pincus, Vogel, Burton, Santos, & Field, 2006), and increasingly considered as promising targets for clinical management. However, psychological factors may also be considered as barriers to communication, suggesting that factors such as anxiety can influence how reassurance is perceived (Linton et al., 2008). The results of a prospective cohort study suggest that patients with low and high psychosocial risk may require different reassurance techniques (Holt et al., 2018). However, the assessment of psychosocial

factors remains challenging. Research to date has not only failed to identify any combination of well-defined psychological risk factors but also failed to identify any intervention, focusing on psychological factors, which significantly reduce risk in a cohort of patients (Ramond-Roquin et al., 2015). Any single factor might explain only a very small fraction of the variability observed in any cohort, however, it can be of major importance for a certain patient. Important factors might vary considerably from one person to another, as well as vary from one period of time to another for a given patient. MLBP may be related to individual or even intimate difficulties rather than collective issues and especially for chronic MLBP it appears that there is a variable combination of multidimensional factors that interact with various problems (Ramond-Roquin et al., 2015). The effects of a psychological factor may also be modified by other risk factors which are more amenable to alteration (Vargas-Prada & Coggon, 2015). For example, pain catastrophizing and heightened depressed mood have an additive and adverse effect on the impact of pain and limit pain treatment outcomes, relative to either alone (Linton et al., 2011). It might be that some people are generally more aware of symptoms, and predisposed to report them. It is also possible that individuals who experience low mood inhibit their own recovery because they tend to worry more about their health, give more attention to pain, and as a consequence are more inclined to avoid activities that exacerbate their symptoms. Although it is well established that psychological factors are important determinants of persistent MLBP, the pathways of interactions have yet to be fully elucidated (Vargas-Prada & Coggon, 2015). For example, factors such as fear avoidance has been criticised for its conceptual clarity in that measures failed to distinguish between fear of movement, fear of exercise, and beliefs about damage (Pincus, Smeets, Simmonds, & Sullivan, 2010). In addition, there is contradictory evidence about the associations between fear avoidance and subsequent long term outcomes in people with MLBP (Pincus et al., 2006). Finally, research has often focused on single factors, but psychological factors share much of their variance, thus, there is also lack of clarity of the unique and shared aspects of different concepts and their measurement (Linton & Halldén, 1998; Linton & Boersma, 2003).

With this in mind, several risk assessment tools have been developed with the aim to support the clinical decision-making process. The tools are designed to identify modifiable biopsychosocial (social, psychological, biomedical) risk factors that have

the potential to predict delayed improvement or poor outcome. This is not only useful for counselling, planning, managing and monitoring patient's LBP but also useful to inform the patients themselves more specifically about their likely outcome (Hayden et al., 2010). Based on the outcome of those recognized prognostic indicators people are divided into subgroups. Those stratified care strategies not only develop a broad understanding of the special needs in treatment but further generate optimal treatment pathways with an optimized chance of a good outcome for the patient (Pincus et al., 2013). Even though this is the optimal aim, matching treatment to patients needs is not always as straight forward as it seems. A literature review, including 16 studies with 11 different validated risk assessment tools, aimed to assesses the most accurate one tool for identifying people with LBP at risk of poor outcome or delayed improvement (NICE, 2016). It was found that the Start Back screening tool (Hill et al., 2008) had sufficient evidence and levels of discrimination and calibration to consider it as reasonably useful in assessing functional outcome. Additionally, it is considered as being feasible to use in a clinical setting as it is not time consuming to complete. In conclusion, it was the only risk assessment tool that the Guideline Development Group (GDG) warranted a recommendation. The Start Back screening tool is not designed for an individual purpose (e.g. occupational setting), but developed to identify prognostic indicators (physical & psychological) relevant to allocate and prioritize treatment for the entire spectrum of patients with MSK LBP presented to primary care (Hill et al., 2008). The questionnaire assesses the risk of a person developing persistent back-pain related disability. This questionnaire consists of nine items measuring: radiating leg pain, comorbid pain (shoulder or neck), disability (walking & self-care), low mood, bothersomeness, fear, anxiety, and pessimistic patient expectations. An overall score (0-9) and a psychosocial subscale score (0-5) is calculated to divide patients into three categories:

Low Risk group (overall score 0-3): few negative prognostic indicators are present.

Medium Risk group (overall score >3, psychosocial subscale score <4): physical and psychosocial prognostic indicators are present but not a high level of psychosocial factors.

High Risk group (overall score ≥ 4): a high number of psychosocial prognostic indicators are present with or without physical factors.

Patients who experience changing symptoms should be examined and reviewed to potentially consider alternative diagnoses. Once the possibility of a serious underlying pathology is eliminated, and stratification tools, such as the StartBack, were administered to inform on the risk profile of the patient, treatment options should be discussed (Bernstein et al., 2017). Matching treatments through stratified care is more cost-effective than usual care for complex patients (high-risk of persistent disabling LBP) in primary care (Whitehurst et al., 2015a).

The management of CMLBP is likewise of multidimensional nature (Petit, Fouquet, & Roquelaure, 2015) and especially psychosocial risk barriers that may hinder recovery need to be considered and measured in research aiming to improve the impact of interventions (Pincus & Mccracken, 2013). The strongest prognostic indicators for poor outcome in chronic LBP are arguably pain catastrophizing (Wertli, Eugster, et al., 2014), distress (Ben-Ami, Shapiro, & Pincus, 2018), fear-avoidance beliefs (Vlaeyen & Linton, 2000; Grotle, Foster, Dunn, & Croft, 2010; Wertli, Rasmussen-Barr, Weiser, Bachmann, & Brunner, 2014), social isolation (Karayannis, Baumann, Sturgeon, Melloh, & Mackey, 2019; Oliveira et al., 2015), and low self-efficacy for managing pain (Da et al., 2011).

Management

The management of persisting, disabling LBP represents one of the greatest challenges in the health care system (NHS Commissioning Board, 2013). Treatment that are commonly used can be divided into three categories: conservative (e.g. education, therapy, injections, medication), complementary (e.g. acupuncture, Yoga massage,) and invasive (surgery). International treatment guidelines for chronic LBP consistently recommend the short-term use of medication, spinal manipulation, exercise therapy, cognitive behavioural therapy, and multidisciplinary programmes (Koes et al., 2010). Nonetheless, no interventions with strong evidence of effectiveness have been identified (Keller, Hayden, Bombardier, & van Tudler, 2007). Unsuccessful treatments may add to the belief that the cause of pain is not known, which may further contribute to the psychological distress of chronic pain

(Mounce, 2002). About 90% of people with LBP will recover in 3-4 months with no treatment, 70% of people with LBP will recover in 1 month with no treatment, 50% of people with LBP will recover in 2 weeks with no treatment, 5% of the remaining 10% will not respond to conservative care (such as physiotherapy), the final 5% are the more challenging cases that do not naturally improve (Henschke et al., 2008). The chances of recovery among the more prevalent cases of chronic LBP are low, with an estimate of about 80% of patients experiencing pain after a year (Hayden et al., 2010). Thus, for those with chronic symptoms treatment focuses on controlling pain and improving activity, since only few may achieve complete resolution (Chou, 2011).

In the UK, the health care system is divided into three care pathways (primary care, secondary care, tertiary care) that map out a process of best practice to be followed in terms of treatment for patients with a particular condition or need. Primary care is often the first point of contact for people with LBP and may be provided by GP's, and pharmacists. Secondary care can either be planned (elective) care, such as operations but also includes hospital services, such as urgent and emergency care. To access secondary care (e.g. orthopaedic teams), requires a referral from a primary care practitioner. Tertiary care refers to highly specialised treatments (e.g. neurosurgery). According to the NICE guidelines for the care of lower back pain and sciatica in the UK (2016), once serious underlying causes are excluded, the pathway recommended to use risk stratification tools (e.g. StartBack) (NICE, 2016) to determine the complexity and intensity of support the patient may need. The tool should also help to improve outcomes by selecting treatments that are more promising for that group of patients. For people at higher risk of poor outcome, the guidelines recommend exercise programmes (e.g. biomechanical, aerobic, mind-body or a combination of approaches) with or without manual therapy (e.g. spinal manipulation, mobilisation, or massage). When treatments have not been effective the guidelines recommend using a psychological approach (e.g. cognitive behaviour therapy), but only as part of a treatment package including exercise, to overcome patients' significant psychosocial obstacles. At all stages the return to work or normal activities of daily living should be encouraged. The use of opioids to manage chronic LBP is not recommended. When non-surgical treatment has not worked for patient at this stage, the referral for assessment of radiofrequency denervation should

be considered, but only after patients had a positive response to a diagnostic medial branch block. Spinal cord stimulation is not recommended for patients with ischaemic origin, only for chronic pain of neuropathic origin and after a successful trial of stimulation as part of the assessment. Acupuncture, electrotherapy, traction, orthotics, belts, and corsets, spinal injections, disc replacement, and spinal fusion unless part of an RCT, are not recommended (NICE, 2016).

As previously discussed, chronic LBP is now more and more perceived as a life-long condition instead of a single entity that can be treated with a therapy that leads to complete recovery. Thus, it is even more crucial for secondary care teams (surgeon, etc) to address back pain through the three dimensions of the biopsychosocial model (Pincus, Kent, Bronfort, et al., 2013). Commissioners are interested in treatments that can deliver results, such as improved physical function and mood, decreased use of prescriptive pain medication and healthcare utilization, and encouraged return to work and self-management, all possibly at the lowest cost (Clare et al., 2013). Although intensive multidisciplinary biopsychosocial pain management programmes are more effective than usual care and physical treatments (Kamper et al., 2015) and are often recommended for chronic disabling LBP (Savigny et al., 2009), they are time consuming, not readily available everywhere, resource intensive, and costly, making it an easy target for cuts (Balagué et al., 2012; Clare et al., 2013). Healthcare professionals are limited in a sense that they cannot heal the subjective experience of pain on behalf of their patients although they provide health services that promote the healing of the body and mind. For most chronic disabling LBP patients self-managing their pain is an important aspect of care, which consists of a lifelong task. The optimum self-management in patients with long-term disabling LBP may only be achieved when patients and practitioners develop an effective partnership, which entails a mutual understanding, communication, defining the roles of health professionals, providing information, assessing patients' involvement, allowing the individualisation of care and healthcare services (Fu, McNichol, Marczewski, & Closs, 2016). Therefore, the focus should be on developing individualized and flexible pain treatment plans that combine different modalities to maximise the potential of achieving the successful management of the condition over time. Keeping in mind that research concedes the most effective treatment to be built from a combination of psychological and physical therapies (Steffens, Maher, Pereira, et

al., 2016) and most important that patients know about all possible management alternatives in order to make an informed decision about their treatment modalities (Carlson & Carlson, 2011).

When surgery is not indicated and no further treatment options are available

The main focus of this thesis are patients with persistent non-specific low back pain presented in secondary care. This may imply that the LBP experienced by those patients is highly complex and they typically had multiple treatment trials without success. Those patients right at the end of the treatment pathway may consult for spinal surgery as their last resort treatment, yet they may be told that ‘all possible treatment options have been exhausted’ and that ‘there are no further options available’. This message may have also been delivered more than once by different health care professionals throughout the patient’s journey, especially considering that patients with persisting, debilitating LBP often spend many years seeking help from a variety of specialists and sometimes get stuck in a vicious circle of care seeking (Clare, Andiappan, MacNeil, Bunton, & Jarrett, 2013). Those patients often hear from health care providers that they do not know the cause of the pain, which can lead to the misconception that their pain might be caused by a serious underlying disease. This may result in increased fear avoidance beliefs and behaviours. In addition, repeatedly hearing from doctors that there are limited or no medical treatment options available and certainly no cure, might lead to the misconception that poor outcomes are to be expected. These misconceptions might feed into pain catastrophizing which might also adversely affect outcome (Maher, Underwood, & Buchbinder, 2017; Traeger et al., 2017). Expectations about uncertain cause, management, and recovery of pain, that may be shaped by previous experiences with health care professionals, drive coping behaviour and are associated with subsequent disability, work absenteeism, and decreased wellbeing (Linton & Shaw, 2011). This suggests that at least some patients, especially those who have heard this message more than once, might enter their specialist consultation with extremely low expectations about a good outcome, making motivational communication about self-management more difficult for practitioners.

There has been no research literature on the outcome of this minority patient group presented to secondary care. In effect, this currently means that those patients are forced to return to self-managing their condition. In retrospect, the National Institute for Health and Clinical Excellence (NICE, 2009) issued clinical guidelines for people suffering from persistent MLBP, encouraging them not only to keep active but further to self-manage their condition. Carnes, Homer, Underwood, et al. (2013) reviewed the literature to design and test a practical and acceptable self-management intervention for chronic back pain. This intervention investigates on the basis of the current psychological framework and treatment approach to chronic pain, which is dominated by the cognitive behaviour model and cognitive behaviour therapy (CBT). They found that psychological components showed the most beneficial effects. However, the explicit underlying psychological processes in LBP patients generally are unknown (Pincus, Anwar, McCracken, et al., 2013), let alone in regards to the psychological emergency state that may be triggered when told: ‘all treatment options have been exhausted’. Thus, determining the optimal composition of psychological treatment modalities specifically for the needs of this small patient group will presents a huge challenge. Future research may want to consider developing a ‘last resource’ programme aimed to help those patients, who have been told that that all treatment options have been exhausted, to self-manage their condition. Bearing in mind that people are living busy lives with many additional demands, such as managing domestic duties, caring for children, active careers, alongside attending medical appointments, the internet may be an extremely promising modality empowering patients with an easy access at a low cost to informational, experiential and interactive components directed towards a self-managing approach.

However, instead of focusing on the development of such web-based interventions that help people with no further treatment options to effectively self-manage their pain, another solution may be effective reassurance. The final consultation disclosing the message of ‘no further treatments are available’, is not only the last contact between the health care system and the patient, but might also present the last chance for the system to implement an effective treatment modality: reassurance for improved patient’ outcomes. Why should reassurance not work when telling a patient that there are no further treatment options available because all treatment pathways

have been exhausted? What happens when reassuring a patient that their pain is now no longer an acquired illness but a life-long condition and that complete recovery without reoccurring pain episodes should not be expected, instead, the focus should lie on acquiring the skills necessary to effectively self-manage the condition?

CHAPTER 2: REASSURANCE

Introduction

As discussed in Chapter 1, biopsychosocial mechanisms are in complex interplay not only influencing the transition from acute to chronic MLBP but also its maintenance. The psychological obstacles to recovery in long-term LBP patients are of huge complexity. Patients at this later stage often lack clear diagnosis and prognosis, resulting in feeling disbelieved, uncertain, struggling to be recognised, and overall bombarded by despair. They might also enter their specialist consultation with certain beliefs, concerns, and high levels of depression, anxiety, and, fear-avoidance behaviour, etc. There is limited information available about how practitioners in surgical settings respond when confronted with complex pain presentations nor how to reassure and how to match reassurance to the specific and complex needs of those patients. Moreover, unlike practitioners in primary care and pain management teams, who are trained to manage pain and thus are expected to address patient's psychosocial needs, surgeons and their teams may not consider pain management, outside of surgery, as their remit. Thus, it might be interfered that their ability to provide reassurance may significantly differ from that of other pain practitioners. In addition, patients for whom surgery was not indicated might receive messages ranging from symptoms resolved to all reasonable treatment avenues are exhausted. In case of the later, patients may be discharged of care without further treatment options whilst indicating to self-manage their condition. Conveying this message, in addition to juggling patients' psychological obstacles to recovery, is an extremely difficult task for professionals. For some patients this might be their last contact of care to a health care provider, whereas for most it is the last contact to a secondary health care provider before they fetch up again in primary care. The communication during consultations might impact on the patient's understanding, thoughts, and subsequent behaviour in self-managing their pain, therefore providing effective reassurance can be considered as utmost importance.

In this chapter, elements of effective consultation-based reassurance and its

connection to patients' outcomes are assessed. As there is little information available on how surgical teams communicate with long-term LBP patients, the evidence from primary care is explored. Prior to outlining the available evidence, the history of consultation-based reassurance in terms of patient-centred communication in medical settings is reviewed and the evolution of the existing consultation-based reassurance model is outlined. The evidence on how to reassure when faced with psychological obstacles to recovery, such as uncertainty, is presented. Furthermore, the literature on communication for self-management is outlined to shed light on how to time-efficiently deliver discharging messages whilst introducing to patients the complexities of self-management, a task which is normally undertaken by multi-disciplinary pain management programmes (e.g. Epping-Jordan et al., 2004) over a prolonged period of time.

Patient-provider communication

According to Rogers (1961) core therapist attitudes of congruence, empathy, and unconditional positive regard are both necessary and sufficient for enforcing therapeutic change in clients. Most models of good practice during consultations are based on principles of patient-centred care (PCC). The provision of health care has evolved from applying traditional 'biomedical', 'illness-centred', or paternalistic approaches of 'doctor knows best' to PCC. There is no universally agreed upon definition of PCC (Delaney, 2018). However, it is believed to be embedded within the paradigm of holism that views individuals as a biopsychosocial and physiological whole (Ekman et al., 2012). In relationship to the making of clinical decisions PCC is a paradigm based on values and partnership seeking to ensure the needs of individuals are met with respect and responsiveness. Today, research studies, governments, and policy organisations (e.g. World Health Organization, 2000) advocate and endorse the need for health care institutions to place greater emphasis on the individual by recognising the importance of a PCC approach in the delivery of health care (Delaney, 2018).

Patients want consultants to adopt PCC which (a) explores their main reason for visiting, concerns, need for information; (b) seeks to understand the patient as a

whole person including all aspects of their problem, emotional needs, and life style/issues; (c) finds a common ground on their problem and mutually agrees on management; (d) enhances health promotion as well as prevention, and (e) enhances a continuing relationship with the health care professional (Stewart, 2001). Little et al. (2001) found patients desired patient- centred care, such as communication, partnership, and health promotion, more than 'biomedical' aspects of the consultation, such as an examination or prescription. Furthermore, they found that patients with a very strong preference for PCC are those who were vulnerable either socioeconomically, psychologically, or because they felt especially unwell and/or worried. This implies that patients with LBP in secondary care, who are expected to have high and complex vulnerabilities due to suffering from LBP for a prolonged period of time, may require surgeons and their team to utilise PCC approach. Considering the biopsychosocial nature of LBP, adopting a holistic, patient-centred approach in health care settings dealing with its management may be imperative. Nevertheless, surgical settings, in particular, still present an area of health care dominated by the traditional biomechanical and paternalistic approach in that they are often characterized by a professional monologue in which consultants instruct and prescribe treatments (e.g. surgery) with limited input from patients and families. Likewise, patients often perceive surgeons as the 'expert who knows best' and therefore may be reluctant to question their advice in regards to surgery. Differences of opinions on treating LBP and a patient's right to self-determination can be challenging, especially when the patient is subjected to treatments that are deemed futile (e.g. injections/surgery), imposing additional stress upon them as well as causing the health care provider to feel morally distressed. It may cause patients to decline advice provided by surgeon and their teams (e.g. not being recommended injections/surgery) in favour of alternative treatments (e.g. wanting injections/surgery). In such cases, it is especially important for health care professionals to ensure that they provide the patient with the necessary medical information, education, support and making the patient understand decisions are reflective of his/her own values and preferences (Delaney, 2018). When patients feel empowered and capable, they may appropriately apply this information to better evaluate their own health status and manage their pain. Evidence on improving the quality of health care for other chronic conditions (e.g. on chronic heart failure), consider PCC as a core ingredient of quality of care (Epping-Jordan, Pruitt, Bengoa,

& Wagner, 2004). Moreover, guidelines for the diagnosis and treatment of chronic heart failure (CHF) (Dickstein et al., 2008), which is similarly to MLBP a disabling lifelong progressive condition, argued that '*active patient involvement is a self-evident requisite for effective self-management*' (p. 1112, Ekman et al., 2012). Therefore, secondary care consultants who discharge chronic LBP patients without further treatment whilst suggesting to self-manage their condition, may aid patients in the transition process by adopting a PCC approach when delivering this message in the last consultation.

However, long-term LBP patients in surgical settings consult in an area of health care where the conventional way of doing medicine or 'biomedical model' is predominantly applied. Within this context, patients' report the possibility of the existence of underlying serious disease, which may directly lead to further care or treatment advice being dominated by focussing on treating standard disease entities. It is inaccurate to view the 'biomedical model' as a single approach, however, it is generally associated with a certain way in which medicine is practised, which influences content and style of the relationship between patient and consultant. According to Mead and Bower (2000) patient-centred medicine differs from the biomedical model in terms of five key dimensions:

- (1) **Biopsychosocial perspective-** Many illnesses (e.g. LBP) presented in health care systems cannot adequately be assigned to conventional disease taxonomies. Thus, a combined biological, psychological and social perspective is regarded necessary to account for the full range of problems. Therefore, the biopsychosocial perspective is a key theme of PCC, requiring practitioners to be willing to become involved in the full range of difficulties patients bring to the consultation and not only acknowledge their biomedical problems.
- (2) **The 'patient-as-person'-** A biopsychosocial perspective alone is not sufficient to fully understand patient's experience of illness, which depends on the individual's biography (e.g. LBP is experienced the same way by two different patients, one may be less distressed as the other). It becomes evident that personal meaning can have many dimensions. Economic insecurity may make individuals reluctant to acknowledge symptoms as disease for fear of being

labelled unfit to work. Similarly, culturally determined norms and beliefs influence how individuals conceptualize illness and pain. The individuals' psychological and social world is crucial to gaining an insight into whatever unconscious motivations or attitudes the patient has towards her illness, making it of paramount importance for any therapy. Thus, PCC perceives patients as experienced individual rather than the object of some disease entity. Attending to the patient's story of illness requires exploring presenting symptoms in context of their life. Therefore, it is important to elicit patient's concerns, expectations, feelings and fears about illness, in order to understand illness in the context of the individuals unique experience of it.

- (3) **Sharing power and responsibility-** The social relations model suggests the patient deference to medical authorities is important for the social function of medicine, serving the interests of doctors and patients. Within this model, the asymmetrical relationship between the two, whereby authority and control lie within the side of doctors, is considered as an inevitable 'consequence gap' between medical professionals and lay patient. Promoting this mutuality and reciprocity approach between the two parties may be criticised with the argument that conflict between medical authority and patient autonomy is fundamental to the doctor-patient relationship. Socio-political critiques of medicine, especially feminist critiques of medical patriarchy, point out issues around power and control in the doctor-patient relationship. These translated into calls for greater medical recognition of legitimacy of lay knowledge, understanding, and experience, as well as greater respect for patient autonomy. Professionals failing to provide adequate explanation and information, to reach consensus through negotiation, and to recognise patients as experts in their own illness, were associated with patient non-compliance and dissatisfaction. A shift in doctor-patient relationship is advocated, whereby 'co-operation-guidance model', which is analogous to a 'parent-child relationship', converts into 'mutual participation', which is analogous to a 'relationship between adults'. Ideally, patients are empowered to become actively involved in their care with shared responsibility and power. While it is unclear to what extent the doctor-patient relationship can, in practice, become genuinely symmetrical, PCC medicine is concerned with encouraging greater patient involvement. PCC

medicine requires doctors to encourage patients to voice their ideas, listen to what they have to say, reflecting on it and offering collaboration rather than discouraging greater patient involvement which is generally associated with the 'biomedical model'.

- (4) **The therapeutic alliance-** Whilst diagnosis and treatment are essential parts of decision-making procedures, the quality of relationship of the doctor conveying messages is associated with positive outcomes from management decisions (e.g. friendly and sympathetic manner may increase likelihood of patient adherence). Conversely, negative emotional responses (e.g. resentment, frustration) displayed by either party may lead to complicated medical judgement that may result in diagnostic error or cause patients to default from their treatment. Thus, there is an affect indirectly impacting outcome, mediated through medical management. In the absence of active treatment, positive emotional responses may affect improved patient outcomes. Patient-centred medicine affords far greater priority to the concept of 'therapeutic alliance', the personal relationship between patient and doctor. While conventional biomedicine can involve aspects of it, it is not regarded as necessary. Moreover, within the biomedicine view the effects of medical treatment are seen as 'real' whilst 'relationship effects', theoretically distinguishable, are mysterious but potentially beneficial side-effects.
- (5) **The 'doctor-as-person'-** This dimension concerns the influence of the personal qualities of the doctor. How to apply diagnostic and therapeutic techniques is a fundamentally objective issue within the biomedical model. Although doctor subjectivity is not necessarily benign, it is regarded inherent in the doctor-patient relationship. Besides lack of skill leading to error, there is no theoretical reason why well-trained doctors should not be essentially interchangeable since doctor subjectivity does not impact on diagnosis and treatment. Moreover, in cases where doctor's subjectivity, including influencing factors such as doctor's uncertainty, is apparent, it is suggested to be remediable through education and better instrumentation. Therefore, the biomedical model as 'one-person medicine', referring to a satisfactory clinical description, does not require

consideration of the doctor. By contrast, patient-centred medicine or ‘two-person medicine’ considers the doctor an integral aspect of any description.

Many ideas have shaped the five dimensions above, yet most development of the patient-centeredness concept has occurred within general practice, which may be different to professional concerns in specialist settings. Interest in patient-centred medicine is rapidly emerging in other medical disciplines, since evidence emerged suggesting interpersonal aspects of care are key determinants of patient satisfaction. Surgeons and their teams may be less likely to use this approach because their primary focus is on finding serious disease that can be treated through surgery. In short, they may be looking for a cure and not a management, and their concern is certainly not the negotiation of self-management for patients with complex pain.

Reassurance

The evidence outlined in the previous section suggests that patient-centred medicine has increasingly become of interest. The manner in which doctor’s reassurance impacts on their health status. There is confusion about the meaning of reassurance in that it could be something that practitioner do, but also something that patients feel. This creates pragmatic and methodological problem in terms of how to measure it. For example, the Compact Oxford English Dictionary (OED, 1991), describes the verb ‘to reassure’ as ‘to restore a person to confidence’, and ‘to confirm again in an opinion or an impression’. Likewise, the LEXICO dictionary, powered by Oxford University Press (OUP), defines reassurance as ‘the action of removing someone’s doubts and fears’ (OUP,2019). Whereas, the Cambridge dictionary defines it as: ‘words of advice and comfort intended to make someone feel less worried’ (Cambridge University Press, 2020). However, there is no general agreement over which words or actions constitute ‘reassurance’. To examine the effects of reassurance in the treatment of pain problems, it needs clear defining, which was rigorously approached by a systematic review of the literature on reassurance (Linton, McCracken & Vlaeyen, 2008). This review was used as our starting point because the authors systematically unravel the conceptual confusion around reassurance, since it can refer to a process, method, or outcome. The authors

described a variety of techniques used by practitioners that essentially include a combination of information, instruction and persuasion:

‘...Reassurance removes the fears and doubts about pain and/or illness with the effect to comfort. It always takes place within the dynamic of the interaction between the caregiver who has the intention to reduce worry, and the patient who is concerned. Ultimately, reassurance is achieved if the patient changes his/her behaviour, understanding, or thoughts. The method of reassurance, on the other hand, is in the behaviour of the healthcare provider...’ Linton et al. (2008), p. 5.

Guidelines recommending reassurance for MLBP

Reassurance is specifically recommended for patients seeking care for back pain (Linton et al., 2008). Over the past decade there was a drastic growth in research base informing the development and change of clinical guidelines for MLBP. A previous systematic review assessing clinical guidelines from 11 countries concluded guidelines produced fairly similar advice regarding the diagnostic triage (See Chapter 1 for details), yet discrepancies in recommendations regarding pain management and patient information (Koes, van Tulder, Ostelo, Kim Burton, & Waddell, 2001). Common recommendations include restricted use of imaging, advice on early and progressive mobilisation instead of bed rest and the recognition of psychosocial factors as a risk factor for chronicity, which were also consistent across all guidelines (Koes et al., 2010).

Reassurance within the context of good practitioner-patient interaction is considered as ‘the corner stone of treatment’, particularly for patients with MLBP (Pincus et al., 2013). Since 2006, guidelines recommend reassurance as first line intervention at the earlier stages of MLBP (National Spinal Taskforce, 2013; NICE, 2009; Van Tulder et al., 2006). According to these guidelines, at the first visit, physicians should provide reassurance explaining LBP is normal (‘LBP is common, reoccurring, might arise from various structures such as muscles or discs, hurt does not mean harm, no serious underlying pathology or nothing dangerous’), has an excellent prognosis (‘rapid recovery can be expected, good outlook’), and, in most cases, is not debilitating on a long-term basis. Kessel (1979) suggested ‘sick people want their

doctor to take charge' and that reassurance entails always sounding confident, giving of the impression that they have experienced this all before and therefore know what they are talking about, as well as always being positive and optimistic especially in terms of patient outcome. Whilst adequate information, being supportive, and, avoiding negative messages may avoid making patients insecure by stating nothing was found, theoretically, it should also decrease the likelihood of the patient developing chronic pain syndrome (Manchikanti et al., 2008). At the end, effective reassurance should result in patients perceiving their LBP as self-limiting and that their best method of coping is to maintain active without ceasing work.

Clinical guidelines have also recommended reassurance for the later stages of MLBP (NICE, 2016; Savigny et al., 2009). In secondary care they state effective reassurance should result in better compliance with prescribed medications and exercise as well as assisting professionals in preventing unnecessary surgical procedures. Patients undergoing similar treatments or surgical procedures have widely varying self-reported disability and pain scores, with limited correlations between objective data from imaging tests or physical exam and patient self-report (Vranceanu, Beks, Guitton, Janssen, & Ring, 2017). Research in patients with a variety of musculoskeletal illness concerns, suggest psychological factors, such as symptoms of catastrophic thinking, depression, and anxiety are consistently linked with pain intensity and disability (Vranceanu et al., 2017). Moreover, growing evidence showed, at least for patients with back pain, pain-related fear as a in terms of anxiety may be more disabling than pain itself. This suggests improving patients' concepts in regards to expectations/beliefs may facilitate training and physical activity and positively influence the outcome (Crombez, Vlaeyen, Heuts, & Lysens, 1999). Despite the emphasis on providing reassurance and making it sound like an approach that is straightforward to describe and administer, yet little is known about what exactly constitutes of effective reassurance and how to match it to specific patient needs. According to Linton et al. (2008) effective reassurance is not well understood and how to deliver it remains one of the most deserted areas of research. While there is qualitative and quantitative evidence from primary care (e.g. (Bair et al., 2009; Holt et al., 2018) and qualitative evidence from pain management (e.g. Bergman, Matthias, Coffing, & Krebs, 2013), about the importance of effective communication, much less is known about surgeons and their teams. In particular,

reassurance during secondary care surgical consultations, in which patients' symptoms have not yet been resolved, surgery has been ruled out as treatment, no further active treatment has been recommended, and, patients are being discharged into a void with or without indication to self-manage their pain.

Evolution of Consultation-based Reassurance Model

The previous section demonstrated how guidelines recommend reassurance without specifying how to apply this complex concept. In the following section the evidence for the evolution of the consultation-based model is outlined. Thórarinsdóttir and Kristjánsson (2014) conducted a framework analysis of 60 qualitative studies of person-centred participation in healthcare from the patient's perspective. They found patient participation manifested itself via three intertwined phases in a consultation. The first phase, 'the human-connection phase' refers to the initial phase of a consultation where patient and consultant establish trust. This requires having an inviting, friendly, warm atmosphere that makes patients feel respected and recognised as equal human beings as well as sensing that they have the genuine attention and interest of the health care provider. The second phase, 'the phase of information processing', referred to patients seeking and receiving the appropriate information, which entails the health care provider to answer questions and allow for a knowledge-building dialogue. The third phase, referred to as 'the action phase', entails empowering patients to feel confident in themselves and accepting or delegating responsibility towards a shared decision-making process that makes patients feel they were in control over their care decisions. In summary, a consultation structure fundamental to the person-centred approach begins with a phase of warm, empathic, listening behaviour displayed by the physician, followed by a second phase in which information-giving and shared decision-making is emphasised. In the final stage the care decision is made in cooperation with the patient. Although, patient participation may only occur during the first phase, authors note it may also advance across all three. Nevertheless, it has been argued that patient-centeredness is becoming a widely used, but poorly understood, concept in medical practice. Moreover, it may be most commonly understood for what it is not—disease centred, doctor centred, technology centred, hospital centred. Stewart (2001)

states; *'definitions of patient centred care seek to make the implicit in patient care explicit'*.

Linton, McCracken, and Vlaeyen (2008), reviewed the literature and described an implicit conceptualisation model of reassurance that proposes providing information effectively to potentially correct mistaken beliefs may lead to a reduction of worries and fears based on those false beliefs. Once thinking and emotions are in congruence, healthy functioning behaviour will follow. However, different people have unique beliefs, thoughts, and moods that have a varying impact on behaviour for different situations. Thus, complex pain experiences and complex situational factors may influence the outcome of providing reassurance. Although, the model has face validity, it cannot account for the complexities in the experience of pain nor situational factors. Reassurance is a complex process that involves interactions between an individual's experience, thoughts, beliefs, and emotions in a social context, all occurring within a dynamic interaction between the patients and health care providers (Linton et al., 2008). Effective reassurance is achieved if the patient changes their understanding, thoughts, and behaviour about their condition. On the other hand, Linton et al. (2008) state the method of 'reassurance' is in the behaviour of the health care provider. Practitioners commonly deliver reassurance in the form of corrective information, which entails physical explanation of symptoms and/or the explanation of diagnostic tests, and ideally a prognosis. Although this information might be accurate, there is no guarantee that behavioural change will occur, since reassurance may only be accepted when the explanations are tailored to the individual's unique physical and psychological needs. Linton et al. (2008) summarised that recommendations for reassurance are premature. It requires clarification to whether direct attempts in providing corrective information whereby suppressing fear and anxiety, or providing empathy and enhancing acceptance, is the more appropriate alternative.

In a departure from patient-centred approaches, Coia and Morley (1998) proposes an early evidence-based model that explicitly focused on reassurance. The model is largely deducted from experimental work, a theoretical framework incorporating an extant theory about patients' mental models or illness representations, which determined patient's perception of health, and, theory on persuasion. It translates into

an array of techniques for health care providers, which essentially includes verbal and non-verbal processes of information, instruction, and persuasion. Coia and Morley (1998) categorise communication in reference to reassurance and education into 2 processes:

- **Affective communication:** aiming to create rapport, building trust to practitioners and their knowledge and experience, whilst reassuring them through a sense of being understood, heard, cared for and supported. It is heuristic and evokes a rapid shift in emotional response, which may lead to immediate reduction in anxiety, concerns, and worry.
- **Cognitive reassurance:** aiming for a neutral transmission of information or education in order to change patients' perceptions, beliefs, cognition, and behaviours in adhering to advice or understanding the course of their condition. It is systematic, slow, iterative, and demanding, whilst its impact is preserved.

The model suggests affective communication evokes immediate responses in patients. Nevertheless, such responses are transient. This becomes difficult when the problem returns, since without the presence of a reassuring clinician, the patient has not been empowered with new tools to deal with it. On the other hand, cognitive reassurance is more time consuming, but its impact leads to more effective behavioural actions on the patient part in the longer term. Crucially, the model asserts that cognitive and affective reassurance are mutually exclusive, patients may engage with affective or cognitive reassurance, but they will not engage with both simultaneously. Affective communication should therefore be avoided entirely considering it is easier to engage with and therefore assumed to demotivate patients or limit their capacity to engage properly with processing information to enable cognitive reassurance to take place. Thus, the authors advice practitioners to abstain from using affective reassurance since they suggest it can cause more harm than good. On the other side, Thórarinsdóttir and Kristjánsson (2012) refer to the 'human-connection phase' as fundamental to person-centred participation. Especially, in the early stages, affective reassurance may achieve empathic and sensitive communication, which elicits patients concern, fosters rapport and trust. Therefore,

Coia and Moreley's (1998) assertion that these behaviours are to be entirely avoided is counter-intuitive and highly controversial. It not only challenges current practice but further calls for a complete shift in training and delivery of care.

Especially for people with LBP where clear cause cannot be established, reassurance is one of the most commonly used strategies in primary care. Delivering reassurance effectively is not only a core skill for all practitioners, it further has the potential to improve health outcomes, reducing onward referral, and hence reducing health care costs (Pincus et al., 2013). The delivery of reassurance is complex, including factors associated with quality of care and practitioner-patient beliefs, values, and behaviours. Linton et al. (2008) suggested 'reassurance creates conceptual confusion and requires defining since it can refer to a process, method, or outcome'. Coia and Morley's (1998) model is limited in that sense, since it does not account for measurements of known outcome predictors outside of consultation-related factors, nor provide a detailed description of reassurance components at different stages of the consultation or divide outcomes into short, medium, and long-term. For example, a study in Denmark investigated the quality of communication between health care providers (n = 21) and patients with low back pain (n = 79) and found practitioners (doctors, physiotherapists, chiropractors) are particularly bad at communicating with patients with non-specific pain. The quality of communication became worse the longer patient had suffered low back pain. Poor communication quality also seemed to be associated with older patients (Gulbrandsen, Madsen, Benth, & Lærum, 2010). Coia and Morley's (1998) model does not take into account patients' individual risk factors and how they may or may not determine the response to reassurance. It requires the synthesis of such research evidence to redefine a model of reassurance, which helps in the identification of gaps for training and delivery of informed interventions to improve patient' outcomes.

Pincus et al. conducted a series of research using a stepped mixed method approach. To begin with, a systematic review of prospective cohort studies in primary care was conducted, measuring cognitive (education) and affective/emotional (caring) reassurance in relation to patient outcomes (split into short-, medium-, long- term), including mood, beliefs, and changes in behaviour that resulted in improved coping and management of the problem (Pincus et al., 2013). One key aspect of reassurance

was the uncertainty patients and practitioners had to deal with, concerning unclear prognosis, aetiology, and weak evidence on effective interventions. Nonetheless, a categorisation of practitioner's reassurance behaviours into affective versus cognitive was achieved. Out of 16,059 abstracts and 58 read publications, 16 studies were identified measuring both types of reassurance and hence met entry criteria. The literature suggests eliciting and addressing patients' expectations, having a positive approach, and involving patients in the consultation, improves outcomes, whereas, practitioners expressing uncertainty reduced patients' sense of reassurance. There was contradictory and insufficient evidence for other factors, such as empathic communication, practitioner style, and for request fulfilment for tests, medical prescription, and referrals. Furthermore, it was found that affective reassurance at best only sometimes improved patient satisfaction at consultation exit, and, at worst, evidence suggested an association with poorer patient outcome (higher symptom burden). On the other hand, cognitive reassurance (giving clear explanation about aetiology, prognosis, discussing management plan, etc.) improved patients' outcome in terms of improved symptoms and decreased healthcare utilisation, not only in the short term, but also at 3-months follow up. Overall, findings support the notion that cognitive reassurance is more beneficial than affective reassurance (Pincus et al., 2013).

The findings generally seem to support Coia and Morley's (1998) model, however, the authors emphasise that no causal path can be inferred in observational studies. Not all studies included adjusted for severity of symptoms, mood, and function at baseline, which may have affected practitioners' behaviour. Most likely, practitioners may have identified the additional needs in patients who were more likely to have worst outcomes, whilst trying to improve emotional and pastoral support. The authors recognised that patients seem to rate 'receiving information' as a more important aspect of patient-centred care, compared to practitioners, who prioritize receptiveness and affective components. Considering the time pressure, practitioners have to prioritize certain behaviours, such as providing clear explanation and information about prognosis, explicit exclusion of serious illness, and discussion of management plan. Based on this provisional evidence an early 'model' evolved, aiming to guide future research rather than providing a definitive model of evidence-based reassurance. Conceivably, some aspects of reassurance are more beneficial

than others, for example, data-gathering in relation to symptoms, signs, concerns, and the impact of the problem is a prerequisite to reassurance. Whilst, reassurance itself, is the response of the health care provider to the data gathered. Furthermore, the model explores measurements of known predictors of outcomes outside consultation-related factors, consultation components at the different stages of the consultation, and, outcomes divided into short, medium, and long-term:

- The first stage of the consultation, '**data-gathering**', affects the next stage both in terms of practitioners' and patients' behaviour. Whilst the clinician is involved in exploring symptoms, eliciting concerns/feelings, elicit illness perceptions/ causal attributions, exploring expectations, and, where appropriate, carrying out examinations, the patient engages in describing the problem and its impact, voicing beliefs, concerns, and requests.
- The next stage of the consultation, '**information giving**', affects immediate outcome, which in turn affect medium and long-term outcomes. It involves the clinician offering affective and cognitive reassurance. Whilst cognitive reassurance results in changes in understanding, knowledge, increased locus of control and changed beliefs, the precise mechanisms of affective reassurance are unclear. Some evidence suggests an association between affective reassurance and changes in short- term outcomes, such as perceived support, satisfaction, and reduced anxiety, yet evidence is insufficient in denoting a causal path that conclusively suggests improved or worsen medium and long-term outcome. In addition, the question remains whether cognitive reassurance can be delivered effectively and independently of affective reassurance.

In summary, the review showed that patient and practitioner related factors will affect the process of reassurance, and some, but not all, patient-practitioner interactions are related to patients' outcome. Consultation-related components associated with practitioner-patient interaction have a direct impact on short-term changes in patients' beliefs and concerns, which impacts their behaviour in relation to their condition, resulting in long-term changes in outcome. Nevertheless, at this stage, a reliable and valid measure of affective and cognitive reassurance had not

been developed and hence longitudinal observational studies examining reassurance levels and its definite impact on patients' outcome, were lacking.

The research team conducted two qualitative studies in primary care, informing the development of a reliable consultation-based reassurance measure. The first study by Holt, Pincus, and Vogel (2015) aimed to explore what patients with LBP perceived to be reassuring when visiting their physicians. Twenty-three patients (13 males & 10 females, mean age of 57.2), who had recently consulted for their LBP were recruited from nine general practice surgeries. Semi-structured interviews were conducted and data was analysed using a framework approach. Three main themes emerged out of the data and were organised under the following headings:

- **Patient factors:** concerns factors that patients brought with them to their consultations, such as their unique pain experience, mood, interactions with comorbidities, expectations, beliefs, concerns that they wanted the doctor to hear and understand.
- **Implicit reassurance:** refers to behaviours that patients found reassuring outside the spoken messages from their doctor. It involves the practitioner's manner, such as being taken seriously, listening and understanding patients pain experience, receiving an examination, doctor giving of the impression they want to help and are there supporting the patient. It also included the doctor-patient relationship (relationship-building) whereby patients felt they had rapport and trust if they either had a relationship with their practitioner or felt their efforts of building one. Lastly, patients appreciated feeling that the practitioner is readily available to them when needed.
- **Explicit reassurance:** refers to direct and verbal informational reassurance. Addressing patients' concerns by providing explanations to the cause of their pain, such as what may have contributed to the onset or physical structures explanations, which indicates the ruling out of serious disease, e.g. cancer. Advising patients on how to resolve their pain, by discussing treatment options and explaining what each option entails including its benefits, provides patients with a sense of control over their problem. Lastly, patients

appreciated statements on prognosis, such as expectations in terms of recovery/outcome and explicit information to empower patients towards self-management.

The focus of this study was on which behaviours patients perceived as reassuring. If they felt unsatisfied with their consultation, it was generally due to feelings of being rushed, dismissed, and ignored. Patient related factors have a major impact on the consultation. The themes implicit and explicit reassurance correspond with the ideas of affective and cognitive reassurance, respectively. Explicit reassurance (cognitive-reassurance) through explanations and valued information was perceived as most reassuring because it was most effective in addressing and reducing patients concerns, helping them to manage their problem and hence empowering them towards self-management. Affective reassurance can be achieved through implicitly reassuring behaviours such as providing a credible examination and listening. Such behaviours appear to be linked to increased satisfaction in previous research (Pincus et al., 2013), as well as in the current study (Holt, et al., 2015). Patients indicated that implicit (affective) reassurance was appreciated, yet did not lead to a reduction in worrying thoughts about their pain. Although patients viewed implicit behaviours positively, they reported it require explicit explanations and information for them to feel less concerned and more enabled. Therefore, findings are in support of the notion that cognitive reassurance behaviours improve patient outcomes (Coia & Morley, 1998; Pincus et al., 2013). The study found no direct evidence to support the notion that affective reassurance is associated with poorer patient outcomes later on, unlike previous theoretical notions (Coia & Morley, 1998), on the contrary, findings suggest patients not only appreciated affective reassurance (being understood, taken seriously) but also considered it as important. Nonetheless, the association between implicit reassurance, in the form of relationship- building and empathy, remained unclear. It required future research, at this stage, to clarify the relationship between affective behaviours and patient outcomes and evaluate the extent to which affective reassurance is required for successful cognitive reassurance to take place.

A second qualitative study recruited twenty chronic LBP patients from an osteopathic and pain management clinic and examined their understanding, feelings, and behaviour in response to their diagnostic labels. A major theme that emerged

concerned the absence of effective cognitive reassurance whilst lacking a clear diagnosis, which were linked to negative implications such as distress, further treatment seeking, and uncertainty (Serbic & Pincus, 2013). The details of this study are further discussed later in this chapter (under the ‘Empathy’ section).

A series of quantitative studies were conducted to develop and test a theory-driven, reliable and valid questionnaire measuring the key processes in consultation-based reassurance. Items were extracted from previous qualitative interviews and theoretical review of empirical studies. This a-priori model allowed the formulation of conceptual maps describing different aspects from consultation-based reassurance to generate items (Holt & Pincus, 2016). Preliminary items were sent to a team of experts and patient groups for review. Once the most coherent responds mode was established, a cross-sectional study adopted the questionnaires to patients presenting for LBP at 43 GP surgeries. Data was analysed using Item Response Theory (IRT) and data reduction using RASCH modelling. Two samples from the same population were used: first ($n = 157$, follow-up $n = 84$) for explanatory analysis and the second ($n = 162$, follow-up $n = 74$) for confirmatory testing. The external validity of the items was assessed by comparing responses to the questionnaire with response to satisfaction and enablement scales. Test-retest reliability was assessed through participants completing questionnaire again one-week later. The data reduction procedures resulted in a questionnaire with 12 items, separated into four subscales: data-gathering, relationship-building, generic reassurance, and cognitive reassurance, each containing three items (please see details of items, Chapter 3). Findings indicated the new consultation-based reassurance questionnaire performed well by demonstrating consistent responses across groups, good content validity, and generally acceptable reliability. Inter-Class Correlation Coefficients (ICC) on the sub-sample of patients who completed the measure a week later showed good test-retest reliability. The four subscales were all significantly positively correlated with scores on the established satisfaction and enablement scales, demonstrating good external validity. There was a weaker correlation between reassurance sub-scales and enablement than those between reassurance and satisfaction. Reassurance may be considered as a minimal intervention by GPs, hence it may require more invasive interventions for some patients, especially those who are more of risk for chronicity, to feel enabled. Cognitive reassurance was more strongly correlated than the other

sub-scales to enablement. This is in line with the previous notions that cognitive reassurance equips patients with the knowledge and skills to manage their problem (Coia & Morley, 1998; Pincus et al., 2013; Holt et al., 2015; Serbic & Pincus, 2013), whereas, generic reassurance, significantly correlated with satisfaction, showed the weakest correlation of the four sub-scales in both samples. Nonetheless, the relationship between generic reassurance and patient outcome as well as the interaction between consultation-based reassurance and patients' psychological risk remained unknown.

Psychological factors have been associated with increased risk of transitioning to chronicity and maintaining of chronic pain (Linton, 2005; Pincus, Smeets, Simmonds, & Sullivany, 2010). The more severe LBP, in terms of pain-related disability and psychological distress, the poorer the predicted long-term outcomes (Pincus, Santos, Breen, Burton, & Underwood, 2008). Patients' differences in individual characteristics (e.g. expectations, mood, illness-related cognition) may influence how they respond to different types of reassurance at different points of their pain journey (Linton et al., 2008), and may also influence practitioners' behaviours (Holt, Mansell, Hill, & Pincus, 2018). Reassurance has a direct impact on short-term changes in patient's belief and concerns (Holt et al., 2015), which is believed to impact on behaviours resulting in long-term changes in outcomes (Serbic & Pincus, 2013; Holt et al., 2018). The strongest impact on patient outcome, from patients' perceptions, appears to be resulting from patient factors, which are factors specific to each patient (Holt & Pincus, 2016). Depending on patients' 'risk profile', it may be possible to identify specific sub-groups who may require different approaches to reassurance. Identifying key modifiable factors that should be addressed is crucial to optimise reassurance to the individual's needs. Evidence on effective methods of reassurance, providing either too much or too little, or how to tailor certain types of reassurance according to the patient's clinical profile, remains scarce and lacking conceptual clarity. Therefore, there is a need to examine how psychological risk interacts with or moderates the impact of reassurance on outcomes.

To investigate the relationship between consultation-based reassurance and clinical outcomes at 3-months follow-up consultation, in patients with and without

psychological risk, Holt et al. (2018) conducted a prospective cohort study in 147 patients who consulted their GP for LBP on the previous month. They measured at post-consultation (defined as baseline); pain, duration, disability, psychological risk using items from the StartBack screening tool assessing fear avoidance and catastrophizing, satisfaction, enablement, reassurance using the new 12-item questionnaire divided into 4 components of data-gathering, relationship-building, generic reassurance and cognitive reassurance, and at three months follow-up they measured disability, pain, anxiety, depression, and further healthcare utilization. Linear regression models were implemented to test the association between the four reassurance components, patients' psychological risk (depression, anxiety, catastrophizing, or fear-avoidance), and, post-consultation outcomes (satisfaction, enablement, disability, pain). The confounders adjusted for in the models were age, sex, education, sex congruence of patient and physician, length of current pain episode, and number of previous consultation (Block 1), pain intensity and disability at baseline (Block 2), and dichotomized psychological risk score at baseline (Block 3). Results showed that greater perceived reassurance (all types of reassurance together) was strongly associated with greater patient's satisfaction, accounting for 69% of the variance, and enablement outcomes, accounting for 29% of the variance. Psychological risk predicted all outcomes at 3 months whereby several significant interactions were observed. For example, low-risk patients who perceived higher levels of generic reassurance showed a reduction in depression, whereas the opposite was found for patients with a high-risk profile. For high-risk patients, cognitive reassurance was associated with more pain at follow-up, whereas the opposite was found for low-risk patients. Low-risk patients with more perceived implicit reassurance (eliciting concerns and relationship-building) were associated with increased anxiety. Overall, this suggests that optimistic messages are probably good for patients without a complex psychological risk profile but not for complex cases. Therefore, it strongly suggests that different reassurance behaviours are associated with different patient' outcomes. Findings showed generic reassurance increased enablement after the consultation but not at 3-months follow-up, which seem to be in support of Coia and Morley's (1998) model, that argues generic reassurance may result in immediate reduction of anxiety, but that the sense of reassurance is only temporary and dependent on the clinicians' presence, whilst later on when the problem rearises patients lack new tools to deal with it.

Consultation-based reassurance model

Based on the synthesis of existing research evidence the following model has been developed by Pincus and colleagues (please refer to Figure 1). The model is aimed as a guide to key modifiable factors that should be addressed in future research when designing and evaluating complex interventions to enhance reassurance. Nevertheless, these interventions may be complex because they are likely to include factors associated with quality of care, such as values, behaviours, and beliefs from patients and practitioners. In the model below, the associations between consultation-based reassurance, patient and problem characteristics, and outcomes, are colour-coded. The solid arrows indicate associations for which there is now robust evidence. The dotted arrows suggest priorities for research.

The preliminary evidence outlined in the previous section demonstrated that all aspects of the consultation-based reassurance are strongly and positively linked to post consultation satisfaction and enablement (Holt et al., 2018). **Long-term outcomes** are associated with **problem and patient characteristics**. Problem characteristics refers to factors such as pain, disability, and/or duration, whilst, patient characteristic concern factors such as depression and expectations. Pain and functional incapacity as well as psychosocial distress in long-term LBP severely impacts people's quality of life (Bailly, Foltz, Rozenberg, Fautrel, & Gossec, 2015; Pincus & Williams, 1999; Pincus & Morley, 2000; Pincus, 2002, & MacCracken, 2013). The model recognises that **patient and practitioner related factors** affect the process of reassurance. The strongest impact on patient outcomes results from factors specific to the individual, including the experience of their problem/ illness identity, beliefs, personal circumstances, perceptions of personal control, pain self-efficacy (Foster, Thomas, Bishop, Dunn, & Main, 2010), mood (Pincus, Burton, Vogel, & Field, 2002) and expectations (Hayden, Tougas, Riley, Iles, & Pincus, 2014). The weighting and dominance of the interplay between various patient factors are complex and unique within each individuals pain presentation. Whilst some of these factors may be modifiable (e.g. mood, beliefs, behavioural response) others may not be (e.g. socioeconomic and social circumstances). The challenge for the practitioner is to consider the relative contributions of modifiable versus nonmodifiable patient factors that may moderate outcomes and decide whether or not

it requires additional targeted multidisciplinary care (O’Sullivan, Caneiro, O’Keeffe, & O’Sullivan, 2016). Ideally, practitioners differentiate high-risk patients, identify their psychological obstacles, sieve out those which are modifiable, target a response to it, and link such risk identifications with targeted treatment (Main & George, 2011). Additionally, evidence suggests that **practitioner characteristics** will affect their interactions with patients (Åsbring & Närvänen, 2003; Pincus, Woodcock, & Steven, 2009; Pincus et al., 2013; Street, Makoul, Arora, & Epstein, 2009). However, the relationship is not as straightforward as it seems, for example, practitioners job satisfaction may benefit patients’ experience of quality of care but is not directly associated with improved health outcomes in patients (Grembowski et al., 2005). Therefore, the exact mechanisms influencing health outcomes weeks and months after the consultation mainly occur via more indirect routes (Street et al., 2009).

The **early stages** of the consultation typically comprise of **implicit and non-verbal** reassurance processes, which consist of **data-gathering and relationship-building**. This phase of the consultation serves the purpose of eliciting data (e.g. patient history) and building a relationship, where the physician lets the patient know that they are in good hands, listened to, being heard, understood in that their pain is credible and not just in their mind, cared for, and being reasonably confident that they can help without providing false reassurance. Implicit reassurance aims to create rapport, reduce anxiety, and produce trust (Main & George, 2011). Rapport is required because it helps patients express their beliefs and concerns and enables practitioner to explore their needs, fears, and expectations. Reducing patients’ level of anxiety, especially when they are high, is important because it may interfere with patients’ ability to process information and make effective choices. According to Thom, Hall, and Pawlson (2004, p.124): *‘Trust is a vulnerable and fragile commodity, which is perniciously difficult to quantify’*. It is needed because patients who trust their health care provider, are more likely to seek care, to comply with treatment recommendations, and to return for follow-up care (Thom, Hall, & Pawlson, 2004). Therefore, effective implicit reassurance at early stages of the consultation is important and when successfully implemented may lead to immediate reduction in concerns and anxiety, and, increased satisfaction and enablement.

The **later stages** of the consultation typically involve **explicit or information giving** reassurance processes, which entails **generic reassurance and cognitive reassurance**. There is contradictory evidence on how effective generic reassurance, which includes general statements such as ‘I don’t think you need to worry’ or ‘I’ve seen this before’, affects patient’ outcomes. Thus, the association is not straight forward and requires clarification as shown in the previous outline of evidence. In contrast, effective cognitive reassurance entails providing education and information, causes of the problem, the most likely prognosis, treatment options, discussion over obstacles of treatment and how they feel about it, assessing compliance to treatment, and empowering patients to self-manage. Effective cognitive reassurance may result in patients having a better understanding of their condition and treatment pathways, enhanced self-efficacy and control over managing their problem, and result in a better buy-in to clinical decisions enhancing treatment adherence. Not only at immediate stages of outcomes but also several weeks down the line, it will allow patients to manage their concerns and anxieties, without the practitioner being present (Coia & Morley, 1998). Whilst immediate outcome may result in better self-care and appropriate utilization of health care, long-term outcome may result in better management of problems and well-being (Coia & Morley, 1998; Pincus et al., 2013; Holt et al., 2015; Holt et al., 2018; Serbic & Pincus, 2013).

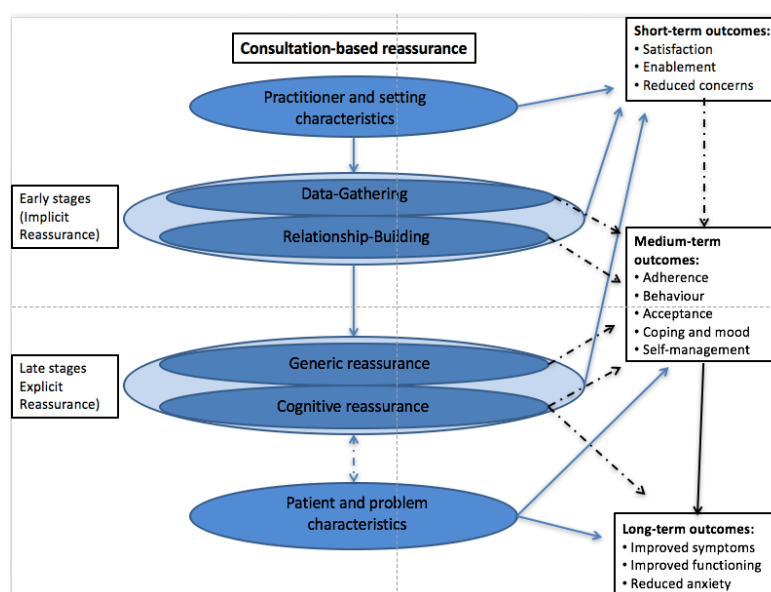


Figure 1: Consultation-based reassurance model

A main strength of the consultation-based reassurance model is that it was derived from a series of research that included a literature review (Pincus, Holt, et al., 2013), qualitative work (Holt, Pincus, & Vogel, 2015a; Serbic & Pincus, 2013) and quantitative research (Holt, Mansell, Hill, & Pincus, 2018; Holt & Pincus, 2016). The model seems to have face validity and it reflects established models of consultations in which behaviours can be organised into different stages and mapped to different outcomes. It is a pioneering work in dividing outcomes into short, medium, and long-term whilst providing a clear and simplified graphical illustration of the reassurance mechanism and their interactions with factors outside of the consultation, e.g. patient and practitioner characteristics. It also overcomes many limitations associated with previous research, such as illustrating the consultation components at different stages of the consultation and including measurements of known predictors of outcomes outside of consultation-related factors. Nonetheless, there are some criticisms of the model. In reality there is probably an iterative process between patients and practitioners where behaviour can happen at any given point of the consultation, rather than an ordered stages process. The measurement derived from the model does not include when things happen, so although it mentions that some behaviours should take place before others, there is no way to measure whether they do. It also has to be acknowledged that not all consultations can be expected to uniformly follow the prescribed structures. It fails to include physiological effects that interact with cognitive and emotional processes, such as reduction in arousal. In addition, according to Traeger et al. (2017), the reassurance model does not sufficiently account for the role of pain-related fear, which stems from the Fear Avoidance Model that outlines how fear, worry, and illness information can lead to chronic disability. The model does not explicitly explain how fear avoidance can be reduced by reassurance, despite the fact that this process is a major part of clinical sessions with people living with MLBP. Of importance the model does not include reassurance through behavioural exposure, which is a fundamental component of the fear-avoidance model. In other words, allowing patients to experience the movements they are afraid of could significantly reassure them and has been shown to significantly reduce catastrophizing (Sullivan, Adams, Rhodenizer, & Stanish, 2006).

The role of emotions

Although the correspondence between pain and bodily damage is variable and it has been acknowledged that pain is partially an emotional experience, experts in pain research and practice still not fully appreciate it in general practice settings and often treat it as a purely sensory experiencing reflecting underlying tissue damage (Lumley et al., 2011). Chronic pain is exacerbated by life stress, social rejection, daily hassles, interpersonal conflict, and the resulting emotional state of depression, anxiety, and anger (Lumley et al., 2012). The main focus of efforts to assist patients in the management of persistent pain is directed towards decreasing pain and the negative affect (NA) that often accompanies it (Davis, Zautra, & Smith, 2004). Lumley (2010) argued that a common problem with MLBP patients is that they often have the preference for externally oriented thoughts rather than introspection and lack the ability to identify feelings, differentiate among them, label or describe them, which is referred to as the term alexithymia ('no words for feelings'). A study with persistent MLBP patients found that greater ambivalence over emotional expression was associated with higher levels of evaluative and affective pain as well as higher levels of trait anger and the tendency to hold angry thoughts and feelings (Carson, Keefe, & Lowry et al., 2007). In contrast, research on the dynamic model of affect (Davis et al., 2004) suggests that the ability to differentiate and accurately label one's feelings is adaptive. It helps patients to differentiate between NA and positive affect (PA). Reducing NA but enhancing PA, which is seen as a motivator to engage in reward seeking, growth, interpersonal connections, and creativity, may not only predict a reduction pain but it might also lead to more self-regulation and motivation among people with persistent pain. In the effort to promote better health and functioning, various emotional experiencing interventions, such as mindfulness, compassion and acceptance therapies, emotional disclosure, and emotional exposure-based interventions, have been tested for the effects on pain. For patients with persistent MLBP, mindfulness-based stress reduction program (Morone, Greco, & Weiner, 2008) and loving-kindness meditation program, which aims to develop love and transform anger into compassion (Carson et al., 2005), have shown benefits.

The communication with patients suffering with pain is always challenging, especially when pain is relentless and the cause unknown or incurable. Patients

emotional state affect their pain experience, thus addressing them in the consultation is important. Especially, when dealing with persistent pain, which is exemplified by a host of co-occurring negative emotions that range from depression to anxiety, communication may be particularly difficult (Linton, 2015). Patients may also express their emotions in a variety of ways, including behaviours that reflect pain catastrophizing (Lumley et al., 2011). On the other hand, clinicians and caregivers may experience stress from seeing a person suffer from pain and hence may find it difficult to differentiate their perception of the patient's pain from their own personal affective response. Observers often struggle to estimate pain in patients and tend to overestimate or underestimate it, which may lead to unsupportive responses and distress (Lumley et al., 2011). In addition, health care providers often feel overwhelmed or stressed by the patients' display of negative emotion (Linton et al., 2017). Pain-related communication is complicated, and, despite their best intentions, clinicians often respond to pain communication in ways that patients perceive unhelpful. For some patients, encouraging disclosure (talking about their suffering) has been shown to be important (Lumley et al. 2012). Thus, behaviours that from clinicians that address these (reduce anxiety, encourage disclosure) are necessary.

Affective reassurance is emotional and appeals to patients' fears and concern by telling them not to worry and that things will turn out to be fine, which should reduce their anxiety. According to Traeger et al. (2017) affective reassurance aims to enhance the relationship between patients and practitioner through building rapport, empathic communication and simple assurances that everything will be alright. Coia and Morley (1998) originally proposed a possible harmful effect of affective reassurance, this was based on the notion that perceived affective reassurance reduces patients' motivation to engage with cognitively reassuring messages and hence limit their own ability to cope with their symptoms. In primary care, affective reassurance was found to be indeed harmful (Pincus et al., 2013). Nonetheless, this notion that receiving affective reassurance reduced patient's engagement with cognitive reassurance has not been supported nor was the opposite found (Holt et al., 2018). Moreover, Linton et al. (2008) reported that providing reassurance may reduce patients' worry in the short-term, but not long-term. Although the authors advise health care providers to express empathy to increase patient's engagement in treatment, it remains unclear how to do so in a reliably effective way. There are a

variety of models available, which are characterised by emotional empathy, listening, shared understanding and decision making (Linton et al., 2017). In terms of efficacious treatment options for chronic MSK pain patients with comorbid emotional problems, a hybrid treatment targeting transdiagnostic (psychological mechanisms) emotion-regulation mechanism through integrating exposure methods based on the fear-avoidance model, as well as, emotional-regulation approaches, informed by procedures in Dialectical Behaviour Therapy, was found to be credible and superior compared to a guided Internet-delivered pain management treatment based on CBT principles (iCBT) (Boersma, Södermark, Flink et al., 2019). However, providing training to improve routine consultations with non-psychologists remains difficult because there are no given strategies currently recognised as the method-of-choice (Linton et al., 2017). One promising candidate to improve reassurance is validation, a concept that has gained attention in recent years. It entails health care professionals expressing their understanding of the patient's pain experience and worries as something that is real and valid without judging it. Validation plays a key role in regulating emotions, central to the dialectical behaviour therapy (Linton et al., 2017). The finding from a study examining the effects of validation on MSK pain patients' outcomes suggest that higher levels of validation are associated with higher levels of satisfaction, and lower levels of negative affect and pain intensity rating (Vangronsveld & Linton, 2012). This suggests that validation might be a viable technique that can be used in terms of affective reassurance for pain-related consultations.

Patient-related factors in orthopaedic setting

In the previous section we discussed how patients' emotional states clearly affect their pain experience, hence addressing them is important. Patient-related factors have also gained increased acceptance in assessing the outcome of joint replacement surgery, and it is clear that the presence of co-morbidity results in worst outcomes, as measured both by disease-specific and generic assessments tools (Rolfson et al., 2009). Rolfson et al. (2009) showed that the impact of mood (anxiety and depression), were significant variables in predicting satisfaction and pain relief after patients underwent total hip replacement (THR) because of primary osteoarthritis.

Those patients with high anxiety and depression scores, reported higher pre-operative pain scores. Although this might suggest that anxiety/depression may increase pain, the relationship between pain because of a disease or anxiety/depression is complex making decisions about the indications for surgery outcome difficult (Rolfson et al., 2009). This study of joint replacement surgery suggests that psychometric variables (e.g. anxiety/depression) play a key role in patients consulting for surgery and thus might also play a key role in those who are not recommended to undergo surgery. Especially, when informing reassurance aiming to improving health-related quality of life in chronic pain patients, those variables need to be carefully examined and addressed.

Yet, trials attempting to intervene on psychological factors in these settings focus on preparation for surgery. For example, in 2004, research adopting a holistic peri-operative rapid-recovery program, because surgery (hip and total knee arthroplasty) alone were not considered as a keystone to rapid recovery. The programme included elements of pre-operative patient education, nutrition, vitamin and herbal medication supplementation, etc., which was based on research looking at patients' psychological evaluation prior to surgery and using psychoeducation to better prepare patients for the stress of surgery and recovery. The programme led to a significant reduction of inpatient stays and readmissions following the surgery as well as reduced pain-medication usage (Berend, Lombardi, & Mallory, 2004).

Ibrahim, Khan, Nizam, and Haddad (2013) presented an evidence-based review of common interventions available aiming to achieve enhanced recovery, reduced hospital length of stay, and improve functional outcomes after hip and knee arthroplasty. The summarising literature suggested peri-operative rehabilitation is pivotal for accelerated recovery and reduced hospital length of stay. Although, there are different pathways and protocols in use, individualized pre-operative teaching programmes, either by phone or in person, showed an effect on patients' hospital length of stay after their surgery, whereby education alone reduced their length of stay by 24 hours. Further, the review suggested it is necessary to understand patient expectations to ensure optimal patient-reported outcome measures, opposed, to dissatisfaction resulting from expectations that were not addressed or met. There is often a discrepancy between the expectations of patients and surgeons, especially in

regards to post-operative outcomes where patients have higher expectations than surgeons. In order to clarify these concepts with each patient individually, effective pre-operative education and communication are required. The authors discussed a randomized control trial that assessed patient's anxiety and pain levels when receiving pre-operative multidisciplinary standardised information sessions compared to the normally provided verbal information, which showed a significant pre-operative reduction of both anxiety and pain scores but not post-operative levels in the intervention group. Findings were confirmed by a meta-analysis of studies ($n = 9$) showing pre-operative education moderately reduced pre-operative anxiety. However, there is controversial evidence on the cost-effectiveness of these programmes. Overall, the authors conclude that following surgery a good outcome with enhanced recovery, better functional mobility, and reduced hospital length of stay can be achieved through multimodal interventions that combine earlier discussed peri-operative measures. An adoption of multimodal clinical pathways could also lead to reduced overall cost (Ibrahim et al., 2012). This demonstrates that reassurance in the form of education should result in reduction of anxiety which is linked to better patient outcomes. Traeger et al. (2017) in his review added that especially patients with high distress require reassurance in term of structured education, to improve their short-term and long-term outcomes.

Although the process of reducing emotional distress with reassurance in patients with LBP is not straightforward (Traeger et al., 2017), orthopaedic surgeons involved in the care of chronic pain patients consulting for surgery should at least be aware and alert to the fact that psychosocial factors may influence patients' pain experience, health-related quality of life, and recovery. Despite the abundant research on the impact of mood, beliefs, and expectations on pain disability in both surgical and nonsurgical orthopaedic patients, as well as evidence on the efficacy of psychosocial interventions to improve pain and disability, the majority of surgeons still practice within a biomedical model. A recent study of 350 orthopaedic surgeons examined their attitudes and practice of noticing, screening, discussing, and referring for psychological treatment as well asking them to rank listed barriers to engaging in those processes. Findings suggest that although surgeons are likely to notice and discuss psychological factors with patients, the majority did not formally screen for them, nor were they likely to refer patients for their psychological problems.

Interestingly, surgeons who were more likely to refer for patients for psychological treatments were those who were engaged in research. The highest ranked barriers to the process of screening, noticing, discussing, and referring for psychological interventions were lack of time, being unsure how to notice, screen, discuss or refer, stigma and feeling uncomfortable (Vranceanu et al., 2017).

An appropriate assessment of psychosocial patient factors may enable the management of patients to be modified, which may result in the optimisation of their outcomes at later stages, regardless of receiving surgery, other treatments, or no treatment. Thus, surgeons have a pivotal role in transitioning the care of orthopaedic patients, from a biomedical to a biopsychosocial model (Vranceanu et al., 2017). However, in the effort to foster this transition, more research needs to be conducted to understand how surgeons can overcome their barriers and become more comfortable in addressing patients' psychological aspects of their illnesses.

Diagnostic test

Nationally, guidelines concerning lower back pain discourage the use of routine lumbar-spine imaging and recommend reserving it for the investigation of those cases in which symptoms suggest serious underlying pathology or severe and progressive neurological deficits (e.g. NICE, 2016). Imaging tests also have an acknowledged role in planning surgical management in cases of radiculopathy and spinal stenosis (Sheehan, 2010). Multifactorial and anatomical abnormalities are common in the spine and may not necessarily translate into clinical symptoms. Thus, determining the cause of MLBP is complicated (Sheehan, 2010). The diagnostic process is to distinguish 'simple' back pain from LBP, which occasionally is the presenting symptom of serious underlying disease, such as spinal stenosis, neurologic impairments, or, other specific spinal conditions. Guidelines recommend starting diagnostic triage with history taking and physical examination in order to identify 'red-flags' and classifying patients into the right category. If serious spinal pathology is suspected, imaging scans for patients should be utilized.

In terms of reassurance, a study showed that one third of acute back pain patients, who were told by their practitioner that imaging was unnecessary because their back pain was seen as uncomplicated, continued insisting on the need for imaging (Chou et al., 2011). Patients with CMLBP further desire imaging tests because they believe that there is something seriously wrong with their backs, which has not yet been diagnosed or even discovered (Serbic & Pincus, 2013) and doctors might be worried that they miss something. In order to meet patients' expectations about diagnostic tests, practitioners might still be using imaging routinely or without a clear indication, possibly because they aim to reassure patients and themselves (Chou, Fu, Carrino, & Deyo, 2009). In fact, a survey study with 90 GP's examining the role of radiography in LBP patients, showed that 88% of doctors said they requested radiography to reassure patients and 78% of doctors said they requested it to reassure themselves (Owen et al., 1990). Theoretically, patients should find negative tests reassuring. However, there are several problems associated with increased imaging and the evidence on the benefits of using imaging tests to reassure patients are contradictory.

If imaging tests are performed for the purpose of meeting patient expectations or reassurance, one would expect to see an effect from diagnostic information itself. To test this, Ash et al. (2008) conducted a prospective randomized primary care study examining the effects of knowledge of diagnostic findings (with and without x-ray) on clinical outcome in patients with LBP. A total of 246 patients were randomised to either the unblinded group (imaging results provided within 48 hours) or the blinded group (both patient and practitioner blinded to imaging results), followed by a 6-week conservative management programme. Results suggested that there is no difference in clinical outcome (self-efficacy, fear-avoidance beliefs, general health status) at 6 weeks between the two groups. However, there was an observed difference for the general health subscale, whereby the blinded group showed more improvement than for the unblinded patient group. The authors concluded that the knowledge of imaging results does not alter patient's outcome instead the information that there are degenerative changes of the spine was associated with patients having a lesser sense of well-being. Thus, receiving imaging results shows little clinical value, especially when accompanied by labelling, which seems to make people worse. This illustrates just one of many adverse effects of labelling patients

based on diagnostic findings rather than clinical symptoms. Darlow, Forster, O'Sullivan, and O'Sullivan (2017) explained in their review of evidence that the contents of imaging and accompanying reports strongly affect practitioners' beliefs, the advice they provide, and their clinical management decisions, which in turn impacts patients' beliefs and behaviours. Patients receiving imaging results accompanied by a diagnosis (e.g. degeneration, bulging disc, herniation, etc.), might lead to an enhanced threat and contributes to negative beliefs that are potential barriers to recovery. For example, a patient might interpret those explanations and test results in a way that leads them to believe that their spine is damaged and structurally vulnerable, which in turn results in increased fear and subsequent avoidance/protective behaviours (Darlow et al., 2017). Kendrick, Fielding, Bentley et al. (2001) conducted a randomised (unblinded) controlled trial in the UK, investigating the role of x-rays compared to usual care, without imaging. Patients (n=476) were randomised and followed-up in 3-months and 9-months' time. Results at 3-months follow-up indicated that patients who received an X-ray were more likely to report LBP and lower health status scores, although those differences were not found at 9-months follow-up. Patients who had received an X-ray were more likely to re-consult their GP at 3-months, compared to those randomised to usual care. After 9-months, patients in the X-ray group felt more satisfied, however, they were not less worried or more reassured about their belief that a serious disease might be causing their back pain than those who received no X-rays. At 3-months and 9-months, if patients had the option, 80% of patients from both groups would choose to have an X-ray.

There seems to be misfit with qualitative data from CLBP patients who reported that having visible evidence, such as an CT, MRI or X-ray positive results, serves as a long awaited proof of their symptoms (Serbic & Pincus, 2013). Moreover, practitioners order diagnostic tests because they also expect evidence of no disease (negative diagnostic test) to be reassuring. However, Traeger et al. (2017) reviewed the evidence, and found that a number of RCT's and systematic reviews examined patients' response after receiving negative diagnostic test results, showed no reduction in concerns or fear about illness and might even worsen disability outcome. There is especially limited evidence examining how surgeons and their teams use scan results to reassure patients and how patients respond to it. How do

positive test results (e.g. indication of disease), and negative test results (e.g. surgery not indicated because no evidence of obvious lesion or injury) effect perceived reassurance and outcome? While examination and imaging may in fact pinpoint the diagnosis, patients need to be educated on the primary goal of these investigation methods, which is to evaluate and rule out the other serious underlying disease. When the patient and the healthcare provider are reassured that there is no serious, underlying problem then potential treatment options can be reviewed (Carlson & Carlson, 2011). Providing patients with information and explanations of their pain is perhaps the most cost-effective way to avoid unwarranted imaging tests while satisfying the patients' expectations of care (Ash et al., 2008). Primary care practitioners may benefit from a tested and developed educational package that informs them about the utility of imaging tests as well as on strategies for identifying and meeting patients' needs to be reassured about the absence of serious disease (Kendrick et al., 2001). Whereas, for surgeons it may be pertinent to have guidelines towards methods of using the presence of a scan to effectively reassure patients that surgery is not indicated due to absence of serious underlying disease.

Ideally interventions should only be implemented after accurate diagnoses and consideration of prognostic findings. Yet, in today's environment, there is a rapid access and substantial use of imaging tests to improve diagnostic accuracy (Modic, Obuchowski, Ross et al., 2005). Rapid growth in imaging, especially advanced and costly imaging such as magnetic resonance imaging (MRI) and computed axial tomography (CT) scanning that replaced radiographs, has given rise to the question about the real value of these procedures (Shreibati & Baker, 2011). More tests (and treatment) do not simply reflect a greater incidence of LBP, there carry important implications for back pain (Deyo, Mirza, Turner, & Martin, 2009). There are numerous reasons to why overuse of imaging tests should be avoided, such as the obvious ones including the risk of harmful effects of radiation and the high costs coupled with the type of imaging used (Chou et al., 2009). Guidelines recommend a caution approach should also be adopted to the use of routine imaging for acute LBP. These recommendations are based on research indicating low frequency of serious disease in patients without red flags, weak correlation between findings on lumbar imaging and clinical symptoms (Jarvik & Deyo, 2002a), high likelihood for acute LBP to improve without treatment and lack of evidence that imaging is helpful for

guiding treatment decisions (Chou et al., 2009). Although extensive research and clinical practice guidelines aimed improve the quality of care for MLBP, there is increasing evidence that the quality of MLBP is suboptimal and there are substantial evidence-practice gaps (Lin et al., 2018). For example, more than one quarter of LBP patients in Australia are referred for radiological imaging, even though it is frequently warranted and imaging for LBP patients can increase the risk of iatrogenic patient harm. In 2011, it has been said about 42% of patients with LBP still receive an X-ray, CT or MRI within their first year of diagnosis, of which 80% receive imaging within their first month of presentation to health care (Ivanova et al., 2011).

A systematic review and meta analysis of six RCT's with a total of 1804 patients being randomly assigned, investigating whether routine, immediate lumbar imaging is more effective than usual clinical care without immediate imaging in MLBP patients without features suggesting serious underlying condition. Findings showed immediate, routine imaging for MSLBP without indications of serious underlying conditions did not improve clinical outcomes compared with usual care without immediate imaging. However, results should be interpreted cautiously since limited by small numbers of trials for some analyses and because identification of serious conditions was not a primary outcome in any trial instead most trials relied on routine clinical follow-up to identify these conditions (Chou et al., 2009). Further research assessed whether the early use of MRI or CT is cost-effective, influences treatment and outcome of patients with LBP. They used a pragmatic multicentered (n= 8) randomised control trial study design to compare two imaging policies as applied in routine clinical practice settings in the UK NHS; early imaging, which implies liberal use (n= 393), and, delayed selective imaging, which implies restricted use to patients with clear need (n= 389). Patients were followed up at 8 and 24 months, using a variety of outcome measures and the mean total cost per patient for both groups was calculated. Results showed that the mean total cost per patient for the early group was \$701 (median, \$434) and for the delayed selective group was \$614 (median, \$329). An improved health status was reported for all patients at 24 months, without indication of a significant greater improvement between the two groups nor was there a significant difference between the two groups and clinical treatment. Findings suggest that imaging has no measureable improvement in functional status or health-related quality of life, however, the MRI group indicated a

small direct effect in improved outcome, since they had a greater self-reported reassurance and satisfaction. Therefore, it has been concluded that the early use of imaging did not appear to affect treatment overall, and the small observed improvement in outcome is questionable, perhaps not justifying additional costs (Gilbert et al., 2004).

Most LBP episodes are self-limiting, but about 20% patients are referred for the opinion of a secondary care specialist (Croft et al., 1998). Patients referred to secondary care specialists are likely to receive conservative treatment (Gilbert et al., 2004). Although clinicians routinely request imaging to confirm their diagnosis and provide reassurance, the role of imaging in treatment of these patients is uncertain, poorly defined, variable and associated with the potential for ‘treatment cascades’ (Jarvik et al., 2003; Deyo, 1994). This suggests imaging leads to subsequent procedures that are of low value or futile to patients and would have otherwise never been done (Shreibati & Baker, 2011). Nonetheless, a major decision that confronts professionals in secondary care settings, is whether the condition will respond to conservative care or whether a more invasive intervention such as surgery is appropriate. Finding a method that prospectively determines whether or not patients benefit from conservative care, or likewise, identifies patients who undergo prolonged conservative care who require more aggressive therapy, such as surgery, would be of great value, saving cost of lost work, medical expenses, and personal discomfort (Modic et al., 2005).

Among all imaging modalities, MRI is the preferred method of investigation for most spinal diseases and increasingly requested for LBP patients (Sheehan, 2010). Jarvik, Jeffrey, Hollingworth et al. (2003b) conducted an RCT with LBP patients (n=380) whose primary care practitioner either referred them to an MRI or X-ray. After randomisation, patients were followed-up at 3-months and 12-months. There were no differences between the groups in pain, health-related quality of life (SF-36) and satisfaction. At 3-months follow-up, the MRI group had better disability scores (RMDQ) than those who received an X-ray, however, at 12-months follow-up there was no difference in disability scores between the groups. After 12 months, patients who were randomized to the MRI group felt more reassured (5-point scale) than those who were referred for an X-ray. Modic et al. (2005) aimed to prospectively

determine the MRI findings, prognostic role of them, and effect of diagnostic information on outcome, in 246 patients with acute LBP or radiculopathy. They found MRI did not appear to have a measurable value in terms of planning conservative care nor alter their outcome. Instead it was associated with a lesser sense of well-being. Considering the potential for confounding information, the procedure of imaging may have a detrimental effects in terms of unnecessary patients' therapy and for patients increased worry about the misconceptions of the seriousness of degenerative changes (Modic et al., 2005).

Moreover, research showed that increased frequency of MRI is associated with higher rates of surgery without clear differences in patient outcome (Lurie, Birkmeyer, & Weinstein, 2003). The use of MRI is often associated with receipt of back surgery because patients for whom surgery is indicated often referred to a scan as a precursor to surgery. On the other hand, research demonstrated that many people with no back pain have anatomical features in their back that appear abnormal on scan results (Jarvik & Deyo, 2002a; Jarvik et al., 2003b). Therefore, there is a risk for MLBP patients receiving an MRI scan to have 'positive' findings. However, the abnormality identified may not be the cause of their LBP but instead creates imperative to undertake treatments to correct the abnormality, such as surgery. In the end, many of these surgeries entail large costs and risks for patients, yet aimed at something that might not be the origin of the pain, making them ultimately unsuccessful at relieving patients symptoms. A study investigated the relationship between use of magnetic resonance imaging (MRI) and subsequent receipt of surgery for LBP patients. Results showed that for patients who were referred to an MRI scan by their primary care practitioner there was no association with subsequent surgery, whereas the receipt of an MRI scan for patients who had consulted with an orthopaedist increased the probability of having surgery by 34% points (Shreibati & Baker, 2011). Furthermore, Jarvik et al. (2003b) conducted a RCT comparing the clinical and economic consequences of replaying spine radiographs with rapid MRI for primary care patients and found that despite the higher rates of surgery associated with MRI imaging, the outcomes (patient symptom and function) on average were not improved by using MRI scans as the first imaging test. Thus, they concluded rapid MRI potentially increase the number of back surgery without an apparent benefit to patients and perhaps increasing costs. The authors further acknowledged

that if rapid MRI scans circulate widely and surgical complications being more common than they observed, consequences may be detrimental.

Modic et al. (2005) described the substantial use of imaging as a two-edged sword: imaging technology enables remarkably detailed anatomic assessment whilst also opening up the potential for the identification of incidental findings. Incidental findings refer to the identification of an abnormality that are not responsible for the symptoms, or, the identification of an abnormality that is possibly related to symptoms but not relevant to clinical decision making and outcome. The authors argue that incidental findings, especially for MLBP patients, might lead to additional testing, unnecessary interventions, increased costs of care, and, worst-case scenario it possibly leads to worse outcomes. They argued that the decision to offer surgery to a patient should be a clinical one and thus, based on presenting signs and symptoms. Once an individual has been deemed a potential candidate for surgery, imaging should be utilized as an important preoperative tool in establishing appropriateness and planning any subsequent operation.

Uncertainty

Experimental research evidence proposed that medical reassurance can fail or even have negative effects on patients, which is frequently the case in patients with medically unexplained symptoms (Rief, Heitmüller, Reisberg, & Rüddel, 2006). The process of data-gathering and information giving is especially challenging in non-specific conditions (Traeger et al., 2017). According to the findings of a systematic review of LBP patients' experience and expectations of healthcare, lacking diagnosis made coping more difficult and led to 'delegitimation', the feeling of not being believed, which further led to dissatisfaction. Nonetheless, the process of care mattered greatly to patients. Aspects of care that might facilitate acceptance were a good relationship, receiving a full assessment, considering the individuals' context, empathy (as discussed in next section), and sharing information. When neither a cure nor a diagnostic label available, generic reassurance skills, with importance given to personalization, remain important for patient satisfaction (Hopayian & Notley, 2014). One of the key aspects of reassurance for people with LBP, is the uncertainty

that patients and therapists are having to deal with. This uncertainty is coupled to unclear cause, diagnosis, prognosis, and treatment. Unclear or unavailable diagnosis often correlates with disability, pain and depression (Serbic & Pincus, 2013; Serbic, Pincus, Fife-Schaw, & Dawson, 2015; Serbic, Pincus, & Holloway, 2014). Cognitive processing might be the key mechanism by which perceived uncertainty could impact on patient outcomes. By the time symptoms are chronic, without a specific diagnosis and refractory to multiple treatment options, both patients and healthcare providers are frustrated (Carlson & Carlson, 2011). The results from a causal path analysis testing the paths between diagnostic uncertainty, disability, depression, pain and feeling guilty about pain showed that low mood and diagnostic uncertainty was associated with guilt. Especially social guilt towards family and friends, is an important process, resulting in poorer outcomes (e.g. disability). Study results provide a plausible explanation for the association between diagnostic uncertainty and poorer prognosis (Serbic, Pincus, Fife-Schaw, & Dawson, 2015). The narratives of CLBP patients ($n = 20$) suggested the absence of clear diagnosis not only has considerable negative implications in terms of distress, uncertainty, and further health care seeking but also influenced patient's perception of their social relationships, since having no visible evidence and no clear diagnosis gave their pain less social credibility. Moreover, patients reported feeling guilty towards other people, feeling guilty towards themselves and feeling guilty for not getting better. This indicates that the ability to find meaning is not only an important cognitive process but also an essential component of psychological recovery from stressful health related events (Serbic & Pincus, 2013). Findings pose the question of whether acceptance of pain is possible in the absence of an acceptable diagnosis?

Reassurance is commonly provided in the form of potentially corrective information (Linton et al., 2008), and may involve interpreting results of diagnostic tests, explanation for symptoms, prognosis, and management advice. It appears to be important that the role of emotional factors is discussed, and that all information is tailored to the existing knowledge of each patient individually (Traeger et al., 2017). In primary care, practitioners' messages should be tailored and changed depending on patients' psychological burden (Holt et al., 2015; Holt et al., 2018). Whilst, in secondary care key elements to effective reassurance for patients with CLBP focus on having patient-centred communication, being taken seriously/seen/heard/believed,

being given an understandable explanation of what's wrong, if possible being given a favourable prognosis, and being told what can be done. The study further notes that using open-ended questions, especially when dealing with psychosocial and complex emotional issues, might be beneficial (Lærum, Indahl, & Skouen, 2006). Ideally, this helps to reduce fear and corrects mistaken beliefs about the nature or severity of patients' condition, which may lead to healthier behavioural functioning (Linton et al., 2008). The success of health care providers relies on effective management of emotional distress, however, the process of emotional distress reduction with reassurance is not straightforward (Traeger et al., 2017). Linton et al. (2008) argued that recommendations for reassuring patient with LBP do not take into account the complexities of their pain experience. Although it is known that when ignoring psychological aspects of pain experience, including emotional responses or unhelpful beliefs, it may impede recovery, it is unknown, which psychological aspects should be addressed in consultations (Pincus & McCracken, 2013). How to provide clear and acceptable cognitive reassurance in the context of uncertainty, and how to identify potential patient sub-groups, who require special attention, remains a mystery and should form priority for research (Hasenbring & Pincus, 2015). Especially, when reassurance provided to patients with more complex pain experiences, such as at later stages, matching reassurance to specific patient needs to evoke the best possible outcome, becomes multifarious. What is clear is that an identical message to all patients is inadequate, and for subgroups with high risk, generic messages about expected recovery will constitute false reassurance. Therefore, integrating information on the biopsychosocial nature of LBP into the process of reassurance is highly recommended (Hasenbring & Pincus, 2015).

The process of reassurance occurs within a dynamic interaction between health care providers and patient which also entails an interaction within the patients' unique pain experience, thoughts, beliefs, emotions (Linton et al., 2008). Often, the complexity of people's individual characteristics influences the effects of providing reassurance. Although the information a person may receive about their condition is correct, there is no guarantee that a person will respond with reduced fear about their pain and change their behaviour. For example, patients receiving information that is not directly related to their experience and concerns, or, patients perceiving the information as a lack of understanding the legitimacy of their complaint ('it's not

serious, 'don't worry about it too much'), may respond by asserting their symptoms more forcefully (Linton et al., 2008; Traeger et al., 2017). Likewise, patients might perceive receiving a physical explanation as a lack of understanding and undermining the legitimacy of their condition, which may lead to them to assert their complaints more vigorously (Salmon, 2006). For patients screening for cervical cancer, information that they are likely to recover and that their problem is minor, showed to increase, rather than decrease worry (Michie, Thompson, & Hankins, 2004). This interferes that patients with complex pain experiences (e.g. high levels of anxiety) cannot simply be advised to stop worrying about their symptoms, since such advice appears to increase worry and health care seeking. Michie et al. (2004) argued receiving negative test may result in patients not feeling reassured, having less trust in the results opposed to those receiving positive test results and wanting further, unnecessary screening.

Dowrick, Ring, Humphris, & Salmon (2004) qualitatively explored audio recordings of the dialogue in routine consultations of GPs (n = 21) attempting to convey to patients presenting unexplained symptoms (n = 36) that they do not have a serious disease. It was found that GPs reassure patients by providing information and diagnostic test results. In their attempts to provide a normalising explanation, some approaches are ineffective and may exacerbate patient's presentations. When doctors provided simple reassurance based on clinical knowledge, such as providing a physical explanation not related to the patient's concerns, or attempted to dismiss the likelihood of serious disease, for example, with the authority of negative investigation, patients either responded by further elaborating their symptoms, requesting further tests or expressing more uncertainty and concerns. Only when doctors provided reassurance that included a tangible mechanism that absolves the patient from blame; in other words, an explanation that was relevant to the patient's specific concerns, linking physical and psychological factors, patients were more likely to accept the explanation. Cooper, Smith, and Hancock (2008) interviewed chronic LBP patients (n = 25) and found patients appreciated highly when diagnoses and treatments were well explained not only to their individual need and individual understanding but also to the extent that patients were able to comprehend what a diagnosis or the absence of the diagnosis meant for them. A qualitative study including observations of consultations (n = 55) followed by patient interviews,

found that LBP patients felt it was important to receive an understandable explanation of why their back hurt, which was required to be adapted to their personal concepts and knowledge, whilst metaphors and physical demonstrations (e.g. with plastic spine models/ imaging) helped to accomplish this. Effective reassurance was achieved when physicians clearly communicated that serious disease could be ruled out, when patients could infer their own conclusions from the information provided, and when telling patients that pain does not necessarily mean harm and an increase in pain when moving/exercising may be a sign of repair process (Lærum et al., 2006).

It has been proposed that uncertainty leads not only to preoccupation with illness, but also to increased depression. Do cognitive processes influence the effects of uncertainty on outcome? Is cognitive reassurance particularly important for these patients? These were questions driving the examination of the relationship between diagnostic uncertainty and recall bias among patients with CLBP (Serbic et al., 2014). Investigators of a study using an experimental design, hypothesized that patients who believed that there was a serious underlying, yet undiscovered problem in their backs would show cognitive biases towards illness-related words. The findings supported the hypothesis, showing all patients recalled more pain-related words, whilst only those with perceived diagnostic uncertainty recall also illness-related words, such as suffering, disabled and ill. The patient group with diagnostic uncertainty had higher levels of depression and disability than comparative group (Serbic et al., 2014).

The role of empathy

It is well established that significant others play a key role in the experience of pain and associated suffering. Facing others in pain elicits different range of responses in the observer, varying from compassion, ignoring distress, and inclinations to comfort or help. It has been argued that the effects of facing other in pain requires an understanding of empathy (Goubert et al., 2005). Empathy refers to the capacity of an observer to sense emotions and feelings of another being, implying a shared phenomenology wherein the observer is able to accept and understand the expression of another beings experience since it reflects the own experiences (Cohen, Quintner,

Buchanan, Nielsen, and Guy, 2011). Whilst self-oriented responses may imply egoistic motivation to reduce personal distress, the other-oriented responses may instigate an altruistic motivation to help the other. Nevertheless, there is a survival value of pain which lies within the actions taken to deal with it. This might involve actions of the observer (e.g. care, assistance) or actions of the person experiencing pain (e.g. escape, protection). Empathy represents a tool through which the adaptive outcome of an observer's behaviour toward the person experiencing pain might be achieved (Goubert et al., 2005).

Empathy is central to the practice of medicine and important for effective patient-centre communication, whereby especially distressed patients might find it easier to open up or disclose concerns to practitioners (Decety & Fotopoulou, 2014). A lack of empathy when attempting reassurance may cause patients to feel misunderstood and seek further health care, urging practitioners to be primarily empathic and collaborative (Traeger et al., 2017). A qualitative study, exploring physiotherapists' perceptions of empathy during consultations with patients with musculoskeletal conditions, was conducted (Allen & Roberts, 2017). The focus group with clinicians suggests that the majority perceive empathy as an innate characteristic, although there was a divergence on its acquisition and the extent to which it can be taught. Senior physiotherapists tend to place greater emphasis on the importance of empathic communication than students or junior physiotherapists. The latter group considered limited clinical experience to be a barrier to delivering empathic communication, suggesting empathic communication improves over time and through experience. The authors concluded that there is misfit between perceived importance of empathic communication by practitioners and the time they spent acquiring and developing those skills (Allen & Roberts, 2017). Another study, a recent systematic review and meta-analysis collected data from available randomised control trials of empathy interventions (where clinician deliver enhanced empathy) or expectations interventions (where clinician delivers positive messages to promote positive patient expectations about outcomes) on patient outcome. Out of 26,902 search citations, 28 studies (n = 6017) were eligible for inclusion. In 7 trials, empathic communication improved satisfaction, by reducing pain, and anxiety by a small amount (-0.18; 95% [-0.32 to -0.03]). In 8 trials the effects of positive expectations communication showed modest benefit (-43; 95% [-0.65 to -0.21]). In 11 trials there was no evidence

of adverse effects (odds ratio 1.04; 95% confidence interval 0.67 to 1.63). In summary, greater empathy from practitioners can have small patients benefits in terms of reduced pain and anxiety, especially for pain conditions, and are unlikely to harm patients. However, in most analysis, the quality evidence was low and the risk of bias was low to moderate (Howick et al., 2018).

Carl Rogers (1957) proposed the influential account of empathy in clinical models of therapy, which concludes that therapists require empathy in order to attempt to help others. It is a fine line of intruding someone's private world as if it were their own but without losing the 'as if' quality, which is needed to avoid becoming overinvolved and/or overwhelmed by the patient's experience (Goubert, 2005). Empathy presents a critical element, especially for (chronic) medically unexplained symptoms (Linton et al., 2008). Cohen et al. (2011) discussed the significant role of empathy in chronic pain medicine. Whilst the biopsychosocial nature of conditions such as chronic LBP has overall been accepted in most recent literatures, it seems paradoxical that stigmatization of people with chronic pain persists. Authors question whether this development of stigmatization of chronic pain patients is likely to be related to 'abnormal empathy'. It might be the result of strong negative emotional valence (negative empathy), a sense of personal danger, hostility, prejudice, and doubting the oppositions legitimacy, because morally clinicians are challenged with chronic pain. Facing them with the risk to be placed in 'moral jeopardy' (e.g. failing to validate pain) may result in challenging clinicians' power and control by denoting their motives are suspect to doubting the legitimacy of symptoms. Cohen et al (2011) proposed the idea that 'negative empathy' may overwhelm health care professionals and lead to increased stigmatization. In order to reduce avoidance or other restrictive behaviours, empathy and acceptance should be provided ruling out any attempts to suppress fear and anxiety. Alternatively, it may require a fundamental change in collective worldview (paradigm) to evoke change in practice.

Coia and Morley (1998) argued that 'no disease' explanations, are problematic for reassurance for two reasons. First, explanations are important in reducing illness. Patients who lack credible explanation of their symptoms experience emotional distress, which in turn may result in an illness-inducing vicious cycle. Furthermore, there seems to be a relationship between failure to understand that symptoms may

occur without disease and continuing illness. Second, there are numerous reasons why patients may not understand no-disease explanations. In this sense, authors propose the ideal form of medical reassurance might be to ensure patients that there is nothing anatomically wrong in their back, no disease (negative tests), whilst acknowledging that they have back pain. Moreover, health care providers may require to carefully measure the amount of emotional reassurance required against the quality and quantity of the arguments indicating that disease is absent. Arguably, the authors encourage practitioners to actively withhold their attempts to provide emotional reassurance to patients (Coia & Morley, 1998). Pincus et al. (2013) found indeed that outcomes seem to worsen after patients received emotional reassurance, although it has not adequately been tested yet. Nonetheless, their model proposed that empathic and sensitive communication might be essential at the early stages of consultation-based reassurance to achieve gaining patients trust and eliciting their concerns (Pincus et al., 2013). Especially in the context of uncertainty about aetiology and prognosis, it proposes that good clinical practice is both affective/emotional communication (creating rapport, showing empathy, and generic reassurance statements) to achieve an immediate reduction of patients' anxiety and cognitive reassurance (providing information in form of explanations, education and discussing treatment options) to achieve a long-term effect of changing patients' beliefs and behaviours (Pincus et al., 2013). Nevertheless, it is unclear whether Coia and Morley's (1998) notion of switching to a more neutral reassurance style is overall beneficial, but more so whether it is beneficial to patients who suffer from persisting, long-term pain conditions. At these late stages, once pain and disability have become entrenched, empathy may be required to effectively convey cognitive reassurance after all.

CHAPTER 3: METHODOLOGY

Introduction

Chapters 1 and 2 outlined the previous literature for LBP and reassurance. The current Chapter provides an overview of the methodologies and analyses employed for the empirical work carried out within this thesis. It provides the objectives and justification for the choices made in terms of methodologies and analyses that were used to address our research questions. In the proceeding chapter, we discuss some of the ethical considerations that grasp on the extended report submitted to the Integrated Research Application System (IRAS), which is a single system that is used to apply for the permission to conducting health research in the UK. Subsequently, we outlined why we choose to adopt a mixed-method approach, and further examine qualitative and quantitative research methodologies, retrospectively. For the qualitative study, we provide an overview of the methods history and discuss our choices in regards to participants, measures, design, and analysis, in comparison to available alternatives. Lastly, we discuss our prospective cohort study, by addressing important details about the design of the study and introducing the measures that we choose to use to examine baseline and outcome variables. Details about the methods used to analyse the results from our prospective study are outlined separately and can be found under the analyses sections of Chapter 6 and 7.

Ethical Considerations

The nature of our research required access and permission to study patients with persisting, long-term LBP consulting in secondary care, which entailed access to confidential NHS patient's information. To achieve data access, the researcher completed the 'Introduction to Good Clinical Practice eLearning in Secondary Care' (eGCP) Care) qualification, Disclosure and Barring Service (DBS) check, and Immunisation History Report in order to being inclined for a Research Passport that allowed her working with NHS patients (please see Appendix A for the Honorary Contract). In addition, we submitted an extensive form to the IRAS. The research methodology employed was classified under low-risk studies. Our studies involve no

deception and full informed consent are obtained from patients. The main considerations involved the burden of completing the questionnaires and answering questions that are potentially of sensitive nature (e.g. about mood). To sub-vert this we have used validated questionnaires that are commonly used in clinical research and reduced questionnaire questions to a minimal, where possible. All patients were informed that there may be some questions sensitive in content and that they may skip these without having to give an explanation. Participants were also informed about the aims of the study, that there are no right or wrong answers, their right to withdraw at any given time without having to provide a reason, that their responses will not be shared with their consultant and that participation will not affect their treatment. In concordance to 'Good Practice' Guidelines, general practitioner (GP's) were sent letters informing about the patient's involvement in this study, once they had agreed to taking part (please see Appendix B for GP letter). All participating spine specialist were informed about the objectives of this study.

This study was granted ethical approval by the ethics committee at Royal Holloway, University of London and from NHS Bromley Research Ethics Committee (REC reference: 16/LO/1833) (please see Appendix C for HRA approval letters, REC approval, sponsor letter, funding award letter, public liability indemnity). Our study was also deemed eligible for the inclusion onto the National Institute of Health Research (NIHR) Clinical Research Network (CRN) portfolio, which meant data collection was facilitated by the Comprehensive Local Research Network (CLRN) nurses. The entry relating to the study was available on the UK Clinical Trials Gateway. All recruitment information was regularly updated to the Clinical Patient Management System (CPMS). To assure confidentiality, we complied with the Data Protection Act 1998. The initial contact to patient information was conducted by the CLRN research nurses, who are employed from each NHS Trust. The researcher only had the contact details of patients that volunteered to enter the study, after the research nurses first made contact. Invitation letters to patients were sent well in advance, providing patients with at least 48h 'cool down' period to reflect on the information and consider participation. No reimbursement was offered for participation.

Following the cyber-attack on the NHS in May 2017, the NIHR IT consultants advised us against the use of iPad and e-mail response modes, for security and time-effective reasons. The main mode of response was through questionnaires, at baseline, and telephone, at follow-up data collection. Phone calls were only conducted through hospital phones or a research specific mobile phone. All patients' data was anonymised through unique identifying codes. Interviews were audiotaped referring to patients only by number, and identifying information was removed from recordings prior to transcribing. Audio tapes were transcribed by an external transcribing company (transcript.com UK), which was familiar with principles of confidentiality. Each recruiting site stored the consent forms in a locked cabinet at the R&D office, and the anonymised questionnaire data was stored in locked cabinets in the PI office in the department of psychology, Royal Holloway University of London. The site files and data storage were regularly verified by the local hospital PI. The transfer of data was only conducted via NHS email accounts and computerised data was only available to the researcher. During the study, the researcher obtained the contact details from participating patients, who allowed follow-up. To reassure the safety of the researcher during qualitative interviews, a text message was sent to the research nurses' phone, who had immediate access to patients' information, once the interview had started and finished. The coded data sets were available to the research team, without identifiable information.

Mixed Method Approach

Broadly speaking, qualitative research approaches, such as semi-structured interviews or focus groups tend to generate non-numerical data, while quantitative research approaches such as clinical trials, generate numerical data. Quantitative research remains the dominant paradigm in health research, using a deductive approach (testing a priori hypothesis) associated with the positivist stance that reality can be measured objectively. Qualitative research, on the other hand, usually comes from an interpretative framework based on the belief that there are multiple realities shaped by personal meanings whereby acknowledging the role of the researcher and the context of the data. It is described as an inductive approach since the analysis

allows hypothesis to emerge from the data (Tariq & Woodman, 2013). The goal of this mixed-method approach is not to replace either of them but instead to draw from the strengths and counterbalance the weaknesses of both across our studies. Ideally, the qualitative research procedures, given it is of high-quality, may allow us to generate a robust theory of consultation-based reassurance in secondary care, whereas, the quantitative research procedures, given it is based on a large and representative sample, may allow us to generate generalizable findings with minimized confounds. It is not believed that mixed methods research is in the position to provide a perfect solution, instead it can be seen as an attempt to combine the insights provided by qualitative and quantitative into a workable solution (Johnson & Onwuegbuzie, 2004). Although the aims and outputs of both methodologies are quite different, used in tandem to study the same phenomena, their combined use has been described as powerful (Snape & Spencer, 2003). Moreover, it can be perceived as an expansive and creative form of research that rejects the traditional dualisms, whereby, looking over traditional debates such as subjectivism vs. objectivism, but alternatively focuses on things that matter - finding a workable research methodology/technique to solve the actual problem (Johnson & Onwuegbuzie, 2004). This emergent methodology adopted in a single study, or, series of connected studies, as presented in this work, is increasingly used by health researchers, especially within health services research (Tariq & Woodman, 2013). Therefore, it provides us with a more satisfactory investigation technique to explore our broad, multifaceted, and complex research questions, which we believe in turn produces a more comprehensive understanding of our problem than either one alone.

To our knowledge, previous research has not exclusively focused on consultation-based reassurance in surgical settings, especially not in the context of surgery not being recommended as an appropriate method of treatment. To accommodate for the lack of research in this secondary care setting and the assumption that several changes can be expected from research in primary care settings, we used an integrated methodology of qualitative and quantitative research techniques. By using a mixed-method approach, we gain an in depth understanding while offsetting the weaknesses inherent to using each approach by itself. One of the main advantages is triangulation, which allows us to identify aspects of reassurance more comprehensively whilst approaching the enquiry from different vantage points, using

different data sources, methods, and techniques. The successful implemented triangulation comprises of carefully choosing the right method of analysis by making use of the information provided by each methodology (qualitative & quantitative), including its strength and weaknesses. Qualitative research methods are often used in advance to explore issues that are poorly understood (Spencer, Ritchie, Lewis, & Dillon, 2003). Considering the complexity of the subject matter, we first aimed to identify the underlying constructs key to effective reassurance in order to structure and generate the 'real life' language of a battery of questionnaire items compiled to measure levels of reassurance in this setting.

In our preparation work we used qualitative methods in the form of semi-structured interviews to explore the communication between surgeons and LBP patients, from the patient's perspective, within this specific secondary care setting. This may provide an insight into the key modifiable factors necessary for effective reassurance in this setting, which in turn informs our adaptation process of the methodological/clinometric properties of our reassurance questionnaire/measure. Once we had ensured that our measure of consultation-based reassurance is appropriate and comprehensive for this new setting, a qualitative method was adapted. The prospective cohort study was implemented to determine the overall and specific impact of consultation-based reassurance on post-consultation and three months' outcome in this patient group. In this mixed-method approach, the qualitative methods may help to address questions surrounding the nature of why patients perceive certain aspects about the consultant's communication more reassuring than others. Meanwhile, the quantitative research would be concerned with the measurement of reassurance, its distribution among those patients in this setting, and how reassurance can be mapped to certain outcome variables. Whilst examining the relationship between reassurance and outcomes (short-term, at 3-months) in this cohort of patients, the moderating effect of practitioners' profession and treatment outcomes are also taken into consideration. This way the main differences in perceived reassurance between patients who were recommended surgery and those who were not, can be established.

Qualitative Research

History

In response to challenges from other methodologies and paradigms (e.g. positivism, postmodern critique), researchers evolved more sophisticated research processes, such as using peoples' 'life stories' to understand their experiences (Snape & Spencer, 2003). It was the recognition that there is not just one truth (positivism) but there are many realities and it depends on which one we want to understand. This becomes especially difficult when trying to understand someone else's reality, whilst being thrown into a world operating through objects, relationships and language. Our being-in-the-world is always perspectival/ subjective and temporal or in relation to something that matters to us, making it difficult to relate, understand, capture and retell someone else's story. It could be argued that the lived experience of being a 'body-in-the-world' can never be entirely captured, but an attempt may entail not to ignore it. In response to those challenges qualitative research methods were developed, aiming to understand experiences and social constructs (Snape & Spencer, 2003). Qualitative research has been described as an activity that situates the observer in the world, consisting of interpretative practices that allows the world to become visible. Those practices enable turning the world into a series of representations such as interviews or recording (Snape & Spencer, 2003). It involves an inductive (bottom-up) approach, a naturalistic or interpretative way of collecting data. Thus, qualitative research study means attempting to make sense of things in their natural setting, sometimes known as 'real-world inquiry' (Henwood, 2014). Although at this level it means recognising the subjective experience of phenomena in terms of the meanings that people make of them. Therefore, qualitative research aims to provide an in-depth understanding of experiences, perspectives and histories in the context of personal circumstances or settings of those being studied (Spencer et al., 2003). In this study, we aim to study patients' narratives of their specialist consultation, which will entail researchers' attempts to interpret the patient's perception of their experience of this consultation.

The qualitative inquiry entails central research activities such as carefully looking, listening, recording, and contextualising peoples' experiences, thoughts, actions,

reflections and lastly, interpreting them (Henwood, 2014). This way, a deeper insight into the phenomenon can be gained allowing theories to be generated. Thus, a literal way of defining qualitative research is to perceive it as a form of inquiry, involving collecting and analysing non-numeric data, such as talk or text (Henwood, 2014). In contrast, experimental methods rely on isolating variables in strictly controlled environments to assure no unknown or confounding variables are operating when trying to objectively measure specific variables as well as their predicted effects. This indifference, particularly in relation to the variables, arose as concern in the twentieth century, when positivism became a dominant paradigm increasingly influencing quantitative research methods, such as survey research methods. Especially, the interpretative aspects of qualitative research methods can be criticised because of its comprising subjectivity. As a result, qualitative research was often being criticised as lacking rigour or not being 'scientific' enough, since variables unlike in an experimental research method are not controlled. Therefore, it has been argued that qualitative research may achieve ambiguous results (Snape & Spencer, 2003). It took until the late 1980's for qualitative methods to be used more systematically in psychological research although psychology as a discipline at the time was still heavily emphasised on experimental methods. In recent times, especially in the more applied clinical psychology domain, modern methods such as discourse analysis and grounded theory, are being used for investigations (Snape & Spencer, 2003). Modern qualitative methods have been argued to be more suitable to capture the experiences of patients (Hopayian & Notley, 2014), and their narratives of their perspectives of health and illness can enrich medical education (Ziebland & McPherson, 2006).

Design and methods

There is a range of options available in methodologically approaching qualitative data collection. However, the choice of selection should heavily be influenced by the aim of the specific research question. It can thus be said that a good qualitative research study design is in coherence with the research questions, has a clearly defined purpose, is realistic with regards to practical constraints and research context and generates valid and reliable data (Snape & Spencer, 2003). The first division in approaches that must be considered when collecting qualitative data is between a

naturally occurring phenomenon (e.g. use observation) and those that generate data through the interventions of the research (e.g. use interviews). The research behaviour under investigation is reassurance in a surgical setting involving subconscious elements (e.g. catastrophizing) that are of complex manifestation. Thus, the research aim is to generate data through re-telling or reconstructing patients' attitudes, beliefs, and behaviour in response to consultation-based reassurance. This allows us to gain an insight into patients' own perspectives and interpretations of reassurance expressed in their last consultation and more crucially it allows us to understand the meaning they attach to different aspects of it, which in turn determines their outcome. The most widely used method in qualitative research to generate data is individual interviews in different forms (Snape & Spencer, 2003).

In our qualitative study we used in-depth individual interviews because it was the most suitable approach to address our research enquiry. Compared to focus groups and trait interviews, face-to-face interviews allow an undiluted focus on the individual, whilst providing the researcher with the opportunity to explore, elaborate, clarify, and understand patients' personal contexts, which shaped their perspective and experiences of their pain (Snape & Spencer, 2003). We chose to conduct the interviews at a location of the patient's choice, which included the hospital, university, and their home. Except for one patient who chose her community centre, all patients requested the interview to be conducted at their homes. In most cases this decision was not just convenience based but often linked to severe morbidity constraints. According to Gagnon, Jacob, and McCabe (2015) the physical location is a fundamental aspect of the interview process because it becomes an active element in its own right, unfolding power dynamics, social relations, identifies and meanings in multiple ways. The authors state: 'it fosters a level of intimacy and reciprocity that cannot be reproduced elsewhere' (Gagnon et al., 2014, p. 210). However, it may also give rise to challenges for the interviewer, such as adopting a flexible interview style to redirect or reinforce the interaction when the natural flow of the conversation was disrupted by frequent environmental factors (e.g. phone rings, husband enters).

A widely used efficient method to gather medical information from patients is the use of semi-structured interviews with open-ended questions (DeJonckheere & Vaughn, 2019). The semi-structure style allows the researcher to structure the

interview around relevant questions and work flexibly around them, whilst patients are given room to respond with spontaneous descriptions, thoughts, and narratives (Pope, Ziebland, & Mays, 2000). The open-ended question style allows patients to discuss their concerns freely and assure the data was provided by patients accounts and not the researcher's expectations. The interview schedule was developed by a team of experienced low back pain researchers, who revised drafts until a final version was agreed up on. During data collection, it was further revised and changed, which is considered as good qualitative practice (Ziebland & McPherson, 2006). At all times, the researcher should resist from interrupting, expect for clarification to produce relatively unstructured, narrative data. One limitation that should be noted is that we did not use an extensive guide to assure that we are conducting qualitative research in line with good practice guidelines. An example of good practice guidelines that could have been utilised is the framework for appraising the quality of qualitative evaluations, which was developed by Spencer, Ritchie, Lewis, and Dillon (2003). This framework may be chosen because it operates within the boundaries of philosophical assumptions prescribed, offers a series of core principles concerning the contribution, defensibility, rigour, and credibility of qualitative research, covers different stages and processes of qualitative work and was designed to assess qualitative evaluation across the spectrum of substantive fields covered by Government Departments. The framework presents 18 appraisal questions that cover the key features and processes in qualitative research (design, sampling, data collection, analysis, findings, reporting) that aid the assessment. In addition, the framework also presents guiding principles in relation to general features of research conduct, such as ethics, auditability, reflexivity, and neutrality.

Approaches to data analysis

Analysing qualitative data was a relatively neglected subject until the latter part of the 20th century. Fortunately this has changed and different as well as more systematic approaches have been developed (Snape & Spencer, 2003). However, there is a range of different approaches to analysing qualitative data. They may differ in their philosophical base, rationale, process of analysis, outcomes, and evaluation of trustworthiness. Whereas, the common procedure in the different approaches is the categorisation and identification of themes, which usually is based on an

interpretative philosophy. In this process, the researcher devised a common code of categories, which is applied manually or with computer across the whole data set, aiding the navigation through the labelled data later on (Snape & Spencer, 2003). The data is categorised, patterns are identified, and once emerging themes have exhausted the data collection stops. Although different methods of analysing qualitative data can be used interchangeably or in conjunction, the right choice is yet fundamental to addressing research questions. Our analytic approach should focus on examining the meaningful and symbolic content of the data to understand what patients find reassuring during their consultation in this setting.

Discourse Analysis, Narrative Analysis, and Conversation Analysis may have a different focus, concerned primarily with the structure of interactions and language. Thus, they are not appropriate to address our research question as we were interested in what patients said opposed to how they said it, requiring a different analytic function. Interpretative Phenomenological Analysis (IPA), Grounded Theory, Thematic Analysis and Framework Analysis, are concerned with the substantive meanings of data, which are more appropriate methods for this study, as we aiming to uncover common themes in patients' experiences of consultation-based reassurance. IPA especially concerned with understanding the experience of patients, is not deemed the appropriate choice for our analysis, since it is based on a case-by-case design aiming an in-depth analysis of one particular person, context or phenomenon at a time, whereas, our interest is to capture and summarise the experience of a group of people (MLBP patients consulting orthopaedic teams). Thematic analysis method was strongly influenced by grounded theory, which is an approach to analysis but is not restricted to it. This theory was one of the first systematic approaches and originally developed by France Strauss, who came from a philosophical background and Barney Glaser, coming from a methodological background (Glaser & Strauss, 1969). This approach of analysis is mainly concerned with generating theory, systematically obtained and grounded in data. Thus, it is an inductive approach that requires the researcher to have no pre-conceived idea instead have a conceptual understanding, letting emergent themes and constant comparative method generate theory whilst analysis is parallel to data collection (Cho & Lee, 2014). Nevertheless, the aim of our research question was not to develop a completely new theory, instead expand the existing reassurance model from primary

care by shedding light on the patients' experience of consultation-based reassurance in this new setting.

The most widely used and overarching analysis within those most analytic approaches is the thematic analysis (TA). According to Braun and Clarke (2014), TA can be defined as an analytic methodology for identifying, analysing and reporting patterns or themes that emerge within data. Although the history of TA is unclear, it was used interchangeably with content analysis in the 1970's. Thus, it can be seen as the minimum organization and description of a set of data that is widely used as a basic method in qualitative data analysis showing its advantage- flexibility (Javadi & Zarea, 2016). Although a straightforward thematic analysis may seem an appropriate approach since our research question was narrow (what do people find reassuring?) and narratives were dominated by anticipated themes (Ziebland & McPherson, 2006), it yet seemed too simplistic for our rather complex goal. Moreover, it has been criticised for lacking depth and transparency in terms of developing themes, whereas emphasis being placed on illustrating the link between the different stages of analysis (Smith & Firth, 2011).

We aimed to adopt a flexible analysis, that allows for an inductive and deductive approach to our data. Seeing as prior knowledge about reassurance in this secondary care setting is limited, data should be approached inductively. This can be achieved by drawing the initial codes and themes directly from the interviews. Subsequently, data should be approached in a deductive manor. In this process, preconceived codes that were derived from prior research on reassurance in primary care (Holt et al., 2015) are being used to compare with our data. This way, confirmatory, contradictory, and contemporary factors can be identified and combined to form a new model that comprehensively accounts for consultation-based reassurance in this secondary care setting. The framework analysis is recommended when an existing model is being compared with the data (Gale et al., 2013) and was deemed as the most appropriate tool to approach our data. In addition, framework analysis is said to be 'aptly suited' for research that 'has a specific- question, a limited time frame, a pre-designed sample and a priori issues' (Srivastava & Thomson, 2009), which is also true for our enquiry. In medical and health research it has also started to become an increasingly popular approach (Gale, Heath, Cameron, Rashid, & Redwood,

2013). It is a form of or an approach of doing thematic analysis or qualitative content analysis, whereas using a different method in structuring. In fact, the name 'Framework' was derived from 'Thematic Framework' (Richie & Spencer, 1994). It concerns to define concepts that create categorisations, find associations and develop new theories. Its key characteristics are the case (individual interview) and theme (interpretive concepts) based approach, reducing data through synthesis, matrix display, retaining links to original data and producing outputs that allows for comprehensive and transparent data analysis (Gale et al., 2013). While key themes are analysed in-depth across the whole data set, the individual views of patients remain connected to the other aspects of their account within the matrix and therefore the contexts of the individual's view are not lost. This way comparing and contrasting data across and within cases is eased as part of the structure and process of framework analysis (Gale et al., 2013).

To answer the question of how large a sample is sufficient to uncover all themes of interest in qualitative research is an area of conceptual debate and practical uncertainty. Undoubtedly, the most widely used principles for determining sample size in qualitative research and evaluating its sufficiency is that of data saturation (Vasileiou et al., 2018). A review that applied framework analysis, included 60 qualitative studies out of an initial search of 1754 articles, found that the sample size in each study ranged from 7 to 406, although in most cases it was about 20 to 40 participants (Thórarinsdóttir & Kristjánsson, 2014). For our qualitative work we consulted previous research that also adopted a framework analysis (e.g. Holt et al., 2015; McGowan et al., 2010) to inform on what seems to be an adequate sample size. In addition, we stopped further data collection when fresh data (inductive stage of our analysis) no longer added new insights and indicated data repetition.

Coding

Within framework analysis numerical or textual codes are used to identify specific sections in the data which corresponds to identified themes (Gale et al., 2013). Coding is the process of attaching labels to lines of text in a transcript. This ensures the volume of data is manageable and that researchers can compare related information to one another. Whilst codes can have explicit or implicit meanings

(semantic or latent), relating to raw information that can be evaluated in a meaningful way or to the most basic parts of the data (Javadi & Zarea, 2016), a theme is the structural meaningful unit of data and hence represents the outcome of coding. According to Srivastava and Thomson (2009) when framework analysis is adopted to research it should sort the data in accordance with key issues and themes using five steps: 1. familiarization, 2. identifying a thematic framework; 3. indexing; 4. Charting, and 5. mapping and interpretation (according to Richie & Spencer, 1994). Following the familiarization with transcripts, data labelling is adapted to ease navigation and retrieval (Ziebland & McPherson, 2006). The initial codes should be derived through a line-by-line (open) coding approach, whereby the researcher should not be after something beyond what the patient said in their interview. Subsequently, the key themes that emerged out of the data (inductive, bottom-up approach) should be checked for overlaps and build into main themes (e.g. interview schedule structure) to formulate an initial explanatory (guided by research question) thematic framework. This is achieved by using axial coding, this is the process of relating codes to each other, allowing the formation of categories and concepts. Coding and conceptual categories should constantly be compared, reviewed, and refined in the light of new interview data, allowing for a further exploration of emerging themes. In addition, the extracted codes of each theme should form a consistent pattern and themes should repeatedly be validated to the entire data set. In Framework Analysis, charts or coding matrix, which uses the headings from major themes and sub-themes to chart data through separate matrices, are used to constantly review and revise the framework. Matrices outputs show participants responses across thematic coding categories. In the later stages of analyses (exploratory), the data is approached deductively (top-down), which entails reading the holistic patient narratives with a model (e.g. reassurance) in mind, looking for evidence in the transcript that not only describes each reassurance event, but also describes the impact this event has on them. The aim is to target analysis so to allow matching narratives to the existing model, which is achieved through selective coding or focused coding. Emergent themes should be discussed between the researchers, aiming to achieve consensus. When no new themes emerge and the research team is satisfied that analytical saturation is reached, data collections ends.

Prospective Cohort Study

Design

As a result of discussing the critique of positivism and qualitative research in the previous sections of this Chapter, the importance of rigorous psychological research was highlighted. Both, qualitative and quantitative research methodologies, may be combined to achieve the ultimate outcome. The aim of the qualitative research is to explore patients' perceptions and responds to consultation-based reassurance and to adopt the consultation-based reassurance measure to the needs of patients in secondary care. To further test the association between consultation-based reassurance and short-term changes in patient's beliefs as well as the long-term impact on their behaviours, a prospective cohort study is conducted. The study measured patients baseline shortly before the consultation, implementing the previously adopted consultation-based reassurance measure in the post-measure questionnaires one week after the consultation, as well as examining and three-month outcomes.

Being offered surgery or not is a natural incidence. Therefore, using an RCT would not be appropriate for our study enquiry because it be unethical to manipulate who is being offered surgery and who is not. In addition, we aim to assess multiple outcomes, such as satisfaction and enablement (short-term outcomes), and long-term outcomes (e.g. disability, sick days), hence a case-control study that only assess one outcome at the time would not be suitable for our enquiry. Longitudinal observational cohort studies can be argued to be mandatory in this scenario, providing a more natural way to measure events in temporal sequence. Because variables are measured chronologically, it allows for the assessment of potential risk factors (predictors) before the outcome has occurred and so establish cause and effect (Mann, 2003). In our research scenario, naturally, not all patients were discharged, the other groups (patients offered surgery or other treatments) can be used as an external control group to compare our target group to. This further avoids the debate as to which is cause and effect through demonstrating that these risk factors precede the outcome. The simplest and one of the cheapest cohort designs is prospective because it entails following patients group forward in time. One of the main

limitations of prospective cohort study designs is the inability to control for confounding variables (other influencing factors) that might differ between the groups. Another problem with this type of design is the loss of patients to follow-up, which can affect the outcome (Mann, 2003).

Sample size and power

Accurate sample size calculations are important for reliability of results because it tells us the likelihood of detecting an association when there is a 'true' effect that exists. To account for the expected drop-outs and achieve an adequately-powered study design, the sample size calculation should be inflated for longitudinal prospective cohort designs. Common admonitions for multiple regression to assure the subject/variable ratio is sufficient include: 10 or 20 patients per predictor, a minimum of 100 patients plus 10 per predictor, and 300 patients if there are more than 10 predictors. Vanvoorhis and Morgan (2007) proposed a 'rule of thumb' to increase power in accessible ways, such as increasing the sample size. They recommend using 10 participants per predictor variable to estimate the minimum sample size required for efficient power. Our analysis consists of three predictor blocks, with a total of 14 variables, and so around 140 participants with full data will be required. Based on response rates from cohorts in similar settings (e.g. Grotle, Foster, Dunn, & Croft., 2010) a response rate of around 50% was expected, and therefore we would need to recruit a minimum of 300 participants at baseline, which should provide a safe margin of error to ensure sufficient numbers for analysis. However, there are more 'formal' ways to conduct power analyses to determine an adequate sample size. Currently there is no published data from surgical settings, hence our power calculations were based on data collected in primary care (Holt et al., 2018). Although initially we planned to adopt the median split depending on the STARTBACK scores, which used a comparison based on the group of patients who received high cognitive reassurance (median split) against those who received low cognitive reassurance, as seen in previous research (Holt et al., 2018). Scores on disability were used as one of the outcome variables, which is the same for one of our long-term outcomes. However, this median split approach based on the STARTBACK did not seem to capture our primary research enquiry, which was to see if there is a difference in perceived reassurance between those patients who

received treatment and those who were discharged. This power analysis was used to make the problem traceable, but does involve number of simplifying assumptions to accommodate for the complexity of our research situation. We utilised G*Power version 3.19.2 for multiple regressions to calculate our sample size. For a medium effect (0.15), the power was set to 0.90, the alpha was set to 0.05, as in previous research, and 14 was entered as the total number of predictors. This indicated we may require 88 patients in each group, which suggests we have to collect data on a sample of at least 176 patients. In addition, we will collect data from 75 participants who are recommended surgery, providing a control group to test differences in reassurance levels. This group will not be asked to provide follow-up data. Considering, a worse-case scenario, the follow-up rate might be around 50% (based on our prospective cohort in primary care, with used no reminders or alternative to postal options), we require a minimum of 352 participants to be recruited into our prospective study at baseline.

Feasibility

To establish the time that is needed to recruit the number of eligible patients required, we based our estimates from collecting qualitative data over 4 non-consecutive weeks from the 3 of the participating hospitals. Each site saw on average 4 eligible patients a week across a total of 7 practitioners ($n = 12$). From estimations 50% of these will consent to take part in the study, resulting in a total of 24 patients recruited per month. Therefore, recruitment will take place over an estimated 14 months' period. In case recruitment fall short of anticipated numbers or to allow for slippage during national holidays, we have planned for this stage to take place over 16 months. Best practice is utilized to ensure maximum response rates at post-measure collection and follow-up. The primary mode of follow-up is through a phone call by the same researcher who approached patients in the clinic for consent and baseline measure collection, which may provide patients with a sense of consistency in the person of contact and may minimize drop-out rates. Throughout the post-measure collection period of 7 days from the initial consultation and the follow-up period of 2-weeks after 3- months from the initial consultation, phone and voice note reminders are facilitated to prompt patients for responds. As far as possible, reasons of attrition will be noted down to further provide an insight about

why patients did not want to further take part in the study. Differences between non-responders versus responders will be compared on their key characteristics and variables.

Missing Values

We expected missing values, as they can never be totally prevented (De Leeuw, 2001). Missing data is defined as: ‘values that are not available and that would be meaningful for analysis if they were observed’ (Little et al., 2012, pp.1). There might be a number of reasons why there is missing data in cohort studies with waves of data collection at different time points. There might be missing data in participants who completed the study but refuse/forgot to respond to certain questions. There might also be missing data because participants are not traceable (e.g. moved, changed contact details), fell ill or other life circumstances (e.g. accidents, death), or withdrew from the study (Karahalios, Baglietto, Carlin, English, & Simpson, 2012). There are no rules about the maximum number of missing values that is acceptable in research, nor are there rules about a universal method of dealing with it, because each study has its own set of design, and measures (Little et al., 2012). Nonetheless, the impact of missing covariate data in research needs to be considered. Especially, when analysing clinical trials, missing data can be a potential course of bias as it limits researchers in drawing definitive conclusions (Chen & Zhang, 2012).

It is important to develop a protocol in the pre-planning phase of cohort studies to establish ways of reducing missing data (e.g. re-contact patients at different times during follow-up) and report methods to how missing data was handled for analysis. An appropriate way of addressing missing data is outlined by the STOBE guidelines (von Elm et al., 2007). For example, the guidelines recommend that the researchers should report reasons for non-response or drop-out as well as outlining how missing data was addressed in the analysis. There is broad range of approaches used to model missing data, whilst not all methods are suitable for all situations, the inference with data is extremely broad (Little et al., 2012). The following are some examples of methods performed to handle missing data: complete-case analysis, multiple imputation, estimating-equation methods, last-observation- carried-forward approach, and Bayesian modelling. In addition, researchers should conduct a

sensitivity analyses to assess the robustness of findings and support the main analysis (Little et al., 2012). To minimize the quantity of missing data in our study, when patients returned their questionnaires, missing sections are pointed out to them to check if patients skipped those on purpose or by mistake. We also employed telephone follow-ups instead of posting the questionnaires and relying on the patient to complete them and sent back. Survey data collection in the form of face-to-face and telephone, generally result in less item nonresponse, compared to postal questionnaires (De Leeuw, 2001). Lastly, we will conduct analysis to determine whether the data was missing at random or certain patient characteristics were associated with it.

Questionnaires

The majority of the variables examined in this study (e.g. demographics, health care utilization, pain duration, pain intensity, StartBack, anxiety, depression, disability) are widely used clinical measures and recommended for cohort studies in LBP research (Pincus et al., 2008). Please refer to the Appendix for all questionnaires. Patients received a self-administered paper questionnaire to assess their baseline data, which they completed before their specialist consultation. Subsequently, the post and follow-up questionnaires were completed by researcher by reading the questions and answers to patients over the telephone. The phrasing of the questions was kept as similar as possible to the original paper-based questionnaires and patients were urged to answer as spontaneous and accurate as possible. Most surveys used in this study have previously been used in research that assessed measures through the use of telephone interviews. A study, using the data from a larger RCT examining the efficiency of twice- compared to once- weekly yoga classes for chronic LBP, examined the reliability of different methods of survey administration (Cerrada, Weinberg, Sherman, & Saper, 2014). They compared self-administered paper questionnaires to computer assisted telephone interviews on LBP-specific outcome variables, such as pain intensity, functional status, satisfaction, pain medicine use, global improvement. They found that there were no main differences between the different survey modes for physical health and behavioural items, such as disability and medical use. However, they found that patients responded slightly more positively to sensitive topics, such as depression and anxiety, when asked by an

interviewer over the phone. The authors recommend having both options available for data collection as it may improve the overall response rate. The outcome variables used in the study closely corresponded to the questionnaires used in our prospective-cohort study to assess short-term and long-term outcomes, as further discussed in the next section.

Before introducing the questionnaires used in our study, there are some important considerations to be mentioned about the measures. Firstly, there may be a conceptual overlap between the measures of reassurance and satisfaction, and their measures. For example, satisfaction typically measures elements of comprehensiveness in exploring the patients' history, a sense of being listened to, and clear explanations about diagnosis, prognosis and treatment plan, and all of these areas are also covered in the measurement of reassurance. Arguably, reassurance focuses on patients' perception of what the clinician actually did, while satisfaction measures their evaluation of whether these behaviours, along with other factors, such as waiting time, reception etc, were acceptable to them. However, similar items between both measures may result in multicollinearity which occurs when two or more independent variables (e.g. reassurance and satisfaction) are highly correlated with each other and provide redundant information about the response. As a consequence, their distinct value as predictor on outcomes may be unclear, leading to problems with understanding which variable contributes to the variance explained in the dependent variable (Laerd Statistic, 2015). There are two stages to identify multicollinearity: the inspection of 1. correlation coefficients and 2. variance inflation factors (VIF) and tolerance. If there are no correlations larger than 0.7, which is the recommended cut-off point (Laerd Statistic, 2015), there is most likely no collinearity problem. In reality, VIF is simply the reciprocal of Tolerance ($1 \div \text{Tolerance}$), thus we are only required to consult one of the two. If the Tolerance value is less than 0.1 – which is a VIF value exceeding 10 - there may be a collinearity problem (Laerd Statistic, 2015) and we can assume that the regression coefficients are poorly estimated. A solution may be to cut out the overlapping items from the satisfaction measure, but this may be difficult seeing as it needs to be assured that the good psychometric properties are retained and test-retest reliability is not compromised. In response to the above problems, we decided not to enter reassurance and satisfaction simultaneously as predictor variables, instead, in the

analysis we only enter reassurance sub-scales as predictors for satisfaction as outcome variable. It might be that the conceptual overlap of the measures leads to increased estimated values of regression coefficients and indicate reassurance as strong predictors, yet it still provides us with an understand to which of the sub-types of reassurance best predict total satisfaction in this sample. Regardless, the results of the regression model that entered reassurance as predictors for satisfaction must be interpreted with great caution given both measures are highly correlated.

Secondly, it is important to understand the constructs of acceptance and catastrophizing individually, how they relate to each other, and their influence on outcomes to prevent and treat chronic pain (Gatchel and Neblett, 2017). These constructs are complex, overlapping, and the measurement requires separate and comprehensive questionnaires. In consideration of the burden to patients, we had to limit the number of questionnaires given. The single item may not capture the full scale of catastrophizing or acceptance, but it is an indication of the extent to which these patients accepted the explanations they were just given in the consultation. Therefore, the results of the two regression analyses that aimed to predict acceptance and catastrophizing should be interpreted with caution and future research should be encouraged to use more appropriate measures. Chronic pain acceptance questionnaires typically include sub-scales such as pain willingness and activity engagement, whereas, catastrophising measures typically entail subscales such as magnification and helplessness. However, in this study, we were focused on acceptance of the message received, so do they accept the explanation they received and/or do they believe there is still something serious that has not been mentioned in the consultation. Possibly the label acceptance and catastrophizing are misleading here, as they are interpreted to mean a valid and reliable measure of the whole construct, whereas, ours is a pragmatic approach to measure one aspect only: acceptance of the message received.

Baseline Measures

Demographics information: Patients were asked about their age, gender, marital status (married/civil partnership; cohabiting; single; divorced; widowed; other), education status (left school at or before 16; obtained A levels or equivalent;

obtained higher education degree/certification), work status (employed, full or part time; looking after home/family; retired; student; unemployed for health reasons; unemployed for other reasons), and whether they suffered from other serious health issues.

History and Journey: Patients were also asked questions about their history of LBP and their health care journey: if they had previously been told the cause/diagnosis of LBP, the length of their current episode, the overall years lived with LBP, the number of previous consultations (1-2; 3-5; 5-10; 10+), the number of previous treatments and which treatments were received, and whether or not they had received an imaging scan. For purpose of this analysis only the expectation question about surgery was analysed by classifying patients into those who would not like to have surgery, those who are undecided or indifferent, and those who would like to have surgery.

Psychosocial Risk Factors: were assessed using the StartBack screening tool, which is used for prognostic risk stratification (Hill et al., 2008). Originally, the measure consists of 9 items, determining the presence and absence of biopsychosocial risk by asking responders to agree (1) or disagree (0) with the statement whilst thinking about their past two weeks. The original coding of the prognostic tool adds all positive responses to stratify patients into low, medium, and high-risk of developing poor outcome or persistent disabling LBP (Whitehurst et al., 2015b). For the purposes of our research we only used four items (5-8): fear of physical activity; anxiety; pain catastrophising, and depressive mood. These items were identified as a psychosocial subscale and considered as sufficient to classify patients into ‘at-risk’ and ‘low-risk’, avoiding the repetition of similar questions throughout the different measures used in this study. Out of a total of 4, participants scoring 0-2 were considered ‘low-risk’, whereas, scores of 3-4 were considered ‘high-risk’. The measure has substantial test-retest reliability, showing a quadratic weighted kappa score of 0.73 (95% CI 0.57-0.84) for the overall total scores and 0.69 (95% CI 0.51-0.81) for the psychosocial subscale scores (Hill et al., 2008). The tool has been translated in numerous different languages and demonstrated similarly high discriminative ability across the physical and psychosocial constructs for external samples in different countries (Traeger & McAuley, 2013). A growing body of

evidence supporting the psychometric properties and predictive ability particularly in populations with MLBP of variable episode duration (Beneciuk et al., 2015, Field et al., 2012, Firtz et al., 2011). The evidence about the predictive and discriminative ability is contradictory in cohorts with persistent MLBP patients (Kendell et al., 2018; Morsø, Kent, Manniche, & Albert, 2014; Petit, Fouquet, & Roquelaure, 2015).

Pain intensity: was measured by asking patients how intense their pain was, on average, over the past seven days, using a 11-point Numeric Rating Scale from 0 (no pain) to 10 (worst possible pain) (Jensen, Karoly, & Braver, 1986). The scale shows high test-retest reliability (Dworkin et al., 2005). For construct validity, the scale showed to be highly correlated with similar scales, such as the visual analogue scale (VAS) in which pain is shown spatially as distance along a straight line, in patients with chronic pain conditions (pain > 6 months): correlations range from 0.86 to 0.95 (Childs, Piva, & Fritz, 2005).

Functional Status: was measured with the Roland-Morris Disability Questionnaire (RMDQ) (Roland & Morris, 1983). The measure is composed of 24 yes (1) or no (0) questions. The total score is calculated by the total number of items checked, from a minimum of 0 meaning no disability up to a maximum of 24. The questionnaire is a widely used and well-validated measure of back pain related disability (Pincus et al., 2008). The measure has been translated in 36 different languages and versions (Dworkin et al., 2005). The measure has a range of intraclass correlation coefficients between 0.83 and 0.93 (test-retest reliability), which depends on test and retest (Stratford et al., 1996, Jordan et al., 2006). It also has good validity and reliability with a range of internal consistency between 0.83 and 0.95 (Cronbach α) (Stratford et al., 1996, Spanjer et al., 2011).

Anxiety and depression: was measured using the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). It consists of 14 items which evaluate the severity of feeling anxiety and depression in the past week (7 items relating to anxiety; 7 items relating to depression). Scores range from 0 to 21 for each sub-scale; the higher the scores the greater the likelihood of depression or anxiety. The HADS has been widely used in clinical research. During initial testing, good internal consistency was found for the depression subscale (0.81) and for the anxiety subscale

(0.80) (Zigmond & Snaith, 1983). Other studies found acceptable internal consistency reliability, with a range of internal consistency between 0.79 and 0.95 (Cronbach α). Test-retest reliability for the depression scales, as measured by intraclass correlation coefficient, was good, with a score of 0.90, and for the anxiety scale it was lower but considered good, with a score of 0.83 (Bernstein et al., 2018). A systematic review suggested the measure holds high internal consistency with Cronbach α values for the anxiety sub-scale ranging from .68 to .93 (mean .83) and for the depression subscale ranging from .67 to .90 (mean .82) (Bjelland, Dahl, Haug, & Neckelmann, 2002).

Post- consultation measures (Short-term outcomes)

At post-consultation data collection, patients were asked whether they had been told the cause or diagnosis of their LBP in their last consultation or whether they received an explanation for their back pain and if they felt they had the chance to voice their treatment preferences. In addition, patients were asked to provide the consultant's recommendation in terms of treatment outcomes (surgery, discharged, other treatment), and whether they had the intention to re-consult elsewhere and with whom. There were 11-items available for response: 1) sent to imaging tests, 2) referred for another opinion, 3) 6-months open appointment, 4) continue taking your usual painkillers, 5) prescribed new painkillers, 6) referred to Yoga, Pilates, Aquatics, 7) injections, 8) physiotherapy, 9) pain specialist team, 10) discharged without treatment, 11) recommended surgery. For purpose of the analyses, the items were grouped into 3 categories: other treatments (items 7-10), surgery (item 11), discharged without further treatment (item 10).

Consultation-Based Reassurance: was measured using the Effective Consultation and Reassurance questionnaire (ECRQ) (Holt & Pincus, 2016). This is a 12-item questionnaire, including 4 sub-scales with each 3 items: data-gathering, DG (e.g. to what extent did the physician... 'encourage you to voice your concerns regarding your symptoms?'); relationship building, RB (e.g. to what extent did your physician... 'show a genuine interest in your problem'); generic reassurance, GR (e.g. to what extent did your physician... 'tell you that there is no need to worry'); and cognitive reassurance, CR (e.g. to what extent did your physician... 'make sure you

understood their decision about treatment options'). Informed from the previous qualitative study, this measure had to be slightly adopted to the needs of the secondary care group, hence changes in wording (treatment exchanged to management) and order (items 3 and 11 swapped) were applied. Although we did not deviate from the original scoring of the measure, we used numbering to title each response mode that was scored on a 1 (Not at all) to 7 (a great deal) Likert- scale. On each sub-scale the scores ranged between 3 and 21. The measure is reliable and validated in primary care settings (Holt et al., 2018).

Acceptance: 1-item question assessed acceptance, by asking patients whether they accepted the explanation they received (agree/disagree) (Serbic et al., 2013).

Catastrophizing: 1-item question assessed patients catastrophizing beliefs, by asking if they still believed that there is something serious going on with their back which has not yet been diagnosed (agree/disagree).

Consultation Satisfaction: was measured using the Consultation Satisfaction Questionnaire (CSQ) (Baker, 1990). This is a 9-item questionnaire with each item being rated on a 5-point scale from 'strongly agree' to 'strongly disagree'. The minimum score for each item is 0 and the maximum score is 100. The questionnaire can be scored as a whole (0-900) or divided into four different subscales measuring: general satisfaction, satisfaction with professional care, satisfaction with the depth of relationship, and satisfaction with perceived time. The CSQ has been extensively evaluated and studies have shown that the measure possesses good validity and reliability (Richard Baker & Whitfield, 1992). The Cronback's alpha for the questionnaire was 0.91, and for each of the four sub-scales it varied from 0.67 to 0.87, suggesting the measure is sufficiently reliable to discriminate between groups of patients rather than individuals (Baker, 1990). There has also been a number of independent research studies that evaluated and compared the CSQ to other questionnaires, assessing consultation satisfaction in primary care (Richard Baker, Smith, Tarrant, McKinley, & Taub, 2011; Kinnersley et al., 1996; McKinstry, Colthart, & Walker, 2006). One study also found that the level of inter-correlation suggest that total scores may be preferred (Kinnersley et al., 1996), a recommendation that we followed for our analyses.

Enablement: was measured by using the Patient Enablement Instrument (PEI) (Howie, Heaney, Maxwell, & Walker, 1998). This measure consists of 6-items assessing patients enablement, their ability to cope with their problem as a result of the information received in their consultation. The questions are structured according to the following: as a result of your consultation, do you feel you are... ‘1) able to cope with life, 2) able to understand your problem, 3) able to cope with your problem, 4) able to keep yourself healthy, 5) confident about yourself, 6) able to help yourself?’. The answers options were rated on a 3-point scale from either ‘much better/more (2)’, or ‘better/more (1)’, or ‘same or less (0)’ or ‘not applicable (0)’. The total score ranges between 0 and 12. The measure generally shows high internal reliability and proven to be robust and applicable (Rööst, Zielinski, Petersson, & Strandberg, 2015).

Follow-up measures (Long-term outcomes)

At 3-months follow-up data collection the same questionnaires that were used to assess patients’ **pain intensity** (Jensen et al., 1986), **functional status** (RMDQ, Roland & Morris, 1983), **depression and anxiety levels** (HADS, Zigmond & Snaith, 1983) were also used to assess long-term outcomes, allowing for the comparison to baseline data. As additional outcome variables, patients were asked to report how many **sick days** they had due to their LBP in the past 3 months, as well as their **healthcare utilisation** for back pain in the previous 3-months. This was assessed by asking how many times patients went back to see their GP for their back pain since their last consultation and whether they had consulted other practitioners for their back either within the NHS or privately (GP, Surgeon, Osteopath, Physiotherapist, Pain Specialist team, Hospital visits, Other).

CHAPTER 4: ‘DISCHARGED WITH A FEELING OF BEING DISMISSED’: NARRATIVES FROM PATIENTS WITH MSK LBP ATTENDING SECONDARY CARE CONSULTATIONS WITH A SURGICAL TEAM: A QUALITATIVE STUDY

Abstract

BACKGROUND consultation-based reassurance aims to reduce health-related concerns. Previous evidence in primary care has shown that content and style of professionals in consultations for musculoskeletal low back pain (MLBP) are associated with patient outcomes, especially patient satisfaction. Little is known about the role of reassurance in people with MLBP consulting for spinal surgery, especially in cases where surgery is not recommended. There might be several reasons to exclude surgery as a treatment option: these range from positive messages about symptoms resolving to negative messages, suggesting that all reasonable avenues of treatment have been exhausted. **AIM** To explore patients’ perceptions of how professionals deliver reassurance while disclosing that all reasonable avenues of treatment have been exhausted, and how patients respond to this message. **METHODS** Semi-structured interviews were conducted with thirty patients with chronic disabling LBP who had recently consulted for spinal surgery and were advised that surgery is not indicated. Interviews were audio recorded and transcribed, and then coded using NVIVO qualitative software and analysed using framework analysis. Data was coded and analysed by two independent researchers, assuring inter-coding reliability. **RESULTS** Most patients reported feeling dismissed and discouraged. They considered that consultants were better in relationship building and data gathering, conceptualised as implicit reassurance, than in providing any explicit reassurance, such as cognitive and generic reassurance. Major emerging themes included the complexity and confusion of their journey in the national health care system, lack of continuity-of-care, lack of information about their condition, and a sense of dismissal. Patients reported that they needed to be validated and

subsequently reassurance through clear explanations and discussions of pain management, but instead they were discharged into a void. **CONCLUSION** Effective communication with patients attending surgical settings to consult about their back pain is important, especially when no active treatment is being offered.

Introduction

Chapter 1 and 2 provided a comprehensive summary of past research relevant to consultation-based reassurance for patients with LBP. It is important to note that Chapter 2 was written after this qualitative study was finalised. This is an advantage in terms of limiting bias because it meant that the researcher who conducted the initial inductive or bottom-up coding had no pre-conceptualised knowledge or ideas about the topic and hence allowed the data to emerge entirely out of the transcripts. However, there is also a limitation, in that the comprehensive concept of reassurance in all its complexity may not have been explored in the interviews. Previous research shows that a reliable and valid measure of consultation-based reassurance enables testing reassurance against patient's short, medium, and long-term outcomes in primary care. Nevertheless, little is known about the role of reassurance in people who consult for spinal surgery in secondary care settings, especially when surgery is not indicated as treatment option, whatever the reason. It is recognised that there are several reasons to exclude surgery as a treatment option, ranging from positive messages about symptoms resolving to negative messages suggesting the end of the treatment avenue. Nevertheless, patients who are consulting for spine surgery are likely to have exhausted most conservative management routes, such as physiotherapy. Therefore, the challenge lies on the side of the health care provider in reassuring patients that their way forward means effective self-management through on-going living to their best ability opposed to seeking cure in surgical procedures. Thus, the study aims are to investigate how professionals convey to patients that all reasonable avenues of treatment have been exhausted as well as gaining an insight into how patients perceive and respond to it.

Musculoskeletal low back pain (MLBP) remains the leading cause of disability in the world (Hoy et al., 2014) and the sixth biggest contributor to burden of disease

DALYS (Disability- adjusted life years) (Vos et al., 2012). Cost and disability are mainly associated with long-term LBP, accounting for 75% of all LBP health care costs (Becker et al., 2010). Overall, MLBP is estimated to cost the UK economy 12 billion pound per year (NICE, 2016) and thus considered NHS research priority (Donaldson, 2009). High care utilization is more likely to be driven by long-term MLBP patients, who might eventually be referred to orthopaedic surgery consultations. Once all treatment that have been shown to improve pain in MLPB have been tried to no avail, patients may be sent to surgical settings for further explorations and the possibility of surgery. When surgery is not indicated as a treatment option, for whatever reason, patients are often discharged without further treatment option. In this case, the consultation may be the last contact of care between healthcare providers and the patient, until the patient fetches up again in primary care. We therefore hypothesise that the manner in which professionals convey this message to patients is important as it might impact on the patient's understanding, thoughts, and subsequent behaviour in managing their pain.

Clinical guidelines for MLBP recommend reassurance as 'corner stone' of treatment (Koes et al., 2010; Savigny et al., 2009). The method of reassurance is in the behaviour of the healthcare provider (Linton et al., 2008). The act of reassurance aims to reduce fears and concerns about pain and health, encouraging patients to effectively self-manage their condition. A systematic review assessed 16 prospective cohort studies in primary care settings, which examined cognitive and affective reassurance in relation to patients' outcome. It was found that affective reassurance (creating rapport, showing empathy) at best improved patient satisfaction and at worst was linked to poorer patient outcome (higher symptom burden), whereas cognitive reassurance (providing explanations and education) improved patients' outcome in terms of ameliorated symptoms and decreased healthcare utilisation, at 3-months follow up (Pincus, Holt, et al., 2013). Findings from a qualitative study with LBP patients in primary care showed that patients appreciated early implicit reassurance (outside spoken messages) in terms of affective behaviours, such as being understood, being taken serious, relationship building, and the use of clinical examination procedures by the consultant. However, later explicit reassurance (direct messages from doctor), in terms of information and explanation about their problem and how to manage it, was valued more highly by the patients due to its effect of

reducing concerns and empowering towards self-management (Holt et al., 2015b).

A 12-item consultation-based reassurance measure was developed and validated (Holt & Pincus, 2016) and tested in a prospective cohort study with 147 patients who consulted their GPs for LBP in the previous month, testing the consultation-based questionnaire against patient outcome. Findings suggested that reassurance behaviour (content and style) of the GP were associated with patient outcome, most notably with patient satisfaction (Holt et al., 2018).

While existing literature provides an extensive understanding of reassurance in primary care, no study to date was identified which dealt directly with patients with chronic low back pain in surgical consultation settings. How patient's experience consultation-based reassurance when surgery is not indicated as treatment and how to effectively deliver reassurance in this context is unknown. This study is of pioneering work exploring reassurance from patient's narratives within this specific secondary care setting. The study aims to explore patients' perceptions of how professionals deliver reassurance while disclosing that all reasonable avenues of treatment have been exhausted, and how patients respond to this message.

Methods

Participants

The study was carried out with five spinal surgery specialists holding consultations at different clinics. Participating clinics run under the NHS Frimley Health Foundation Trust in Surrey, including three different hospitals. The consultant team (2 males, 3 females) consisted of two spine surgeons, an extended scope practitioner, two senior physiotherapists. Adult patients (aged ≥ 18), who consulted for spinal surgery and were recommended not to undergo surgery, were invited to participate in the study. Low back pain had to be their main complain persisting greater than three months. Patients with prior lumbar surgery, involved in litigation or work-related injuries, and those who lacked fluent English or had problems comprehending were excluded. This study was granted ethical approval from NHS Bromley Research Ethics Committee (16/LO/1833) and by the ethics committee at Royal Holloway,

University of London. The study was adapted to the National Institute for Health Research (NIHR) portfolio and all data was collected by Comprehensive Local Research Network (CLRN) nurses and the researcher.

Materials and Procedures

This study used qualitative in-depth semi-structured interviews. Before data collection, all spine specialists were informed about the objectives of the study. Consultants identified eligible patients between September 2016 and March 2017. CLRN employed research nurses sent letters of invitation and information sheets to eligible patients. Within a week of sending invitation letters, the on-site research nurses phoned patients to see if they were interested in taking part and scheduled the interview appointment at their convenience. Participants were not offered reimbursement for taking part in this study. All interviews were carried out by the primary researcher (KB) who was trained in interview skills. Twenty-nine interviews were conducted in the patients' home and one interview was conducted at a community centre. Upon the interview arrival patients were asked to provide written consent, basic demographic information (age and gender), measures of pain intensity, and pain interference. Pain intensity and interference with daily activity due to pain in the previous week were rated on a scale from 0 (no pain) to 10 (worst possible pain) (Cleeland & Ryan, 1994; Jensen, Karoly, & Braver, 1986). All interviews took place between February and March 2017. Recruitment was suspended once no new themes occurred and the research team agreed data reached saturation. Interviews were audio taped and subsequently recordings were anonymized and transcribed by an external transcribing company. The content of the interviews is of primary interest, hence a clear verbatim (word for word) transcription of the interviews was needed, opposed to including the conventions of dialogue (e.g. pauses) transcriptions (Gale et al., 2013).

The interview schedule was developed by an experienced back pain researcher team and the included questions were adjusted in phrasing and ordering throughout data collection. The interview was semi-structured and divided into five sections. Patients were interviewed on the 'background of their pain', 'expectations prior to the consultation', 'what had happened in the consultation', 'how they felt about it', and

‘how their back has been since’. Specifically, questions exploring the patient’s perspective of effective reassurance, the content of the consultation, satisfaction, whether their expectations were met, and concerns that were or were not addressed. At the end of the interview, patients were asked to provide feedback on an adapted version of the consultation-based reassurance questionnaire to test its methodological properties and inform the measure used in the subsequent prospective cohort study. Participants complete the reassurance measure and went through every item using the ‘think-aloud-method’ (Van Someren, Barnard, & Sandberg, 1994) to see if each question made sense and whether they thought the questionnaire comprehensively captured their perceptions of the consultation. Please refer to Appendix D for the study information sheet, informed consent sheet, telephone screening questions, patient details, and the full interview schedule.

Topic Question	Probes
<p><u>Background</u></p> <p>So, tell me about your back pain.</p>	<ul style="list-style-type: none"> • How long have you had it? • How does it affect you? • How does it affect your mood? • How well are you managing your back pain now?
<p><u>Expectations before consultation</u></p> <p>I will now ask you about your thoughts directly before the consultation with the surgeon.</p>	<ul style="list-style-type: none"> • What were you hoping to get from the consultation? • Was there anything you were particularly keen to discuss? • What did you expect in terms of treatment options? • How did you expect them to be presented? (Multiple list, one single option, personalized?)

<p><u>What happened in the consultation?</u></p> <p>Please tell me as much as you can remember about your consultation.</p>	<ul style="list-style-type: none"> • When was your last consultation? • Who was it with? • What did the consultant/surgeon tell you? • What did the consultant say the problem was? • What did you think when they said that? • What did you say? • When you walked out of the consultation what were you thinking/feeling? • Did he/she discuss a management plan with you? • How satisfied are you with the information you received from the consultation about your treatment options? • What terminology did they use to describe your problem? How you google your problem? • What do you think of that? • Is there another label you'd prefer? • What do you think condition means? • In your whole time of care- did a consultant show you a leaflet about your condition?
<p><u>After the consultation:</u></p>	<ul style="list-style-type: none"> • In retrospect, do you feel your expectation have been met? • What concerns were/ were not addressed in the consultation? • Was there something else you would have liked to ask? • What did you find most/least reassuring? • Is there something else he/she could have said? • In retrospect what do you think about the decision not to have surgery? • How do you feel about this decision now? • Are you still worried about your back pain? • Will you seek further consultations?

<p><u>Questionnaire advice</u></p> <p>Now, I would like your advice on a questionnaire that we developed. It aims to measure how practitioners reassure patients when they see them for low back pain.</p>	<ul style="list-style-type: none"> • Can we go through the items and see if they make sense to you? • Is there anything missing in the questionnaire, which you think, is important? • Are there questions you would not know how to answer?
<p><u>Closing:</u></p>	<p>Is there SOMETHING else you would like to add in terms of reassurance in your experience with LBP consultations?</p>

Table 1: Interview schedule and probes

Data Analysis

Transcripts were analysed using QSR International's NVivo software (version 10) utilising an integrative framework analysis, adopting Richie and Spencer's approach (Richie & Spencer, 1994). The main advantage of using this method is that it allows for a two-stage approach to data analysis (Gale et al., 2013): an inductive (bottom up) coding approach that allows patient's own responses to guide the development of the thematic output as well as an deductive (top-down) coding approach that allows comparison between the existing reassurance model and data. All data analysis was undertaken by the principle researcher using qualitative thematic content analysis methods. One third (10 transcripts) of the data was independently analysed by an independent researcher (TP). The initial coding categories was based on the interview schedule, guided by predetermined topics of interest (please see Table 1). To develop a thematic framework, data was sifted, charted, and sorted in accordance with key issues and emerging themes using a rigorous five-stage method (Pope et al., 2000; Srivastava & Thomson, 2009). Steps of the analysis process involve familiarization with data, identifying a thematic framework, indexing a thematic framework, charting data through separate matrices for each theme, and mapping and

interpreting data in consensus with research team. Themes reaching consensus were checked against participants' original wordings to ensure fidelity to the data. Data collection ended when no new themes emerged from data and the team were satisfied that analytical saturation was reached. To this stage, analysis resulted in holistic patient narratives that only partially focused on reassurance instead provided support for the model of reassurance within this broader context. In contrast, the subsequent deductive analysis targeted the matching of patients' narratives to the existing reassurance model.

Results

Description of Participants

Overall, 55 eligible patients from 5 different consultants were invited to participate in this study. Five patients were unable to be reached by phone to arrange the interview, one patient had dementia and lived in a care home, sixteen declined without given a reason when telephoned to arrange the interview, and thirty-three patients agreed to take part, giving a response rate of 60%. Two of the patients who agreed to take part lived too far away and were placed on a waiting list, and one was not at home for the interview date. As a result, interviews were conducted with 30 patients. Four patients had their consultation with a surgeon, nine with a Senior Physiotherapist, nine with an Extended Scope Practitioner, and eight with a Band 8a Physiotherapist. In total, 30 interviews accounted for 18 hours and 16 minutes of audio recording, which were left for analysis. The summary of patients' background characteristics is presented in Table 2.

Gender (%)	14 males (47%) 16 females (53%)
Average Age (Standard Deviation) Range	50.83 (16.38) years 19-81 years
Average Pain Intensity (Standard Deviation) on a scale: 0-10	5.53 (2.92)
Average Pain Interference (Standard Deviation)	5.49 (2.90)

on a scale: 0-10	
Average Pain duration (Standard Deviation)	12 (16.38) years

Table 2: Patient characteristic

Findings

The coding framework (Appendix E) shows the emergent themes and sub-themes. The table also illustrates how the initial coding framework with its themes and subthemes was mapped onto the final coding framework. The first two columns ('initial coding themes' and 'initial coding sub-themes') show categories of thematic codes that were applied to all transcripts to aid data synthesis. Subsequently, all emergent themes were organised under three main headings:

1. **Factors external to the consultation-** what patients bring with them to the consultation. Four sub-themes emerged within this theme. 'Pain & Impact' in terms of LBP onset, the experience of symptoms, co-morbidities, and how pain impacts every aspect of patients' life's. 'Management and coping', which referred to reports of how patients have gone about managing their LBP and what coping strategies they have adopted to aid management. 'Expectations and beliefs' describing pre-conceptualized attitudes such as suspicion towards doctors or a certain treatment recommended, as a result of having been influenced the media, internet, or, personal experience as well as hopes and expectations patients had before seeing the consultant. 'Previous health journey' describing what patients had to go through before being able to be referred for a specialist option, in terms of the duration of their journey and experienced inconsistencies in advice provided by different professionals.
2. **Consultation and reassurance-** narratives describing what happened in the consultation and how patients felt about it. Four final coding sub-themes emerged within this theme. 'Knowing my whole story', describing patients need for consultants to know their past history, having conducted thorough

tests, and perceiving patients as a whole person. *'The right person'*, referred to the consultant listening, getting the patient as well as patients feeling they are getting on with them, and consultants to know what they are doing or being an expert in the field. *'Nothing to worry about'*, which referred to patients not appreciating direct generic reassurance statements instead expressing a need to feel validated by the consultant. *'Getting to grips with my problem'*, describing patients' urge to receive an explanation to their problem, being spoken to in a language they can understand and not medical jargon, being presented with management options, and feeling being taken care of by being offered an open door to a follow- up appointment.

3. **Response to Consultation-** how patients felt after the consultation. This theme was divided into three sub-themes. *'After the consultation'*, which referred to narratives that showed there was a delay in processing the consultation, how patients felt after the consultation especially in terms of not being recommended surgery and their intentions to consult in the future. *'Response to management advice'*, summarising patients' response to management advice provided by specialist and reasons why they often disagreed with recommended care. *'Worries'*, showing patients left the consultation with concerns about their future with LBP.

Each of these themes and their sub-themes will be explored in more detail with corresponding example quotes of patients in the following section.

Factors external to the consultation

The theme 'Factors external to the consultation' describes factors that patients bring to their consultation. It embedded most themes and sub-themes of the initial coding framework. This theme captures patients' narratives telling the story of their journey with lower back pain before they entered the consultation. It is sub- divided into five overarching themes, *'Pain and Impact'*, *'Management and Coping'*, *'Expectations and Beliefs'*, *'Previous health care journey'*, and *'Situational Factors'*.

Pain and impact

The majority of patients in this sample lived with low back pain for many years before consulting the specialist team about spine surgery. At worst, a patient had lived with LBP for over fifty years. Patients were often able to remember the initial cause of their LBP, reporting it had been through a physical incidence (mainly heavy lifting, spasms), psychological distress (mainly stress at work), or recognised a combined influence of the two:

'... The first time was when I was on the floor, literally it was after carrying something heavy...over 25 years ago... (WX027).'

'... It could be stress related. I was in a job many years ago. I was going to be made redundant which was a factor as well, so I was possibly stressed. It could be stress-related as well. All these things could be linked to pain and your overall well-being. I guess you link a lot of things to the way your mind works as well ... (WX020).'

Some patients remembered how their LBP started years back and vividly described its impact on their lives:

'... I was hospitalized for three days...when I did get out of hospital I still could hardly move but I had to go because I needed to work... Really really slowly. I couldn't get into the car and I couldn't do anything. Once I did get better, I've been having back spasms ever since I was bedded for two weeks because I couldn't get up out of bed and this happens on occasions but not as severe as two weeks. It happens where I just suddenly can't move... All of a sudden I can't move and I end up in pain, crying and I have no idea why... (WX0021).'

Although patients' experience of LBP varied greatly in severity and duration, the majority had experienced at least one severe acute incident where LBP became excruciating. They described it as 'magically' or 'suddenly appearing' pain in form of a 'stab-like', 'sharp' pain that felt like something in the back just 'locked-up' or had gone into 'spasms':

'... the pain, I can't explain what the pain is like when I have a spasm. It's flipping shock. It's just excruciating... (WX0012).'

'... When I bent it locked up... I can't move when it is really bad because it just locks up... (WX030).'

Some patients used analogies to explain to people who do not suffer from back pain what it feels like to experience that much pain:

'... your spine, if you like, is like a zip, and then when it goes out of place it's like a part of it comes unzipped, some manipulation just pops it back into place... (WX028).'

'... it was as if somebody had come behind me and stabbed me in the back. That's the only way I can describe it. It was the most horrific shooting pain, like a very sharp pain. Again, a soft like judder and I'm bent forward... (WX015).'

There were individual differences in patients' accounts of how they experienced the severity of episodes as well as how much it impacted them in terms of function and mobility constraints. Most patients felt there was nothing that would ameliorate the excruciating LBP episode, it was just a matter of *'waiting it out'* (e.g. WX015). For other patients it was just a matter of *'slowly straighten yourself back up'* (e.g. WX006) and in extreme cases it meant *'having to call the ambulance, ending in weeks of hospitalization'* (e.g. WX027). A few patients also mentioned that not even taking morphine was able to kill the pain:

'... so she put me on oral Morphine, and that actually didn't kill the pain either. When it's bad, it is really bad and I can hardly lift one foot in front of the other. I'm okay at the moment and I can walk and I can bend a little bit and do my household chores... (WX001).'

Some patients expressed fear that pain returns any moment and fear of certain movements that might trigger pain or cause more damage to their back, leading to fear-avoidance behaviours:

'... I think what was getting me down was the fear of when it was going to happen again basically... (WX007).'

'... I would like to go exercise, I would like to lose some weight. I know I can't because if I put too much pressure on it, I'm scared there will even be more damage... (WX025).'

Overall, narratives indicated patients agreed that LBP relating to first ever onset and subsequent episodes, had an unpleasant unpredictability about it in the sense that it appeared suddenly in full intensity. Still, they would continue attempting to look for factors that might enable them to predict when an acute episode returns, or the length and severity of those episodes, since not being able to plan into the future was perceived as annoying:

'... sometimes it's bad; sometimes the worst, sometimes it's not as bad...It gets me down. Definitely can affect my mood...It's annoying. It's now, I'm going to be in pain for a few days could be anything from two days up to a week could be longer. It can be annoying... (WX018).'

Accounts of acute LBP episodes showed they 'come and go' whereas over the years pain intensity had 'progressively gotten worst'. Some patients perceived exacerbating factors such as a certain movement (e.g. bending down) that would trigger off the pain, whereas, others argued there is a regularity to their acute episode in terms of the four seasons in the year, suggesting LBP episodes would flair up annually, around spring time. Regardless of how long people have lived with LBP, the length lived with pain over many years seemed to have no influence on patient's ability to predict or recognise patterns that might trigger an acute episode:

'... Is there a pattern to the pain? No. It's either high nor it's not high.... But there is no pattern to it, no. Let's just say I can be fine one minute, and the next minute I can say, I'm going to pick my glasses and... it just goes... (WX028).'

'... I used to work in retail where you stand on your feet all day, every day and I was fine. I have an office job and I'm fine for 51 weeks of the year and then it just goes... at least once every year it locks up and there is no rhyme or reason for it... Nobody can touch me because I'm in pain and there's nothing they can do... I have to wait it out... (WX015).'

Besides the experiences of acute LBP episodes- sudden, sharp, locking-up, spasmic, excruciating pain-patients experienced the sensation of a '*chronic- dull background pain (e.g. WX025)*'. Patients narratives show that almost all patients experienced the presence of this dull background pain was felt '*all the time*'. Only a few patients reported to have pain-free episodes, which they recalled to occur only '*very rarely*' (WX027). On top of experiencing constant dull pain and the occasional excruciating pain episodes, twenty-one patients reported to suffer from additional radiating pain down their legs, on the right or left or both legs, as well as numbness in their feet, legs, buttocks, even hands (e.g. WX012). For some patients the additional leg pain only flared up occasionally whereas for others it was besides LBP one of their main complains, as it constantly restricted their walking:

'... I'm never not in pain...I'm always conscious of it... (WX015).'

There seemed to be a close interplay between patient's inability to continue doing their normal activities, influencing their mood and their motivation for their job. They felt that not being able to do things they normally do contributed to a lacking work-life balance. Out of thirty patients, ten patients in this sample were retired, whereas others reported that their experience of pain was the reason for many sick days in some cases even the cause of early retirement. This becomes especially devastating when having to also provide for members of the family, resulting in guilt feelings of not being '*able to do anything for them*':

'... I feel I had to give up work. I had to resign because it was too much. I couldn't manage getting up in the morning to go to work and then I work in an office so it was a bit stressful... (WX004).'

'... See, I do a lot of fishing as well... Yes, and I need those, the weight training and fishing are my relief from work, my free space and time and the back becomes a bit annoying... (WX018).'

'... I used to have a good work-life balance so when I wasn't working, I'd do sport, I'd go down to the gym, I'd go swimming. I'd do those things to relay and unwind... Now I can't do that... (WX012).'

Beyond pain and disability (physical constraints) chronic LBP affected every aspect of patients' life. Patient narratives showed a complex interaction between the physical, social, and, psychological impacts of pain, reflecting the biopsychosocial nature of LBP. Pain not only stopped patients from physically going out and seeing friends but further changed their mental state, especially mood, to an extent they did not want to go and socialise anymore or become grumpy and snappy towards friends or family. Pain, mood, and socializing seems to be a vicious circle, which patients found hard to break free:

'... It's draining, it makes me ratty, irritable, sometimes at night when it's bad, every time I turnover, when it wakes me, so I'm even more tiered the next day. Sometimes it really, really gets me, because I can't physically do anything. I mean, up to two weeks ago, I couldn't walk my dog, I couldn't walk for more than 20 minutes without being in agony... (WX027).'

The severe mobility constrictions caused by LBP constraints people from getting to places, which is devastating for people living on their own and having to do their everyday activities to get by:

'... Just couldn't get my shopping list. When you're on your own you've got no chance, do you? Who does your shopping? Who does your cleaning? Who does your washing? No one. You do it yourself... (WX026).'

Furthermore, in severe cases, LBP resulted in people not being able to get to friends' places to socialize, or, not wanting to socialize, both lead to isolation. One patient

discussed how she stopped socializing as much because she worried what people may think if she is unable to sit down and might scream because of the pain:

‘... It really made it difficult for me. It limited my activities with my children. It limited the time that I either was sitting down or even socializing because people think what is wrong with her that she can’t sit- because you’ll be screaming in pain literally... (WX025).’

Patients reported their mood to influence their social interactions, because they are more sensitive, easier to wound up, irritated, or grumpy. Some patients reported their mood to be fluctuating due to the inconsistent nature of their pain whereas other patients mentioned that the unpredictability of the length or severity of pain to be annoying. Mostly patients felt pain just ‘gets them down’ and some felt it makes them anxious:

‘... When I get the back pain I can’t do nothing. I get moody. It gets me really down. To be honest with you, sometimes I go blind about it. It’s really just pain for me. Sometimes I struggle with myself to not let it get me down... (WX023).’

‘... My mood, it makes me anxious, it makes you anxious. You think about doing things twice before you might be spontaneous... always counter checking yourself: ‘Am I okay today? Are my legs going to trouble me? Am I going to be in pain? Am I going to be limping a little bit?... (WX025).’

Supplementary to suffering from long-term LBP and trying to manage the pain, there seemed to be a high co-morbidity rate amongst this patient group of either physical diseases or mental diseases or for some a combination of both. About thirteen patients reported one or more long-term chronic illness such as cancer, diabetes, or arthritis, Scheuerman’s disease, Fibromyalgia, Spondylitis, IBS, Crohn’s disease, heart bypass, Rheumathritis, etc., and around six patients reported one or more psychological problem, such as bipolar, anxiety, and depression, etc. However, several of these co-morbidities might have been self-diagnosed. Patients with co-morbid serious physical diseases such as cancer, disclosed that they perceived their LBP as rather minor in comparison, seeing as they ‘knew what pain means’ and

therefore felt their LBP is a manageable problem. On the other hand, patients with co-morbid mental illness, such as bipolar, expressed how difficult it is to tackle both problems at the same time as well as sharing their fears about not being able to manage LBP and co-morbid diseases in future. It is unknown if LBP might have caused co-morbid illnesses, yet it certainly makes coping with LBP more difficult for them. Regardless, of co-morbidities most patients described the impact of pain to be simply ‘depressing’, especially for people who have depressive tendencies it became accentuated:

‘... mostly very depressed. I’m already a depressive so, that accentuates the problem with the depression, when I’m hurting really bad, because I just want it to go away. I get almost like... (WX028).’

‘... I was draining myself mentally, in the morning I felt stiffness, so I said ‘how am I going to cope?’. When I was putting so much in my head as well thinking ‘God, I’ve got pains, so I’m not able to do several tasks. I’ve got this, I’ve got to drop kids, I have to pick up from school, doing the shopping, how I’m I going to cope’. Straight from the beginning I wasn’t motivated. They put me on depression tablets as well because I was tearful, so to know, was this coming from my brain and making that pain worse. I used to be so active, walking a lot, jogging but then I didn’t feel like doing anything because of the pain I felt not motivated at all. Pain drained me I started taking tablets and being very tiered here... (WX010).’

Management and coping

Narratives of how patients were managing their LBP showed patient’s in this sample have come a long way, trying many different management avenues. There also seems to be a great variety in treatment effectiveness between patients, or a certain combination of management options worked better than one alone. Predominantly, patients reported that they had exhausted Physiotherapy, whereas some also recalled having seen a Chiropractor and/or Osteopath for their LBP. Patients often mentioned making use of ‘home remedies’, such as hot water bottle, hot-cold-press, salt bath, and homeopathic medicine to help ease the pain. In addition, most patients recalled having tried at least once Aquatics, Yoga, Pilates, exercise (e.g. weight training,

physio exercises), massages, Acupuncture, and/or steroid injections, or in some cases all of the above:

'...I used to have manipulation treatment, physio...painkillers...aqua therapy, ultrasound treatment, fact joint injections...had all that for about four years and then I was back to square one again...(WX028).'

In addition to trying the above listed management options, all patients in this sample were using pain relief medication, such as Paracetamol, Ibuprofen, Naproxen, Tramadol, Codeine, and Morphine. One patient reported being prescribed antidepressants. Low back pain was often associated by patients to affect their sleep with difficulties to both falling asleep and waking up due to pain, which might be due to being inactive, or, sleeping position, or, a twist to turn over. In cases where LBP interfered with sleep, patients voiced taking sleeping tablets or pain relief medication when waking up to enable them to get some rest. Whilst some patients used pain relief only for acute episodes, for others it had become part of their daily routine.

'... Once it's gone, like I say, I'm still in pain but it's manageable. So just one tramadol a day gets me through... actually Tramadol as well as relieving the pain actually makes me feel more alert, so I am currently using that to go through the pain and wake up... (WX015).'

'... I can hardly be jolly and happy in the morning because I never have had a good night sleep without pain. If I become grumpy, avoid me like the plague...until the painkillers kick in... (WX030).'

However, patients also disclosed the burden of side-effects that present themselves alongside using pain relief:

'... I remember I went to the doctor as well to get a very strong painkiller but that didn't work because it had a side effect I think. I had the diarrhea or something and then I was vomiting, so I did stop it, and then from then on I was just taking paracetamol, but it didn't really work... (WX019).'

'... makes me sick physically and sometimes...Tramadol, just makes me have problems with my memory... (WX012).'

Some patients also expressed concerns about becoming addicted to their pain killers:

'... Well, I was on Tramadol but I think I became a bit hooked on it. It was great but I started becoming obsessed with taking it... (WX013).'

'... it's just basically take-home painkillers and I did go very much overboard on those at one stage just to keep the pain at bay... (WX003).'

The management of long-term LBP also meant for patients that they would have to adjust their environment (e.g. work) to meet their personal needs, for example one patient explained she had a special chair at work (WX015) or reported adjusting his sleeping position to 'fetal position' to comfort his back whilst sleeping (e.g. WX005). Some patients reported acquiring different auxiliary objects to help them overcome restrictions caused by LBP, such as walking sticks to help them get around or gadgets to help them pick things up from the floor. Rarely, patients also reported the use of belts, bandages, or in one case the use of a body armour helping them to support their back. Moreover, narratives indicated patients adopted certain coping strategies such as pacing, which describes taking breaks and stopping oneself from doing too much.

'... I used to clean the house but not anymore now. So what I do is I do something and then I have a cup of tea. I can't do what I used to do before... I used to clean the house, do this, do that. And quite the energy which I can't slow down... (WX004).'

'... I know exactly what my limitations are now. I mean, as far as housework and ironing, and even walking. If I walk too fast, it plays me out, I can only do a certain amount of housework before I have to take a break. Yes, I am adapting to actually my condition. Well, if I do ironing for example, half an hour tops, and then I have to walk away from it. Same with housework, I can manage housework for about an hour and I have to stop... WX003).'

Nevertheless, the majority of patients visited their GP countless times for pain relief and had tried multiple management avenues to help them cope with their LBP. Therefore, they entered the specialist consultation with a common sense of *'I've been everywhere, I've tried everything, and nothing helped'*. They often adopted the coping strategy of perceiving their LBP as an *'everyday thing I just got used to'* that was *'just something I've got to live with'* (see summary tables for quotes). Nevertheless, this did not imply patients had accepted it and were effectively self-managing their condition, on the contrary, it reflected a hopeless attitude of *'there is nothing I can do or nowhere I can go'*. Therefore, they consciously or unconsciously developed different coping strategies to adopt not only how they perceive their pain (e.g. 'a companion', 'no-one else has pain like me') but further how they go about managing it.

'... If tried physio, swimming, yoga..., exercises the physiotherapist gave me...wasn't working...Nothing... I've tried it all... (WX021).'

'... I'm not neurotic, it sounds like it, but I've done my round. I've been everywhere. I even went to India... but no result... (WX004).'

'... It's always there but you have to live with it. There's—what you can do about it if you come see the professionals and the professionals have told you that nothing can be done about it. You've also—you can't just always just focus on that. You have other things in life, like kids and your family life, your work, and all the rest of it. You just--- when the pain is really bad, I suppose you just lie on the floor try to do a few exercises to eliminate the pain but it's always there. It's like a companion that you just carry on with... (WX006).'

On the contrary, knowing there is nothing more that can be done or nowhere else to go might also lead to acceptance that self-management is the only way forward. Patients voiced factors such as remaining a healthy mind set at all times, not feel sorry for themselves, or, allowing the pain to take over were perceived as important when transferring to self-management:

'... There is no point allowing me to restrict myself in any way... I think that's half a problem is getting your mind set right... If you can accept the pain and you deal with it and then move on from there... All I would say is get yourself right upstairs as well as physically as well. You know and try and do a little bit of something, don't allow something to stop you doing anything. That's all I can say, don't allow the pain to -- Because it is dead easy to actually say, "Oh I'm in pain." People can use that as an excuse to sort of maybe excuse yourself but don't feel sorry for yourself!. That probably is a key as well... (WX020).'

'... I also think you need a sense of humor if you don't find a way getting through life, you know, you can't feel sorry for yourself... (WX024).'

Exceptions & beliefs

The theme 'Expectations & beliefs' captures patients' narratives of their hopes, expectations, and attitudes about certain aspects of their care before they entered the consultation. It is divided into two sub-themes. Patients' hopes and expectations are discussed first in this section and subsequently their pre-conceptualized ideas, referring to possibly unconscious biases or prejudices towards the professionals as well as the advice they provided or did not provide. In terms of what patients recalled to have expected or hoped to get out of the of the consultation, the majority stated finding out 'what the problem is' and/or being told 'a solution to their problem' was considered as most important to them. Patients expressed a preference for these explanations and solutions to be provided from surgeons. Some patients expected to receive an explanation to their pain by getting to see their scan and have it explained to them, whereas for others, scans no longer held any promise of new information:

'... She's going to say there's nothing wrong. I knew she was going to say that because I've had -- I can't even begin to explain it the number of full-body scans that I've had and they've all come back normal... (WX015).'

In terms of finding a solution to the problem, patients often hoped for a 'cure', or at least something to 'alleviate pain':

'... We're not expecting you as a doctor to have everything at your fingertips, but we're expecting you to-- for me when I turn up at your office, at your clinic, for you to have a full grasp of what my problem is, and for you to give me a solution. If you don't have a solution, for you to recommend something to me that will at least make me feel at ease that you have considered all of my issues before dismissing and discharging me... (WX025).

Patients often spoke about holding 'pre-conceptualised ideas' or attitudes that had been influenced by an external source (e.g. internet, friends' testimony, etc.). Common statements were in regards to their symptoms, diagnosis, prognosis, or management options, and often started with things like *'I know I have this because I read about it'*. Some patients expected specialists to advise them to undergo surgery, even though they argued having made their minds up prior to the consultation since they believed it be doing *'more harm than good'*. They stated that they had based their judgement on either their own research which they conducted that had left them unsatisfied with the success rates, or, on knowing someone for whom surgery went badly, which lead to especially strong-held beliefs when that someone was a close friend or relative. Patients narratives often showed their strong held beliefs and attitudes about certain methods adopted by health care professionals (e.g. needing a scan to be sure of diagnosis, physiotherapy). Quotes below show when patients hold strong negative or positive attitudes towards an aspect of their care, it can either lead to immediate acceptance or disregard of the methods adopted, or, the management plan, recommended by health care professionals:

'... I was a bit more relaxed as I had that scan because I got told from quite a few friends, the back issues they had in the past and they said the scan apparently will- IT will show almost everything that I've been told... (WX017).'

'... Unless they can manipulate that disc and put the cartilage back in, which they can't, physiotherapists can't do it, so I don't have much hope in doing that... (WX026).'

Some people revealed prejudice in terms of whether or not they trust doctors and the advice they provide in general. In extreme cases, patients expressed strong

‘suspicion’ towards the authenticity of health care professionals, therefore, they had entered the consultation with pre-conceptualized uncertainty about not knowing who (which professional) and what (advice, diagnosis, etc.) to trust anymore:

‘... surgeons or doctors, whatever and all that, you have to be very very wary. They are probably not as straight forward as they used to be like 20-odd years ago...I have to say now when there are so many different doctors and surgeons and all that, half of them you can’t relax and be sure they doctors anyways... a lot of media cases... person pretending to be a doctors...quite a lot have been kicked out because they found out they didn’t have any qualifications at all... (WX029).’

Pre-conceptualized beliefs and attitudes that patients formulated from having heard or read about an aspect of their care, were not as strong as when they remembered having had a personal experience (e.g. believing that physiotherapy might work or not, depending on whether previous sessions had relieved pain or made it ten times worse). At worst, patients are embossed by a previous traumatising experience with a specialist. Naturally, the person would come into the consultation jaundiced by the previous trauma, making reassurance more difficult:

‘... I was told by a specialist years ago, people have bad back pain just get over it so I didn’t actually go back for a while... it was really horrific because he told me to bent down in front of him...It was horrible... he was very dismissive and said ‘Everyone gets back pain’... (WX015).’

Previous health care journey

A major theme emerged from narratives in which patients described the burden of their previous health care journey up until their referral to consult with a specialist. The two sub-themes, refer to patients’ accounts about the duration of this journey (e.g. referral times) and about experienced inconsistencies in the terminology used by professionals when giving a diagnosis to patients, in the advice they were given on how to manage their LBP, and, in seeing the same health care professional.

Patients often raised issues they had with the National Health Care services (NHS). Frequent complaints were about the referral times from the GP to the surgical team,

and then to an imaging test, and back to the specialist team. In worst cases, this cycle took months. Patients were also extremely frustrated with the duration of their NHS journey before it was made possible for them to be referred to the spine specialist team. Patients (e.g. WX010) reported it had taken them over a year, including referrals to physiotherapy, before ending in the last consultation with the scan results and a surgeon. There were cases (E.g. WX005) in which a patient had waited months to see a surgeon but ended up seeing one of the ESP team, leading to feelings of disappointment and them feeling discouraged to re-consulting seeing as going back to the GP asking to be referred can be time consuming and exhausting. More than one patient felt they had to ‘push’ or ‘force’ their general practitioner towards a referral to the specialist:

‘... Actually, to see the specialist, it's like I had to force it through. They will just say, "It's a normal back pain, it's a normal back pain." Normally, they give you painkillers and you walk away... (WX017).’

Some patient’s felt that the NHS does not support them enough (e.g. WX011) or take them serious (e.g. WX011), since referral letters in the past had not come through or treatment referrals to physiotherapy, Yoga, or Pilates never happened. Another patient felt it is not the consultant’s fault but the ‘*overloaded system*’ that makes consultants ‘*send people away*’ over and over again:

‘... To me, it seems the system is overloaded, okay? Any patient that needs treatment, they just send them away, with luck, they won't come back. That's how I've felt the past few years... (WX017).’

Patients reported contradictory advice given to them by different professionals. Around one quarter of patients expressed difficulties with the lack of continuity of care and the inconsistency between the people they are seeing (e.g. random allocation to seeing the ESP opposed to seeing the surgeon that was stated on their referral letter):

'... There's no continuity in terms of the individual that you've seen. It was always someone new. Somebody else is picking up. You have to repeat your whole story every single time even though they've done notes... (WX025).'

'... It took eighteen months to finally get the last appointment I had, where the spinal surgeon wasn't available on the day... (WX028).'

One patient felt seeing an ESP was directly linked to having musculoskeletal back pain, which made him 'move down the ranks' in terms of importance:

'... I went back for another consultation. Oh well, we've got a junior one now, gone down a line.....Wear and tear, age not much you can do. I get the impression basically she was there to let me die... (WX030).'

Whereas, one patient felt that seeing a physiotherapy resulted in her feeling more reassured:

'... she was a physiotherapist. She wasn't just a surgeon, she was someone that had dealt with people for 20 years with back pain, and helped them....So, I have more faith in her than someone that hasn't been hands-on helping someone, without having to have surgery or injections. So yes, I had a lot of faith in her...I have never had a surgeon that said, "Don't worry, it's muscular but if you do this if you do that... (WX0027).'

Overall, most patients had experienced difficulties with the NHS whilst trying to get answers to their lower back pain. One patient said there was '*something missing*' (e.g. WX005) in the NHS. The way the system is designed, both in terms of referral times and in terms of fragmentation and specialising instead of holistic care, '*frustrates*' people and reduces their self-esteem, hence requiring a cultural change:

'... It's like if somebody comes to you and says, "I want- I don't know- a brown color," and you don't have a brown paint, you mix two colors to get a brown paint. You get yellow and you mix it with, I don't know, blue and you get brown...Or red or whatever and you get brown. If you don't have it, you mix it if you're on a paint shop

to give that customer what they need... It doesn't seem to work like that with the NHS...Because it's a free service, it's annoying. It's difficult. It's frustrating and it's killing people. Really is because it's self-esteem that dies for the patient. If the self-esteem is not there and they don't feel confident in themselves, they get more medical problems and as a consequence, you just have a ball- roll off problems with that patient... It needs cultural change, I think. Yes... (WX025). '

Consultation and reassurance

Four themes emerged from the interviews (see Figure 2), which together accounted for patients' perception of what constitute effective reassurance for them.

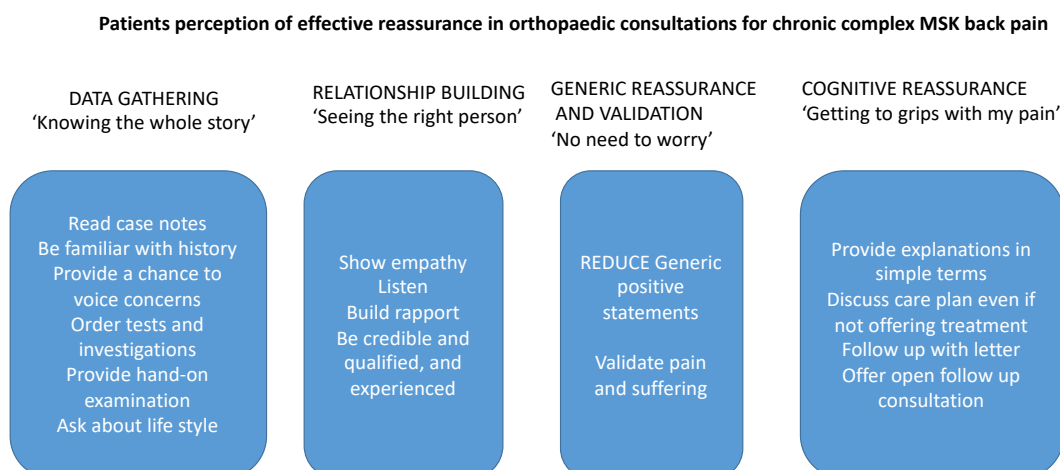


Figure 2: Study findings mapped onto original reassurance model headings.

Know my whole story

Narratives addressing the consultation and how it made patients feel, showed patients considered as important that consultants knew their whole story, which they felt required a combination of having read their notes, having conducted thorough investigations with results available in the consultation, and, asking the right questions to let patients complete the missing parts of their story. Patients stated feeling reassured when consultants knew as much as possible about their journey in terms of doctors they consulted over the years for their LBP, treatments they received in the past, and a basic understanding of their lifestyle in order to being able to match a management plan to the individuals' needs. When this was not the case,

patients felt uneasy and unsatisfied. Especially, in the absence of diagnosis, patients considered it as crucial that consultants at least ‘seemed keen’ or gave of the impression to being interested and motivated to find out what the problem is:

‘... She's quite keen to sort it out, and find out what was happening and why it was happening and she seemed a bit almost annoyed I'd say that she there wasn't something else she would physically tell, like physically see and she tell me... she seemed keen to get it all sorted out... (WX018).’

Past history

When entering the consultation, patients expected the consultant to have read their notes and know about their past history of pain, to feel doctor has all the information needed to provide advice. When this was not the case, patients often felt frustrated about the fact that they had to repeat themselves, wasting time instead of discussing the things they considered as more important, such as receiving an explanation and solution to their problem:

‘... We looked at everything that had been done. He knew my past history, and the previous consultant I had seen, and the pain management team I had seen. He knew everything so he's got all the information. That was the thing... (WX001).’

‘... I don't understand why they have notes, if they don't read them. It's really frustrating... I'm not a specialist’, or, ‘...she didn't know my history. She just read it before I walked into the room, which is annoying because she's missing some gaps and you have to fill that gaps... (WX025).’

Tests (Imaging versus hands on)

Besides knowing their history, patients felt it was important that thorough investigations, such as imaging tests and/or physical examination, were conducted and results present at consultation. Only then, patients felt confident that professionals were able to understand what the problem is and provide advice on management accordingly:

'... When I explained my pain, they were very good and they sent me a full scan from my abdomen all the way down to my leg to check for any nerve issues and I had an MRI scan done, subsections of my body and it all came back fine because my back bones were fine... (WX025).'

'... I don't still feel right, I feel like they need to check what is there is really. If it's coming from there to here or if it's coming from top to my leg, to be search my body or having headache a lot- I don't know... If it's nothing there, so maybe we just try something else. Search my leg, it may be there. Search my body. I don't know. I'm thinking of here just to find a reason what is there, why is there?... (WX010).'

Some patients stated *'no one can know without looking at the scan'*, referring to specialists not being able to understand their problem nor provide advice on management (deliver cognitive reassurance) without having evaluated their recent imaging results. It was not only important for them to know consultants had done everything they can to investigate their problem before providing advice, some patients also needed to see their scan results with or without problem. This was especially important for patients who struggled comprehending the discrepancy of experiencing the physical sensation of lower back pain whilst at the same time no physical abnormality is determinable. Therefore, they often hoped new imaging would result in detecting their problem since *'it be a lot easier to deal with knowing what it is'*. When this was not the case, they required specialists to show them on their scan that there were no serious issues with their back in order for them to understand, believe, and feel at ease with this discrepancy of MLBP:

'... I was a bit more relaxed as I had that scan because I got told from quite a few friends, the back issues they had in the past and they said that scan apparently will-- It will show almost everything that I've been told. Once I had that scan, and obviously, she'd run through with me and she said there's nothing serious, I have to believe now that there's nothing serious, it's just normal back pain... (WX017).'

'... expecting when I went, was to have me at the very least an X-ray or MRI scan... nobody knows what it is because they haven't X-rayed nor done MRI or it could be that the problem has got worse... (WX012).'

Moreover, it was important for people to not only see their scan but also to receive an explanation in layman terms and in relation to their problem:

'... I think I was just more worried about findings out if there's something wrong with my spine. But when they showed me the scan and then explain that everything is normal. I think that put my mind at ease... (WX019).'

'... As far as it could I suppose, it can be a bit more explanatory in their ways rather than just pointing out an x-ray and say this is it, that's that; because obviously they are very, very educated in the field, they know the ins and the outs. You think they do? They should be able to turn around and say to you, "Well you know this links to that, this links to this, this is a normal person this is what's happened to you." Then you could say all right fair enough, but just to point out an x-ray means nothing to me. It's like taking me into an art gallery and saying that piece is worth a million when the one next to it is worth a hundred quid but I might like the one next to it. No, my expectation or expectations were not met and this is where we are... (WX006).'

At best, consultants provided a detailed explanation of the spine in relation to patients' problem whilst looking at their scan results together. In the example below, the patient was able to finally associate her pain sensation with the explanation provided by the consultant:

'... she went on explaining the spine. She did explain everything in very detail... she named them- I know it was L1 or something like that. She was saying about, explained every single one...she explained about it and she's explaining about the gap in between. Then when we got down to the last two. She said, "As you can see, they're very close together when they should be as wide apart as the other discs there. They are very close". Personally, I think when I'm sitting down or I don't know if it happens when I'm walking or standing, it's like these two coming together... It's some idea I got. She demonstrates that, but I'm just going with my -- it comes together, causes the pain... (WX023).'

Some patients felt unsatisfied having received only a physical examination, whereas, other's felt satisfied with an imaging tests alone as a form of investigation. Most patients stated needing a 'hands-on' or physical examination in addition to a scan to feel consultant done everything they could to investigate their problem:

'... I said to her, "Can you just have a look because I'm concerned about this." She did, she took her time, she pressed it she said, "There's nothing to worry about it's almost like a tendon or something that's bruised which again put my mind at rest because I thought I had another disc problem or so... (WX027).'

'... I would have said, "Look, I've waited all this time and for what? What you told me I could have been told that over the phone. You didn't even examine me. You didn't even ask me to move or walk or what movement I've got, nothing. [laughs] Right? You just looked at a set of x-rays and scans and notes from 2015. Could have been done that over the phone."... (WX012).'

'... I don't know, maybe some more -- they're supposed to do, in my opinion, some more researches. To do some more tests on me and things like that not just put the hammer on my knee and that's it... (WX022).'

'... didn't feel rushed... almost like a private patient... She certainly took the time... did physical examinations and other things that helped her diagnosis stuff...it was a pleasant experience, overall...very pleasant with her attitude and the way she treated me. I don't think she could have done anything else... (WX0029).'

When patients felt professionals did not investigate thoroughly, it created uncertainty and contributed to catastrophizing, as shown in the example below:

'... I'm worried at the moment because it's a different type of pain, I don't know if I could have a tumour. I could have something completely unrelated to my original back problem, but nobody's investigating that. That makes me sound as if I'm paranoid or whatever, but I'm not. I just think it's about doing a thorough job, isn't it?... (WX012).'

Me as a whole person

Overall, patients appreciated when professionals adopted a more holistic approach and recognised them as a 'whole person'. Ideally, patients get to see the same consultant, which over time naturally allows them to get to know patients and their story in relation to their problem. However, in reality there were no continuity of care and patients rarely saw the same consultant twice, which meant patients expected consultants to go through everything and let patients explain themselves:

'... if you're seen different consultants you got to obviously, they gotta go through everything to know you as a patient, then you got to explain yourself as well... (WX024).'

'... he's the professional, she's got the notes. She knows why I've come in, and yet they seem to just focus on one part rather than the whole problems that I have come in with. For me, like I said, I'm not in separate components. I'm one person. If I said to you I've got a pain coming from my lower back all the way down my leg, I didn't say to you I have a lower back pain, full stop. I said I have a back pain, and when that back pain starts my leg pain also starts... (WX025).'

'... He said, "We can do is see about managing the pain but he can also look at it from a whole well-being perspective as opposed to just the back." That's what I thought about. That I'm happy now because it seems like I did some progress... (WX012).'

As previously discussed, patients appreciated when consultants knew their past history and had conducted thorough investigations beforehand. In addition, patients felt it was important that consultants worked with them to fill any missing gaps by asking them to tell their side of the story in order to get the whole picture. This included asking patients about their lifestyle and how they were currently managing their pain:

'... she really sort of decided to take notice of things affecting my lifestyle, she's switched on about that... (WX018).'

Patients expressed that it required them to be confident in a sense that they dare to challenge doctors in their attempt to fill missing gaps whilst trying to understand their whole story. One patient argued, untold stories might lead to fatal mistakes being made on the health care providers' side:

'... If you're not a confident patient, you're not going to fill those gaps. You're not going to correct if she makes a mistake because you're thinking I might look stupid. You're not going to-- if you're not, even the most confident person I think would find it reluctant to challenge a doctor. That's where mistakes happen... (WX025).'

Generally, patients wanted practitioners to ask them what concerns they had and to try their best to address those. When patients felt consultants did not do everything they can to investigate their problem and find out their whole story, patients perceived it as a disinterest or demotivation to helping them, naturally leading to dissatisfaction and disappointment. One patient argued doctors nowadays have no interest in finding out the patients' story but instead they felt like they are just a number in the system. At worst, perceiving professionals to lack motivation to investigate further made patients feel as if they wanted to 'get rid of them' or that they were '...a pain to the system that's been removed. So, one less burden... (WX028), left with helplessness and hopelessness to self-manage their condition:

'... I felt like I was on a production line...I think I just mentally I'd convinced myself that it was something worse than it was so I was just felt he dismissed my symptoms and he wasn't interested. Just showed me out the door and that was it... (WX013).'

A minority of patients were satisfied with their consultation, as long as they at least received an explanation for their LBP. Patients, who believed professionals had done everything they could, found it easier to accept the outcome of their consultation, even if it meant they had no solution. On the other hand, most patients expressed feeling no progress was being made on their journey when no active solution had been presented:

'... They've done the scans and all the rest of it and if they think that there's nothing more that can be done. I don't think looking back that there's anything else that I could've said... (WX006).'

'... Although they did an extensive look into my condition...I'm not an expert so I don't know what else they could've done but from what I've gathered, they have come to the end of their investigation and from their point of view, there's nothing more they could do. That still leaves me in a limbo, because I've still got the pain with no solution, in the end... (WX025).'

Overall, people discharged from care without further treatment felt it was crucial for professionals delivering this message to give the impression that everything in their power had been done to investigate their problem, to understand the whole picture (patient & problem), and, to find a solution to their pain, before making the decision to let them go without further recommendations:

'... You shouldn't be running after them to tell them what needs to be done. This is where I keep coming back. They need to be thorough and they need to be up to date with what they know. If they don't know then they need to seek the help of their colleagues. It's not a bad thing for a doctor to say, "I actually don't know the answer to this question but I'll call my colleague," and pick up the phone and call his senior colleague and say, "I have this patient, I have these things." That's why research papers are done. Look at it, read it, people have spent money and time, utilize it. We're not expecting you as a doctor to have everything at your fingertips, but we're expecting you to-- for me when I turn up at your office, at your clinic, for you to have a full grasp of what my problem is, and for you to give me a solution. If you don't have a solution, for you to recommend something to me that will at least make me feel at ease that you have considered all of my issues before dismissing and discharging me... (WX025).'

The right person

Narratives indicated that it was important to patients to feel they were consulting with 'the right person', in a sense that consultant was qualified enough and knew what they talking about, listened to them, as well as, making them feel that they were trying to 'get them' (thoroughly understand them) and get on with them.

Listening

Patients felt it was important for doctors to ‘at least’ give the impression they listened and thus considered their concerns. Listening was strongly linked with satisfaction, and the perception of being taken seriously, and feeling validated, which is discussed further in detail in the following section. It was perceived as a key indication of the professional being keen to help by attempting to get to the bottom of the problem and finding a solution:

‘... I was really pleased with this consultant because he took the time to listen...it’s the first time someone actually listens to me and understood what I’m going through with it... (WX024).’

‘... They don’t listen: ‘...Well, not heard, deliberately not heard or not listening. You hear the first words come out and the rest of the story you can’t tell because he’s writing notes while he makes his decision what he’s going to do... (WX030).’

One patient expressed their attitude about management advice provided depended on who conveyed the message:

‘...probably if I’d seen the surgeon, he might have said, "I’ll do the operation." But because I saw a physiotherapist she probably didn’t have the ability or the -- Well, she had the ability but she didn’t have the-- God, what’s the word I’m using here? I don’t think she was allowed to make the surgery appointments for the surgeon. That’s not her domain, so I don’t think she could go there. She didn’t even say, "Have you had surgery? Have they mentioned surgery?" Because I don’t think she was high enough to undermine a surgeon... (WX026).’

They get me and I get on with them

Patients described the importance of feeling that professionals to have the ‘right attitude’ or that there was the ‘right atmosphere/vibe’ between themselves and the professional. This was often linked to the patients’ perceptions of consultants giving of the impression that they had a general interest in their problem, a sense that they cared, and took the time engage with them. When this did not happen, consultations were perceived as considerably less reassuring and satisfying:

'... I didn't find the connection with the person I was seeing. She didn't have much patience it just felt like in, out, quick and that's it. She didn't take the time to--- and then she said, you haven't got this, you haven't got that which wasn't reassuring without looking, investigating more, so it didn't help... (WX024).'

A common perceived complain was also the duration of the consultation. These varied from 5-10 minutes to up to 45 minutes. Some patients felt the consultant did not give them sufficient time to address their problem:

'... How the hell can someone who's got to see a person one every 10 minutes from a variety of life, how can he do it (know about my case)? I don't know... WX005).'

Regardless of the connection felt between the patient and consultant, patients seemed to pick up the mood of consultants, which strongly influenced their satisfaction, especially in connection to feeling rushed:

'... That was a very disappointing consultation..., he was running late and my perception was that he was late and in a bad mood and just wanted to get me out, so he could catch up with his surgery... (WX012).'

Narratives demonstrated that for most patients, how the specialists made them feel carried more importance than what they said (e.g. receiving explanation) or did (e.g. thorough investigations). This especially applied to patients discharged without further treatment. Patients felt that practitioners should convey this message in the right manner, reassuring patients to walk away encouraged to self-manage their condition, and when this did not happen, they felt frustrated, helpless, and dismissed:

'...Yes, he was encouraging. His whole attitude was, and I accepted that. I told him I'd already got this-- There's a cycle thing, because he was going to suggest I get something like that so that I've got the exercise. My passing words were, "I'll give it my best shot," and he laughed like nobody's business and opened the door for me... (WX001).'

‘... what I found least reassuring was this, that it was too bad. Nothing I could do. It was insensitive. That is the way I would describe it. I wouldn't say it was aggressive but stirred is the way I would describe it. A very stern manner... I just think if I was a different type of a person, then I might have just accepted that, and I don't think that's right... (WX002).’

Knowing what they are doing

Patients expected consultants to be professional, experienced, well trained, and, generally know what they are doing and talking about. When this was the case, patients felt they could rely on the consultants' advice and were more able to accept the explanation provided or care direction recommended. Some patients differed to the practitioners in a generic, respectful way, simply because they were practitioners:

‘... You're kind of thinking, "Well, they're the professionals". You can't really argue with them. They tell you that, "This is how it is". You just have to take it on the chin, don't you?... What can you say? You put your trust in these people. They're the professionals... (WX003).’

‘...She explained that's what causes the pain. I accepted it, I accepted it. I trust the doctors. They know more than I do. She's experienced what do I call that, She's trained for that. She knows what she is talking about. I was amazed to see my spine... (WX023).’

Patients seemed less concerned with the qualification professionals held, but focused instead on their level of experience:

‘... Yes, because I tell you what it was, and this is why I trusted her, I think more than anyone I've ever seen, is because she was a physiotherapist for 20 years before going into whatever she does now.... (WX027).’

Other patients were more questioning and judgemental:

‘...I have been back to the doctors and they referred me and I had Pilates and physio... I feel they're like children and they don't really understand what they're doing so I'd rather pay someone privately to help me... (WX015).’

Practitioners' job title was of importance to several patients. These patients believed surgeons to be more qualified than ESP's. However, patients often only started complaining about the fact that the person they were seeing was not a surgeon once they were dissatisfied with a certain aspect of the consultation content. Often the factor of dissatisfaction was linked with the outcome of the consultation, in which case, patients argued that if they were to see a surgeon, they would be able to provide them with a different explanation and solution to their problem. Thus, some patients felt that whatever the ESP had said only counted once they had seen a surgeon to confirm:

'... I can appreciate that, it's not tying up consultants' time when they've got people that are probably in more urgent need, but yes, I did come away from there thinking, "That was actually a waste of time." I could have actually have been told that by my GP, and given that option by my GP. I know she (ESP) wouldn't have been able to have done anything anyways... (WX003).'

There is nothing to worry about

Everything will be fine

Patients reported having very different responses to the message delivered by the practitioners that there was no cause for worry, no significant pathology existed in the spine- as evidenced by the MRI, and therefore surgery was not indicated. For some this generic message was extremely reassuring:

'... The most reassuring? Knowing there wasn't anything there to worry about, and knowing that it was just general wear and tear...Just knowing that there was no major issue, there was no serious problems with my lower back you know it was just general wear and tear... I accepted it... (WX020).'

'... I think one of the most key things for me any doctor can say to someone is, "Mr. S there's nothing major going on with your back... All right. I'll tell you and everything would be fine... You got nothing to worry about." I think when they say that that is quite key to allowing you to move on... (WX020).'

Simple optimistic messages were sufficient to reassure some patients:

'... He did say I would get better and he's really sure of that because the MRI didn't really show anything serious... (WX013).'

'... I was more confident when then he told me what I already knew which is, "The spines are going to get better, however, the things that I'm doing were the right things." He had confirmed the way I was doing was good... (WX012).'

Reassurance was stronger yet when messages focused on reassuring them about the unlikelihood of future damage resulting from activity:

'... that she said was, "I just want you to know that when you start exercising and you do it properly, build up, you are not going to damage your spine in any way." That was the biggest fear for me of doing anything. I thought it was damaging it even more. She said, "If you exercise properly you will not damage your spine." So yes, she really reassured me... (WX027).'

However, this type of reassurance was difficult to convey to patients, and it was often misunderstood. For some patients, it was difficult to reconcile the message with their pain experience. At worst, patients interpreted it as professionals disbelieving them or undermining their problem, and for some this resulted in increased worry:

'... In some ways, I was like, "Great. There's nothing wrong. There are no chopped nerves I don't need spinal surgery which would be hideous." On the other side, I know that there's something wrong with my back because I just do, I know there's something wrong. I guess it's not their fault if they can't identify the problem. If it's not showing on the scan, they're not a magician... (WX007).'

'... The worst thing anybody can say to you is: don't worry. Of course, you worry, that's why you're there. You don't go and see someone a doctor or something like that because you're not worried and to say to someone, "Don't worry about this." You immediately go the opposite, of course you do. What isn't this person telling me... (WX005).'

'... Because when they told me that everything is fine, and that to keep saying that for a couple of years. How am I supposed to feel reassured if I feel there is something wrong with me, and they keep telling me that everything's fine. There's something wrong with them, actually... (WX022).'

'... Frustrated, because obviously, the point of you going to the doctor is to seek help. When all they've done is just kind of reassured me that there's nothing wrong with my back. But it's just like feels like, they've abandoned you halfway; you have to do it on your own. They haven't really given me any treatment... (WX019).'

Patients mentioned the level of pain experienced on the day of consultation seemed to also have an influence on how patients digested being told there was nothing seriously wrong with their back:

'... because I wasn't having really bad day of pain that day, I was quite happy that she told me there's nothing wrong... (WX015).'

In some cases, patients felt conflicted about being told there was nothing serious. On one side, they felt it was reassuring to know that nothing major had been found, but at the same time they expressed their hopes that something would be found to explain their pain:

'... That's a difficult one. Nothing serious, okay, that is one thing. I think that is about the only thing I can say. That was reassuring me, nothing serious, they haven't found anything major. But, at the same time, I wish they had. At least I'd have known, do you know what I mean?... (WX021).'

For some patients, being told there was nothing serious going on and no further treatment options would be offered to them, it immediately indicated self-management:

'... I was happy because she said, 'We can't do anything, first of all.' I knew it wasn't really serious, so I said, 'Fine, I'll live with it.' That's what, I'm living with it... (WX008).'

However, especially for patients who expected to get their problem fixed, it was not enough to be told that there is nothing wrong with their back, instead, they required subsequent cognitive reassurance in terms of being provided with an explanation to why nothing serious can be found and/or given some sort of solution to their problem:

‘... After that, I felt relieved that obviously nothing's wrong with me or with my back. But at the same time, as I said, I felt like they haven't given me enough reason to explain why I am getting this back pain... (WX002).’

Especially, for patients discharged from care without further treatment, it was crucial for professionals to convey this message whilst communicating encouragement for patients to actively tackle their problem by beginning to effectively self-managing their condition. If successfully conveyed patients felt empowered to tackle their problem on their own. For some, however, self-management was something they needed to do under the guidance of health care professionals, and only in this supported arrangement did they feel sufficiently reassured to try:

‘...Yes, it was her absolutely yes...she reassured me, I believed her 100% when she said, "You can do this yourself, you can do it. You can manage it you can do the exercises." But she didn't send me away saying, "Go and exercise" But she said, "You can't do it on your own, you have to have pain relief. "She wasn't just sending me away whereas years ago it was like, you can't have surgery. It's wear and tear off you go, she just says, "Yes you can do this but we will help you, we'll give you physio, we'll give you hydrotherapy, we'll give you pain relief but you have got to help yourself and I promise you, you will be able to do it because I've spent 20 years helping people with bad backs... ‘...she said, "I just need to put your mind at rest and tell you that you will not damage your spine."...when she said it, it was just a relief just this huge relief that I can do it myself and I'm not going to damage my spine... now, she's made me determined to fix it myself... (WX027).’

Validation

A major emergent theme paramount to patients was the need to feel that their pain and suffering were believed. Instead, patients disclosed often feeling that friends,

family, and health care professions, do not seem to take their complaint seriously and that they felt disbelieved. In some but not all cases, this was linked to the fact that patients had not received a clear diagnosis for their problem, and despite having gone through several investigations, practitioners were unable to determine an anatomical abnormality in the patients' back:

'... There is a problem, because--- But, I feel like the majority ...don't really believe me, because, I don't know, they probably can't see anything, any clues to something. I don't know, they—It just feels like they don't believe me in such way... (WX014).'

'... She hasn't seen any problem in my lower back, she just asked me if I want painkillers and she said she's going to write a letter to the GP to say I've still got the pain...I'm still having them, so I'm not lying. It's coming to the point zero with everything... (WX010).'

Patients' wanted professionals to convey a certain degree of acceptance of their story, communicated through making patients feel that their pain and related feelings are understandable and legitimate:

'... She didn't make me feel like a fraud that wasn't in pain, because she had dealt with so many people with serious back pain that had been able to manage it with exercising and pain relief... (WX027).'

'...No, but like I said before he's probably seen really, really bad cases so he just probably-- that's how I felt like I'm just a silly girl who or a silly woman who's just making a big thing out of nothing. That I don't know if he well, if he did it on purpose but that's how I felt... (WX013).'

'... I felt quiet dismissive like I felt he was being quite dismissive he's probably seen this all the time. But then I have my pain and I knew what it felt like. He doesn't know how it feels like... (WX013).'

Getting to grips with my problem

Explaining what the problem is

One of the main complaints voiced by patients concerned not having received a clear diagnosis on their journey with LBP. Terms and definitions used for diagnosis, varied between professionals as shown in the example below. Patients in this sample reported that specialist referred to their LBP in their last consultation by using terms like 'degenerative' or 'wear and tear'. Patients' response to such explanations and labelled depended on the manner in which they were conveyed, and how well the labelled matched their own conceptions and experiences:

'... I think a little bit relieved, because I had an explanation of the pain. Because all over the years, when I went to see my own doctorand they just said to me, "It's muscular pain"...But at least I know now, that it's from the spine and not muscular....They always said oh it's muscular, the pain's travelling to that. Now I know it's coming from the spine to make me feel like that and not muscular, you know what I mean. Yes, I feel relieved that I know what it is. Yes, I trust her. She was very helpful... (WX023).'

Patients often believed that knowing what the problem was and/or receiving a clear diagnosis, helped to decrease their uncertainty, made other people more likely to believe them, and enables them to deal with the problem much better:

'... want, yes, a diagnosis. Just call it after me. Just call it KJ syndrome...But if it had a name than it just feels like, ah you know, I suffer from back problems, and if they never suffered from back problems they really if I had a bad back from gardening, it's completely different, when your back completely locks up and you actually- you can't even undress yourself...It's humiliating, but if I could call it something and say hey I got KJ syndrome. Yeah if I- I don't know, I think psychologically it would help to say I got this... (WX015).'

'... She was superb. She was absolutely brilliant. She stood me up and said, "Look, most people have an arch in their back. Yours is completely straight, it's so tight. So, most of your pain is from that tightness." And said, "Until you get pain relief and

then you're able to relax, start to relax that muscle. The pain will be there all the time... She was very good at explaining it. Then she got me to stand up and made me realize that my back is so straight up a plank rather than having a natural arch. That's how she explained it to me.... (WX027).'

'.... I'd rather have a definite answer and go instead of just saying, "Oh, I don't know you have the spine of an old. This is why the pain is, or you can see there's this, this, and this is causing the pain, but saying "We don't know what's causing your pain." It was a bit disheartening, because not a definite answer... (WX009).'

Patients felt it was not only important to have received a clear explanation to what their problem was but further a clear explanation why certain treatment recommendations were provided, how they are to be applied, and, how they benefitted them. Patients found it helpful to receive a clear explanation about treatment options available to them, including the pro's and con's of each. They believed this enabled them to be fully aware of each option and consequently make informed decisions about how to continue with their pain management:

'... Yes, like I said before I wanted him to explain why it's happening then if it wasn't what he thought it wasn't in the MRI and what can I do to manage it. Like he wrote a prescription but he didn't explain why. He referred me to the pain clinic but he didn't tell me what they do or what their role is in anything. I just feel I was left in the lurch sort of thing. No one even looked very helpful that's all I thought. It's just maybe procedure, that's probably what they always do... (WX013).'

Language and terms – clarifying care decisions

Patients struggling with uncertainty appreciated explanations that were clear, thorough, precise, educational, informative, and, going into detail, which enabled them to fully understand what was going on. Besides needing professionals to provide clear explanations and solutions to their problem, patients appreciated being talked to in a language they could understand instead of professionals throwing a medical jargon at them:

'.... I mean she was a very pleasant lady. She spoke to me in terms that I could

understand so that would put you straight at ease, you know... I just, well, unless you're a medical person you really haven't got a clue what they're talking about... (WX003).'

'...She sort of explained everything and showed me the MRI scan which is good to see...the way she delivered it, was good because she used layman's terms as well. I could understand it wasn't all medical jargon... (WX009).'

'... Explained that she had the photo of the spine and everything. The X-ray of the spine and that. To someone who's not medically knowledgeable, it didn't mean a lot to me. To be honest... (WX026).'

Patients expressed feeling unclear not only about the meaning of terminology used by professionals but also feeling confused about decisions on management options (e.g. 'what can physiotherapy do for me', or, one patient was told there are no treatment options available but she only realised this meant being discharged from care when opening her follow-up letter), further investigations ('if the MRI doesn't show anything why are they not investigating further'), diagnosis, prognosis, etc. In order for them to process and accept certain aspects of the consultation, patients required clarification, which was granted through asking the right questions as well as receiving satisfactory answers:

'... No, not at all there was nothing. Nothing like, "Oh God I wish I would have asked that. "She discovered everything, everything, nothing I needed to ask... (WX027).'

Instead, patients often felt they 'wanted to ask questions but never got the chance to' (e.g. WX001). Especially before being discharged from care without a solution to their problem, it was considered as imperative to be given the chance to ask questions. Likewise, it was appreciated when specialists encouraged patients to share with them if they were unclear about terminologies or care decisions and for professionals to give the impression that they wanted to take the time to provide answers and clarifications to resolve any uncertainties. Above all, it was important for professionals to have created an environment in which patients felt comfortable

to ask anything ('stupid-questions-do-not-exist-atmosphere'), allowing patients to exit the consultation with confidence knowing that they were discharged:

'... My doctor, he didn't rush, took plenty of time and he answered any questions I had, and he explained things. Yes. I don't think there's -- I can't fault him in that respect. They'd done a good job with me. The only thing they didn't do was wave a wand and get rid of it. The pain... (WX002).'

'... She said, "Oh, that's sick. That's the information thing whereby to a nerve end- it will be too technical to describe." I said, "Fine, I'll stop asking all good questions. Just go away." So, that's why I stopped asking....I say try and put it in layman's terms and she said, "No, I can't."... (WX028).'

One patient stated she would have found it reassuring if specialists had asked her if she was happy with the outcome of the consultation before discharging her:

'... Yes, she could have asked me if I needed to see somebody else. She didn't even ask if I was happy with the outcome of my investigation and the conclusion of my investigation. She didn't ask me. She didn't ask me if I was-- "Do you have any questions? Are you anyway dissatisfied with that? What would you like me to do for you next?" I could have asked her, "Refer me to someone else?" but she didn't give me that option... (WX0025).'

I have options

Above all, patients in this sample appreciated professionals providing them with treatment options. This was not only the most frequently occurring element when asking patients what they found most reassuring, it was also the most frequently stated reason for dissatisfaction as well as most reoccurring element of suggestions for improvement (what patients would have found reassuring). Patients needed some sort of plan of action that allowed them to move forward in their management instead of feeling abandoned:

'... Frustrated, because obviously, the point of you going to the doctor is to seek help. When what they've done is just kind of reassured me that there's nothing wrong

with my back. But it's just like feels like, they've abandoned you halfway; you have to do it on your own. They haven't really given me any treatment... (WX019).'

It seemed important for professionals to outline different management options, and, as discussed in the previous section, to go into depth explaining what each option entails. This would enable patients to formulate their own management plan. However, for some, the information that treatment option had now been exhausted remained a bitter pill, regardless of delivery:

'... I was clear, yes. I mean, I knew what it is. I knew what my options were, but I wasn't actually given any management plan afterwards. I would get more out of my GP. She said, "Oh, you've really got to start exercising your core muscles to try and get the strength back into the spine. Blah blah blah." No, nothing came out of that consultation... (WX003).'

'... Yes, well, yes. She just said obviously, as I do sports, a bit of exercise, just don't overdo it, if you think it's making it worse. Don't overdo it....I said, "I really would like to have a plan so I can stick to it" because like I said to her, Okay, we had the scan, which is positive. Now, maybe I can concentrate more if I have like-- I don't know, a plan, what to do. (WX017).'

'... The options were all laid out to me. So, let's be fair. She went through and said, "These are what options are available." and systematically talked me out of each and every one of them. How do I feel about the information? The information was relayed in a very medical way, which was good. On a scale from one to ten, probably a six or seven, brilliant. Then she slowly took every point off, by telling me that wasn't going to help me. I said, "As it stands today, there is no treatment that you could recommend, or suggest that is going to make it easier for me to manage when I am in pain." She said, "As I said, if you'd maybe take up swimming that would be good." Oh, thanks. That helped... (WX028).'

Patients often requested advice, tailored to their personal lifestyle, on how to cope with their back pain. Therefore, patients did not appreciate receiving advice that was too generic (e.g. painkillers, exercise):

'... there's no repair available, it is what it is, and I understand that. But, just advise me, "We think you'd benefit from some physiotherapy aligned with these pain management controls. There's still the option of facet injections, but, hey, you know, we know it's not a permanent thing, but we're happy to still do that if it manages your pain for you. We don't advise the surgery because of da-da-da or if that's the case... (WX028).'

Open-door follow up

Being told there was no solution to their problem itself was perceived as disappointing and difficult to process. However, in combination with being discharged from care without knowing where else to go, naturally was seen as a very scary concept to most people. Patients discharged of care, regardless of being provided with another management option or not, often felt *'left on the latch without knowing where to go from now'*, and in worst cases, feeling there is absolute *'no hope'* anymore:

'... He couldn't have done more than he did, and that was that. The fact I was disappointed, I think, is a perfectly natural thing... I felt or so there was nowhere else for me to go, and that was it... (WX001).'

'... still thinking about it. It still annoys me and I just feel like there's no hope. I'll suffer for the rest of my life...It's never, ever, going to go away... (WX021).'

Therefore, patients appreciated when professionals expressed they cared by providing them with the chance to call them to ask unanswered questions and/or to receive the chance for an open appointment. Patients especially appreciated being given the chance for a six-month open appointment where they are able to call back any time and get an immediate SOS-appointment with the same consultant who discharged them:

'... She also said, "You can get in touch with me if you've got any questions."...We didn't feel as if we'd just been chucked-...Left in the dark, right... (WX029).'

‘... The fact that I've been given six months for an appointment if anything goes wrong is satisfactory. I know I just have to pick the phone up and ask for an appointment within that six-month time frame, if I feel that it needs looking at further. It wasn't a case of I've got to go back on to waiting, this type of thing, to be seen by them, blah, blah, blah... (WX003).’

‘... She just discharged me.. she might have said, "If you've got any more problems, go back to your GP." I haven't come back to my doctor here, I'm in pain now... (WX015).

When asked what they would have found reassuring, patients mentioned their wish for a discharging summary letter of what had been done, explanations to their problem and solutions, as well as providing validation that patient will gradually get better:

‘... Getting a summary letter saying what the problem is and what is being done- would have found reassuring... (WX012).’

Response to consultation

Delayed processing

Patients’ narratives indicated they often experienced a delay in processing the contents of the consultation as well as its meaning (what had happened in the the consultation and what the outcome now meant for them). Narratives indicated patients’ immediate response to the consultation was at first merely emotional, stating they felt shocked, upset, relieved, happy, sad, etc. As a result, patients often stated being unable to ‘think straight’, expressing that they were incapable of reacting rationally. This led to patients not being able to ask professionals to clarify aspects of diagnosis, prognosis, and, decisions made on management options, which in turn lead to increased uncertainty, dissatisfaction, and difficulties understanding the meaning of certain consultation contents:

‘... I didn’t ask him, but at that point I just felt low that I just didn’t want to speak to anybody or anything like that. I was very upset and disappointed basically... (WX021).’

Patients recalled it had taken them from a few days up to a couple of weeks to come to terms with consultation contents and meanings:

'... Well, yes, I just walked out in a daze really I felt like someone just sold me a car for a 100 quid that was worth a pound. I was like, I go home and I said, "They signed me off." She said, "Why?" I said, "Because there's nothing they can do for me now, that's it. Effectively. I was like, "Okay, well..."I'm sure if I had been angry immediately at the time and thought of these things, I would've said them...I felt overwhelmed to get the meeting, appointment done and finished, get out. I had already waited maybe two years to get to that point, to that one moment. If you're happy this time they sign you off the record. No, I wasn't happy but I'm confused, baffled a bit by the signs of what I was being talked through. A bit shock, a little bit and there was no apparent treatment available and by the time you left the room it's kind of done, like go home... (WX028).'

Some patients stated that they were upset at first not being recommended surgery, whereas, looking back they recognised it was the right decision:

'... she explained to me, that because my core is so weak, my back is so tense because I don't use my core...when I left there I wasn't happy, I was really upset. Then a few days later, I accepted it. She's right. Once I got the painkillers, and I just started slowly building up on the exercise... (WX027).'

Feeling dismissed into care void

When patients were asked how in retrospect they felt about the consultation and whether or not their expectations and concerns were met, responses were mixed but more negative than positive. When responses were positive, patients mainly spoke about being satisfied or *'feeling relieved'* because they knew it was *'nothing serious'* or were not advised surgery. However, more often patients felt upset, angry, frustrated, and down after the consultation. Some patients felt the consultation was a waste of time because it was not helpful or that they had wasted the professionals' time, since it seemed they just *'wanted to get rid of me'*. Some patients accepting that there was simply *'nothing more they could have been done'*:

'... Well, they may have been addressed (concerns) but there wasn't any positive outcome. If you only feel telling them, "I've got a pain and I'll go through that proper procedures", but at the high end of the day I didn't walk away happy or satisfied....I just think they're the specialists. They do the procedures that they need to do. They've done the scans and all the rest of it and if they think that there's nothing more that can be done. I don't think looking back that there's anything else that I could've said... (WX006).'

'... didn't find anything reassuring because I was dismissed. I was effectively signed off for, there's not a lot we can do for you...It's just she took me through the options saying those aren't really right for you. So, we'll just sign you off then. Go swimming. Not very reassuring. They didn't reassure me that there was anything anyone could probably do moving forward. When I finally got back, I wasn't looking forward too hopeful to the next 34 years of my life with no line of treatment should I be in pain again which I am, regularly... (WX028).'

'... It's not his fault. He's not like a miracle worker. And it's a very brief consultation as well. Isn't it now in three minutes and it was a bit dismissive... (WX013).'

The decision to have / not have surgery

Patients varied in their beliefs about who should make the decision to have or not have surgery. Some patients felt that the consultant is the *'expert- she knows what she's talking about and if it relieves pain'* (WX023) and should thus make this decision, whereas others felt *'it should be my decision to make. Not his. I know my body, I know my rate of pain- he doesn't'* (WX025). Patients felt unqualified or reluctant to respond to advice provided by consultant because they felt they did not understand it in full. Patients who were *'annoyed'* by not having been recommended surgery, felt that the consultant *'doesn't know if I need it or not'* (WX025) because of insufficient testing (e.g. *'not having surgery would be okay if I knew what it was'*, WX021), or, argued it was because of the NHS funds:

'... I'm not happy. I would like to have a go at it. In the back of my mind I'm thinking, "Well, it can't be that bad." I'm thinking, "Well, it's not that bad but for

how long?" Well, how much is it going to be before I have to do something and can't do it because it's too bad, too old? Wish it couldn't cost a lot of money. Prevention is better than fixing but it's too late now. Any intervention, prevention might have been cheaper... (WX030).'

Some patient's response to surgery being ruled out was an ambivalent mixture of relief with disappointment because surgery was seen as the 'last treatment resort' (WX001). This was expressed in the dissonance within patient's attitudes that 'anybody really wants surgery unless they really, really have to have surgery' (WX006) or 'unless it's absolutely necessary, you don't want it' (e.g. WX023, WX028, WX027) but at the same time perceiving surgery as the 'solution' that can 'fix' their problem in which case patients expressed they 'would love to have' (WX010) surgery, staying open to this option in case pain becomes worst in the future (WX012):

'... I don't know, really. No idea what to think about it. I was thinking about it, "That can help me," with, but I'm scared as well. That's really serious things, so I'm a bit scared. I can't answer that; I don't really know what to feel... (WX022).'

Response to management advice

Patients responded with suspicion, disappointment and disparagement to most of the management advice they were given, especially if this advice did not take into account their individual circumstances (see above under 'gets the whole story'). Generic life style change advice was perceived as patronising:

'... That's when she recommended lifestyle changes as if I didn't know. People are not ignorant. I find it very condescending when doctors recommend lifestyle changes to somebody who's well aware of their pain... (WX025) '

'... I didn't want to seem challenging to her position if you like. If you question them and say, "Why you say that?. You don't know anything about me. I could be having an hour-long massage every day and time for myself. How do you know I don't have that time to myself? Even though I have three children, I could be having maids. You don't know." She just assumed and it's that assumption which-- That's why I said at

the beginning, they assumed patients to be ignorant, if you like. We're not ignorant. We might not be medically trained, but we're not ignorant... (WX025).'

Several patients felt that the advice was unrealistic because of cost or time implications:

'... Which my reply was I would love to do something like that but I have two children, where I can't just go to a Yoga or Pilates class. I've got two children that I need to find child care for. When I explained my situation with my husband, being away lot of work, I can't just go out on evening because of no child care. I can't go to a class... (WX009).'

'... Have physio. Oh, and do Pilates."...Of course they can't, how can they afford a physio? Okay, there's national health but once every four weeks... (WX025).'

In some cases, the advice was at odds with their circumstances, which made them feel that the consultant knew nothing about them:

'... Consultant X mentions in that letter that I need to do swimming and yoga, and whatever. I'm doing that (laugh). I WORK in a disability sports centre and when we do Pilates, and we have yoga and swimming, so that's there readily available to me and I've actually been doing that... (WX012).'

Patients often believed that there are a series of steps to treating LBP and having surgery is the 'final one'. Thus, patients not only expected to be informed about their next step of treatment, moreover, they expected to see a surgeon instead of an ESP, because patients believed only they had the 'ability' to make decisions on their condition as well as on treatment:

'... She didn't put me at ease because I was expecting a lot more. When you go there you think, "What's the next step?" because you think it's a series of steps, don't you? When you go there you're expecting them to turn around and say, "All right Mr. G, that didn't work, this didn't work. Now we're going to have to take this to the next level," but it wasn't. It was throw away the key. See you later, bye... (WX006).'

'... I expected to see a surgeon. Surgery was the next-- I've had three episodes and the next two. So five-- You go through a series of five series on your back....There's two options left apart from the painkillers and this, that and the other. The two options were injections, which they inject into the spine. The final one was surgery. I haven't been offered those two....I expected surgery... Pain injections and then surgery, that was my expectations of it. Because they said it goes a sequence of five. One was the MRI scan then there was painkillers and then they exhausted both plus the therapy. Then it was injections and then there was surgery. They stopped at three after me. Probably thought I was too old to bother... (WX026).'

Intention to re-consult

One of the main reasons for patients wanting to re-consult for their back pain in the future was feeling dissatisfied with the explanation and the proposed management (if any) that they received in the consultation. Patients felt that the consultants could not find anything wrong with their back because the investigations were not done thoroughly enough and therefore they felt it was important to look further into their condition:

'... You go back after a year. You tell them that yes, you've still got to pain but they say, "Look, there's nothing that can be treated. This is your X-ray". So I say, "Right, fair enough". Then you have to just kind of think, "Well, maybe I need to go and see someone else. Maybe I need to go to someone and pay someone to -- maybe somebody in the NHS ain't willing to help you "... (WX006).'

When alternative treatment was recommended, some patients stated that they intended to re-consult as soon as these were completed, and when no alternatives were offered, some patients stated they intended to seek alternative care immediately:

'... Not until I've let this physio work for two or three weeks. After that, I'll probably go back to the doctor and say, "Nothing's worked."... (WX026).'

‘... There were no options to have either surgery or medication, or anything else. None of that was offered to me, and that really was annoying. That’s why I was thinking as soon as I left that consultation, seek help elsewhere.’... (WX025).’

However, for most patients the idea of going back to the GP and being referred to a specialist again seemed long and off- putting:

‘... Here, you are left with unanswered questions which are frustrating for people and they keep going back to the GP and it is just another day, another time, another look. You're like on a hamster-wheel just going round and round and round. It is frustrating... (WX025).’

‘... You can go back to GP again and start the whole process again but-- you've been let down once, do you really want to go through that again?’... (WX006).’

Final consultation outcome: patients’ worries and concerns

For the majority of patients there remained fears and concerns about their backs, not only in reference to their present pain, but in the future. For some, this led directly to fear and avoidance of activity:

‘... I am worried because I think to myself, "Look if the pain's like this now, what's it going to be like in the next 10 years or 10 years beyond there if I'm still around?" That's the one thing that does play on my mind because I was very, very active... (WX006).’

‘... I’m really worried about that happening again. I think the only reason it hasn't happened again because I'm so careful now. I'm not doing any of the things I was doing before no exercise. I’m not running. I’m not spinning. I think that it will go again at some point. Obviously, I'm just taking things really carefully... (WX007).’

‘...Everyday. I’m careful how and what I do all the time. So that I don’t put myself in pain unnecessarily... (WX028).’

'... I think I'm always going to be worried about it, you know? I'm sitting here now and it's aching, and I'm hoping it's not going to get any much worse, but I think I'm always going to be worried. I'm very, very careful of how much I lift or carry, but at the end of the day you have to do it, you know, and try and put a brave face on it at the same time... (WX003).'

Some patients expressed catastrophic thoughts about their pain:

'... Yes, because I have the funny feeling I'm going to be disabled by it eventually...If I'm losing my ability now, then eventually it's going ... (WX030).'

'... I'm worried about at the moment because it's a different type of pain, I don't know if I could have a tumor... (WX012).'

In contrast, for a minority of patients, the consultation provided sufficient reassurance to alleviate their worry:

'... Not as much now. No. I used to think that I was going to end up in a wheelchair, because I think, why is pain so bad? But now, she's explained everything to me. I'm not worried anymore. I'm worried for the future because the discs are -- you know when she showed me there's one that's weak -- not brilliant but that's -- so yes, in the future maybe I will be one of the people that need an operation, but not now. And I'm talking 20 years time. If I can strengthen my core muscles, and exercise, and keep fit, then I won't need an operation... (WX027).'

Discussion

Summary

Overall, patients reported feeling dismissed and discouraged, coming away empty handed from their specialist consultation where surgery was not recommended as a treatment option. Before being referred to a specialist about their LBP, patients reported that their journey in the national health care system was complex and

confusing. At the consultation, they expected consultants to know about their whole story before providing them with clear explanations and a discussion of pain management. This combination of comprehensive knowledge about the patient, and concrete advice about management appears to be necessary for patients to feel they can get to grips with their problem, and failure to deliver resulted in patients feeling they were discharged into a care void. Additionally, patients expressed a strong need for validation of the pain, before they were able to hear positive messages such as that there was no need to worry, in order to feel empowered and encouraged to self-manage their condition. Thus, reassurance strongly affected how patients responded to the consultation contents in terms of satisfaction, intention to re-consult, and concerns.

Fit with existing theory and evidence

Findings are in line with the model of reassurance proposed by Pincus and colleagues (2013), which was based on evidence from primary care. Emerging themes around the consultation and reassurance in this study mapped well, and supplemented aspects of the existing model of reassurance, as shown in the following:

The theme ‘knowing my whole story’ mapped closely onto the theoretical domain of data-gathering. The importance of giving patients the opportunity to voice their concerns and tell their story has been described in the literature for patient centred care (Mead & Bower, 2000). This study adds details to inform practitioners of the list of behaviours needed for patients with more complex pain conditions to believe that the information about their problem is known in full by the practitioner. These include evidence that the practitioner read the case notes and was familiar with the patients’ previous health care history; tests and investigations; hands on examination and gathering information about the patient’s lifestyle.

The theme ‘seeing the right person’ mapped onto the domain ‘relationship-building’. As in the original domain this theme contains elements of perceived empathy, feeling listened to, and having rapport with the practitioner. In addition, for this group there was a sense of mistrust and suspicion, resulting from a long history of consultations and contradictory advice, so feeling reassured depended also on professionals

demonstrating that they know what they are doing through displaying professional skills and authenticity at all times. For this group, seeing a surgeon rather than an extended practice professional from a different discipline was important. In addition, patients felt more reassured when practitioners informed them that they had extensive experience with their problem.

The theme 'no need to worry' mapped onto the domain 'generic- reassurance' but was considerably extended to now reflect both positive and negative aspects of explicit statements that do not contain new information. The systematic review by Pincus et al. (2013), based on a model of persuasion proposed by Coia and Morley (1998) argued that generic positive statements aiming to improve patients' expectations are not necessarily useful. This contradicts common advice and practice: There is evidence to suggest that positive expectations in people with LBP are associated with better outcomes (reviewed in Main & Foster, 2010) but there is less evidence suggesting that when practitioners express such positive, optimistic expectations, patient outcomes improve. A recent systematic review of RCTs across all health problems in people above age 12 examined those that randomised participants to enhanced positive messages aimed at promoting positive patient expectations about recovery ('expectation interventions'), and concluded, from the 22 trials identified, that such interventions have a modest (around 0.4) effect size on psychological outcomes, and a small (around 0.2) on physiological outcomes (Howick et al., 2018). Most guidelines for back pain explicitly recommend that positive statements about expectations are included in the consultation, voiced in terms of the fact that the spine is strong and most people recover from episodes of low back pain. However, there appear some groups within the population of people with back pain, for whom these generic messages are unacceptable, and possibly even damaging. A prospective study of people with low back attending primary found that such messages had little effect on people with no psychological risk factors, but for those high on depression, anxiety and catastrophic thinking, optimistic messages were associated with higher depression three months later (Holt et al., 2018). A study of 496 patients consulting for back pain in the USA identified a specific cluster- those with high disability but positive expectations for recovery at baseline- had significantly worse outcomes in terms of function, mood and return to work three months later. The current study adds to this body of evidence, suggesting

that such positive messages from practitioners may be appropriate for less complex patients, but are probably unbelievable and inaccurate for people with high disability and considerable psychological distress (Carstens et al., 2014).

In addition, this study found evidence that patients appreciated, and possibly required, explicit validation of their pain. This is in line with experimental research that showed validation compared to invalidation increased adherence to repeated pain tolerance tests and more positive affect and less worry (Linton, Boersma, Vangronsveld, & Fruzzetti, 2012). Edmond and Keefe (2015) described validation in chronic pain as the practitioners' expression of hearing and comprehending the patients' disclosure, conveying the message that the patients' narrative is understandable, acceptable, reasonable, valid, and, legitimate. The so-called 'invalidation' statements, which might be a simple 'looking away' or 'change of subject', provide patients with the feeling that their pain experience is not important nor true and may result in more negative affect and increased pain behaviour (Linton, 2015). However, validation does not imply that the practitioner necessarily agrees with disclosure nor that they are encouraging potential maladaptive behaviours (Edmund & Keefe, 2015), instead, it may promote the asking of open questions that support problem solving and shared-decision making (Linton, 2015). Thus, especially for those discharged from care without further treatment options and without improvements in a long-standing condition, practitioners should try to avoid using empty optimistic statements, and ensure they provide validation to reinforce future disclosure. The results from a study that investigated the immediate effects of providing 22 medical students with two 45-minute sessions of an empathic validation programme, indicated improved communication with increased satisfaction for both the patient simulators and medical students (Linton, Flink, Nilsson, & Edlund, 2017). This suggests that providing surgeons and their teams with empathic validation training may be feasible and may lead to improved patients' outcomes.

Following the discussed of the role of emotions in the consultation on page 75, it has become evident that communication may be particularly challenging when dealing with chronic pain patients who also struggle with a host of co-occurring negative emotions, especially if clinicians are not trained in skills for dealing with emotionally sensitive issues (Linton et al., 2017). Thus, patients often report feeling dissatisfied,

disbelieved and misunderstood. The concept of validation as a technique in consultation-based reassurance may increase satisfaction and reduce negative affect and pain (Vangronsveld & Linton, 2012), especially for patients with high levels of psychological problems and pain interference it might be beneficial to focus on decreasing invalidating responses and/or increasing validating responses (Edlund et al., 2017). However, the concept of validation is not straight forward and clinicians are often unsure about the extent to which empathy should be incorporated into validating responses without inadvertently reinforcing pain behaviour (Linton, 2015). In addition, there are some key elements that contribute to the complexity of validating communication and might influence the aspired outcome of it, such as: the source of validation (e.g. friend, lover, practitioner, etc), the patient population (acute vs. chronic pain, medically unexplained conditions vs. explained conditions, certain patient characteristic- e.g. Edlund et al. (2017)), the manner in which validation/invalidation is delivered, and the timing of validating (Edmond & Keefe, 2015). However, clinicians might be inclined to use ‘validation’ in the fear of causing more harm than good, which may be based on behavioural theory principles, that offering positive reinforcement for pain complaints will increase behaviour. Instead, it has been suggested that empathic validation in pain communication serves the role of soothing negative affect, increasing disclosure to promote problem solving and shared decision making (Linton, 2015). We thought of validation as a sub-category of affective reassurance, that offers an opposing continuum on the theme ‘no need to worry’, by representing that worry, in these circumstances, was normal and understandable. This was mapped onto the domain ‘generic reassurance’ in the consultation-based reassurance model. However, when considering the suggestion to see empathic validation with the purpose of ‘soothing negative affect and increasing disclosure (Linton, 2015), then it could also be categorised under the ‘relationship-building’ part of the model. Either way, validation is a key to better communication with patients with persisting pain and emotional distress and research findings demonstrated it is feasible to train clinicians in empathetic validation (Vangronsveld & Linton, 2012), therefore it serves as an essential part of the consultation-based reassurance model. This suggests we could cooperate it under both, ‘GR’, aiming to train clinicians about the difference between validating and invalidating statements (e.g. not empathetic agreement but encouraging problem solving skills ‘I understand it is difficult to do yoga but I wonder how we get you

back to moving?') and 'RB', aiming to convey acceptance and understanding of pain-related thoughts and feelings as a means of enhancing the relationship and increasing disclosure (e.g. 'I get you're in pain and it must be so frustrating, tell me more about how it affects your life?').

For this group of extremely long-standing problems, validation in the presence of partners and family were particularly important. This fits in with previous research showing that lacking social support when coping with chronic illnesses is a key predictor of poor outcome. Not only to understand long-term LBP better as well as guiding management it is important to acknowledge the role of psychological and relationship aspects (Bailly et al., 2015), as it appears that LBP patient's with greater social participation may have also a better physical health status (Takeyachi et al., 2003). According to Edmond and Keefe (2015), the interpersonal process model of intimacy applied to patients with chronic pain interacting with close others (e.g. family) about their pain, predicts validating disclosure (pain-related thoughts and feelings) might lead to 'perceived partner responsiveness', leading to increased intimacy, positive affect, and relationship satisfaction, which in turn lead to lower levels reported pain. A study with 20 couples, of whom at least one partner reported chronic pain, employed a brief validation training session (without their spouse's knowledge) to examine if it associates with fewer invalidating responses towards the person suffering and changes in emotion and pain level for the person in pain (Edlund, Carlsson, Linton, Fruzzetti, & Tillfors, 2015). The results indicated that the training associated with increased validating and decreased invalidating responses and the partner in pain reported a decrease in negative affect. This might suggest to offer workshops or training courses for people close to chronic LBP patients informing them on how to effectively validate pain disclosures of their spouse.

The theme 'getting to grips with my pain' mapped onto the domain 'cognitive reassurance', and included reassuring behaviours such as receiving a clear explanation for the pain, and an appropriate individually tailored plan of management. Previous research showed that absence of a clear diagnosis and understanding about one's condition is associated with uncertainty, distress, and, further treatment/health care seeking (Serbic & Pincus, 2013). The findings from the current study suggest that even after long and extensive journeys within the health

care system, patients still lacked a clear diagnosis, explanation and understanding about their condition. Findings also suggest that when providing an explanation, it is crucial to use understandable language and avoid medical terms, in order for patients to comprehend and recall information provided. Darlow et al. (2013) showed people's beliefs and attitudes, especially in regards to their understanding about the meaning of their symptoms, and prognostic expectations about their LBP were stronger influenced by health care professionals, even for those who searched the internet and looked to family or friends for advice (Darlow et al., 2013). For these patients, effective cognitive reassurance clearly needs improving. While almost nothing is known on how to improve consultations in surgical settings, much can be learnt from research in primary care: Burton, Lucassen, Aamland, and Hartman (2015) produced a Cochrane review of the effectiveness of enhanced primary care interventions for after negative tests, and Rosendal et al. (2015) described a framework for rational explanations of symptoms for medically unexplained symptoms. Our study suggests that in terms of recall, comprehension and feeling that they fully understood what was conveyed in the consultation, it seems that sending out follow-up letters that summarize consultation contents and outcomes might play an important role.

Having a proposed plan of action to manage their pain, even if discharged without the option of surgery, was paramount to patients. Previous research also showed health care providers tend to approach LBP management from a biomedical approach, which is largely structural and mechanical (Froud et al., 2014). Many therapies offered for LBP, such as the expansion in physiotherapy, focus on symptom palliation and/or correcting supposed biomedical faults (O'Sullivan et al., 2016). This study confirmed this narrow approach: neither patients nor clinicians in the current study showed awareness of multimodal management of pain, and specifically, of psychosocial aspects of the condition.

In terms of effective reassurance in consultation that end in discharge without treatment, it might entail recognition of the importance of the biopsychosocial approach to management and the availability of other treatment avenues (e.g. psychologists and/or pain management teams etc.). For patients, any recommended treatment was better than the discharge they received. Patients stated that they

appreciated receiving a referral to physiotherapy, even though they were aware there is nothing more that could be done and treatment might only lead to short-term pain relief. Patients also felt that in order for them to know their optimal short-term pain relief management preferences, they need to have the option to explore as many different management avenues as possible, to find out what works best for them. They strongly resented the health system that restricted such options. While this ‘no-limits’ approach might be costly in the short term, it is not known whether it might not reduce the economic burden of chronic pain in the long run. Our study also suggested that offering patients the opportunity of a 6-months ‘open door’ appointment might be essential for them to feeling at ease, especially when discharged without further treatment options.

According to Linton et al. (2008) reassurance should take place ‘within the dynamic of the interaction’ between consultation and patient. Surgical settings present some obstacles for this effective interaction. The patients in this study described their reluctance to voice their concerns due to perceiving consultants as ‘too superior’ for patients to question treatment decisions. Patients often felt that surgeons and their teams conveyed a sense of being a high professional authority figure, resulting in making patients feel too intimidated to question or challenge advice provided. For the health care provider side, this should mean placing more importance on encouraging patients to raise concerns, and encourage willingness to get involved in the decision of their management plan.

In combination, all reassurance components mentioned above (see Figure 2) seemed to affect how patients considered, evaluated, accepted, and, responded to information disclosed in the consultation. In line with previous evidence in primary care (Holt et al., 2017), it became evident that the lack of effective reassurance in this sample led to increased worries and intention to further consult, which potentially results in further exhaustion of health care facilities in the long run.

The hypothesis under examination emerges from the proposition that the manner in which professionals convey the message of discharge and self-management, is important as it might impact on the patients’ understanding, thoughts, and subsequent behaviour in managing their pain. In contrast to our hypothesis, it could

be argued that the consultation in respect to the length and entrenched journey of suffering that patients have gone through, is highly unlikely to impact on patients' outcomes, especially considering patients have tried everything, including attending pain management programmes, and consulting various different clinicians who, despite their best intentions, were unable to encourage this group of patients to self-manage their condition. However, this would suggest that there is no help for this certain group of patients, whereby, from our interviews we know that for some this consultation was the turning point after a long journey of hopeless cycles of care seeking. Thus, attempting to improve communication skills to reach those patients that can be impacted by this consultation and provide them with the information that they require to get better, is worthwhile. We recognise that the influence of consultation-based reassurance on the outcomes measured is likely not direct: it will be mediated through changes in beliefs such as catastrophic thinking, and behaviours, such as increased activity. This in turn is likely to be influenced by other factors external to the study, such as attitudes from family, media messages and individual circumstances.

Strengths & Limitations

This study is the first to look at consultation-based communication between people attending surgical setting for low back pain and surgical teams. However, there are several limitations inherent in the design. The sample size is comparable to similar qualitative studies, but is still small, and the response rate from invited patients was 60%. Thus, the findings from this study may not represent other patients in different surgical settings. There are also the limitations associated with qualitative studies, which provide rich data from a personal perspective, but are susceptible to interviewee and researcher bias. In addition, this study relied on patient's delayed recall and post-hoc interpretation of consultation contents. Thus, the use of video or audio- tapes of the consultation itself, may be suggested to assure patients' narratives are interpreted within context and comparable to the actual communication that took place during the consultations. However, since patients filter, interpret, and remember information at the level of their understanding and in the context of their pre-existing beliefs, attitudes, and motives (Darlow et al., 2013), the messages patients remembered might be more important than what consultants said or intended. Future research could also use dyad approaches and include interviewing

surgeons to explore the discrepancies between patient and consultants report of consultation-based reassurance. Another possible limitation is that the time to interview post consultation was not standardized, so the duration differed between patients. Similarly, the setting, timing and length of interviews (which took place in patient's homes) could not be standardized, but this may also have been an advantage, as it reduced the inhibitions patients reported about expressing their true views in medical settings. Finally, this study provides an initial insight into factors relevant to effectively conveying reassurance at these late stages. It requires quantitative research, measuring consultation-based reassurance against patients' outcomes in larger samples to disentangle the mediating role of those different types of reassurance on outcomes, adjusting for psychological risk, pain and disability prior to the consultation.

Conclusion

In conclusion, this study provided a rich framework of communication/reassurance factors that are important to patients with complex long term persistent back pain who are consulting surgeons and their teams. Effective communication with patients discharged of care is imperative, especially when no active treatment is being offered. For those discharged from care without further treatment, it may be particularly important that professionals deliver reassurance, aiming to encourage patients towards effectively self-managing their condition. While self-management at earlier stages of LBP is easier to adhere to, at these late stages, once pain and disability have become entrenched, this message is difficult to accept and likewise difficult to convey.

CHAPTER 5: PROSPECTIVE COHORT STUDY (BASELINE & POST-CONSULTATION DATA)

Introduction

In the previous Chapter 4, a rich framework of reassurance factors that are important to patients who were discharged from orthopaedic specialist consultations, was presented. Patients coming away from discharging consultations often felt dismissed, discouraged, and were in the urgent need of changes in their health care journey and perceived consultation-based reassurance. So far, the thesis considered patients perspectives and clinicians response to those, however, there is a lack of quantitative evidence providing sufficient empirical support to conclude that the framework is accurate. Therefore, quantitative research methods were used in the form of a prospective cohort study and a much larger sample size, with the aim of shedding light onto consultation-based reassurance components that are associated with patient' outcomes in secondary care.

The global prevalence of low back pain is estimated to be 31.0% and the one-year prevalence around 38.0% (Hoy et al., 2012). Individuals aged between 20 and 59 have a chronic LBP prevalence of 19.6%, whereby the prevalence rate for older people is 25.4% (Meucci et al., 2015). Approximately 3-4% of the younger adult population (below 45 years old) and about 5-7% of the older adults (over 45 years old) are chronically disabled by MSK LBP (NICE, 2016). Unfortunately, for most people, there is no cure that can relieve the pain permanently (Blyth et al., 2004). Patients often spend many years seeking help from a variety of specialists and sometimes get stuck in a vicious circle of care seeking (Clare et al., 2013). Recurring, persisting, disabling, long- term MSK LBP is not only of driving force in lost productivity and healthcare utilization, and hence associated with major clinical and economic problems, it is of substantial toll on the affiliated, their loved ones, and thus of detrimental cost for society in general (Croft, Blyth, & van der Windt, 2010).

Reassurance in the form of good practitioner-patient communication is perceived as

the ‘corner stone of treatment’ (Pincus et al., 2013) and guidelines recommend it for the early and later stages of MLBP (NICE, 2016). Reassurance in the form of providing information effectively is suggested to correct mistaken beliefs, such as catastrophizing, or fear-avoidance, resulting in the possible reduction of worries (Linton et al., 2008) and can direct patients towards active behavioural-change strategies (O’Sullivan et al., 2016). Evidence from primary and secondary care suggest certain aspects of reassurance impact varying short-term outcomes such as satisfaction and long-term outcomes such as further health care seeking (Holt, Mansell, Hill, & Pincus, 2018; Linton, Boersma, Vangronsveld, & Fruzzetti, 2012; Moseley, Nicholas, & Hodges, 2004; Pincus et al., 2013). What may be required is a shift in training and delivery of care, away from the focus on treating patients through multidisciplinary interventions with considerable financial burden and towards placing importance on training practitioners to acquire effective communication skills that result in optimized patients’ outcomes. By informing and eventually optimizing the method of reassurance, its impact on patients’ outcomes and how to match it to specific patients’ needs, clinicians are equipped with a powerful tool, a form of an ‘indirect treatment modality’, which may not only deliver results in terms of optimized outcomes but also reduce the burden of CMLBP on the individuals, clinicians, and society.

To test and quantify the importance of communication skills of practitioners on patients’ outcomes, a reliable and valid consultation-based reassurance questionnaire was developed, dividing reassurance into four sub-scales with each 3 -items; data-gathering (DG), relationship- building (RB), generic- reassurance (GR), and cognitive- reassurance (CR). The measure was tested in primary care settings with patients consulting their GP for their LBP (Holt & Pincus, 2016). Subsequently, the measure was implemented in a prospective cohort study with LBP patients examining the role of reassurance on clinical outcomes at 3-monhts follow- up (Holt et al., 2018). The results showed that all reassurance components were strongly associated with short-term outcomes, such satisfaction and enablement. Generic reassurance was associated with less pain and cognitive reassurance was associated with more pain at 3-months. Moreover, higher perceived generic reassurance was associated with less depression at 3-months for low-risk patients but also associated with more depression at 3-months for high-risk patients. The later interaction

between risk-profile and reassurance may occur because practitioners might have given patients false hope with a positive prognosis, whereas when the pain returned patients were let down in their expectations that there will be an improvement.

While the existing literature provides an extensive understanding of reassurance in primary care, no study to date was identified which dealt directly with measuring reassurance against patients' outcome in those with chronic LBP in surgical consultation settings. How patient's perceive consultation-based reassurance when consulting with a surgical team, is under-researched and thus how to effectively deliver reassurance within this context is unknown. The surgical teams examined within this study consisted of surgeons and Extended Scope Practitioners (ESP), which are also called Advanced Practitioner Physiotherapists (APP). In one of the sites, ESP's or APP's were part of the surgeons' team but operated under the name of musculoskeletal (MSK) services and were hence referred to as the MSK practitioners. Considering the length of the scheduled consultations differed between those two types of practitioners, whereby consultations with an ESP were substantially longer than those with surgeons, it may be that patients perceive reassurance differently depending on who they get to see.

The decision to look at different professions in our analyses came from the difference in consultation time between orthopaedic surgeons and other practitioners, as well as from the findings of our qualitative study, which indicated that as a result of patients' long history of consultations and contradictory advice, they often felt mistrust towards health care professionals. For this group, seeing a surgeon rather than an APP was important and often led to patients feeling more reassured. In addition, the findings indicated that patients perceived differences in reassurance behaviours depending on the practitioners' professional discipline, which suggests that they might use different reassurance styles because of their professional background. Therefore, we wanted to investigate this effect quantitatively in our prospective cohort study. There were also reasons for us to look at different sites. First, we checked whether patients were similar in their baseline characteristics and found that they were not depending on the sites they were recruited from. Secondly, some sites operated slightly differently in terms of pre-consultation imaging tests and in that one site also had an incorporated MSK team, whereas the other two sites did

not. Thus, we wanted to examine more closely whether there are differences in perceived reassurance, depending on the care setting.

Patients consulting at this later stage might have tried all treatments to no avail and experience entrenched pain and disability, thus they are expected to enter their specialist consultation with high levels of distress, requiring professionals to adjust their reassurance style accordingly. The consultation-based reassurance model proposes patients and problem characteristics (e.g. pain, disability, StartBack, mood) are important factors which impact on the patients' journey at all stages (Pincus et al., 2013; Pincus & Morley, 2000; Pincus et al., 2002; Pincus & MacCracken, 2013; Foster et al., 2008). The emotional state and personal distress patients express at baseline, before entering their consultation, may affect how they perceive and interpret reassuring messages delivered by professionals (Linton et al., 2008). Nonetheless, the reduction of emotional distress through reassurance is far from straightforward (Traeger et al., 2017). It is an aspect that has not received a lot of attention, especially not in surgical settings. The previous outlined evidence in primary care (Holt et al., 2018) was limited in a sense that it did not measure the baseline characteristics of MLBP patients before they consulted with their GP but instead up to 1-month post-consultation, which was arguably not a 'true measure of baseline'. Moreover, the study in primary care relied on patients to return their follow-up questionnaires by post, resulting in a low response rate, which may have led to problems with statistical power. Counteracting on limitations of previous research, the current study measured baseline characteristics shortly before patients enter their specialist consultation, aiming to capture the 'true' baseline and problem (e.g. expectations) characteristics. In addition, to achieve high response rates, in the data collections processes of the current study, postal options for follow-up were not adopted instead follow-up data was collected over the phone by the same researcher that approached patients in clinics at baseline.

The analyses in this Chapter focuses on patients' baseline characteristics and history, their association with perceived reassurance and certain treatment outcomes, as well as the differences in perceived reassurance between practitioner types (surgeons, and other professionals in the orthopaedic team, mostly physiotherapists). Whereas, in the proceeding Chapter 6, reassurance in relation to patients' short-term and long-

term outcomes, after controlling for the effects of baseline characteristics, will be the focus of analyses.

Aims

The aims were to examine the characteristics and history of patients consulting with orthopaedic team and to investigate:

1. The associations between perceived consultation-based reassurance, patient characteristics and clinical history.
2. Whether patients' clinical history and individual differences are significantly associated with the consultation outcomes (whether patients are discharged or referred for further treatments).
3. Whether patients perceive reassurance differently between surgeons and ESP.

Methodology

Design and Recruitment

This was a prospective observational cohort study of patients consulting orthopaedic surgeons and their teams for their persisting MLBP. Hospitals and associated clinics were located in the south/west of the UK. In total, 3 orthopedic teams specializing in spine care participated across 8 different hospitals and clinics. Hospitals were grouped into three different geographic sites, each employing the same orthopaedic team:

- Site 1 (3 hospitals- WX, HW, SM): employed 2 surgeons (males) and 3 ESP/APP's (females). Recruitment was open from 27th June 2017 until 20th October 2017.

- Site 2 (3 hospitals- FPH, AH, FH): employed 4 surgeons (males), 1 Fellow (male), 2 Registrar's (1 male, 1 female), and 2 ESP/APP's (1 males & 1 female). Recruitment was open for 12th March 2018 until 30th August 2018.
- Site 3 (2 hospitals- RSCH, CH): employed 1 surgeons (male), 3 Registrar's (2 males, 1 female), and 4 MSK practitioners (1 male GP, 3 females). Recruitment was open from 19th November 2018 until 6th March 2019.

Surgeons, fellows and registers were all coded 'surgeons', as they represent the same professional discipline. In total, patients from 13 surgeons (11 males & 2 females) and 9 ESP/APP/MSK's (7 females & 2 males) were recruited between June 2017 and March 2019, and the last follow-ups at 3-months were collected in June 2019. The study was supported by the National Institute for Health Research Clinical Research Network (NIHR CRN). Each site employed a different team of research nurses, of whom in total 5 were allocated to help in the recruitment process of our study. Due to time restrictions, priori screening from the referral letters by the NIHR research nurses was not possible. Thus, the allocated research nurses sent letters of invitation and information to all patients who had an appointment with the specialized outpatient back clinic in the following week (please see Appendix F for the letter of invitation). Patients interested to participate were asked to come in 15 minutes before their consultation. All patients who received an invitation were approached by the researcher in the clinic to find out if interested and eligible. The inclusion and exclusion criteria were as follows:

Inclusion:

- LBP being the main complaint and reason for consulting
- Adult patients (18 years and above)

Exclusion:

- Previous spinal surgery
- Cauda equina and ankylosing spondylitis
- Pregnancy
- Severe disability or end of life disorders

- Cognitive impairment
- Unable to read or speak English

Patients were informed that their responses at any given stage of the study are anonymous, would not be shared or revealed to their consultant, and would never interfere with their treatment. Eligible patients who provided consent (see Appendix F for consent sheet) were asked to complete their baseline questionnaire in the waiting room area shortly prior to their consultation. Completed questionnaires were returned to the researcher and were not available to the surgeons and their teams. The researcher called patients for their post-measures within 1 week of their consultation and again at 3-months follow-up (see Appendix F for questionnaire bundles). For more details on the reliability and validity of the measures used in this research, please refer to the Methodology Chapter 3. Subsequent to post-consultation data collection patients were divided into four sub-groups according to their consultation outcomes; those who received a referral to further treatment (e.g. physiotherapy, injections), those who were discharged without any treatment, those who were recommended to undergo surgery, and those who were sent for further investigation (e.g. imaging tests). Patients for whom surgery was indicated and patients who were referred for further investigation were not followed-up at 3-months (please see Figure 3 for Participant flow chart).

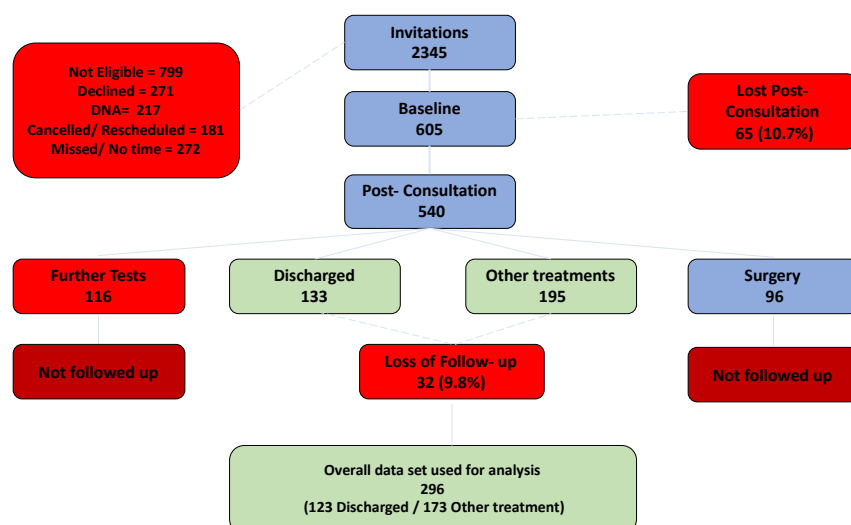


Figure 3: Participant Flow Chart

Measures

The measures used are discussed in detail under the ‘Questionnaire’ section in Chapter 3. A quick recap to the measured used at all stages of recruitment, please refer to Table 4. In the following Chapter, only the data from baseline and post-consultation were used for analyses.

Baseline	Post- consultation	3- month follow- up
Age	Received diagnosis, (Yes/No)	Pain intensity (Jensen et al.,1986)
Gender	Acceptance of Explanation	Disability, RMDQ (Roland & Morris, 1983)
Marital Status	Catastrophizing (1-item) (Serbic et al., 2013)	Depression & Anxiety, HADS (Zigmond & Snaith, 1983)
Education	Intention to re-consult	Further health care utilization (GP visits, number of different professionals seen, re-consulted)
Work Status	Reassurance, ECRQ (Holt & Pincus, 2016)	Sick days
Number of pre-consultations	Satisfaction, CSQ6 (Baker, 1990)	
Number of pre-treatments	Perceived reassurance, 1-item Enablement, PEI (Howie et al., 1998)	
Expectations (9-items)		
StartBack (Hill, 2008)		
Pain intensity (Jensen et al.,1986)		
Disability, RMDQ (Roland & Morris, 1983)		
Depression & Anxiety, HADS (Zigmond & Snaith, 1983)		

Table 3: Questionnaire measures used at the three stages of recruitment

Analysis

In this chapter, patients’ baseline characteristics and reassurance were the main focus of the analyses, whereas, in the following Chapter 6, the analyses were focused on the effects of reassurance on short-term (post-consultation) outcomes and on long-term (3-months follow up) outcomes. All analyses were performed using SPSS version 23 (IBM Corp, 2015). The assumption of normality for all variables were assessed via graphical methods (e.g. histograms, Q-Q Plots) because the numeric

methods (e.g. Shapiro-Wilk) are not recommended for sample sizes above 50 participants, since tests would flag even minor deviations from normality as significant (Laerd Statistics, 2015).

Correlations between baseline variables and reassurance were examined through either the Spearman's or the Pearson's correlation. For nominal/ordinal variables (e.g. gender, marital status) or variables that were not normally distributed (e.g. DG, RB, CR) the Spearman's correlations was used. For continuous variables which were normally distributed (e.g. GR) the Pearson's correlation was used. For the Spearman's correlation coefficients, preliminary assumption checking involved the examination of scatterplots to check for monotonic relationships between the variables. For the Pearson correlation coefficients, preliminary assumption checking involved: examining for linear relationship between variables by assessing scatterplots or partial regression plots, testing for normality by assessing histograms and normal Q-Q plots, and removal if univariate or multivariate outliers via assessment of boxplots and case wise diagnostic tables (Laerd Statistics, 2015).

Before the main analyses, a one-way multivariate analysis of variance (one-way MANOVA) was conducted to assess whether patients who were recruited from different sites and different professionals within the orthopedic teams entered the study with similar baseline characteristics and clinical histories. The following tests were used for preliminary assumption checking for a one-way MANOVA: (1) inspection of boxplots (values > 1.5 box-length from edge of box) to assess univariate outliers, (2) inspection of histograms and Q-Q Plots to see if data is normally distributed, (3) assessment of Pearson correlation ($r < .9$) to check for multicollinearity, (4) inspection of scatterplots for linearity, (5) examination of Mahalanobis distance (after adjusting for the number of DV's and implementing the appropriate critical value) to check for multivariate outliers in the data, (6) testing of homogeneity of variance-covariances matrices by inspection of Box's test of equality of covariance matrices ($p < .001$), (7) examining of Levene's Test for Homogeneity of Variance ($p < .05$) (Laerd Statistics, 2015). In addition, baseline differences between those patients who saw a surgeon compared to those who saw an ESP's, were investigated using a Hotelling's T^2 statistical test, which is a special case of one-way MANOVA, whereby the independent variable (IV) has only two categories

and more than two dependent variables (DV's) are examined at the same time. The same tests as for the one-way MANOVA were used for assumption checking.

To investigate aim 1; whether perceived consultation-based reassurance behaviours from orthopaedic team consultants is associated with patient characteristics and clinical history, four multiple linear regressions models were performed. Each reassurance type (DG, RB, GR, CR) was entered individually as the outcome variable. The predictor variables remained the same for all 4 models being: age, gender, education, number of previous treatments, pain, StartBack, disability, anxiety and depression. Preliminary assumption checking for the multiple linear regression models involved: (1) assessment of the Durbin-Watson statistic for an approximate value of 2 to check for independence of residuals, (2) visual inspection of scatterplot of unstandardized predicted values against studentized residuals for linearity between IV's and DV's collectively and inspection of partial regression plots to check for linearity between each IV and DV, (3) assessing homoscedasticity of residuals by inspecting scatterplots of studentized residual against unstandardized predicted value or plotting standardised residuals against standardised residuals, (4) assessment of correlation coefficients (< 0.9), Tolerance (> 0.2), and VIF (< 10) values to check for multicollinearity, (5) assessing studentized deleted residuals (± 3 SD), leverage values (< 0.2), and influential points (Cook's distance < 1) to determine outliers, (6) inspection of P-P Plots to check if residuals were normally distributed (Laerd Statistics, 2015).

To examine aim 2; whether patients' history and characteristics can predict which treatment group they were being allocated to, two binary logistic regression were performed. We did not investigate predictions for the surgery group because the MRI scan and obvious clinical marks should be predictive of recommending surgery. Thus, a dichotomous variable was created through dummy coding and used as outcome variables in the binary logistics regression. Predicting variables were entered in two stages to control for the variables that were entered first. In Block 1, sites and consultant professions were entered as covariates, and in Block 2 the association with age, gender, education, number of previous treatment types, Pain, StartBack, disability, depression and anxiety were investigated. Preliminary assumption checking for the binominal logistic regressions involved: (1) using the

Box-Tidwell (1962) approach to assess linearity between the IV's and the logit transformation of the DV, (2) assessing the correlation coefficients (< 0.9), Tolerance (> 0.2), and VIF (< 10) values, to make sure there is no multicollinearity, (3) examining the 'casewise diagnostic table' for standardized residuals (± 2 SD) (Laerd Statistics, 2015).

To examine aim 3: whether reassurance is rated differently by patients if received from surgeons and ESP's. The IV (type of consultant) had 2 levels (ESP vs surgeon) and the DV (reassurance) had 4 levels (DG, RB, GR, CR). Instead of using a one-way MANOVA to examine the difference between groups on the combined Dv's, four independent sample t-tests were performed. Tests to check for preliminary assumptions involved: (1) boxplots for values greater than 1.5 box lengths were inspected for extreme values, (2) determining if data is normally distributed by visual inspection of normal Q-Q plots and histograms, and (3) assessing the Levene's test for equality of variance to check for homogeneity of variances.

In the results and findings section, for each analysis, only the assumptions that were violated and their corrections were stated but not when assumptions were met.

Results

At baseline, 605 patients were recruited from three different sites. Retrospectively, patients who were sent for further investigation ($n = 116$, 19.2%) and those who did not respond post-consultation ($n = 65$, 10.7%) were excluded from these analyses. Patients were lost at post-measure collection or 3-months follow-up when the researcher was unable to get hold of them because of wrong or changed contact details, patients did not pick up or return the calls, or patients asked to be withdrawn from study (please see Chapter 3 for details on missing data). The initial response rate at post-measure collection was 89.3%. A binary logistic regression was performed to see whether patient history or characteristic can predict patients who provided follow-up data from those who did not complete their 3-months follow-up measures. The model was not significant, $\chi^2(12) = 17.782$, $p = .122$. Patients characteristics and history did not predict responders from non-responders. From the Table 5 below we can see that patients who completed their post-consultation

measures were slightly older, and less disabled and anxious. Otherwise, patients do not seem to significantly differ from patients who were lost at post-consultation. Therefore, it can be assumed that data is missing at random and hence was excluded from the analyse and not computed for missing values instead.

	Responders M (SD) N = 424	Non-Responders M (SD) N = 32
Age	54.56 (17.33)	50.01 (16.05)
Pain	5.67 (2.51)	6.08 (2.34)
No of pre treatments	1.66 (0.76)	1.46 (0.89)
StartBack	1.90 (1.27)	2.31 (1.38)
RMD	10.49 (5.93)	12.10 (6.23)
Anxiety	7.45 (4.67)	8.46 (4.31)
Depression	6.14 (4.01)	7.00 (4.11)

Table 4: Baseline Characteristics of responders vs. Non-responders

In total, data from 424 patients were left for analyses, of whom 133 (31.4%) were discharged, 195 (46.0%) were referred to other treatments, and 96 (22.6%) were recommended to undergo surgery. The number of patients send for further imaging is surprisingly high, considering the NICE (2018) guidelines explicitly state to not offer imaging for low back pain. The percentage of those who are offered surgery is also unusually high, although not compared to the USA, and it suggests that guidelines are not yet incorporated into practice. However, within this study there is no way of testing whether those referred to surgery were all ‘suitable for surgery’ beyond the surgeon’s opinion- we did not use independent ratings of imaging. Descriptive statistics for the overall sample can be found in Table 6.

Age M (SD) Range	55.21 (17.14) 19- 90
Gender N (%)	Female = 245 (58) Males = 178 (42)
Marital Status N (%)	Single = 64 (15.1), Cohabiting = 47 (11.1), Married/Civil Partnership = 227 (53.5), Divorced = 37 (8.7) Windowed = 35 (8.3) Other = 9 (2.1) Missing = 5 (1.2)
Education N (%)	Left School before 16 = 159 (37.5) A-level equivalent = 82 (19.3)

	Higher Education = 156 (36.8) Missing = 27 (6.4)
Work Status N (%)	Employed= 216 (50.9) Looking after home= 25 (5.9) Retired = 138 (32.5) Student = 6 (1.4) Unemployed health reasons = 26 (6.1) Unemployed other = 9 (2.1) Missing = 4 (0.9)
Other serious health issues N (%)	None = 265 (62.5) 1 = 116 (27.4) 2+ = 40 (9.4) Missing = 3 (0.7)
Told cause/ diagnosis of LBP N (%)	Yes = 147 (34.7) No = 273 (64.4) Missing = 4 (0.9)
Imaging tests N (%)	Yes = 371 (11.8) No = 50 (11.8) Missing = 3 (0.7)
Duration N (%)	< 1 month = 29 (6.8) 1-6 months = 97 (22.9) > 7 months = 291 (68.6) Missing = 7 (1.7)
Previous consultations N (%)	1-2 = 98 (23.1) 3-5 = 113 (26.7) 5-10 = 88 (20.8) 10+ = 119 (28.1) Missing = 6 (1.4)
Number of previous treatments M (SD)	2.19 (1.58) Missing = 4 (0.9)
Pain M (SD)	5.92 (2.47) Missing = 4 (0.9)
StartBack M (SD)	2.04 (1.28) Missing = 4 (0.9)
Disability (RMDQ, 0-24) M (SD)	11.02 (6.07) Missing = 4 (0.9)
Anxiety (HADS-A, 0-21) M (SD)	7.67 (4.66) Missing = 8 (1.9)
Depression (HADS-A, 0-21) M (SD)	6.5 (4.00) Missing = 8 (1.9)
Reassurance, (ECRQ, 0-21) Data- Gathering (DG) Relationship- Building (RB) Generic- Reassurance (GR) Cognitive Reassurance (CR)	17.23 (4.46) 17.19 (4.75) 13.95 (5.50) 16.20 (5.17)

Table 5: Descriptive Statistic Baseline Characteristics (n = 424).

Findings

Results from the Spearman's Rho and Pearson's correlations revealed, patients who were older perceived more data-gathering and relationship-building. Marital status was also positively correlated with DG, RB, and CR. Work status was positively correlated with RB. The more previous consultations and the more different types of treatments patients had, the less GR they perceived. The more pain patients reported, the less GR and CR patients perceived. The more disability they reported, the less RB, GR, and CR they perceived. People with a high-risk profile on the StartBack measure and higher measures of anxiety and depression, perceived that they received less reassurance in all four sub-scales, DR, RB, GR, CR. The correlations for each reassurance sub-scale with baseline characteristics are displayed in Table 7.

	Data- Gathering, N= 417	Relationship- Building, N= 418	Generic - Reassurance, N= 417	Cognitive - Reassurance, N= 417
Age	.123 *	.198**	-.063	.065
Gender	-.026	.004	.013	-.052
Marital status	.115*	.164**	-.038	.103*
Education	.004	.025	.057	.068
Work status	.097	.123*	-.045	.059
Other health issues	-.006	-.006	-.068	-.011
Number of consultations	-.088	-.082	-.159**	-.081
Number of pre treatments	-.055	-.024	-.142**	-.047
Pain	-.066	-.078	-.154**	-.105*
StartBack	-.105*	-.202**	-.191**	-.153**
Disability (RMD)	-.079	-.146**	-.179**	-.101*
Anxiety	-.184**	-.235**	-.146**	-.188**
Depression	-.205**	-.247**	-.196**	-.203**

Table 6: Correlations between baseline characteristics and reassurance.

Notes: * correlation is significant at $p < 0.05$; ** correlation is significant at $p < 0.01$.

Differences in Baseline characteristic

Sites

Out of the total of 424, 118 (27.8%) patients were recruited from site 1, 153 (36.1) were recruited from site 2, and 153 (36.1%) were recruited from site 3. To test whether there were differences in patients' characteristics and clinical history (pain, number of different previous treatments, StartBack, RMD, anxiety, depression) between the sites, a one-way MANOVA was conducted.

The assumption of homogeneity was violated for disability ($p = .019$) and depression ($p = .022$), as assessed by Levene's Test of Homogeneity of Variance ($p > .05$). To correct for this violation the Games- Howell post-hoc comparison test was used to report on those two variables. There was a significant difference between the sites and patients' baseline characteristics, $F(14, 804) = 3.319$, $p < .001$; Wilks' $\Lambda = .894$; partial $\eta^2 = .055$. A Bonferroni alpha (α)- level correction was applied to adjust for multiple comparisons. The adjusted α - level was $p < .008$. Follow-up univariate ANOVAs showed that except pain ($p = .009$), and StartBack ($p = .025$), all other baseline characteristics were significantly different between the sites: Number of previous treatments ($F(2, 411) = 8.675$, $p < .001$; partial $\eta^2 = .041$), disability ($F(2, 411) = 7.193$, $p = .001$; partial $\eta^2 = .034$), anxiety ($F(2, 411) = 6.818$, $p = .001$; partial $\eta^2 = .032$), and depression ($F(2, 411) = 7.884$, $p < .001$; partial $\eta^2 = .037$). Bonferroni post hoc-tests revealed: patients in site 3 had significantly less previous treatments than in site 2 ($p < .001$) but not different to site 1 ($p = .053$). Patients had less anxiety in site 3 compared to site 1 ($p = .001$). Games- Howell post-hoc revealed that patients recruited from site 3, scored significantly lower on disability than site 1 ($p = .003$) and site 2 ($p = .003$). Likewise, patients recruited from site 3 reported significantly lower depression scores than those recruited in site 1 ($p = .001$) and site 2 ($p = .004$). Please see Table 8 for mean and standard deviations (SD). The observed differences in patient characteristics at baseline were mainly between site 3 and the other two sites, but not between site 1 and site 2. To control for the differences in

baseline characteristics between sites, a dummy variable was created which was entered in the first stage as a covariate to all of the following regression models in this and the following chapter.

	Site	Mean	SD	N
Age	Site 1	53.72	15.79	109
	Site 2	57.02	16.83	152
	Site 3	54.75	18.24	147
	Total	55.32	17.10	408
Number of previous treatments	Site 1	2.25	1.66	109
	Site 2	2.51	1.60	152
	Site 3	1.78	1.39	147
	Total	2.18	1.57	408
Pain	Site 1	5.92	2.58	109
	Site 2	6.36	2.39	152
	Site 3	5.51	2.34	147
	Total	5.93	2.44	408
StartBack	Site 1	2.17	1.29	109
	Site 2	2.16	1.22	152
	Site 3	1.82	1.30	147
	Total	2.04	1.28	408
Disability	Site 1	11.89	6.16	109
	Site 2	11.82	6.37	152
	Site 3	9.61	5.23	147
	Total	11.04	6.01	408
Anxiety	Site 1	8.89	4.78	109
	Site 2	7.68	4.43	152
	Site 3	6.73	4.56	147
	Total	7.66	4.64	408
Depression	Site 1	7.24	4.29	109
	Site 2	6.89	3.96	152
	Site 3	5.50	3.55	147
	Total	6.48	3.98	408

Table 7: Baseline characteristics across sites

Reassurance between sites

One-way MANOVA was run to determine the effects orthopedic teams in different sites had on perceived reassurance. Inspection of the boxplot for values greater than 1.5 box length from the edge of the box and inspection of Mahalanobis distance ($p > .001$) revealed univariate but no multivariate outliers. Outliers were kept in the

analysis after comparing the models with and without outlier removal. The assumption of homogeneity of variance-covariance was violated, as assessed by Box's M test ($p < .001$), hence Pillai's Trace instead of Wilks' Λ was reported. The assumption of homogeneity of variances was violated for data-gathering ($p < .001$) and generic reassurance ($p = .037$), as assessed by the Levene's Test ($p > .05$). Correcting for the violation of this assumption the Games and Howell post-hoc test was used instead of the Bonferroni multiple comparison test.

There was a significant difference between patients across the three different sites and the combined dependent variables (reassurance types), $F(8, 828) = 5.165$, $p < .001$; Pillai's Trace = .095; partial $\eta^2 = .048$. Using a Bonferroni correction, accounting for the multiple comparison of 4 DV's, the adjusted α level was set to .013. Subsequently, the results from the follow-up ANOVA's revealed that there was no significant difference in perceived relationship-building, $F(2, 416) = 1.918$, $p = .148$; partial $\eta^2 = .09$ and perceived cognitive reassurance, $F(2, 416) = .459$, $p = .632$; partial $\eta^2 = .002$, between the three sites. Results indicated a significant difference for data-gathering, $F(2, 416) = 4.738$, $p = .009$; partial $\eta^2 = .022$, and generic-reassurance, $F(2, 416) = 9.336$, $p < .001$; partial $\eta^2 = .043$. The Games and Howell post-hoc tests showed that patients recruited from site 3 perceived DG with 1.66 points higher than patients recruited from site 1 ($p = .007$), 95% CI [-.0196, 3.346]. There was no significant difference between site 2 and site 3 in perceived DG. In addition, patients recruited from site 3 perceived GR with 2.841 points higher than patients recruited from site 1, 95% CI [.950, 4.734] and 1.614 points higher than patients recruited from Site 2, 95% CI [-.273, 3.501], both were significant at $p < .001$ and $p = .029$, respectively. Please see Table 9 below for means and SD.

	Site	Mean	SD	N
Data- Gathering	Site 1	16.31*	5.15	116
	Site 2	17.29	4.46	152
	Site 3	17.97*	3.57	151
	Total	17.26	4.42	419
Relationship-Building	Site 1	16.51	5.20	116
	Site 2	17.55	4.62	152
	Site 3	17.48	4.36	151
	Total	17.23	4.71	419
Generic	Site 1	12.48*	5.16	116

Reassurance	Site 2	13.71*	5.89	152
	Site 3	15.32*	5.04	151
	Total	13.95	5.50	419
Cognitive Reassurance	Site 1	15.83	5.43	116
	Site 2	16.28	5.19	152
	Site 3	16.42	4.98	151
	Total	16.21	5.18	419

Table 8: Reassurance across sites

Consultant profession

In this study, 217 patients who consulted the surgeon, and, 207 patients who consulted an ESP, were recruited. Of those patients who were recommended surgery ($n = 96$), 70 patients were told this message by a surgeon and 26 by an ESP. Considering patients were allocated to their practitioner after triaging, there might be a difference in baseline characteristics between consultants' professions. To investigate this, a Hotellings T^2 test (one-way MANOVA), was conducted.

The homogeneity of variance was violated for disability and the number of previous treatment types, as assessed by the Leven's Test of Equality of Error Variances. Both variables were moderately, positively skewed, hence the square root transformation was applied, which corrected the problem. There was a statistical significant difference in baseline characteristics and consultant profession on the combined DV, $F(6, 407) = 3.844$, $p < .001$; Wilks' $\Lambda = .946$; partial $\eta^2 = .054$. After the Bonferroni-corrected alpha (α) levels for multiple comparison of 6 DV's ($p < .008$) with a simultaneous 95% confidence level, none of the DV's showed to be significantly different between the consultant professions.

Aim 1 – Baseline characteristics predict reassurance

Four hierarchical multiple linear regression were conducted to examine whether baseline characteristics predicted reassurance types. For all four regression models, site (Block 1) was entered first, followed by baseline characteristics (age, gender, education, number of previous treatments, pain, StartBack, disability, anxiety, depression) in Block 2.

The assumption of normality was violated, as assessed by the P-P Plot. Multiple regression models are fairly robust for the violation of the normality assumption (Laerd Statistics, 2015), thus no transformations of the variables were applied. The addition of sites (Block 1) to the prediction of data-gathering lead to a significant increase in R^2 of .015, $F(1, 380) = 5.695$, $p = .018$. The addition of baseline characteristics (Block 2) to the prediction of DG, lead to a significant increase in R^2 of .062, $F(9, 371) = 2.767$, $p = .004$. The full model of site and all baseline characteristic (Block 2) was statistically significant, accounting for 7.7% of the variance in DG, $F(10, 371) = 3.084$, $p = .001$, adjusted $R^2 = .052$. None of the individual predictor variables significantly predicted perceived data-gathering.

For RB, the assumption of normality was violated, as assessed by the P-P Plot. As in previous analysis no transformation was performed. Block 1 did not lead to a significantly change in R^2 , whereas, adding Block 2 lead to a significant increase in R^2 of .107, $F(9, 373) = 4.979$ ($p < .001$). The overall model significantly predicted RB, $F(10, 773) = 4.522$, $p < .001$. The only significant predictor variable was age ($p = .016$). The older patients were the more RB they perceived.

For GR, Block 1, $F(1, 374) = 12.544$, and Block 2, $F(9, 365) = 3.588$, both significantly ($p < .001$) predicted changes in GR. The overall model (Block 2) accounted for 8.7% of variance in GR, $F(10, 365) = 4.562$, $p < .001$, adjusted $R^2 = .087$. People who tried less previous treatments types, perceived more GR.

For CR, Block 1 did not significantly add to the prediction of CR. The addition of baseline characteristics (Block 2) lead to an increase in R^2 of .078, $F(9, 357) = 3.361$ ($p = .001$). The full model (Block 2) accounted for 8.1% of the variance in CR, $F(10, 357) = 3.128$ ($p = .001$). The more educated ($p = .021$) patients were, the more they perceived CR. Please refer to Table 10, for the Beta values and the corresponding confidence intervals.

Variable	DG	RB	GR	CR
	B [95% CI]			
Constant	18.360** [16.275, 20.445]	17.159** [14.928, 19.391]	19.747** [17.136, 22.357]	16.948 [14.639, 19.257]

Sites	-.760 [-1.659, .139]	.138 [-.827, 1.102]	-1.109 [-2.245, .027]	.013 [-.993, 1.020]
Age	.012 [-.014, .038]	.034* [.006, .062]	-.029 [-.062, .004]	.018 [-.012, .047]
Gender	-.360 [-1.235, .515]	.074 [-.864, 1.012]	.945 [-.157, 2.047]	-.084 [1.058, .890]
Education	.393 [-.480, 1.265]	.346 [-.591, 1.282]	.087 [-1.013, 2.047]	1.146* [.171, 2.120]
Pre. treatments	-.014 [-.288, .261]	.073 [-.222, .368]	-.504** [-.850, -.158]	.003 [-.307, .313]
Pain	.030 [-.179, .239]	.052 [-.172, .276]	-.062 [-.324, .200]	.004 [-.227, .236]
StartBack	.214 [-.253, .680]	-.230 [-.728, .269]	-.320 [-.908, .267]	-.050 [-.568, .467]
RMD	.037 [-.061, .135]	-.034 [-.139, .071]	-.054 [-.178, .069]	.008 [-.101, .117]
Anxiety	-.137 [-.274, .001]	-.117 [-.265, .031]	-.116 [-.291, .059]	-.121 [-.274, .032]
Depression	-.171 [-.343, .000]	-.126 [-.311, .059]	-.033 [-.250, .183]	-.142 [-.335, .052]

Table 9: Hierarchical multiple regression examining the relationship between reassurance and baseline characterises.

Notes: n= 382; B= unstandardized regression coefficient; 95% CI= confidence interval.

**** p < .01, * p < .05.**

Aim 2 - Predicting treatment outcome

A hierarchical binomial logistic regression was performed to ascertain the effects of age, gender, education, number of previous treatment types, StartBack, Anxiety, Depression, Disability (Block 2), after controlling for the potential confounding variables site and consultant profession (Block 1), on the likelihood of being discharged without further treatment versus being referred to other treatment. For the outcome a dummy variable was created, coding treatment as 0 and discharged as 1.

The Hosmer and Lemeshow Test was not significant ($p=.184$), which meant the model is a good fit. Block 1 of the logistic regression model was statistically significant, $\chi^2(2) = 9.146$, $p = .010$. The addition of baseline characteristics (Block 2) added significantly to the predictability of the model, $\chi^2(9) = 52.115$, $p < .001$. The full logistic regression model was significant, $\chi^2(11) = 61.261$, $p < .001$. The model explained 25.4% (Nagelkerke R^2) of the variance in being discharged. The model correctly classified 72.9% of the cases overall. Sensitivity (discharged cases correctly classified) was 54.7% and the specificity (treatment cases correctly classified) was 84.8%. The positive predictive value (% of correctly predicted cases who were discharged compared to the total number of cases predicted to be discharged, $100 \times (64 \div (27 + 64))$) was 70.3%. The negative predictive value (% of correctly predicted cases who received treatment to the total number of cases predicted to receive treatment, $100 \times (151 \div (151 + 53))$) was 74.0%. As an overall measure of discrimination (the ability of the model to discriminate between those patients who received and who did not receive treatment), the visual representation in form of a plot called the Receiver Operating Characteristic (ROC) curve, was conducted. This is a plot of sensitivity versus 1 minus specificity (Hilbe, 2009, as seen in Laers Statistic, 2015). The area under the ROC curve was .755, 95% CI [.698, .812], which is an excellent level of discrimination ($0.8 \leq \text{AUC} < 0.9$) according to Hosmer et al. (2013) (Laerds Statistic, 2015).

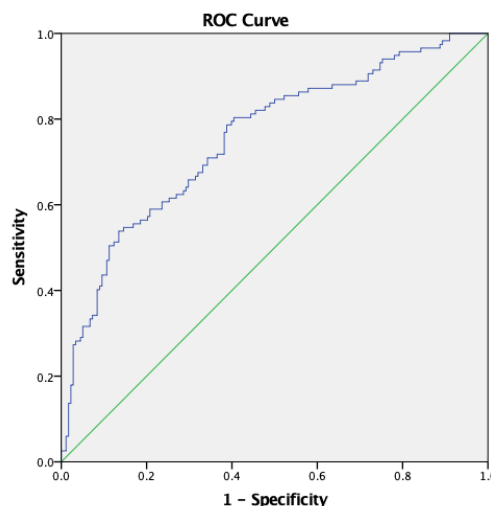


Figure 4: ROC curve

Of the 11 predictor variables only three were statistically significant: Consultant profession ($p = .004$), pain ($p < .001$), and anxiety ($p = .049$). Surgeons were more

likely to discharge patients than ESP's. Patients with less pain but higher levels of anxiety were more likely to be discharged than offered treatment. Please see Table 11 below for Beta, standard error, Wald, and 95% confidence intervals for odds ratio.

Variables	<i>B</i>	<i>SE_B</i>	<i>Wald</i>	<i>95% CI</i>
Sites	.518	.280	3.427	[.970, 2.908]
Consultant profession	.812**	.285	8.155	[1.290, 3.936]
Age	.009	.008	1.093	[.992, 1.026]
Gender	.104	.283	.134	[.637, 1.933]
Education	-.316	.293	1.165	[.411, 1.294]
No treatments	.130	.091	2.026	[.952, 1.361]
Pain	-.311**	.066	21.975	[.643, .834]
StartBack	-.247	.154	2.569	[.577, 1.057]
RMD	-.022	.030	.530	[.922, 1.038]
Anxiety	.092*	.047	3.878	[1.000, 1.201]
Depression	-.034	.056	.368	[.867, 1.078]
Constant	.226	.690	.107	

Table 10: Hierarchical binominal regression model predicting patients who were discharged.

Notes: n = 295; B= unstandardized regression coefficient; 95% CI= confidence interval.

** p < .01, * p < .05

Aim 3 - Reassurance differences between consultants

Four independent sample t-tests were used to examine the differences in reassurance type between the consultant professions. There was a no significant difference in data-gathering between surgeons and ESP's, $t(418) = 1.093$, $p = .275$. There was a significant difference in perceived relationship-building between the consultant professions, $t(419) = 2.056$, $p = .040$, with ESP's scoring .949 higher than surgeons, 95% CI [1.85, .044]. There was a significant difference between in generic-reassurance between surgeons and ESP's, $t(418) = 2.644$, $p = .009$, with ESP's scoring 1.41 higher than surgeons, 95% CI [2.46, .36]. The assumption of homogeneity of variances was violated for cognitive reassurance, as assessed by the Levene's test ($p = .005$). Thus, the variance not assumed row was reported. There was a significant difference in cognitive-reassurance between surgeons and ESP's, $t(414.129) = 2.006$, $p = .046$, with ESP's scoring 1.01 higher than surgeons, 95% CI

[1.99, .02]. The mean and SD of all types of reassurance between consultant profession are shown in Table 12.

	Consultant profession	Mean	SD	N
Data- Gathering	Surgeons	17.00	4.58	214
	ESP	17.48	4.32	206
Relationship-Building	Surgeons	16.7209	5.01	215
	ESP	17.6699	4.43	206
Generic Reassurance	Surgeons	13.2617	5.60	214
	ESP	14.6699	5.31	206
Cognitive Reassurance	Surgeons	15.7116	5.50	215
	ESP	16.7171	4.76	205

Table 11: Mean and SD for reassurance between consultant professions.

Discussion

The analyses of the associations between perceived reassurance and baseline factors revealed several significant relationships, such as differences between recruitment sites and professional groups.

Demographics and Sites

The findings indicate that there were significant differences in patients' baseline characteristics and perceived levels of reassurance between the hospitals. The differences were mainly observed between site 3 and the other two sites. Patients recruited from site 3 reported having tried fewer number of different treatment types, lower disability, depression, and anxiety levels. Yet, whether the health care journey in terms of experimenting with less types of futile treatments may have alone influenced improved disability and mood scores, remains unknown. Nonetheless, there may be numerous reasons to account for the observed differences in baseline characteristics, some concern the process of care and some concern the patient themselves. Site 1 and 2 operated in a traditional surgical setting, which entails ESP/APP's operating as an extension to surgeons. In site 3, instead of having ESP/APP's, the team of surgeons was extended through a team specialized in musculoskeletal spine pain (MSK). Thus, instead of obtaining further surgical knowledge the MSK team may be characterized with a more comprehensive

knowledge about MSK pain. There were no major differences in educational background of professional discipline (e.g. specialized physiotherapists, GP) between those employed as part of the ESP/APP's team or those employed as part of the MSK team. The MSK and ESP teams, both, reported directly to the surgeons and often run their clinics simultaneous to those of the surgeons. This way, it provided the opportunity for ESP/APP/MSK practitioners to consult with surgeons for advice when having uncertainties about diagnosis or treatment. Unlike the MSK team, who had their own unit within the hospitals, the ESP's run clinics within the same outpatient's department. Therefore, patients who were recruited from a site employing ESP's, often expected to see a surgeon because the majority of the times their referral letters did not specify when they were scheduled to see an ESP. Whereas patients recruited from the MSK team, received a referral letter that did not include the terms surgeon or surgery, instead prepared them to see a practitioner from the MSK team. Thus, patients recruited in site 3 expected surgery or to consult with a surgeon significantly less than those recruited in the other two sites. Considering site 3 is known for not advocating surgery instead pledge for treating patients with conservative means, referring GP's may have handled patients' expectations at an early stage by explaining to them that surgery will only be indicated when absolutely necessary. Whether patients' expectation about surgery are the main reason for their better reported health status remains unclear. Another possibility is that patients recruited from site 3 were recruited from a county in the UK with is considered as wealthy with much better economic prospects than the counties home to site 1 and 2. A review of socioeconomic status in the experience of chronic pain stated: *'those at the lower end of the spectrum are more likely to develop chronic pain, be more disabled by it and experience more serious impact on their lives'* (Bonathan, De, Williams, & Hearn, 2013, p.159). Patients may have reported better health statuses because of their socioeconomic backgrounds, suggesting the 180 patients recruited from site 3 may not be representable to the rest of the UK's chronic LBP population. Although income was not measured in this study, there were no significant differences in education status and work status between the sites, suggesting socioeconomic status is not likely to be the reason. Moreover, it may then also be argued that the whole study's population, since recruited from the south east, may not be representable for the rest of the UK which is considerably poorer.

Demographics and consultant profession

We did expect patients to be different on their baseline characteristic depending on the type of practitioner they consulted, because theoretically prior screening would have allocated patients with more pain and disability who appear eligible for surgery to consult with a surgeon, rather than an ESP. However, none of the individual characteristics were significantly different between the practitioners' profession, suggesting allocation may have been at random. Prior screening and allocation procedures may have varied for each clinic, which may have led to not detecting differences in the overall analysis. For example, site 3 used a pre-appointment MRI screening method, whereas site 1 did not. Thus, patients were allocated at random to see a surgeon in site 1, but allocated to see surgeon depending on imaging test results in site 3. Further analyses should examine allocation processes within the individual sites whilst excluding patients who received surgery.

Reassurance and sites

Patients recruited in Site 3 perceiving more DG and GR than those recruited from Site 1 and 2. It is surprising that the study shows differences in perceived DG, since this part of the consultation represents an aspect of reassurance which all clinicians were trained for. This difference might also be due to time restrictions, seeing as clinicians in Site 1 had on average less time scheduled for their consultation than practitioners in Site 2 and 3, and observed differences for DG were only between Site 1 and 3. Differences in health status at baseline may have also influenced how patients perceived practitioners' communication. Evidence from primary care showed interaction affects between patients' risk-profile and perceived levels of reassurance (Holt et al., 2018). An exploratory study with 701 patients with chronic LBP who were surveyed before they started rehabilitation in Germany, found that patients with psychological risk factors, such as fear-avoidance beliefs, had generally higher expectations of physicians communication (Farin, Schmidt, & Gramm, 2013). Patients with improved health status and mood may have perceived higher levels of reassurance but practitioners did not actually differ in their expression of DR and GR between sites. This discussion over whether patients perceived more reassurance or clinicians provided more reassurance needs to be considered throughout this thesis. Without a voice or video recording of the actual contents of the consultations, we can only speculate on what actually took place and hence have to base our knowledge on

how patients perceived them. Nonetheless, their perceptions may have been coloured by their levels of pain, disability and expectations. On the other hand, consultants may have either disregarded underlying psychological mechanisms or failed to address patients' psychological needs.

Reassurance and demographics

Perceived reassurance in this study was associated with demographic factors, specifically, age, number of previous types of treatments and education. The quality of care provided, in terms of reassurance, may be influenced by patient's perception of the clinician as a person, likewise, the clinicians' communication skills may depend on their liking of patients. Both the clinician's perception of their patients and the patient's perception of their practitioner affects the quality of communication and relationship (Beach, Roter, Wang, Duggan, & Cooper, 2006; Street, Gordon, & Haidet, 2007). The perception of each-other appears to be influenced by the initial, inevitable, natural and/or potentially unconscious observation about demographics. Research showed that clinicians may provide more information, empathy, and positive affect toward patients that they perceived as more favourably (Beach et al., 2006; Street et al., 2007). Previous literature indicated certain patient characteristics can be barriers to effective communication, such as for example, patients' gender (Bertakis, 2009), ethnicity (Street et al., 2007), and/or socioeconomic background (Willems, De Maesschalck, Deveugele, Derese, & De Maeseneer, 2005), which are associated with the quality of communication in consultations and outcomes.

In line with the study from primary care (Holt et al., 2018), older patients were more likely to perceived higher levels of RB. A study examining demographics factors that influence patients' satisfaction ratings of physicians, found older patients tend to rate physicians higher (Duberstein, Meldrum, Fiscella, Shields, & Epstein, 2007), which may explain why older patients reported they perceived more RB. However, there is also contradictory evidence: a qualitative study conducted in Denmark, videotaped 79 clinical encounters informing chronic LBP patients about their MRI results (Gulbrandsen et al., 2010). Findings indicated that the consultation communication quality, measured by the Four Habits Coding Scheme (4HCS) which entails elements of RB (habit II- eliciting patients' perspective) was poorer with patients who had suffered longer with LBP and those who were older. In addition, research suggested

that elderly people tend to be more vulnerable to poor communication with health care providers, since they tend to have more difficulties understanding speech, which may be due to environments with ambient noises and/or a result of having difficulties understanding clinicians who use rapid speech mixed within a jargon of medical terms (Cohen et al., 2017). The findings from our recent qualitative study with chronic LBP patients (Braeuninger-Weimer et al., 2019), indicated that patients indeed struggled to understand consultants use of language in terms of unknown medical terminology. This would suggest that older patients in combination with the language practitioners use would struggle to understand contents, which in turn should negatively affect how patients perceive clinicians and reassurance overall. Farin et al. (2013) examined predictors of communication preferences in patients with chronic LBP and found older patients had a lower preference for patient-centred and open communication instead appreciated communication about personal circumstances (Farin et al., 2013). Surgeon and their team may have also been more empathic to elderly patients, since research suggests relationship-building require a certain expression of empathy ('To put someone at ease requires to feel that someone is not at ease') (Epstein, Alper, & Quill, 2004).

Patients who tried more types of treatment in their past, perceived lower levels of GR. This might be due to the fact that most of these patients have had a long history of consultations with several different types of practitioners involving different treatment, which in most cases did not solve their problem. The likelihood is high that they were told numerous times by different practitioners that 'there is no serious concern about their back, stop worrying, it will be fine'. Over time, their pain and disability worsened and they stopped believing in positive generic statements, thus may have perceived less GR once they have heard it enough times to eventually consider it as a hopeless promise. This is in line with the findings from our qualitative study, which indicated that patients were not in favour of the GR items on the questionnaire because they felt those were not always realistic or applicable (e.g. 'how can the doctor tell me that it will be fine or I shouldn't worry?- It hasn't been fine, it won't be fine, and I know this hence I worry') (Braeuninger-Weimer et al., 2019). Stating that there is 'no serious concern' undermines the legitimacy of their complaint, which according to Salaman (2006) may lead to patients asserting their complaints more vigorously.

Patients who were more educated, perceived more CR. Considering previous suggestions that surgeons and their teams bombard patients with a jargon of medical terminology (Braeuninger-Weimer et al., 2019), it is not surprising that patients with higher levels of education are more able to understand consultation contents and thus perceive more CR. A systematic review investigated social differences, measured by income, education, and occupation, in the doctor-patient communication, assessed in the form of explicit reassurance, including instrumental and affective behaviours, and implicit reassurance, including non-verbal patient-centred behaviours (Verlinde, De Laender, De Maesschalck, Deveugele, & Willems, 2012). They found that patients of higher social class (more educated) received less physical examination, more overall communication, more information and explanation, more emotional support, and a more directive and participatory consulting style characterised by shared-decision making for example in treatment decisions. In turn, patients educational level influences how they communicate with their clinicians, in terms of question-asking, affective expressiveness, assertiveness, and opinion-giving. An important factor emphasised by the review concerned the importance of reciprocity within the doctor-patient communication (Verlinde et al., 2012). The review suggests that patients who need instruction most (low education, low health literacy) receive the least. A question that remains is whether practitioners provide less information to people with less education, or do patients with higher education recall and maintain education better? According to Clack, Allen, Cooper, and Head (2004) effective communication not only requires the occurrence of ‘meeting of the mind’ between both parties but also at least one but preferably both need to be open for adjustment to the communication style. Ideally, practitioners are trained in communication skills, so that they can individualize their reassurance style and remain flexible in meeting patients communication needs, seeing as patients have different preferences for communication (Farin et al., 2013). Thus, surgeons and their teams may benefit from determining the appropriate format for conveying CR, optimizing patients’ chances to understanding the information provided leading to behavioural change and improved outcomes. Future research should address whether it is the former, an unconscious bias that might be influencing practitioners to give less education to those least able to find information elsewhere, or the latter, practitioners need to learn to change the way they provide education to match health literacy.

Predicting who gets discharged

The recommendations of treatment outcomes should not be indicated by patients' characteristics but instead by clinical decision and patient's involvement in the form of share-decision making. However, it was found that health care setting, practitioner type, patients' characteristics and history explained around 25% of the variance in the practitioner's decision to discharge. Patients who consulted with surgeons were more likely to be discharged than those who consulted an ESP. This may be because of the limited time frame, requiring a quick decision, or because once surgery is ruled out, surgeons may feel that their job is done and that they are no longer responsible for other treatment options. Another significant predictor of being discharged was pain, whereby patients with less pain were more likely to be discharged. Patients in this study may have been discharged because their symptoms were resolved, or the polar opposite, because all treatments avenues have been exhausted. Patients from both ends of the spectrum were included in the 'discharged' sample, as evidenced by the large SD on pain ratings. Although there is evidence to suggest patients with low levels of pain are being discharged, there is still a small but important sub-group of patients ($n = 36$, 27%) who were discharged with high levels of pain, equal to or above 7, who also perceived reassurance as lower and no doubts about worst outcomes. Patients with high level of anxiety were also more likely to be discharged. This is an interesting finding, since it may have been that practitioners discharged those patients because they were faced with high levels of anxiety and counterintuitively responded through the 'it's all in their head' hypothesis by discharging them. Those patients might represent the group of patients that was investigated in our qualitative study (Braeuninger-Weimer et al., 2019).

Reassurance and different professions

There was no difference in DG between surgeons and ESP's because most likely they were all equally trained in data- gathering. Patients consulting with an ESP perceived more reassurance (RB, GR, CR) than those who consulted a surgeon. This may be due to differences in duration of the consultations. Although the length of the consultation was not measured in this study, according to the clinic list, patients were scheduled for 10- 15 minutes when consulting a surgeon and for 20- 30 minutes when consulting an ESP/MSK, depending on the site. On the other hand, perceived differences were especially large for GR and CR, which suggest that perhaps ESP's

are better in pain validation and better in providing explanations in lay-man terms compared to surgeons. This is in line with our previous qualitative study (Braeuninger-Weimer et al., 2019). People living with chronic, complex LBP need to consult a skilled practitioner who not only knows how to take history including eliciting patients' concerns (DG), but more importantly, knows how to demonstrate empathy, provide explanation and information, and engages in motivational conversations in order to increase patients' coping and self-management (Gulbrandsen et al., 2010), which are all qualities required for RB, GR, and CR. Except for GR the statistical significance differences were not large but still significant. However, it could be argued that they do not translate into clinical significance, which would be contradictory to our findings of the previously outlined qualitative study. In terms of face validity, it would be strange if there were no observed differences in perceived reassurance and information provision from consultations that are 30 to 45 minutes (ESP's) compared to 10 to 15 minutes (surgeon). It is difficult to know whether these differences, albeit significant, have a clinical difference. There are no studies providing indications of clinically meaningful change/difference in measures of reassurance.

Strengths and Limitations

The strengths of this study included; data collection on a diverse range of socioeconomic catchment populations recruited from 8 different hospitals with a large geographical spread; a low follow-up attrition rate; testing patients at 3 time points making comparisons to before and after consultation-based reassurance possible and being able to evaluate its impact on outcomes.

There were also a number of study limitations such as the variability in the time of post-consultation measure collection, whereby some patients provided their answers on the same day of their consultation and others up to 7 days later. There may have also been problems with the consultation-based reassurance measure, whereby patients struggled to accept the GR items as found in our previous qualitative study. One way is to either videotape the consultations and have independent raters analysing the consultations, or, another way is to have an additional observer present in the consultation, whereby patients, consultant and observer fill out the

consultation-based reassurance questionnaire straight after the consultation and comparing the results between the three different perspectives.

Conclusion

In conclusion, this Chapter illustrates four important things: 1. Different institutions and pathways operate differently and this impacts on the patients' journey, 2. Certain patients' baseline demographics are associated with some reassurance types, and 3. Characteristics and setting factors are predictive of who gets discharged, and 4. practitioners may benefit from training that helps them to recognise patients with special needs (e.g. higher levels of anxiety, older, more previous consultation, education) and how to adopt their reassurance style accordingly. In relation to the patients' journey, there is a need to create a consistent pathway across the UK. Considering that the observed differences in baseline characteristics were mainly between site 3 and the other two sites, it appears that pre-appointment imaging, and incorporated MSK services might not only ease patients' journey but might also positively impact their physical and mental health. Ideally, patients would have access to a local MSK triaging centres, that would provide them with skilled MSK clinicians who can explain to patients why imaging and referral to surgeons are not required. In the current system, most people get directly referred to the orthopaedic department by their GPs. In sites that did not use pre-consultation screening, patients are required to have one additional step in their care journey, which is: getting excited to see the specialist and to finally get some answers, being told that they have to get a scan and come back, to a long waiting time for imaging and results, going back to seeing a different specialist who repeats the same procedure as the previous one but this time with the imaging results present, yet the outcome is often the same, being discharged. This extra step of the journey that patients have to go through might take them up to a year of waiting as well as that it involves 2 specialist appointments which contributes to the overall overburden on the health care system. It could be argued that just this extra time spent on the journey, that most patients in Site 1 and some in Site 2 had to go through, shaped their expectations, and may have negatively impacted on the communication in this consultation. It is also important to reflect on our findings that those who showed elevated anxiety were more likely to being discharged. Therefore, training clinicians in recognising patients who are more

anxious as well as recognising those with certain patient characteristics that we found to influence the communication (e.g. age, education, and number of previous treatments) might be beneficial when trying to individualise and optimise care for this group of patients. Future research is required to understand how patients could best benefit from changes in their health care journey as well as having trained clinicians who are skilled in empathic and clear communications

CHAPTER 6: PROSPECTIVE COHORT (POST-CONSULTATION & FOLLOW-UP DATA)

Introduction

In the previous Chapter we looked at the associations between baseline factors, recruitment sites, consultant profession and perceived reassurance. The results revealed differences between recruitment sites in patient's baseline factors and perceived reassurance. Certain patients' demographics are associated with certain aspects of reassurance, baseline and setting factors are predictive of who gets discharged. Further professional groups are associated with different levels of perceived reassurance. In the following Chapter our focus is on the associations between reassurance and post-consultation and 3-months follow-up outcome variables. To take into account the observed differences in baseline characteristics between the sites and the differences in perceived reassurance between the consultant professions, those variables were always entered as covariates into the first stages of the outcome regression models in this Chapter. The following introduction is aimed as a short recap on what we know about the associations of perceived reassurance and patients' outcomes.

The over-riding hypothesis is that consultation- related factors associated with doctor- patient interactions will directly impact short- term outcomes, such as changes in patients' beliefs, which in turn will affect behavioral change resulting in changes of long- term outcomes. Effective reassurance in secondary care should result in better compliance with treatment modalities, motivation to self-manage, and a mutual understanding that surgical procedures are unnecessary for patients with LBP. A reliable measure of consultation-based reassurance for people with LBP was validated in primary care settings and enables testing reassurance against patients' outcomes (Holt & Pincus, 2016). Using qualitative interviews (Chapter 4) the reassurance measure was adopted to represent consultation-based reassurance in orthopedic surgical settings. It was further found that in order for patients to feel reassured coming away from their specialist consultation, they require practitioners

to display certain behaviors, which were grouped into four categories; ‘Knowing my whole story’, ‘Seeing the right person’, ‘Nothing to worry about’, ‘Getting to grips with my problem’ (Braeuninger-Weimer et al., 2019). The behavioral groups closely matched onto the consultation-based reassurance model (Chapter 2), which proposes the early stages of the consultation typically involves implicit reassurance (data-gathering & relationship-building) and the later stages of the consultation typically involves explicit reassurance (generic & cognitive reassurance) (Pincus, Holt, et al., 2013). All aspects of reassurance are strongly linked to short-term outcomes, such as satisfaction and enablement and certain reassurance aspects are also associated with long-term outcomes, such as depression (Holt et al., 2018). The model implies the strongest impact on long-term outcomes is linked to patient (expectation, depression, anxiety) and problem (disability, pain, risk-profile) characteristics, although practitioner characteristics will also impact on the interactions with patients, which was supported by findings in the previous Chapter that showed practitioners’ profession affects all aspects of perceived reassurance, except DR.

Coia and Morley (1998) argued that beneficial reassurance effects will dissolve in the absence of the reassuring practitioner, unless reassurance is successful in changing patients’ illness cognition which equips and empowers patients with a new tool that can be used to deal with the impact of LBP, once the problem returns later on in real life. Linton et al. (2008) supports this claim with evidence that showed patients experience a reduction in anxiety during the consultation followed by a subsequent rise in anxiety later on, suggesting reassurance may only be beneficial for patients with low levels of anxiety. This might not be the case for all patients, whereby specific sub-groups of patients may require practitioners to apply different approaches to reassurance to optimize outcomes. For example, some patients who perceive high levels of CR might improve regardless of the absence of affective reassurance. The results from the primary care study showed patients’ psychological risk profiles (StartBack tool measuring fear, catastrophizing, anxiety, low mood) predicts all outcomes at 3-months follow-up and several significant interactions with reassurance, such as high-risk patients who perceived high levels of GR or high levels of CR were more depressed and reported more pain, at 3-months follow-up, respectively (Holt et al., 2018). This suggests consultation-based reassurance requires to be tailored to patients’ special needs, however, there may be several

reasons to believe that patients with persisting, long-term LBP consulting orthopedic surgical teams have different needs to those consulting in primary care settings (Braeuninger-Weimer et al., 2019; Gulbrandsen et al., 2010). Moreover, evidence suggests that orthopedic surgeons are particularly poor communicators for a number of reasons, such as a tendency to focus mainly on technical aspects of care-giving, lacking listening skills, using closed questions, inconsistencies in the terminology they used and the use of medical jargons, and, expressing infrequent signs of empathy or a caring nature towards patients (Frymoyer & Frymoyer, 2002; Herndon & Pollick, 2002; Kampa, Pang, & Gleeson, 2006; Levinson & Chaumeton, 1999; Kyle & Shaw, 2014; Tongue & Forese, 2005). Nonetheless, it has been argued that the communication between orthopedic surgeons and their patients are particularly important, requiring sophisticated communication skills, such as the effective exchange of information, responding to patients' emotions, and engaging in informed and collaborative decision-making (Braddock et al., 2008; Levinson, Hudak, & Tricco, 2013). Levinson and Chaumeton (1999) argued it should not be assumed that communication skills that are effective for primary care practitioners are appropriate for surgeons and their teams. Unlike primary care consultations, practitioners in secondary care are likely to use imaging results to explain to patients why surgery is not indicated. Although there is contradictory evidence on the use of imaging tests to reassure patients (Ash et al., 2008; Kendrick et al., 2001), we expect differences to primary care findings in how CR is delivered and perceived.

The StartBack tool was originally developed to allow primary care practitioners to sub-group patients with LBP to low-, medium-, and high- risk of poor prognosis and stratify patients to the appropriate care pathway (Kendell et al., 2018). The study in primary care (Holt et al., 2018) measured patients risk profile by selecting 4-items of the StartBack tool, instead of its 9-items, and sub-grouping patients accordingly into high- or low- risk. This may be criticized because the study did not use the complete measure to stratify. A recent prospective cohort study (n = 290) examining the predictive ability of the StartBack tool with chronic LBP patients, concluded that the tool had poor predictive and absent discrimination ability for outcomes of pain and global perceived change (self-measure of improved vs. not improved), respectively, but had moderate predictive and acceptable discrimination ability for disability, at 1-year follow-up. The authors argued that the tool may not be adequate to capture

prognostic risk in patients with long-term, complex and multifaceted LBP presentations and hence may be limited in its ability to stratify care in this population (Kendell et al., 2018). Therefore, assessing patients risk profiles to determine how to match reassurance style might also not be appropriate in patients with chronic LBP. Unlike the study in primary care, we did not examine the interactions between reassurance and risk-profile by dividing the tool into its stratification categories (e.g. low-, medium-, high-risk), instead, we used the total score, measured through 4-items, as predictor variable in the regression models.

Aims

- 1.) To explore the association between reassurance, satisfaction and enablement at post consultation.
- 2.) To explore the relationship between reassurance and acceptance of explanation, thinking there is still something serious going on (catastrophizing), and the intention to further consult.
- 3.) To determine the impact of consultation-based reassurance on 3- month outcomes (Pain, Disability, Anxiety, Depression, GP visits, Sick days) in patients for whom surgery was not recommended.

Methodology

Design and Recruitment

Please refer to the Chapter 6 for recruitment processes and Participant Flow Charts.

Measures

In the following analyses, the measures from post-consultation and follow-up, were used (please see Methodology Chapter 3 for details on the measures used).

Baseline	Post-consultation	3-month follow-up
Age	Received diagnosis, (Yes/No)	Pain intensity (Jensen et al., 1986)
Gender	Acceptance of Explanation	Disability, RMDQ (Roland & Morris, 1983)
Marital Status	(Serbic et al., 2013)	Depression & Anxiety, HADS (Zigmond & Snaith, 1983)
Education	Intention to re-consult	Further health care utilization (GP visits, number of different professionals seen, re-consulted)
Work Status	Reassurance, ECRQ (Holt & Pincus, 2016)	Sick days
Number of pre-consultations	Satisfaction, CSQ6 (Baker, 1990)	
Number of pre-treatments	Perceived reassurance, 1-item Enablement, PEI (Howie et al., 1998)	
Expectations (9-items)		
StartBack (Hill, 2008)		
Pain intensity (Jensen et al., 1986)		
Disability, RMDQ (Roland & Morris, 1983)		
Depression & Anxiety, HADS (Zigmond & Snaith, 1983)		

Table 12: Questionnaire measures used at the three stages of recruitment

Analyses

All statistical analyses utilised SPSS Version 23 (IBM Corp, 2015). As seen in the previous chapter Spearman's and Pearson's correlations were used to measure correlation coefficients between short-term and long-term outcome and the four reassurance types. A one-way MANOVA was conducted to assess the differences in perceived reassurance and the three treatment outcomes (surgery, discharged, other treatments). Please see previous chapter for tests used for preliminary assumption checking. One-way ANOVA's were conducted to examine the difference in satisfaction and enablement between the three treatment outcomes and consultant profession. The following tests were used for preliminary assumption checking: (1) inspection of a boxplot for outliers, (2) inspection of histograms to check if dependent variables were approximately normally distributed, and (3) the Leven's test of equality of variances to check for homogeneity of variances.

When the outcome of the regression was dichotomous (indicated below next to the outcome variables), a binary regression was used to analyse the data. The stages of entering variables remained the same as shown below. Please see the analyses section of the previous chapter for the methodology used for preliminary assumption checking before conducting binominal regression models. Prior to conducting binominal regressions, Chi-square test of homogeneity or also known as test of two proportions, was conducted to determine whether there was a difference in the dichotomous variables (e.g. acceptance of explanation, catastrophizing) between the treatment outcome groups or the consultant professions. Preliminary assumption checking only involved making sure that there was sufficient sample size, which was the case.

All other regression analyses were sequential multiple linear regressions. Hierarchical multiple regressions were chosen to facilitate the controlling for known covariates, before entering the variables of interest, reassurance types, in the last stages of the regression. Such covariates were the differences between sites and consultant profession. As shown in the previous chapter, there was a significant difference in baseline characteristics between sites, hence this variable was always entered in the first stage of all the regression models in order to control for the observed differences. In addition, for each short-term and long-term outcome variable, a one-way ANOVA or a Chi-square test (as applicable), was conducted prior to the regression analyses, to examine whether there were differences in the mean scores or proportions of that variable (e.g. pain, catastrophizing) between consultant profession and treatment outcomes. When the analysis showed significant results, the variables ‘consultant profession’ and/or ‘treatment outcome’ were added as control variables in addition to site, in the first stages of the regression models. Therefore, the first stage of the regression model varied across the different analyses, whereas stage 2 and 3 remained the same throughout.

Overall, predicting variables were entered in 3 stages:

- Block 1: Site (accounting for the difference in baseline characteristics between RSH vs. WPH+FPH), consultant profession (differences between

ESP vs. surgeon), and treatment outcome (differences between surgery, discharged, and treatment group)

- Block 2: Baseline demographic variables (age, gender, education, number of different previous treatments, StartBack, pain, disability, anxiety, depression)
- Block 3: Reassurance variables (DG, RB, GR, CR)

The short-term outcome variables:

- Satisfaction
- Enablement
- Acceptance of explanation (binary regression)
- Catastrophic belief (binary regression)
- Intention to re-consult (binary regression) – this was investigated for the discharge group only since patients who were referred for further treatment would naturally re-consult to receive their treatment

Please note that for satisfaction as outcome variable, treatment outcome was dummy coded accounting for the 3 categories of the nominal variable, whereas, for the long-term outcome the variable only controlled for the differences between 2 categories.

The long-term outcome variables:

- Pain
- Disability
- Depression
- Anxiety
- Health care utilisation: GPs (number of consultations)
- Sick days (this was a sub- group analysis whereby investigating only those patients who stated at baseline that they were employed)

For all regression analyses the following tests were used for preliminary assumption checking: (1) assessment of the Durbin-Watson statistic for an approximate value of 2 to check for independence of residuals, (2) visual inspection of scatterplot of unstandardized predicted values against studentized residuals for linearity between IV's and DV's collectively and inspection of partial regression plots to check for linearity between each IV and DV, (3) assessing homoscedasticity of residuals by

inspecting scatterplots of studentized residual against unstandardized predicted value or plotting standardised residuals against standardised residuals, (4) assessment of correlation coefficients (< 0.9), Tolerance (> 0.2), and VIF (< 10) values to check for multicollinearity, (5) assessing studentized deleted residuals (± 2 SD), leverage values (< 0.2), and influential points (Cook's distance < 1) to determine outliers, (6) inspection of P-P Plots to check if residuals were normally distributed.

It is not uncommon that one or more assumptions are violated. For every analysis outlined in the findings section below, violated assumptions and corrections were reported. Corrections included situations where ± 3 SD standardized outliers had to be removed or variables had to be transformed because they were not normally distributed.

Results

As outlined in the previous Chapter, patients who were sent to further investigations or those lost at post-consultation were excluded from the analyses, retrospectively. Data from a total of 424 patients were left for analyses at post-consultation, of whom 133 were discharged without further treatment, 195 patients were offered some form of other treatments, and 96 were recommended to undergo surgery. Of those patients for whom surgery was recommended, 59 (61.5%) patients decided to undergo surgery, 27 (28.1%) patients decided against surgery and 10 (10.4%) patients said they were unsure about their decision to undergo surgery at this point in time. Of those patients who received a referral to a future treatment ($n = 173$), 89 (51.4%) patients were recommended to have one or a series of injections, 71 (41%) patients received physiotherapy, and 21 (12.1%) were referred to the pain specialist team, 8 (4.6%) patients were referred to Yoga, Pilates and/or Aquatics. Of those patients who were discharged, 48 (36.1%) said they do not have the intention to re-consult, whereas, 84 (63.2%) said they intended to seek further care elsewhere. Within this group, 82 (61.7%) reported they were not offered the chance for a 6-months open appointment, compared to 51 (38.3%) who stated they received an open-appointment.

There was a single item question asking patients whether they felt they had the chance to voice their treatment preferences or not. In the surgery group, 73 (76%) patients stated they agreed with the statement. In the treatment group, 131 (67.2%) patients stated they agreed with the statement, compared to 60 (30.8%) patients who did not agree. Lastly, in the discharged group, 55 (41.4%) patients agreed, whilst 68 (51.1%) patients felt they did not receive the chance to voice their treatment preferences. Please refer to Table 14 for the descriptive statistics for the post-consultation questionnaires divided by treatment outcome groups.

Variables	Treatment Outcome		
	Surgery (n = 96)	Discharged (n = 133)	Treatment (n = 194)
Received diagnosis or explanation	No = 12 (12.5%) Yes = 84 (87.5%) Missing 0	No = 40 (30.1%) Yes = 93 (69.9%) Missing 0	No = 40 (20.5%) Yes = 154 (79.0%) Missing 1
Total Acceptance of Explanation 2-item N (%)			
1 – received explanation?	Disagree = 6 (6.3) Agree = 87 (90.6) Missing = 3 (3.1)	Disagree = 37 (27.8) Agree = 92 (69.2) Missing = 4 (3.0)	Disagree = 39 (20.0) Agree = 152 (77.9) Missing = 4 (2.1)
1 – agree with explanation	Disagree = 7 (7.3) Agree = 88 (91.7) Missing = 1 (1.0)	Disagree = 29 (21.8) Agree = 99 (74.4) Missing = 5 (3.8)	Disagree = 37 (19.0) Agree = 153 (78.5) Missing = 5 (2.6)
Total Acceptance of explanation M (SD)	1.84 (0.49)	1.46 (0.83)	1.58 (0.80)
4- believe smth else going on? (Catastrophizing)	Disagree = 72 (75.0) Agree = 21 (21.9) Missing = 3 (3.1)	Disagree = 77 (57.9) Agree = 53 (39.8) Missing = 3 (2.3)	Disagree = 111 (56.9) Agree = 76 (39.0) Missing = 8 (4.1)
Reassurance (0-84)			
Data-Gathering	18.81 (2.79)	15.91 (5.27)	17.55 (3.96)
Relationship-building	18.26 (3.72)	16.27 (5.60)	17.63 (4.06)
Generic R.	13.36 (5.46)	14.15 (5.94)	14.33 (5.14)
Cognitive R.	17.96 (2.57)	15.05 (5.96)	16.23 (4.93)

0-21			
Total Satisfaction 0-900	M= 685.26, SD= 159.93 Missing= 1 (1%)	M= 581.49, SD= 230.04 Missing= 2 (1.5%)	M= 628.50, SD= 196.43 Missing= 2 (1%)
Perceived Reassurance N (%) 0-100	78.46 (26.59)	66.67 (35.02)	66.67 (28.02)
Total Enablement 0-12	M= 2.32, SD= 2.89 Missing= 1 (1%)	M= 1.88, SD= 2.98 Missing= 2 (1.5%)	M= 2.22, SD= 3.26 Missing= 2 (1%)

Table 13: Post-consultation sample characteristics

Patients for whom surgery was indicated as treatment option were not followed-up at 3-months, leaving 328 patients to be followed-up. At 3-months data collection, 32 (9.8%) were lost, compared to 296 patients who provided follow-up information. The response rate at 3-month follow-up was 90.2%. Consistent with the data lost at post-consultation measure collection, patients lost at 3-months follow-up were likewise excluded from the analyses instead of computing the overall mean or similar computations for missing values. In the discharged group, 10 patients were lost to follow-up, resulting in 123 patients provided the complete data set. Of those patients who were referred to other treatments, 22 patients were lost to follow-up and of the remaining 173 patients, 121 (69.9%) patients stated they received their treatment referral, whereas, 52 (30.1%) patients did not receive their treatment at 3-months. Please refer to Table 15 and Table 16 for the descriptive statistics of the 3-months follow-up data split by treatment outcome group and consultant profession, respectively.

Variables	Discharged M (SD) N = 123		Treatment M (SD) N = 173		Total N = 296	
	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
StartBack	1.48 (1.18)		2.06 (1.27)		1.82 (1.26)	
Pain	4.61 (2.60)	4.53 (2.71)	6.47 (2.14)	5.49 (2.60)	5.70 (2.51)	5.07 (2.69)
Disability	8.54 (6.06)	9.84 (6.85)	11.22 (5.71)	12.68 (6.65)	10.12 (6.0)	11.50 (6.87)
Depression	5.20 (3.66)	4.86 (4.74)	6.62 (4.05)	6.36 (4.90)	6.04 (3.95)	5.74 (4.88)
Anxiety	6.31 (4.74)	5.72 (4.87)	7.83 (4.47)	7.09 (4.98)	7.21 (4.64)	6.52 (4.97)
GP visits		0.69 (1.55)		0.71 (1.48)		0.70 (1.51)

Table 14: Descriptive statistic by treatment outcome

Variables	Surgeon M (SD) N = 131		ESP (SD) N = 165		Total N = 296	
	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
StartBack	1.91 (1.29)		1.75 (1.24)		1.82 (1.26)	
Pain	5.84 (2.47)	5.22 (2.82)	5.59 (2.55)	4.95 (2.58)	5.70 (2.51)	5.07 (2.69)
Disability	10.29 (6.35)	12.23 (7.06)	9.98 (5.72)	10.91 (6.67)	10.12 (6.0)	11.50 (6.87)
Depression	6.14 (3.96)	6.09 (4.83)	5.96 (3.95)	5.45 (4.92)	6.04 (3.95)	5.74 (4.88)
Anxiety	6.99 (4.44)	6.84 (5.12)	7.38 (4.79)	6.27 (4.85)	7.21 (4.64)	6.52 (4.97)
GP visits		0.73 (1.60)		0.68 (1.43)		0.70 (1.51)

Table 15: Descriptive statistic by consultant profession

Further health care utilization

The further healthcare utilization statistics indicates the different types of professionals' patients re-consulted for their back pain over the 3-months follow-up phase, however, it does not reveal the number of times patients re-consulted with that professional. For example, it showed the number of patients who re-consulted a private physiotherapist but does not indicate how many physiotherapy sessions that patients had over the past 3-months. Moreover, the numbers and corresponding percentages were taken from the total, whereby, some patients might have sought further care from more than one practitioner, e.g. went back to their GP, got referred to see a surgeon, and had private physiotherapy.

Out of those patients who were discharged (n = 123), 54 (43.9%) patients did not seek further consultations elsewhere, whilst 69 (56.1%) stated they did seek further care whether privately or through the NHS. Of the total group (n = 123), 49 patients stated they had re-consulted within the NHS, compared to 74 who did not. Out of those who did, 37 went back to their GP, whereby, 19 patients only went back once, 7 went back twice, and 11 patients went back more than 3 times, within the past 3-months. Within the NHS, 14 patients saw a physiotherapist, 11 patients saw a surgeon, 6 (4.9%) patients reported having gone to hospital/ A&E, 2 patients saw an osteopath and 2 patients saw the pain specialist team. Out of the total of 123, 37 patients stated they had also re-consulted privately, whereby, 14 patients saw a physiotherapist, 9 patients saw an osteopath, 1 patient saw a surgeon, 1 patient saw a private pain specialist team, and 1 patient went to a private hospital. Additionally, about 4 patients reported having been to acupuncture, 10 patients reported having seen a chiropractor, 9 patients had at least one massage, and there was 1 patient each who reported having tried hypnotherapy, manual therapy, and electric therapy. Numerous patients stated also having tried Yoga and Pilates in the past 3- months.

Out of the 173 patients who were referred for other treatments, 55 (31.8%) re-consulted their GP for their LBP in the previous 3-months. Thereby, 27 stated they only saw the GP one time, 12 patients said they saw their GP twice, and 16 stated they saw their GP 3 times or more. In addition to receiving or waiting for their

treatments, 43 patients said they re-consulted in the private sector, whereby, 13 patients saw a physiotherapist, 12 stated they had at least one massage, 11 patients saw a chiropractor, 8 patients saw an osteopath, 7 mentioned they went to acupuncture and 1 person saw a surgeon. Some patients also reported having to pay for Yoga and Pilates sessions. Within this treatment group ($n = 173$), 52 (30%) patients did not receive their treatment at 3-months follow-up. Out of those people who did not receive their treatment at 3-months follow-up ($n = 52$), 18 stated they re-consulted within the NHS. 39 patients did not re-consult their GP, compared to 13 who went back to their GP. Within the NHS, 4 patients saw a surgeon, and 2 patients each went to the hospital/ A&E, a pain specialist team and to see a physiotherapist. 9 patients stated they re-consulted privately, of whom 5 patients saw a chiropractor, 4 patients each reported they saw an osteopath and had at least one massage, 2 patients each stated they saw a physiotherapist and had acupuncture.

Reassurance

Spaereman's correlations were run to examine the correlation coefficients between reassurance and short-term and long-term outcomes (please see Table 17 for correlation coefficient). All four subscales were strongly positively correlated with satisfaction, 1-item measure about perceived reassurance, acceptance of explanation (2-items), and negatively correlated with catastrophizing (1-item). There was a moderate positive correlation between reassurance and enablement. Variables measured at post-consultation and reassurance were not only measured at the same time but also correlate strongly with short-term outcomes, so they were analysed separate to the long-term outcomes to ensure reassurance in its own right can be examined without being diluted by shared variances. There were mostly moderate negative correlations between the four types of reassurance and long-term outcomes, except further health care seeking in terms of GP visits, which showed weak negative correlations. The correlation coefficients between reassurance and short-term outcomes are much larger than those between reassurance and long-term outcomes, possibly because of the short time that has elapsed between the consultation and data gathering, but most likely because the measures share more variance with reassurance as there is some conceptual overlap between satisfaction and reassurance. Over time, as life goes on, events happen, including pain experiences,

any lingering direct effect from reassurance is assumed to diminish, and only non-direct effects, possibly through change in beliefs and behaviours remain. Thus, we anticipate correlations to be much smaller. This inflation of correlation coefficients, especially for satisfaction, enablement and perceived reassurance, might be due to the conceptual overlap between the questionnaires. Similar to the conceptual overlap between the satisfaction and reassurance (please see p. 109 for the discussion on the conceptual overlap of the measures), enablement also has two items that are similar to those of the other two measures (item 2: ‘able to understand your problem’ and item 3. ‘able to cope with your problem’). However, the inflated correlation between perceived reassurance and the reassurance measure may not be inflated, but rather represents a validity indicator, in which a single item reassurance question should and is highly correlated with the questionnaire sub-categories.

	DG	RB	GR	CR
Short- term outcome (n= 396)				
Satisfaction	.676**	.743**	.558**	.697**
Perceived R.	.647**	.676**	.546**	.644**
Enablement	.428**	.458**	.450**	.443**
Acceptance of explanation	.327**	.312**	.227**	.343**
Catastrophizing	.396**	.388**	.235**	.414**
Long-term outcome (n= 290)				
Pain	-.174 **	-.200**	-.229**	-.181**
Disability	-.268**	-.292**	-.337**	-.261**
Depression	-.235**	-.311**	-.324**	-.261**
Anxiety	-.285**	-.331**	-.273**	-.274**
GP visits	-.148*	-.175**	-.171**	-.126*

Table 16: Correlations between reassurance and short- term outcome and long-term outcomes.

Notes: * Correlation significant at $p < .05$ (2- tailed), ** Correlation significant at $p < .01$ (2- tailed)

Treatment outcome groups

Unlike practitioners in primary care and pain management teams, surgeons and their teams may not consider pain management and addressing patient’s psychological needs, outside of surgery, as their remit. Thus, we expected there to be a difference in perceived reassurance, once surgery is ruled out. In addition, our previous qualitative study indicated that patients are often dissatisfied when they were

discharged without further treatment options. Therefore, we wanted to investigate whether there is a difference in perceived reassurance for those who received a treatment referral and those who were discharged without a plan B.

A one-way MANOVA was conducted to determine the difference in perceived reassurance between the three outcome groups. The assumption of homogeneity of variance-covariances matrices was violated, as assessed by Box's test of equality of covariance matrices ($p < .001$). To correct for the problem, the Pillai's Trace, which is robust when there are unequal sample sizes, was reported instead of the Wilks' Lambda (Λ). There was homogeneity of variances for GR, as assessed by Levene's Test of Homogeneity of Variance ($p = .156$). There was no homogeneity of variance for DG ($p < .001$), RB ($p < .001$), and CR ($p < .001$). To adjust for the heteroscedasticity of those three variables, the Games and Howell multiple comparison test was reported for DG, RB, and CR, but Bonferroni for GR.

There was a significant difference between the treatment outcome groups on the combined reassurance types, $F(8, 828) = 6.412, p < .001$; Pillai's Trace = .117; partial $\eta^2 = .058$. Follow-up univariate ANOVAs were inspected with a Bonferroni adjusted α level of .013. There was no significant difference in **generic-reassurance scores** between patients in different treatment outcome groups, $F(2, 416) = .718, p = .488$; partial $\eta^2 = .003$. There was a significant difference in **data-gathering scores** between patients with different treatment outcomes, $F(2, 416) = 11.515, p < .001$; partial $\eta^2 = .052$). The Games and Howell post-hoc tests showed that patients in the surgery group had significantly higher mean scores than patients from the discharged group ($p < .001$) and the treatment group ($p = .002$). The treatment group had significantly higher scores than the discharge group ($p = .046$).

There was a significant difference in **relationship-building scores** between patients in different treatment outcome groups, $F(2, 416) = 5.681, p = .004$; partial $\eta^2 = .027$. The Games and Howell post-hoc tests showed that patients in the surgery group had significantly higher mean scores than patients from the discharged group ($p = .002$) but not significantly different to the treatment group ($p = .075$). There was no significant difference in scores between the discharged group and the treatment group ($p = .175$).

There was a significant difference in **cognitive reassurance scores** between the treatment outcome groups, $F(2, 416) = 9.306$, $p < .001$; partial $\eta^2 = .043$. The Games and Howell post-hoc tests showed that patients in the surgery group had significantly higher mean scores than patients from the treatment group ($p = .001$) and discharged group ($p < .001$). There was no significant difference in scores between the treatment group and the discharge group ($p = .232$). Looking at the differences in means of reassurance types between the treatment outcome groups, it indicates that on average patients in the surgery group perceived CR by 3-point higher and DG and RB by 2-point higher than the discharged group. Whereas, there was only a 1-point difference in means when comparing the treatment group with the other two groups. Although there are no rules for a reassurance scores cut-off points that indicate clinical significance, it could be argued that a 3- and 2- point difference may translate to the real world, whereas, a 1-point difference is less likely to. It might be argued that for the individual it may not translate to clinical significance, however, for the population it may be suggested that if the whole distribution were to shifted even a small amount it might translate into a meaningful clinical difference. Please see Table 18 below for mean and SD.

	Treatment outcome	Mean	SD	N
Data-Gathering	Surgery	18.81	2.79	95
	Discharged	16.03	5.23	131
	Other Treatment	17.34	4.23	193
	Total	17.26	4.42	419
Relationship-Building	Surgery	18.38	3.55	95
	Discharged	16.27	5.61	131
	Other Treatment	17.32	4.42	193
	Total	17.23	4.71	419
Generic Reassurance	Surgery	13.36	5.46	95
	Discharged	14.10	5.93	131
	Other Treatment	14.15	5.23	193
	Total	13.95	5.50	419
Cognitive Reassurance	Surgery	18.00	3.56	95
	Discharged	15.06	5.99	131
	Other Treatment	16.10	5.03	193
	Total	16.21	5.18	419

Table 17: Descriptive statistic for reassurance across the three treatment outcome groups.

Short-term outcomes

Satisfaction

The satisfaction scale was scored out of a possible of 900. There were four subscales, general satisfaction, satisfaction with professional care, satisfaction with the depth of relationship and satisfaction with perceived time. Within this thesis, the four subscales of the consultation satisfaction measure were strongly correlated with the total score, so it was not divided into its sub-scales.

A one-way ANOVA was conducted to examine differences in overall satisfaction between the consultant professions. Patients who saw a surgeon ($M = 598.01$, $SD = 212.20$) were significantly less satisfied than those recruited from an ESP ($M = 656.59$, $SD = 189.63$), $F(1, 417) = 8.849$, $p = .003$.

A one-way ANOVA was also conducted to examine the difference between overall satisfaction between the three treatment outcome groups. The assumption of homogeneity of variances was violated, as assessed by Levene's test for equality of variances ($p < .001$). There was a significant difference between satisfaction scores and the three treatment outcome groups, Welch's $F(2, 231.904) = 7.685$, $p < .001$. Patients were most satisfied when they were recommended to undergo surgery ($n = 95$, $M = 685.26$, $SD = 159.93$), less satisfied when they received other treatments ($n = 172$, $M = 636.63$, $SD = 188.34$), and least satisfied when they were discharged without further treatment ($n = 123$, $M = 581.50$, $SD = 232.55$). Games-Howell post hoc tests revealed a significant difference in satisfaction scores between the surgery and discharge group ($p < .001$), whereby the surgery group had a mean increase in satisfaction scores of 103.759, 95% CI [38.96, 168.56]. There was no significant difference in satisfaction between the surgery and treatment group ($p = .68$), nor between the treatment and discharged group ($p = .079$). Please see Figure 5 below for the bar chart with error bars indicating the mean differences of satisfaction scores between treatment outcome groups.

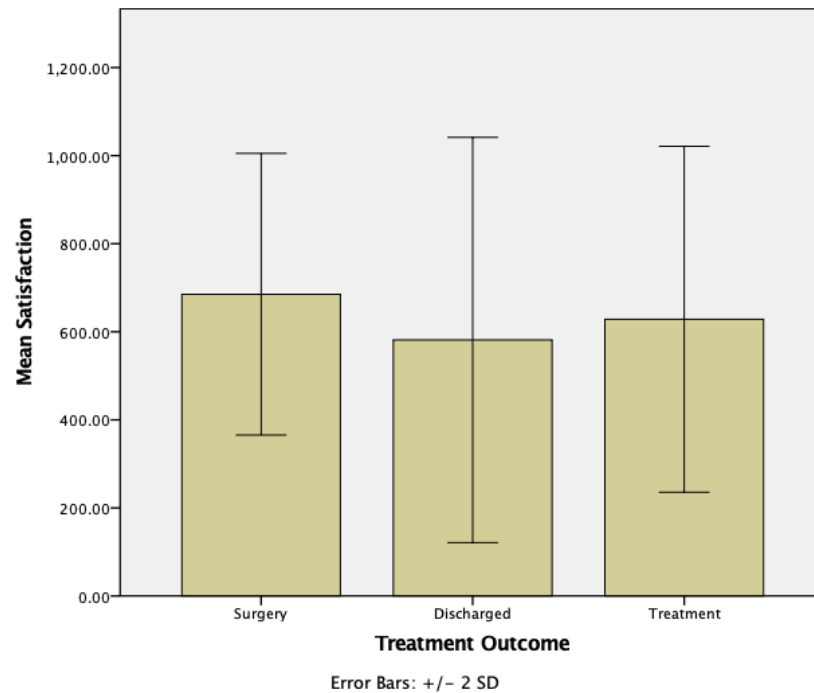


Figure 5: Bar chart showing mean satisfaction scores between treatment groups.

A hierarchical multiple regression was conducted to ascertain the effects of reassurance on satisfaction. Preliminary assumption checking revealed all the assumptions were met. All models significantly added to the prediction of satisfaction. Model 1 (site, consultant profession, treatment outcome group) showed a significant increase to the prediction of satisfaction, R^2 of .094, $F(4, 355) = 9.164$, $p < .001$. Model 2 (baseline characteristics) showed a significant increase to the prediction of satisfaction in R^2 of .084, $F(9, 346) = 3.939$, $p < .001$. When adding reassurance (Model 3) to the prediction of satisfaction, the model accounted for an additional of 53.2% of the variance, $F(4, 342) = 157.112$, $p < .001$. The full model 3, after adjusting for Block 1 and Block 2, significantly predicted satisfaction, accounting for 71.0% of the variance in satisfaction, $F(17, 342) = 55.040$, $p < .001$, adjusted $R^2 = .696$. After controlling for site, consultant profession, and baseline characteristics, consultant profession remained a significant predictor ($p = .005$), suggesting patients who had their consultation with a surgeon were less satisfied than when consulting an ESP. Females were significantly less satisfied than males ($p = .028$). Patients with lower levels of anxiety at baseline were significantly more satisfied ($p = .048$). All four types of reassurance added significantly to the prediction of satisfaction, whereby higher levels of perceived data-gathering ($p =$

.004), relationship-building ($p < .001$), generic-reassurance ($p = .001$), and cognitive reassurance ($p < .001$) were associated with higher levels of satisfaction. Please see unstandardized coefficients, standard error, t -values, p -values, and confidence intervals in the Table 19.

Variable	<i>B</i>	<i>SE_B</i>	<i>t</i>	<i>95% CI</i>
Constant	33.477	43.509	.769**	[-52.102, 119.056]
Sites	-21.257	13.249	-1.604	[-47.317, 4.804]
Consultant	-35.557	12.697	-2.801*	[-60.530, -10.584]
Surgery	32.702	15.929	2.053*	[1.372, 64.032]
Discharged	-4.644	15.12	-.307	[-34.385, 25.096]
Age	.639	.383	1.669	[-.114, 1.393]
Gender	-27.706	12.535	.416*	[-52.361, -3.051]
Education	5.228	12.570	.416	[-19.496, 29.953]
No treatments	-4.059	3.951	-1.027	[-11.832, 3.713]
Pain	1.366	3.154	.433	[-4.839, 7.570]
StartBack	1.457	6.694	.218	[-11.709, 14.623]
RMD	-1.242	1.363	-.911	[-3.923, 1.439]
Anxiety	-3.909	1.968	-1.986*	[-7.779, -.038]
Depression	3.101	2.421	1.281	[-1.669, 7.862]
Data- G.	8.515	2.972	2.865*	[2.669, 14.361]
Relationship B	15.346	2.909	5.275**	[9.624, 21.069]
Generic R.	4.816	1.429	3.369**	[2.005, 7.627]
Cognitive R.	8.655	1.866	4.638**	[4.984, 12.325]

Table 18: Reassurance as predictor for satisfaction at post-consultation.

Note: B = unstandardized regression coefficient; SE_B β = standardized coefficients; t = t -values;

95% CI= confidence interval, $n = 360$, * $p < .05$, ** $p < .001$.

Enablement

On the enablement scores at post-consultation, 12 was the highest possible score. The mean and correlation coefficients with reassurance can be found in Table 14 and Table 17, respectively. One-way ANOVA's were conducted to assess the difference in enablement scores between the three treatment outcome groups and consultant professions. The enablement scores showed a strong positive skew, but log or square root transformations did not seem to correct for the problem, hence the variable was not transformed. There was no significant difference in enablement scores between

the different treatment outcomes, $F(1, 292) = .615$, $p = .433$. For consultant profession, the homogeneity of variance was violated, so the Welch's statistic was reported. There was a significant difference in enablement scores between surgeons and ESP's, $F(1, 284.864) = 10.329$, $p = .001$. Patients who had their consultation with an ESP ($M = 2.64$, $SD = 3.52$) felt more enabled than patients who consulted with a surgeon ($M = 1.64$, $SD = 2.52$).

A hierarchical regression was conducted to investigate the relationship between reassurance and enablement. To recap, there was no difference in enablement scores between the treatment outcomes but between consultant professions, so only the later was added as covariate into Block 1. Block 1 (site, consultant profession) led to a significant increase in R^2 of .027, $F(2, 357) = 4.988$, $p = .007$. Adding the baseline characteristics (Block 2), did not significantly add to the prediction of enablement, $F(9, 248) = 1.154$, $p = .324$. Adding reassurance (Block 3) significantly predicted a change in F, accounting for 16% of the additional variance in enablement, $F(4, 344) = 17.487$, $p < .001$. The full model (Block 3) was statistically significantly predicting around 21.5% of the variance in enablement, $F(15, 344) = 6.281$, $p < .001$, adjusted $R^2 = .181$. In the final model, patients who saw an ESP ($p = .046$), those who were more educated ($p = .027$) and those who perceived more generic-reassurance ($p < .001$), felt significantly more enabled post- consultation. The results were displayed in Table 20.

Variable	<i>B</i>	<i>SE_B</i>	<i>t</i>	<i>95% CI</i>
Constant	-3.252	1.031	-3.154*	[-5.331, -.467]
Sites	.237	.338	.702	[-.450, 1.13]
Consultant	-.627	.313	-2.001*	[-1.244, -.011]
Age	.006	.010	.608	[-.017, .028]
Gender	-.224	.321	-.697	[-.900, .617]
Education	.711	.321	2.214*	[.079, 1.343]
No treatments	-.002	.101	-.018	[-.249, .231]
Pain	.102	.077	1.326	[-.105, .245]
StartBack	-.103	.171	-.604	[-.547, .256]
RMD	.009	.035	.268	[-.076, -.082]
Anxiety	-.042	.050	-.843	[-.140, .094]
Depression	.047	.062	.760	[-.117, .167]
Data- G.	.107	.075	1.417	[-.020, .337]
Relationship	-.053	.074	-.711	[-.266, .089]

B				
Generic R.	.153	.036	4.232**	[.082, .224]
Cognitive R.	.085	.047	1.810	[-.042, .173]

Table 19: Reassurance as predictor for enablement at post-consultation.

Note: B = unstandardized regression coefficient; SEB β = standardized coefficients; t = t-values;

95% CI = confidence interval, N = 360, * $p < .05$, ** $p < .001$.

Acceptance of explanation

When patients were asked at post-consultation whether they received an explanation to their back pain or not, 331 (78.1%) stated they did receive some sort of explanation, whereas, 82 (19.3%) said they did not receive an explanation. Subsequently, they were asked whether they agreed with the explanation they received. Around 73 (17.2%) patients stated they did not agree with this explanation, whereas 340 (80.2%) stated they did agree.

Two independent chi-square tests of homogeneity were conducted to determine whether there was a difference in acceptance of explanation at post-consultation between the three treatment outcome groups and consultant professions. There was no significant difference between the three treatment outcome groups and acceptance of explanation, $p = .818$. There was a significant difference in the proportion of patients who rejected the explanation they received when consulting an ESP, ($n = 24$, 15%), compared to those who consulted a surgeon ($n = 36$, 28.3%), with a significant difference in proportions, $p = .008$. Mean and SD for each treatment group were displayed in Table 14.

To examine the relationship between accepting their explanation and reassurance a binary logistic regression was run. After adjusting for Block 1 (site, consultant profession) and Block 2 (baseline characteristics), the overall model, after adding reassurance types, was significant, $\chi^2(15) = 73.366$, $p < .001$. The model explained 31.5% (Nagelkerke R^2) of the variance in acceptance of explanation and correctly classified 97.3% of cases. Sensitivity was 97.3% and specificity was 35.0%. Of the 15 predictor variables only 4 variables were statistically significant: anxiety ($p = .015$), depression ($p = .009$), data-gathering ($p = .030$) and cognitive reassurance ($p =$

.033). People who were more anxious but less depressed, and those who perceived more DG and CR, were more likely to accept their explanation.

Variable	<i>B</i>	<i>SE_B</i>	<i>Wald</i>	<i>95% CI</i>
Sites	-.403	.376	1.151	[.320, 1.396]
Consultant	-.334	.351	.908	[.360, 1.424]
Age	.021	.011	3.704	[1.000, 1.044]
Gender	.125	.363	.119	[.557, 2.307]
Education	-.156	.351	.197	[.430, 1.703]
No treatments	-.075	.104	.523	[.757, 1.137]
Pain	-.065	.089	.532	[.788, 1.115]
StartBack	-.036	.184	.038	[.673, 1.383]
RMD	-.035	.038	.844	[.897, 1.040]
Anxiety	.137	.056	5.937**	[1.027, 1.280]
Depression	-.170	.065	6.909**	[.743, .958]
Data- G.	.162	.075	4.701*	[1.016, 1.362]
Relationship B	-.016	.071	.054	[.857, 1.130]
Generic R.	-.003	.040	.007	[.922, 1.077]
Cognitive R.	.094	.044	4.570*	[1.008, 1.198]
Constant	-1.753	1.094	2.567	

Table 20: Reassurance as predictor of acceptance of explanation, at post-consultation.

Note: B= unstandardized regression coefficient; SEB β= standardized coefficients; t= t-values;

95% CI= confidence interval, N = 360, * p< .05, ** p< .01.

Catastrophizing

This was a 1-item question, concerning patients catastrophizing thoughts, by asking them whether they believed that there is something else going on in their back, which has not yet been diagnosed. Patients answered with either agree or disagree. In total, 260 (61.3%) patients said they disagreed with the statement, compared to 150 (35.4%) patients who stated they agreed. The individual frequencies for each treatment group can be found in Table 14.

A chi-square test of homogeneity was conducted to determine if there is a difference in patients catastrophizing post-consultation between the three treatment outcome groups and consultant professions. 21 (22.6%) patients in the surgery group left their consultation with catastrophizing thoughts about their LBP compared to 48 (40%) patients in the discharged group, and 65 (39.4%) patients in the treatment group,

$\chi^2(2) = 8.938$, $p = .011$. The post- hoc comparison analysis entailed pairwise comparisons using the z-test proportions with a Bonferroni correction. The proportion of patients with catastrophizing thoughts was significantly lower post-consultation for patients in the surgery group than for those in the discharged and treatment group, $p < .05$. There was no significant difference between the treatment and discharged group. There was a significant difference in the proportion of patients who had catastrophizing thoughts after consulting a surgeon ($n = 80$, 40.6%), compared to those who consulted an ESP ($n = 54$, 29.8%), $p = .032$.

A binomial logistic regression was performed to ascertain the effects of reassurance on the likelihood of patients leaving the consultation with catastrophizing thoughts. Due to the differences between the treatment outcome group and consultant profession, those variables were added as a control variable in the first stage of the binary logistic regression. All stages significantly added to the prediction of catastrophizing. The overall model, after adjusting for Block 1, Block 2 and adding reassurance was significant, $\chi^2(17) = 69.324$, $p < .001$. The model explained 24.8% (Nagelkerke R^2) of the variance in catastrophizing and correctly classified 71.9% of cases. Sensitivity was 44.4% and specificity was 87.1%. Of the 17 predictor variables only 3 variables were statistically significant: consultant profession ($p = .011$), treatment outcome ($p = .004$), and cognitive reassurance ($p = .023$). People who saw a surgeon had .697 times higher odds to leave their consultation with catastrophizing thoughts than patients who saw an ESP. People in the treatment or discharged group were more likely to have catastrophizing thoughts post-consultation, compared to the surgery group. The less CR patients perceived the more catastrophizing thoughts they reported after their consultation.

Variable	<i>B</i>	<i>SE_B</i>	<i>95% CI</i>
Sites	-.009	.284	[-.569, 1.728]
Consultant	.697	.273	[1.176, 3.426]
Discharged	1.007	.405*	[1.237, 6.058]
Treatment	1.188	.356*	[1.631, 6.595]
Age	.001	.008	[-.985, 1.017]
Gender	.420	.272	[-.893, 2.593]
Education	.426	.276	[-.892, 2.627]
No treatments	.079	.082	[-.920, 1.272]
Pain	-.004	.069	[-.869, 1.141]

StartBack	-.069	.142	[.706, 1.233]
RMD	.044	.029	[.986, 1.107]
Anxiety	-.019	.042	[.903, 1.065]
Depression	.052	.051	[.952, 1.165]
Data- G.	-.053	.062	[.840, 1.072]
Relationship B	.027	.061	[.912, 1.158]
Generic R.	-.040	.030	[.906, 1.019]
Cognitive R.	-.089	.039*	[.848, .988]

Table 21: Reassurance as predictor of catastrophizing at post-consultation.

Note: B= unstandardized regression coefficient; SEB β = standardized coefficients; 95% CI= confidence interval, n= 360, * $p < .05$, ** $p < .001$.

Intention to re-consult

Out of 123 patients who were discharged without further treatment, 44 (35.8%) patients said they did not intent to seek further consultations, compared to 78 (63.4%) who stated they intended to seek further care elsewhere. A chi-square test examined differences in the proportion of patients who stated they had the intention to re-consult and those who did not between the consultant professions. There was no significant difference in proportion, $p = .448$. Thus, consultant profession was not entered as a covariate in the first stage of the following regression.

A binary regression was conducted to examine the relationship between the four types of reassurance and patients' intention to re-consult. Only people who were discharged without treatment were included in the analysis because patients who received treatment stated they intent to re-consulted for their treatment referral. Block 1 ($p = .244$) did not significantly add to the prediction, whereas Block 2 ($F(9,11) = 28.933$, $p = .001$) and Block 3 ($F(4, 15) = 22.912$, $p < .001$) were significant. After adding the reassurance variables, the full model (Block 3) significantly predicted intention to re-consult, $F(4, 15) = 54.668$, $p < .001$. The model explained 54.9% (Nagelkerke R^2) of the variance and correctly classified 82.4% of cases. Sensitivity was 90.1% and specificity was 67.6%. Of the 15 predictor variables only 2 variables were statistically significant: site ($p = .004$) and relationship-building ($p = .032$). Patients who were recruited from Site 1 and Site 2 were more likely to seek further care compared to patients recruited from Site 3.

Additionally, patients who perceived less RB, were more likely to have the intention to re-consult elsewhere. Please see Table 23 for the results of this analysis.

Variable	<i>B</i>	<i>SE_B</i>	<i>95% CI</i>
Sites	2.323*	.799**	[2.133, 48.848]
Age	-.021	.020	[-.942, 1.017]
Gender	1.195	.640	[-.942, 11.574]
Education	.579	.778	[-.388, 8.200]
No. treatments	.381	.204	[-.981, 2.183]
Pain	-.144	.139	[-.659, 1.138]
StartBack	-.405	.336	[-.345, 1.289]
RMD	.047	.062	[-.927, 1.184]
Anxiety	.057	.121	[-.836, 1.342]
Depression	.169	.128	[-.921, 1.522]
Data- G.	.239	.155	[-.937, 1.720]
Relationship B	-.354*	.166*	[-.507, .973]
Generic R.	-.052	.085	[-.804, 1.121]
Cognitive R.	-.143	.099	[-.714, 1.052]
Constant	5.770	2.033**	

Table 22: Reassurance as predictor of intention to re-consult at post-consultation.

Note: B= unstandardized regression coefficient; SEB β= standardized coefficients; 95% CI= confidence interval, N = 108, * p< .05, ** p< .01.

Long-term outcomes

In the previous chapter it became evident that patients recruited from different sites were different on their baseline characteristics. At 3-months follow-up, patients recruited from different sites were significantly different on their long-term outcomes. Patients from Site 1 and Site 2 scored significantly higher on pain, number of subsequent professionals seen, number of GP visits, disability, depression and anxiety than patients recruited in Site 3, $F(6, 284) = 3.493, p = .002$; Wilks' $\Lambda = .931$; partial $\eta^2 = .069$. To account for these differences as well as differences in baseline characteristic, site was added as a covariate in the first stages of the following hierarchical regression models. On the other hand, there was no significant differences in long-term outcomes for patients who saw a surgeon versus an ESP, so consultant profession was not added as covariate in the following regression models.

A one-way MANOVA was also conducted to examine the difference in long-term outcome (pain, disability, depression, anxiety, GP visits, number of different professionals seen) between the two treatment outcome groups. There was homogeneity of variances-covariances matrices, as assessed by Box's M test ($p > .001$) and there was homogeneity of variances, as assessed by Levene's Test of Homogeneity of Variance ($p > .05$). The alpha level was adjusted for 6 DV's with a new critical value of 22.46 and showed there were no multivariate outliers in the data, as assessed by Mahalanobis distance, ($p > .001$). There was a significant difference between two treatment outcomes on the combined dependent variables, $F(6, 284) = 5.451, p < .001$; Wilks' $\Lambda = .897$; partial $\eta^2 = .103$. Patients in the discharged group scores significantly lower in pain ($F(1, 289) = 9.409, p = .002$; partial $\eta^2 = .032$) number of professionals seen ($F(1, 289) = 14.926, p < .001$; partial $\eta^2 = .049$), disability ($F(1, 289) = 13.414, p < .001$; partial $\eta^2 = .044$), depression ($F(1, 289) = 6.800, p = .010$; partial $\eta^2 = .023$) and anxiety ($F(1, 289) = 5.443, p = .020$; partial $\eta^2 = .018$) compared to patients who were referred to treatment. There was no significant difference between the treatment outcome group on number of GP visits, $F(1, 289) = .006, p = .937$; partial $\eta^2 = .000$. To account for these differences, treatment outcome was entered as a covariate in the following regression models. The following variables were entered in 3 stages for all of the following hierarchical multiple regression models:

Block 1: Site, treatment outcome

Block 2: Baseline characteristics

Block 3: 4 sub-groups of reassurance

Pain

At 3-months follow-up, patients were asked to rate their pain from 0 to 10. The comparisons in mean (SD) scores of pain at baseline to pain at follow-up, are shown in Table 14. There were significant correlations between pain and the reassurance variables, as shown in Table 17.

Model 1 (site, treatment outcome) significantly added to the prediction of Pain2 compared to no predictors, R^2 of .052, $F(2, 266) = 7.255, p = .001$. Model 2 (baseline characteristics) showed a significant increase in prediction with a R^2 of .219, $F(9,$

257) = 8.597, $p < .001$. When adding reassurance (Model 3) to the prediction, it did not lead to a significant increase in R^2 , $F(4, 253) = 1.090$, $p = .362$. The full model (Block 3) was significant in predicting Pain at 3- months follow-up, $R^2 = .283$, $F(15, 253) = 6.673$, $p < .001$, adjusted $R^2 = .241$. The more pain ($p < .001$), and disability ($p = .014$) patients expressed at baseline, the higher the likelihood of them scoring high in pain at 3-months follow-up (please refer to Table 24 for results).

Variable	<i>B</i>	<i>SE_B</i>	<i>t</i>	<i>95% CI</i>
Constant	2.526	1.049	2.408*	[.460, 4.591]
Sites	.088	.317	.277	[-.536, .711]
Treatment outcome	-.183	.324	-.565	[-.821, .455]
Age	.011	.009	1.235	[-.007, .029]
Gender	.356	.308	1.154	[-.252, .963]
Education	-.527	.305	-1.729	[-1.128, .073]
No treatments	.007	.097	.077	[-.184, .199]
Pain	.315	.075	4.197*	[-.167, .463]
StartBack	-.068	.163	-.415	[-.390, .254]
RMD	.080	.032	2.482*	[-.017, .144]
Anxiety	.011	.048	.222	[-.084, .105]
Depression	.040	.058	.694	[-.073, .153]
Data- G.	-.012	.072	-.160	[-.154, .131]
Relationship B	-.058	.072	-.813	[-.200, .083]
Generic R.	-.037	.037	-1.000	[-.109, .036]
Cognitive R.	.055	.044	1.267	[.031, .141]

Table 23: Reassurance as predictor of pain at follow-up.

Note: *B* = unstandardized regression coefficient; *SE_B* β = standardized coefficients, *t* = t-values,

95% CI = confidence interval, *N* = 268, * $p < .05$, ** $p < .01$.

Disability

The average disability scores can be found in Table 14 and significant correlations between disability and reassurance variables in Table 17. A sequential/ hierarchical multiple regression was run to examine the relationship between reassurance and disability at 3-months follow-up, after controlling for Block 1 and Block 2. All stages significantly added to the prediction of disability at 3-months follow up. Block 1 (site, treatment outcome), lead to a significant increase in R^2 of .059, $F(2, 264) = 8.255$, $p < .001$. Block 2 (baseline characteristics) lead to a significant increase in

R^2 of .473, $F(9, 255) = 28.624, p < .001$. The addition of reassurance (Block 3) to the prediction of disability, after controlling for Block 1 and Block 2, only led to a significant increase in R^2 of .023, $F(4, 251) = 3.218, p = .013$. The full model (Block 3) significantly predicted disability, $F(15, 251) = 21.415, p < .001, R^2 = .555$, adj. $R^2 = .528$. Out of the 15 predicting variables, 5 were significant: patients' age ($p = .009$), disability ($p < .001$) and depression ($p = .001$) at baseline, as well as perceived cognitive reassurance ($p = .035$). Patients who were older, more disabled and depressed at baseline as well as those who received high levels of CR, were more disabled at 3- months follow-up (see Table 25 for results).

Variable	<i>B</i>	<i>SE_B</i>	<i>t</i>	95% <i>CI</i>
Constant	2.012	1.995	2.101	[-.255, 7.954]
Sites	.257	.573	.449	[-.872, 1.388]
Treatment outcome	-.857	.596	-1.437	[-2.031, .317]
Age	.039	.017	2.335**	[-.006, .072]
Gender	1.059	.558	1.900	[-.039, 1.158]
Education	-.656	.549	-1.195	[-1.738, .426]
No treatments	.114	.178	.644	[-.236, .465]
Pain	.054	.141	.382	[-.223, .331]
StartBack	.071	.301	.237	[-.521, .664]
RMD	.614	.062	9.919**	[-.492, .736]
Anxiety	-.099	.087	-1.135	[-.270, .073]
Depression	.409	.106	3.847**	[-.200, .619]
Data- G.	-.032	.129	-.250	[-.287, .222]
Relationship B	-.206	.129	-1.604	[-.459, .047]
Generic R.	-.148	.066	-2.247	[-.278, -.018]
Cognitive R.	.183	.078	2.362*	[-.030, .336]

Table 24: Reassurance as predictor of disability at follow-up.

Note: *B* = unstandardized regression coefficient; *SE_B* β = standardized coefficients; *t* = t-values;

95% *CI* = confidence interval, $n = 267$, * $p < .05$, ** $p < .01$.

Depression and Anxiety

The maximum score possible for patients to score on the depression and anxiety subscale of the HADS was 21 for each. Please refer to Table 14 for average depression and anxiety scores and Table 17 for significant correlations with reassurance.

For depression at 3-months follow-up, the covariates site and treatment outcome (Block 1), which were entered first, significantly predicted around 7.6% of the variance, $F(2, 263) = 10.831, p < .001$. The addition of baseline characteristics (age, gender, education, number of previous treatments, pain, StartBack, disability, depression and anxiety) significantly predicted an additional 47.8% of the variance in depression, $F(9, 254) = 30.209, p < .001$. At the last stage, the addition of the reassurance variables significantly increased the predictive power of the model but only by an additional 2%, $F(4, 250) = 2.990, p = .019$. The full model (Block 3), explained 57.4% of the variance in depression, $F(15, 250) = 22.469, p < .001$, adjusted $R^2 = .549$. Besides patients who were older ($p = .008$) and more disability ($p < .001$) and depression ($p < .001$) at baseline, patients who perceived lower levels of GR ($p = .050$) and higher levels of CR ($p = .032$) had predicted significantly higher levels of depression, at 3-months.

For anxiety, the addition of Block 1, predicted a 4.2% change in R^2 , $F(2, 263) = 5.724, p = .004$. The addition of baseline characteristics (Block 2) increased the predictive power of the model by an additional 49.9%, $F(9, 254) = 30.725, p < .001$. Adding reassurance to the model lead to an increase in 3.1% of the variance in anxiety, $F(4, 250) = 4.493, p = .002$. The full model (Block 3) predicted 57.2% of the variance in anxiety at 3-months follow-up, $F(15, 249) = 22.272, p < .001$, adjusted $R^2 = .546$. In the final model, being less educated ($p = .003$), and having higher levels of anxiety ($p < .001$) and depression ($p = .010$) at baseline were significant predictors of increased anxiety scores in the long-term. None of the reassurance variables significantly predict anxiety at 3-months follow-up.

Variables	HADS	B	SE_B	t	95% CI
Constant	D	-.016	1.431	-.011	[-2.833, 2.802]
	A	4.168	1.474	2.828*	[1.265, 7.072]
Sites	D	.459	.433	1.060	[-.394, 1.311]
	A	-.199	.447	-.445	[-1.080, .682]
Treatment outcome	D	-.211	.442	-.479	[-1.083, .660]
	A	-.770	.456	-1.688	[-1.667, .128]
Age	D	.033	.012	2.663 *	[.009, .058]
	A	.020	.013	.798	[-.005, .046]
Gender	D	-.358	.422	-.848	[-1.189, .473]

	A	.261	.436	.599	[.006, .072]
Education	D	-.442	.417	-1.060	[-1.264, .379]
	A	-1.317	.438	-3.009*	[-2.179, -.455]
No treatments	D	-.032	.133	-.240	[-.293, .229]
	A	.152	.137	1.108	[-.118, .421]
Pain	D	-.016	.102	-.154	[-.217, .186]
	A	-.093	.106	-.876	[-.301, .116]
StartBack	D	.299	.223	.181	[-.140, .738]
	A	-.083	.230	-.361	[-.536, .370]
RMD	D	.163	.044	3.713**	[.077, .250]
	A	.044	.045	.964	[-.046, .133]
Anxiety	D	.056	.065	.853	[-.073, .184]
	A	.557	.068	8.252**	[.424, .690]
Depression	D	.568	.078	7.243**	[.414, .722]
	A	.214	.082	2.600*	[.052, .376]
Data- G.	D	-.068	.098	-.694	[-.262, .126]
	A	-.109	.101	-1.078	[-.309, .090]
Relationship B	D	-.078	.098	-.798	[-.270, .114]
	A	-.156	.101	-1.551	[-.355, .042]
Generic R.	D	-.099	.050	-1.973*	[-.197, .000]
	A	-.026	.052	-.503	[-.128, .076]
Cognitive R.	D	.128	.059	2.153*	[.011, .244]
	A	.082	.061	1.331	[-.039, .203]

Table 25: Reassurance as predictor of depression and anxiety at follow-up.

Note: B = unstandardized regression coefficient; $SE_B \beta$ = standardized coefficients; t = t-values;

95% CI= confidence interval, N = 265, * $p < .05$, ** $p < .01$.

GP visits

At 3-months follow-up, patients were asked how many GP visits they had for their back pain since their last specialist consultation. For the mean and SD and the significant correlations between GP visits and reassurance, please refer to Table 17. GP visits was strongly positively skewed, the log transformation and square root transformation was applied, in the attempt to correct for this problem but neither transformation was successful, so the raw data was entered as outcome variable.

One-way ANOVA's were conducted to determine the differences in GP visits between consultant profession and treatment outcome. There was no significant differences in GP visits between consultant professions, $F(1, 294) = .069$, $p = .793$.

There was no significant difference in GP visits between the treatment outcome groups, $F(1, 294) = .022, p = .881$. As a result of the ANOVA analyses, when examining the relationship between GP visits and reassurance, the site variable was the only covariate entered in Block 1, since the consultant profession and the treatment outcome variable showed no significant different results.

Block 1, $F(1, 264) = 9.317, p = .003$, significantly predicted about 1.8% of the variance in GP visits at 3-months follow-up. The addition of baseline characteristics (Block 2) significantly predicted a further 10.8% of the variance, $F(9, 255) = 3.583, p < .001$. When adding reassurance (Block 3), it significantly increased the predictive power of the model by an additional of 3.7%, $F(4, 251) = 2.732, p = .026$. The full model significantly explained 18.4% of the variance in GP visits, $F(14, 251) = 4.524, p < .001$, adjusted $R^2 = .138$. In the final model, patients who were more disabled ($p = .005$) at baseline and those who perceived lower levels of RB ($p = .043$), were more likely to report higher numbers of GP visits (the results are displayed in Table 27).

Variables	<i>B</i>	<i>SE_B</i>	<i>t</i>	<i>95% CI</i>
Constant	.354	.452	.784	[-.536, 1.245]
Sites	.238	.147	1.618	[-.052, .528]
Age	.003	.004	.794	[-.005, .012]
Gender	-.113	.142	-.795	[-.394, .167]
Education	-.067	.142	-.476	[-.346, .211]
No treatments	.022	.045	.490	[-.066, .2110]
Pain	.044	.033	1.344	[-.021, .109]
StartBack	-.011	.075	-.147	[-.159, .237]
RMD	.040	.015	2.711**	[.011, .069]
Anxiety	-.012	.022	-.528	[-.055, .032]
Depression	.021	.027	.783	[-.032, .074]
Data- G.	.027	.034	.803	[-.040, .095]
Relationship B	-.068	.034	-2.014*	[-.134, -.001]
Generic R.	-.003	.017	-.173	[-.036, .030]
Cognitive R.	.000	.020	-.017	[-.040, .039]

Table 26: Reassurance as predictor of GP visits at follow-up.

Note: *B* = unstandardized regression coefficient; *SE_B* *β* = standardized coefficients; *t* = t-values; *95% CI* = confidence interval, *N* = 266, * $p < .05$, ** $p < .01$.

Sick days

Out of 296 people that were followed up, 133 did not work and 163 worked. People who worked reported on average 11.09 (25.02) sick days. The average sick days for the discharged groups was 8.23 (22.54) days and for the treatment group 13.29 (2.78) days. The findings from a one-way ANOVA, examining the differences in sick days between treatment outcomes, showed there was no significant difference, Welch's $F(1,159.655) = 1.724$, $p = .191$. There was no significant difference in the mean of sick days between patients who were discharged and those who were referred to further treatment, regardless of whether they received it or not, Welch's $F(1, 121.563) = 2.642$, $p = .107$.

Adding site in Block 1 significantly predicted 4.8% of the variance in sick-days at 3-months follow-up, $F(1, 146) = 7.410$, $p = .007$. The addition of baseline characteristics significantly predicted a further 15.4% of the variance, $F(9, 137) = 2.947$, $p = .003$. Adding the reassurance variables (Block 3), significantly predicted an additional 7.5% to the variance, $F(4, 133) = 3.458$, $p = .010$. The overall model, accounted for 27.8% of the variance in sick days, $F(14, 133) = 3.654$, $p < .001$, adjusted $R^2 = 20.2\%$. In the last model, patients recruited in Site 1 and 2 ($p = .017$), with high levels of StartBack at baseline ($p = .028$), and those who perceived more generic reassurance ($p = .029$), reported more sick days at 3-months (results are displayed in Table 28).

Variables	<i>B</i>	<i>SE_B</i>	<i>t</i>	95% <i>CI</i>
Constant	-42.087	11.190	-3.761**	[-64.220, -19.953]
Sites	8.108	3.342	2.426*	[1.498, 14.719]
Age	.178	.121	1.478	[-.060, .417]
Gender	.877	3.359	.261	[-5.767, 7.522]
Education	1.009	3.507	.288	[5-.927, 7.945]
No treatments	-1.151	1.128	-1.020	[-3.383, 1.081]
Pain	.338	.791	.428	[-1.226, 1.902]
StartBack	4.152	1.868	2.223*	[-.457, 7.847]
RMD	.607	.349	1.737	[-.084, 1.298]
Anxiety	-.249	.532	-.469	[-1.301, .803]
Depression	1.130	.621	1.820	[-.098, 2.358]
Data- G.	.056	.837	.067	[-1.599, 1.712]
Relationship B	.033	.849	.038	[-1.646, -1.711]

Generic R.	1.035	.467	2.214*	[.110, 1.960]
Cognitive R.	.166	.499	.333	[-.821, 1.154]

Table 27: Reassurance as predictor of sick days at follow-up.

Note: B = unstandardized regression coefficient, $SE_B \beta$ = standardized coefficients, t = t-values,

95% CI = confidence interval, $n = 148$, * $p < .05$, ** $p < .001$.

Discussion

Summary of findings

The findings indicated that patients for whom surgery was recommended perceived higher levels of reassurance than patients who were discharged or received other treatments. In the short-term, reassurance associated with satisfaction (strongly), enablement (moderately), increased acceptance of explanation and decreased catastrophizing ideas about undiagnosed problems. For the 3-months follow-up, the pattern of associations was more complicated and there was an anticipated change of direction from findings of the correlation analyses and regression models for the long-term outcomes.

Treatment outcome groups

The different treatment outcomes affected how patients perceived the reassuring behaviours displayed by surgeons and their teams. Patients for whom surgery or other treatments were recommended, perceived more reassurance (DG, RB, CR) than patients who were discharged. There was no difference in GR between the treatment outcome groups, possibly because surgeons and their teams tend to use GR habitually regardless of the individual needs. Patients from the surgery and other treatment group, both, perceived more DG than patients who were discharged. This is in line with the findings from our previous qualitative study (Braeuninger-Weimer et al., 2019), where patients felt that once surgery was ruled out, consultants were not particularly interested in getting to know their whole story. Patients in the discharged group perceived less RB, by 2-points, compared to the treatment group, although there was no significant difference to the treatment group. Patients for whom surgery was recommended perceived more CR, with a 3-point difference to

the discharged group. This might reflect practitioner's difficulty in dealing with uncertainty or that they communicate more clearly when talking about surgery (their speciality) than other treatments. Consultants found it easier to provide CR when they themselves understand what is going on, however, in the presence of uncertainty they found it harder to provide effective CR, which might also explain why CR was associated with worst outcomes, as will be discussed later on in the discussion.

In terms of **short-term outcomes**, patients who were discharged were the least satisfied, then patients who received other treatments, and most satisfied were those who received surgery. This might either be because surgeons are more confident in providing reassurance when surgery is the obvious option and hence patients perceived more reassurance which directly impacted their consultation satisfaction ratings, or that patients were extremely pleased with their treatment outcome since they were expecting surgery and hence rated surgeons higher on the reassurance scale. There were no significant differences between the treatment outcome groups for enablement scores and acceptance of explanation, suggesting treatment outcomes alone may not improve enablement, post-consultation. As discussed previously, there was a small but important number of patients who were discharged regardless of reporting high levels of pain. Of those patients who were discharged, 51.1% stated they did not receive the chance to voice their treatment preference. Patients who were discharged also tended to endorse the 1-item question asking about their belief in undiagnosed serious problems compared to those who received surgery but not those who received other treatments. While two third of patients who were discharged agreed with their explanation, 40% still thought there is something serious going on with their backs which has not yet been diagnosed. According to Serbic et al. (2013), patients with LBP may hold both of these beliefs at the same time, although they contradict each other. In terms of **long-term outcomes**, patients who were discharged reported less pain, disability, depression, anxiety, and further health care seeking in terms of the number of different professionals seen but not in terms of the number of GP visits. This is not surprising considering patients in the discharged group also started off with a better health care status at baseline.

Professional differences

Patients who consulted an ESP were more satisfied, enabled, and reported fewer catastrophizing thoughts, post-consultation, than patients who consulted a surgeon. However, there was no difference, post-consultation, in acceptance of explanation, nor differences in long-term outcomes, between the two professions. For the discharged group, there was no difference in patient's intention to seek further consultation depending on the type of practitioner they saw. It is not surprising that patients who consulted an ESP had better short-term outcomes, which may be the direct result of the findings discussed in the previous Chapter 6 that showed patients who consulted an ESP perceived more reassurance (RB, GR, CR,) than patient consulting a surgeon. Nonetheless, it is surprising that there was no difference in acceptance of explanation between the groups, although patients who consulted an ESP perceived more CR. As discussed in the previous chapter, the observed differences may also result from the differences in the consultation length of time, whereby ESP's had more time (approx. 20-30 min) than surgeons (approx. 10-15 min). Although in primary care longer consultations have been associated with better quality of communication/care and improved health outcomes (Mayor, 2016), an updated Cochrane review, examining interventions to increase or decrease the length of consultations, concluded that there is a lack of high quality studies and hence the benefits of longer consultations remain unclear (Wilson, Childs, Gonçalves-Bradley, & Irving, 2016). A study using video recordings of 40 practice consultations with trainee GP's found that short consultations with high technical medical efficiency were related with bad communication and dissatisfaction (Goedhuys & Rethans, 2001). However, authors concluded that the 'pure' length of the consultation is not the determinant of the quality of the communication nor of satisfaction ratings, but rather that principles of good communication (measures using MAAA-Global, based on national guidelines on medical content and communication), such as careful listening, explaining, and negotiating, require time that cannot be compressed unless at the cost of the quality of the consultation. A cross-sectional study analysed 440 video-recorded GP consultations and associated patient experience questionnaires to examine the relationship between consultation length and patients reported communication (e.g. listening to you, taking your problem serious, asking about your symptoms...), trust, confidence in the doctor, and overall satisfaction (Elmore et al., 2016). They found no association between consultation length and patients

experience of the communication, trust, confidence in doctor, nor overall satisfaction. The authors suggested that especially for patients with chronic, complex or multimorbid conditions longer consultations may be required for maintaining clinical effectiveness and patient safety, which is associated with high- quality care. Excellent communication skills are required for the delivery of high-quality care, which is particularly important for orthopaedic surgeons and their teams because they need to conduct conversations about complicated medical issues, treatment choices, complexities of surgical procedures and options, whilst building trust and allaying patients' fear during short visits (Levinson et al., 2013). A study exploring the quality of informed decision-making in orthopaedic practice, by analysing 133 audio recordings of consultations with older patients (60+) where surgery was discussed, found surgeons expressing fostering information decision-making communication did not have substantially longer visits than their colleagues (Braddock et al., 2008). The authors found excellent informed decision-making is feasible and suggested specific strategies how surgeons can conduct effective informed-decision making conversations within the constraints of a busy clinic.

Predicting short-term outcomes

Enablement and Satisfaction

When comparing the median of enablement and satisfaction scores from the current study to the study in primary care (Holt et al., 2018), it becomes evident that patients in secondary care felt overall more satisfied and enabled coming away from their consultation than patients consulting GP's.

Regardless of the differences between sites, consultation professions, treatment outcome, and consultation-based reassurance is directly associated with short-term outcomes. Especially, the association with satisfaction was strong for all four types of reassurance. This provides support for the findings of the primary care study that indicated consultation-based reassuring behaviours by GP's are most notably associated with increased patient satisfaction (Holt et al., 2018). Although all four reassurance variables were significantly correlated with enablement, the regression analysis revealed that only higher levels of perceived GR were associated with an increased sense of enablement, post- consultation. This is in line with previous

research not only showing effective reassurance improves immediate consultation outcomes but further that regardless of the information provided, patients accepted empathic messages (GR) as enough to feel enabled immediately after their consultation (Holt et al., 2018; Pincus et al., 2013).

Acceptance of explanation

Research evidence suggests receiving a full assessment, a consideration of their individual context, and sharing information facilitates acceptance (Hopayian & Notley, 2014). This is in line with the findings of the current study which showed that patients who perceived high levels of DG and CR were more likely to accept the explanation they received. This is also in line with findings from our qualitative study in which patients felt they needed clinician ‘to have done all the investigations they possibly could before providing explanations and recommendations’ (Braeuninger-Weimer et al., 2019). Patients who were less depressed at baseline were also more likely to accept their explanation, post-consultation, which might be because they were more able to engage in the cognitive process of finding meaning behind the explanations provided by the practitioner and able to link those back to their problem, a fit necessary for acceptance of diagnosis (Serbic & Pincus, 2013). Acceptance of explanation was a one-item measure, asking patients whether they agreed with the explanation or not, which in some cases may have not only been interpreted in relation to diagnosis, but in terms of accepting the explanation for not being recommended surgery. In most cases, visible evidence, such as imaging results, were present and used by practitioners in the consultation to reassure patients that there is no clear indication for surgery. Although negative test results do not provide the long-awaited proof of their symptoms, it reassured patients that their back is not ‘bad enough’ for surgery, which was often considered a relief for patients directly after their consultation (Braeuninger-Weimer et al., 2019). However, there is evidence to suggest that as a result of ‘there is nothing wrong with your back diagnosis’, some patients may return to the search for meaning, experience heightened anxiety, and engage in further health care seeking due to a mistrust in clinicians, later on (Linton et al., 2008). At worst, in the absence of positive test results, patients may feel that the specialist does not believe their accounts of pain, undermining the legitimacy of their problem, leading to increased feelings of guilt

(Serbic & Pincus, 2013), increased worry (Michie et al., 2004) and to patients asserting their complains more forcefully (Salmon, 2006).

Catastrophizing

Psychological factors, such as catastrophizing, have constantly been associated with disability and pain intensity in people with LBP (Vranceanu et al., 2017), yet the role of catastrophizing as a contributing factor for the development of chronicity gained only weak support (Pincus et al., 2002). According to the fear- avoidance model, negative beliefs about pain and negative illness information may lead to patients responding with catastrophizing beliefs in which they imagine the worst possible outcome, resulting in distress and fear-avoidance behaviours (Wetli et al., 2014). Nonetheless, we did not use a full and comprehensive catastrophizing measure, yet only collected data on one aspect of it, the thought that something else, serious, is going on undetected.

The findings from the current study suggest that even after controlling for the differences in treatment outcomes and consultant professions, patients who consulted a surgeon without being recommended surgery and those who perceived lower levels of CR, were more likely to leave their consultation believing there is something else going on in their back, which has not yet been diagnosed. Thus, patients who saw an ESP in contrast to surgeons and those who perceived higher levels of CR endorsed the one-item question less. Patients who were recommended surgery were less likely to endorse the item, most likely because they received a clear diagnosis, taking away the feeling of uncertainty about something else serious going on which is undetected. As previously discussed, differences in consultation length may be the reason for the perceived difference in reassurance behaviours between consultant professions. Thus, it may be suggested that because ESP's had more time, they were able to deliver CR more efficiently, which lead to the reduction in catastrophizing thoughts of patients.

Intention to further see health care and reassurance (discharge group only)

For the discharged group, 63.2% of patients stated they intended to seek further consultations elsewhere. This strongly suggests that reassurance, which as guidelines recommend should promote self-management (Savigny et al., 2009), has failed

miserably. In addition, the percentage of people who reported having the intention to re-consult elsewhere is most likely an underestimation. Long-term LBP patients who were discharged from care were often frustrated and thus stated ‘there is no point’ of seeking further care, which was a response resulting from not knowing where to go next nor wanting to go back to their GP and hence back into the endless care-seeking cycle they came from, before consulting the specialist (Braeuninger-Weimer et al., 2019). Those patients would have reported that they do not intended to seek further consultation not as a result of effective reassurance and the motivation to self-manage their condition, instead, they had virtually ‘given up’ on the health care providers or health care system and in finding a solution.

Around 62% of patients who were discharged, in the current study, reported they did not receive the chance for a 6-months open appointment. Findings from the previous qualitative study indicated patients who were discharged not only appreciated open follow-up appointments but also needed it to feel reassured. The results from the regression analysis revealed that discharged patients who were recruited from site 3 and those who perceived high levels of RB, were less likely to have the intention to re-consult. Site being a predictor for further care seeking may be due to patients, recruited in site 3, feeling overall more satisfied with their consultations than those recruited in the other sites. Patients who received less RB were more likely to seek further consultations elsewhere. The findings are in line with the results of a study looking at the motives of 2880 new patients, visiting orthopaedic outpatient clinics in the Netherlands between 1996 and 1997, to seeking a second opinion (Van Dalen et al., 2001). They found that 30% of new patients sought a second opinion mainly because of communication issues, whereby patients felt disappointed with their original treatment or because they wanted more information about their condition and/or treatment. The evaluation of their relationship with their first consultant was the strongest predictor for patients’ inclination to initiate a second opinion, whereby, patients re-consulted not because they doubted the competence of the consultants, but because of a lack of trust in, or dissatisfaction with, the practitioner who provided the first opinion. The authors urge medical educators to increase their efforts to improve specialists’ communication and hence RB.

Predicting long-term outcomes

Consultation-based reassurance significantly predicted long-term outcomes. Comparing the average pain, disability, anxiety and depression levels from baseline with the 3-months follow-up showed little differences. The cohort studied were chronic pain patients, hence there was little change expected over time in pain and disability. None of the four reassurance types significantly predicted pain at 3-months follow-up.

Disability and depression

High levels of disability at 3-months follow-up were associated with higher perceived CR for patients who were older, more disabled and depressed. Similar results were found for depression at 3-months follow-up, whereby, being older, more disabled and depressed, and perceiving lower levels of GR and higher levels of CR was associated with more depression later on.

Findings suggest that older people suffer more disability and are more distressed, which is positively associated with CR. This may either be because patients did not understand the information provided, or they did not accept it, or it was delivered poorly. Evidence suggests that health care providers' communication is worst with older patients with chronic LBP (Gilbrandsen et al., 2010). The authors stated that the success of CR relies on patients' ability to receive and process the information, yet practitioners often believe that older patients are less capable of this and their improvement may be small, so clinicians often avoid discussing their prognosis. In the previous Chapter 6, we found that patients who were older perceived more DG and RB, which suggests practitioners may have focused on those aspects of reassurance, whereby, neglecting the provision of effective GR and CR. Concerning GR, our findings are contradictory to Coia and Morely's (1998, p. 384) proposition that practitioners should 'withhold their ubiquitous and largely nonverbal attempts to provide emotional reassurance to patients'. Arguably, the findings pose the question of whether GR might be of benefit to patients with long-term LBP, especially to older groups who might be more traditional and prefer a more practitioner-led consultation to shared decision making?

Similarly, findings are contradictory to Pincus et al.'s (2013) evidence indicating CR but not affective reassurance was associated with better long-term outcomes. In terms of CR, the findings are in line with the results from the previous research in primary care which found that a high-risk profile and high CR were associated with worst disability at follow-up whilst the opposite was true for the low-risk group (Holt et al., 2018). However, the findings are contradictory to most of the previous literature suggesting that CR helps patients to manage their pain and hence improves patients' long-term outcomes (Coia & Morley, 1998; Pincus et al., 2013; Holt, Pincus, & Vogel, 2015; Traeger et al., 2017; Braeuninger et al., 2019). It might be that complex patients perceived explanations and information in the consultation as more negative. It might also be that practitioners perceived patients' risk as high and so avoided generic statements, especially those about an optimistic outcome, which they know is not likely. Whether messages such as, 'there really is not much we can do, hence off you go or you need to manage it yourself' may have led to adverse behaviours remains unknown. As mentioned in the previous Chapter, without having an audio or video recording of the actual consultation contents, it remains unclear whether lower levels of perceived GR, or, the interaction with high levels of CR, or, a shared influence of both, are responsible for worst patient' outcomes.

Anxiety

Although reassurance significantly added to the predictive power of the model, none of the four reassurance variables showed a significant association with anxiety at 3-months follow-up. Instead, findings indicated that lower levels of education predicted increased anxiety at follow-up. This is in line with the findings of a cross-sectional study examining the association of risk factors with the prevalence of anxiety and depression in patients with chronic neck pain ($n = 80$), which found that less educated patients had higher chances of being anxious and depressed at 3-months follow-up (Elbinoune et al., 2016).

GP visits

Patients who were less disabled and perceived less RB were more likely to report more GP visits, at 3-months follow-up. This confirms the prediction of short-term outcome, where discharged patients who perceived lower levels of RB were more likely to report the intention to re-consult. Although adding reassurance is

significant, it only accounts for an additional 3% of the variance explained in GP visits. It could be argued that the size of this additional variance explained may not translate to clinical significance. In contrast, it could also be argued that although the effect is extremely small, because the prevalence of back pain is so common, and the clinical and societal costs are so high, even a shift of around 3% would make considerable improvements. In addition, although the effect is clearly very small, it should be remembered that this is an observational study of untrained clinicians, with no stratification to address patients' needs. If we can detect a significant difference, albeit with a small effect size, under these circumstances, what effect might we have when we intervene and train clinicians? The evidence with orthopaedic outpatient department, which was previously outlined, hence supports both findings in that the relationship with the practitioners is the most predictive of patients' seeking another opinion (Van Dalen et al., 2001). In addition, the evidence discussed in the review paper which examined reassurance with non-specific conditions, suggested that practitioners should be primarily empathic and collaborative when attempting reassurance to avoid patients feeling misunderstood and seek another option (Traeger et al., 2017).

Sick-days

Patients who were referred to another treatment (largely, to injections or physiotherapy) reported on average more sick days (13 days) than those who were discharged (8 days). Perhaps, being referred to further treatment provided some legitimacy to taking time off work? A prevalence study with chronic LBP patients ($n = 4437$) in North Carolina, indicated that 40% considered themselves as permanently disabled from employment, thereby, bed days and days off work varied widely, the median was 3 days for both, and the mean was 25 bed days and 20 days off work, per year (Carey et al., 1995). The average number of sick days reported in the current study was much higher with an average of 11 sick days over the past 3-months.

Of those patients who worked ($n = 163$), higher levels of risk on the StartBack scale and higher perceived GR were associated with more reported sick days at 3-months follow-up. A study examining the StartBack tool as predictor for work ability, found that high-risk was associated with poor work ability (Forsbrand et al., 2018).

A systematic review (n = 17 studies) assessing risk factors that predict sickness absence in patients with chronic LBP, concluded that there is no consistent evidence to suggest a general core set of predictors for the total number of sick leave days (Kuijer, Groothoff, Brouwer, Geertzen, & Dijkstra, 2006). However, the study found consistent evidence for patients own expectations of recovery in predicting sick absence at the moment of follow-up measurement. One of the items, selected from the StartBack tool, used in the current study, was whether patients agreed or disagreed with ‘feeling that their back is terrible and never going to get better’. This may be considered as an indicator of patients’ expectations of recovery, which has previously been linked to sick days. A more recent systematic review (n = 22 studies) on factors that predict duration of sick leave in acute and chronic LBP patients, also showed workers’ recovery expectations remain the most important predictor as well as age, functional capacity and claim related factors (Steenstra et al., 2017).

Although patients who perceived more GR felt more enabled, post- consultation, GR may have led to worst outcomes later on. The findings are only partially in line with the results from the study in primary care (Holt et al., 2018), which likewise found GR was associated with an increased sense of enablement, post- consultation, but contradictory found GR lead to a small decrease in pain, at 3-months follow-up. Moreover, the results from the current study are in line with the previous literature (Coia & Morley, 1998; Pincus et al., 2013), suggesting affective reassurance may reduce anxiety and so lead to an increased sense of enablement, shortly after the consultation, but once the problem returns, later on, patients are left without new tools to manage their pain and hence may report more sick days. There seems to be some controversy in the association of GR and outcomes, whereby on the one side, less perceived GR was associated with more depression, and, on the other side, higher levels of perceived GR were associated with more sick days. Whereas the first may reflect practitioner’s reluctance to provide GR to patients with high constant disability, since they are aware that they would be providing false reassurance, the second may reflect the point Coia and Morley (1998) made.

Strength and limitations

To the authors' knowledge, this is the first study that has investigated the association between perceived reassurance and patients' outcomes in patients with chronic LBP consulting in orthopaedic surgical setting. This association has been investigated previously but the setting was in primary care and the analysis did not entail a 'true baseline' measure (Holt et al., 2018). Whereas, the current study measured patients shortly before their specialist consultation, shortly after, and at 3-months follow-up, allowing for the comparison of outcome variables to measures taken before the consultation. The study was able to attract a large and diverse cohort of chronic LBP patients and collected comprehensive data in regard to demographics, psychological constructs, reassurance, short- and long- term outcomes, whilst maintaining a low follow-up attrition rate for both time points and thus increasing the study's ecological value.

To achieve a broad recruitment spectrum, 8 different hospitals were used for recruitment. Nonetheless, we found significant differences between sites on patients' baseline characteristics, perceived reassurance, and their outcome variables. Although we controlled for the observed differences between sites in our analyses, it may be argued that there are factors relating to this observation that may have been ignored but are of potential bias. The follow- up period in this study was restricted to 3 months. Although it is unlikely that long-term persisting LBP patients have major changes in their outcomes when measured over a longer period, future research should examine the effect of reassurance on outcomes further down the line. In addition, previous research in primary care (Holt et al., 2018) showed that the risk-profile interacted with reassurance for certain outcomes. This was not assessed in the current study but should form a priority for future research.

Conclusion

Consultation-based reassurance is associated with short- term and long- term outcomes in patients consulting orthopaedic teams for chronic low back pain. Higher levels of perceived relationship- building play a key role in patients' further health care seeking intentions and behaviours. Therefore, all health care providers, who are involved in the care for chronic LBP patients, might benefit from training in advanced RB skills in order to reduce the extremely high care utilization for this

problem. The results also suggest that low levels of perceived GR and higher levels of CR are associated with worst outcomes, in the form of more disability and depression, but GR was also positively associated with more days off work. Further research is required to disentangle the relationship between GR and CR on patients' outcomes. Our findings provide support for some aspects of the consultation-based reassurance model, for example that CR is directly associated with long-term outcomes, but they also bring out more questions that require clarifying, such as what is effective CR and for whom? The original consultation-based reassurance model does not propose that any sub-category has a particular association with any specific outcome, and in reference to satisfaction our results indicate that this appears to be the case, because they are all equal. However, in reference to long-term outcomes, RB appears to be the most important in affecting further GP visits, CR appears to be most important for disability, and CR and GR, in combination, appear to be most important for depression. In addition, it depends on whether health care seeking and days off work are considered as medium-term or long-term outcomes. If they are considered as medium outcomes, then our findings support the model in that RB and GR are associated with medium but not long-term outcomes, whereas, if they are considered long-term outcomes, our findings would act as an extension to the model by suggesting that RB and GR not only impact on medium but also long-term outcomes.

Implications

The results challenge the current orthopaedic practice and should help focus future targeted interventions. The study provides support for the consultation-based reassurance model, suggesting that certain elements of reassurance are associated with certain outcomes not only for patients in primary care but also patients with long-term disabling LBP consulting in secondary care. The model provides a sound theoretical underpinning which could help to better identify and select patients for targeted treatments and thus help inform on the development and delivery of interventions. Such interventions may not involve patients but instead might involve the training of surgeons and their teams in reassurance to achieve optimized patient outcomes, or changes to the system to ensure that patients receive adequate reassurance regardless of the treatment they are recommended (if any).

It is likely that training programmes may be most beneficial when clinicians match their reassurance style to patients' psychological obstacles to recovery, such as their StartBack risk-profiles which showed to interact with reassurance and outcomes in primary care research (Holt et al., 2018). Research in primary care showed a few psychological obstacles (perception of personal control, LBP duration, illness identity, pain self-efficacy) were most predictive of outcomes for patients with LBP, thus some patients might require more help with making sense of medical advice than others (Foster et al., 2010). For example, the authors suggested the medical advice to keep active and self-manage might be unhelpful to patients with low self-efficacy and weak perception of personal control. Likewise, in secondary care, there might be specific patient characteristics or psychological obstacles to recovery that may be potential mediators and moderators to consultation-based reassurance and patient outcomes. Further studies need to investigate the potential pathways of influence to optimize reassurance and hence outcomes.

CHAPTER 7: DISCUSSION

The aim of this thesis was to examine key elements to effective consultation-based reassurance for patients with persisting, long-term LBP consulting orthopaedic spine teams. The consultation-based reassurance model, developed from evidence in primary care, showed that reassurance can be utilized to improve patients' outcomes. Nonetheless, there was a gap in the literature examining the role of effective consultation-based reassurance in patients with chronic LBP consulting in secondary care. Especially, for those patients for whom surgery was not indicated, whether that meant the recommendation of other treatments or no further treatment advice. In this thesis, we first reviewed the literature on low back pain (Chapter 1) and reassurance (Chapter 2) to build the foundation of required background knowledge to conduct empirical studies. Subsequently, we carried out a mixed-method design study (Chapter 3), which entailed qualitative work (Chapter 4), allowing the generation of theory of consultation-based reassurance adjusted to secondary care needs, and, quantitative work (Chapter 6 & 7), allowing the testing of the theory on a large cohort to generalize the findings. The qualitative interview study (Chapter 4) was conducted with 30 patients, who had consulted and been discharged from orthopaedic spinal care, and aimed to understand what they perceived as reassuring in their consultation. Lastly, the prospective cohort study was carried out to test the associations between consultation-based reassurance and patients' outcomes after the consultation, and at 3-months follow-up.

In the following Chapter we aim to outline how the findings of all studies discussed within this thesis informed the expansion of the existing consultation-based reassurance model to secondary care settings. This entails mapping the new findings of factors that associate with patient outcomes in orthopaedic care, onto the existing model, whilst also outlining how those changes may inform on training needs for practitioners or on changes to the system.

Consultation-based reassurance for patients with LBP consulting orthopaedic care.

The existing consultation-based reassurance model (Figure 6) was developed through a stepped approach that combined systematic literature reviews (Pincus et al., 2013), qualitative research (Holt et al., 2015), the developing and testing of a measurement (Holt et al., 2016), and epidemiological research (Holt et al., 2018), in patients with LBP consulting in primary care. The aim of the original model was to address earlier messages of reassurance to reduce the risk of chronicity. The extension of the model is tailored to the needs of chronic LBP patients consulting in secondary care (Figure 7 and 8). It aims to inform on important factors of consultation-based reassurance that orthopaedic surgeons and their teams need to consider because they may have negative as well as positives impacts on patients' outcomes. As such, effective reassurance might improve adherence, appropriate utilization of health care, management, health and well-being. The extended version of the model (Figure 7 & 8) adapts the structure of the existing model but limits its presentation on the Figure to those outcome components that were actually measured in our prospective cohort study. The additional research evidence about practitioner, setting, patient, and problem characteristics relevant for orthopaedic settings is outlined in text instead of drawn on the figure to avoid confusion. As previously discussed, validation may be seen under the sub-type RB or GR. Therefore, two diagrams are proposed: the first includes validation in RB and the second places it with GR. This way future research could generate items to measure validation (or uses established questionnaires), and collect data from a large sample to allow structural equation modelling to test which model fits the data better. Although research findings suggest that validation increases levels of satisfaction and reduces negative affect and pain (Vangronsveld & Linton, 2012), we did not explicitly examine validation in relation to outcome in our studies.

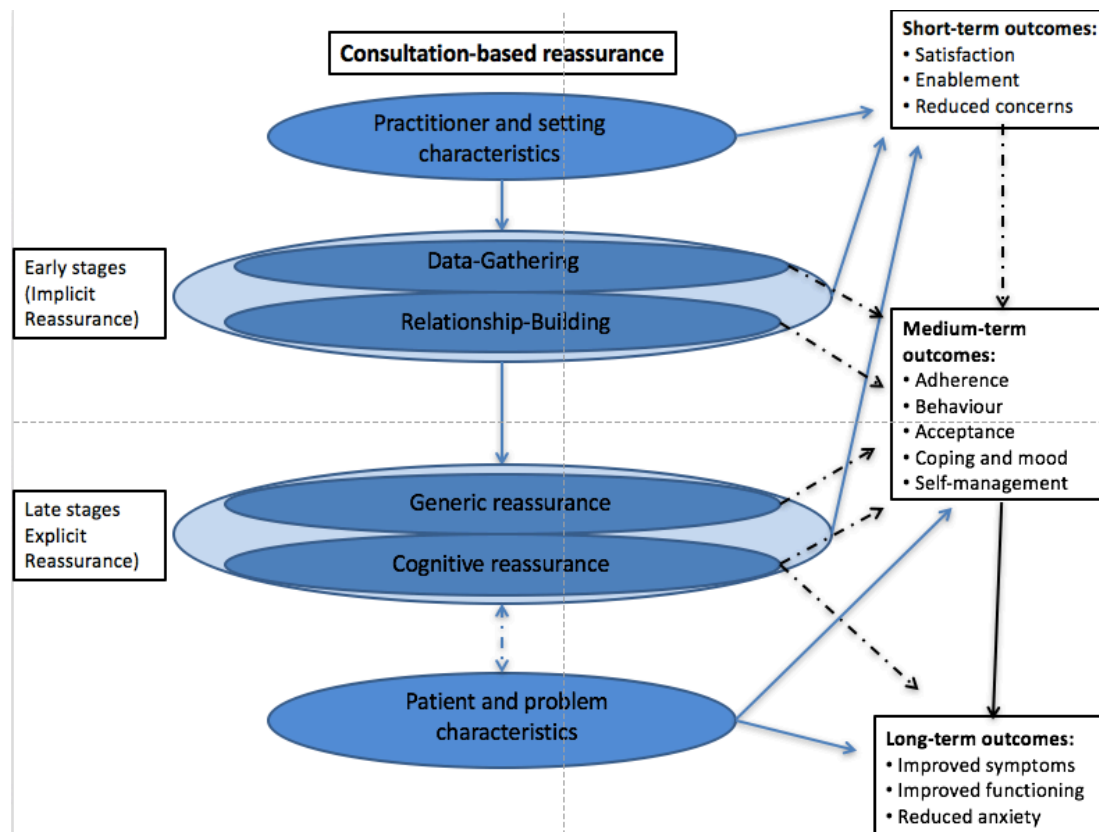


Figure 6: Existing consultation-based reassurance model

Notes: Dotted arrows = research priority; Solid arrows = associations with robust evidence.

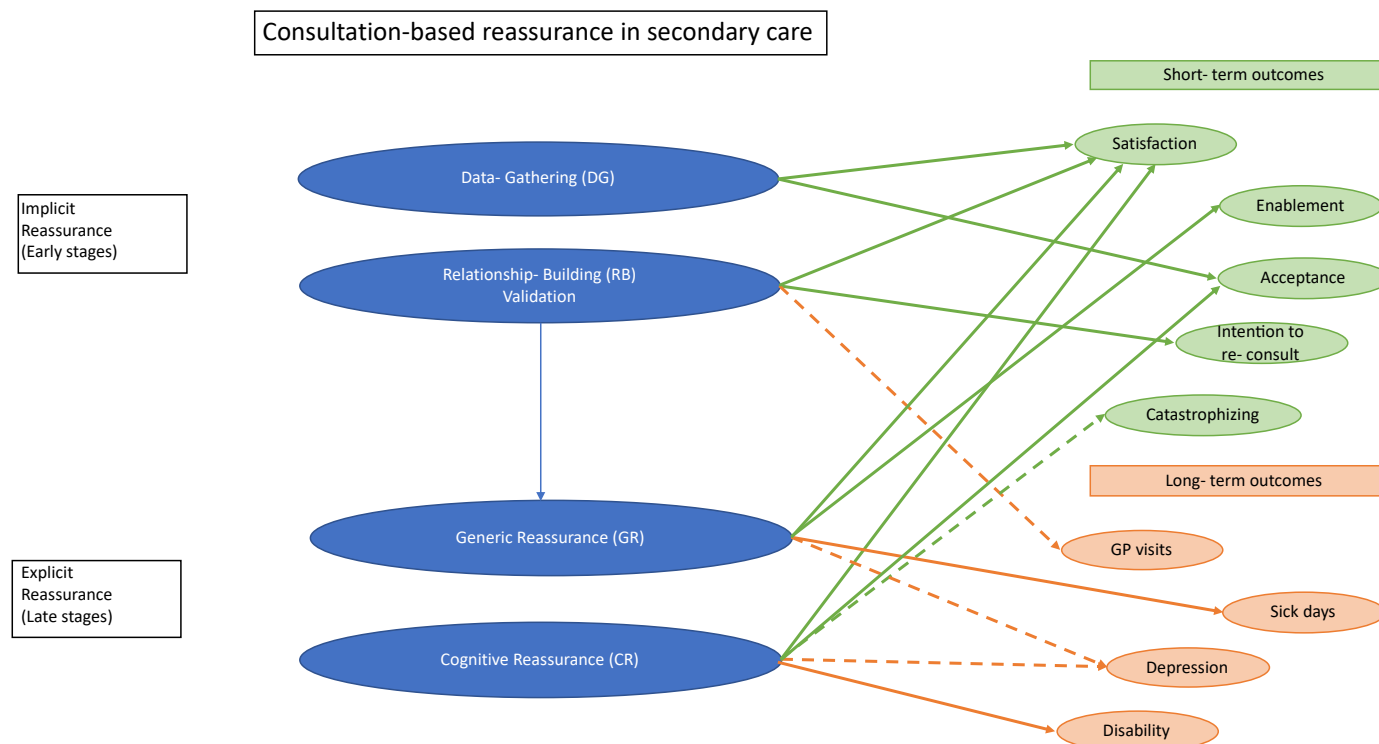


Figure 7: The consultation-based reassurance model and its associations with patient outcomes in orthopaedic settings. Validation incorporated under RB.

Notes: Dotted lines = negative associations with outcome; Solid lines = positive associations with outcome.

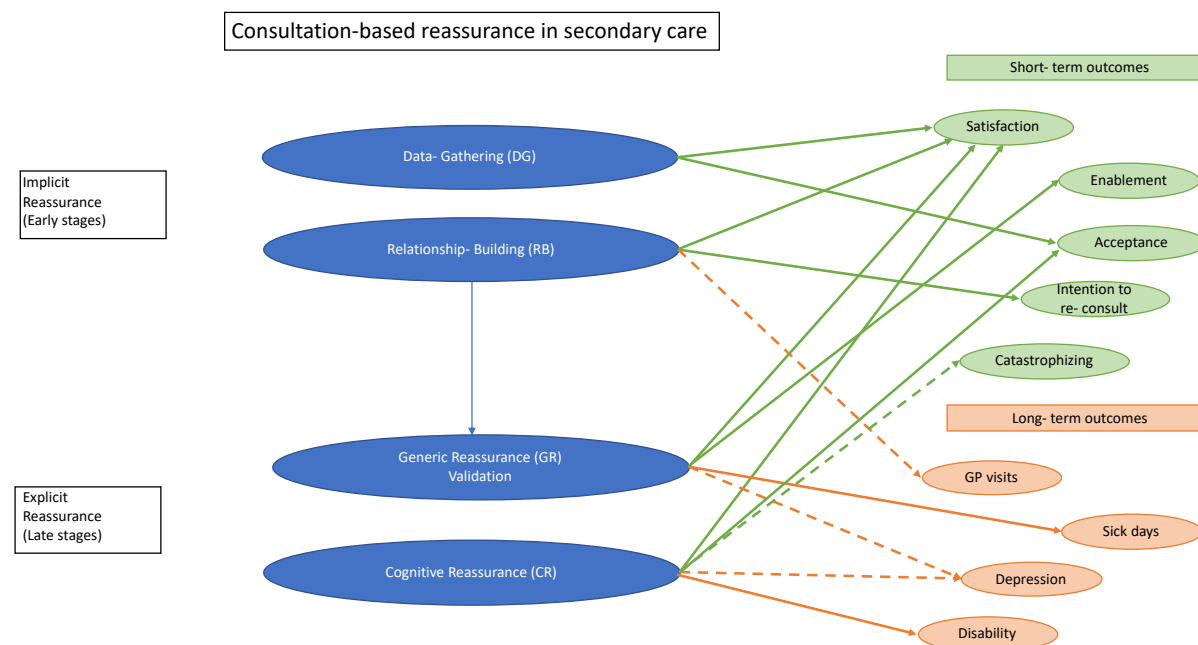


Figure 8: The consultation-based reassurance model and its associations with patient outcomes in orthopaedic settings. Validation incorporated under GR.

Notes: Dotted lines = negative associations with outcome; Solid lines = positive associations with outcome.

Practitioner and setting characteristics

In primary care, this domain of the model suggests that factors such as physicians' gender, intrinsic/personality characteristics, biases such as prejudices, mood, and the practice setting such as the waiting room, consultation room, or lack of time, are potential barriers to effective reassurance. Our work elaborates on this knowledge by showing that in orthopaedic care settings certain factors, some beyond the control of patient or health care providers, form barriers to communication and recovery too. Those factors specific to orthopaedic settings that were grouped under this heading were: **'treatment outcome', 'language use', 'site', 'practitioner profession' and 'consultation length'**. Unlike the model in primary care that suggested practitioner and setting characteristics affect reassurance and short-term outcomes, the extended model proposes that they also directly impact on long-term outcomes (e.g. treatment outcomes associated with reported sick days).

Treatment outcome

To begin, the treatment outcome (defined as treatment offered, and split into surgery, referral or nothing) is an important factor that associated with perceived reassurance and other patients' outcomes. In our studies treatment outcomes, especially being discharged without further treatment, was associated with satisfaction, catastrophizing, and further health care seeking. When no active treatment (discharge) can be offered, consultants need to address this by employing specific behaviours that make patients feel sufficiently reassured and encouraged to self-manage their condition (Braeuninger-Weimer et al., 2019). Our qualitative study revealed that patients who were discharged of care appreciated receiving open-appointments, which may lead to a reduction in their intentions to re-consult, immediately after the consultation. In addition, our quantitative study showed that RB is associated with patients' further care seeking behaviours. For practitioners this may suggest that they should offer open- appointments to those discharged and should improve the RB aspects in their consultation. Despite the abundant research on the importance of psychological factors in the care of patients with MLBP (Pincus & McCracken, 2013), orthopaedic surgeons tend to have a narrow biomedical focus, rather than being biopsychosocial orientated (Levinson & Chaumeton, 1999), which may act as a barrier to effective communication. Orthopaedic surgeons are often

reluctant to screen patients for psychological factors and refer them for psychological treatment because of a lack of time, stigma, and feeling uncomfortable, whereby, surgeons engaged in research are more likely to refer (Vranceanu et al., 2017).

Language use

Surgeons face the unique challenge of having to discuss complicated technical procedures that are confusing to nonmedically trained people (Levinson & Chaumeton, 1999; Levinson et al., 2013). In our qualitative study chronic LBP patients reported that they often did not understand consultants use of technical descriptions and medical jargon, which lead to dissatisfaction (Braeuninger-Weimer et al., 2019) and might also explain the finding of our prospective cohort study that high levels of perceived CR tend to associate with increased levels of disability and depression, at long-term outcomes.

A study found that orthopaedic surgeons, who are considered as more dominant, are more likely to be sued by patients for malpractice litigation because of their tone of voice, compared to primary care practitioners (Ambady et al., 2002). The expression of dominance by consultants is often perceived by patients as a lack of understanding, concern, and empathy, which are qualities that are important for effective reassurance. The authors suggest that particularly for surgeons ‘how’ (interpersonal) they convey information to patients seems to be just as important as ‘what’ (content) they say. One reason to account for this may be that surgical consultations are often emotionally stressful and patients may be especially sensitive to subtle cues of emotional communication (Ambady et al., 2002). Another reason may also be the use of language, which may increase the perceived power imbalance between consultants and patients, hence making patients even more sensitive to the display of dominance (Ambady et al., 2002) and the feeling that consultants are difficult to approach (Braeuninger-Weimer et al., 2019). According to the findings of our focus group with clinicians, this problem may be solved by using different practitioners, such as ESP / MSK teams, to conduct consultations where surgery is not indicated.

Sites

In terms of setting characteristics that impact consultation-based reassurance and outcomes, our work showed that recruiting sites (Chapter 5) were associated with patient's health status at baseline, reassurance rating, and their short- and long-term outcomes. This indicates that how the health care system is structured, the care journey that patients have to go through, is key to their quality of care and affects patients tremendously. Our qualitative study suggested that problems such as 'the long referral times pre-consultation', which might entail some patients having to wait months between their MRI and their specialist consultation, often resulted in frustration. Moreover, how expectations are managed pre-consultation may affect patients' expectations and their health status at baseline. Considering our different recruitment sites operated through different systems, some better than others, our work suggests that certain changes to site management and pre-consultation screening procedures should be implemented by the individual operating sites to substantially improve quality of care. Our findings propose system changes, such as sending out of pre-consultation letters, applying appropriate pre-screening practitioner allocation procedures, setting up MSK teams, might substantially improve patients' health care journey, resulting in improved health statuses.

Practitioners' profession and consultation length

This brings us to our last factor that may act as a barrier to communication and recovery, namely the practitioners' profession. Our findings from the qualitative study suggest that patients were often disappointed when consulting an ESP, rather than a surgeon, because they felt they needed to be told surgery is not an option by someone of highest authority and credibility. This was coded underneath 'seeing the right person', which matched onto RB. However, the findings from our prospective cohort study showed that reassurance delivered by an ESP, rather than a surgeon, was perceived as more reassuring by patients and resulted in better patient' short-term outcomes (satisfaction, enablement, acceptance, catastrophizing). Moreover, there was no differences in patients' baseline characteristics between the two professions, suggesting patient's allocation was often at random. There are numerous explanations for the association between consultant's profession and perceived differences in reassurance that may account for this. The consultation length may have been a contributing factor. More time may be required for effective reassurance

to be conveyed or for patients to feel more reassured. Patients in our qualitative study often stated that being ‘rushed, like on a production line, quick in and out’ made them feel dismissed. However, previous research in primary care suggests that patients can report good experiences from very short consultations (Elmore et al., 2016), which is supporting by the findings from our qualitative study where a few patients, mainly male participants, expressed the attitude of ‘why beat around the bush’ indicating they appreciated the short and direct consultation style when being told that there is nothing further to offer. Nonetheless, if the reason for the observed differences between ESP’s and surgeons is the consultation length, then our results seem to indicate that longer consultations may be necessary for patients to feel reassured and thus achieve clinical effectiveness, especially for patients with complex LBP presentations who are discharged of care. This may be achieved by either allowing more clinic time when scheduling consultations, or, by allocating those patients to consult with a different practitioner, such as an ESP/MSK, who already have more time available.

Alternatively, the differences between surgeons and ESP’s may be due to differences in interpersonal and communication skills, which may be because of differences in their professional backgrounds or personality differences (e.g. dominance). If this is the case, our results indicate an urgent need to equip particularly surgeons with effective reassurance techniques. On the other hand, it might be more beneficial to change the process of care for patients with chronic LBP who are not offered surgery, instead of training surgeons to meet their specific needs. This may entail a change in care pathways, aiming to avoid the allocation of patients for whom surgery is not indicated to consult with a surgeon, since outside of surgery pain management and empowering patients to self-manage is beyond their remit. Further research needs to address the practicality and cost-effectiveness of interventions to train surgeons in effective reassurance compared to changing the process of care by allocating patients to different practitioners with more time. However, it could also be argued that our findings suggest that regardless of professional discipline, there is room for improvement in terms of optimizing patients’ outcomes, which might be achieved by training orthopaedic teams all together in effective reassurance when surgery is ruled out for patients with chronic LBP.

Implicit Reassurance (DG & RB)

According to the existing reassurance model, implicit reassurance at the earlier stages of the consultation, is the foundation for building rapport, trust and hence reducing patient's anxiety to allow the processing of information. Whereas the model developed in primary care suggested that effective implicit reassurance is important to increase satisfaction and emblemment (short-term outcomes), the extended model for secondary care, suggests that the early implicit stages of the consultation also associate with medium-term outcomes (e.g. more DG associated with increased acceptance, more RB associated with less intention to re-consult) and long-term outcomes (e.g. RB predicted GP visits at 3-months follow-up).

Data-Gathering (DG)

The reassurance questionnaires measures DG through 3-items that entail, 'encouraging to voice concerns regarding symptoms', 'listen skills', and 'summarising what patients' said'. Our qualitative study with chronic LBP patients suggested that those patients further needed practitioners to read their case notes, be familiar with their history, order tests and investigations, provide a physical examination, and ask them about their lifestyle, in order for them to feel that they 'know their whole story'. The study also suggested that the DG stages of the consultation were often rushed or not conducted thoroughly, which lead to patients leaving their consultation with dissatisfaction. Our prospective cohort study showed that patients, regardless of treatment outcome, did not perceive differences in DG between the practitioners (ESP/MSK versus surgeons). This suggests that regardless of practitioners' profession or the consultation length (ESP/MSK had 30 min and surgeons 10 min), DG can effectively be conveyed in a time-efficient manner. Nonetheless, for patients who were discharged, it might be important that practitioners take more time for the DG stages of the consultation, because patients need to know that the health care provider has 'done everything they could possibly do for them' (familiar with their history, ordered all investigations/ examinations, and know their whole story) before making the decision to discharge them. This information seems to be necessary for patients to accept not only the explanation they are provided with but further accept their, for some, rather disappointing consultation outcome (discharge).

Relationship- Building (RB)

The reassurance questionnaires measures RB through 3-items that entail, ‘showing that consultant understood concerns’, ‘putting patients at ease’, and ‘showing a genuine interest in their problem’. RB was categorised under the heading of affective reassurance because it involves expressing emotional-based behaviours such as bonding, empathy and expressing support (Holt et al., 2016). The results from our qualitative study suggested that for patients RB entailed ‘seeing the right person’: a practitioner who listens carefully, builds rapport, shows empathy, and where they feel he/she is credible, qualified and experienced. In the development of the consultation-based reassurance questionnaire, RB was identified by the extraction of the previous literature review (Pincus et al., 2013) as one of the key reassurance skills. Patients who lack trust in their health care provider may be more prone to seek care elsewhere and less likely to comply to their treatment (Thom et al., 2004). In orthopaedic care, the relationship with the consultant was found to be most predictive of patients seeking a 2nd opinion (Van Dalen et al., 2001). Our findings in quantitative study results support this by associating RB consistently, across short-term (intention to re-consult) and long-term outcomes (reported GP visits), with patients’ further care seeking behaviour. Alike primary care results, the previous outlined evidence and our supporting findings, seem to strongly suggest that RB is also a key aspect of reassurance in secondary care. When effectively conveyed, RB may reduce health-care utilization by encouraging self-management, which will lead to a reduction in the financial burden coupled with chronic LBP patients’ long-term reliance on healthcare professionals.

However, there are barriers to communication, some that were previously mentioned under the theme practitioner characteristics, that may be specific to orthopaedic surgeons and hence need to be taken into consideration when formulating training programmes. For example, research suggested that the dominance in surgeons’ tone of voice might be perceived by patients as a lack of understanding, concern, and empathy (Ambady et al., 2002). Our quantitative findings further showed that patients perceived RB to be higher in MSK/ESP’s compared to surgeons, which further suggests that there may be certain training needs that are specific to surgeons. Around 75% of orthopaedic surgeons feel that they communicate well with patients

and only 21% of their patients reported that they received adequate communication (Tongue et al., 2005), suggesting that there is a misperception between what surgeons think they convey compared to what patients perceive. Previous research associated the perceived lack of empathy, expressed by surgeons, with patients feeling that consultants failed to understand their concerns (Tongue et al., 2005) and the feeling of being rushed, which was found most predictive of dissatisfaction (Parrish et al., 2016). A review of empathy in the surgeon-patient relationship found that particularly orthopaedic surgeons are susceptible to the decline of empathy that begins during their early clinical years of medical school and may result as a by-product of the nature of their work (Han & Pappas, 2018). The authors argued empathy training is warranted and should be incorporated throughout residency training in the form of role-play, simulations, and apprenticeship to empathic role models. How to best develop interventions that successfully teach orthopaedic surgeons, who are regarded as ‘high-tech, low-empathy physicians’ (Portalatin et al., 2018), the skills of RB, which entails a certain degree of empathy, may be a rather complex task and beyond the scope of this thesis, yet it is a future research query that might be of utmost importance.

Explicit Reassurance (GR & CR)

The existing reassurance model proposed that explicit reassurance, at the later stages of the consultation, focuses on providing explanation and information, which should help patients to better understand and manage their condition. In secondary care, this may also entail conveying to patients that surgery is not indicated and why. In addition, it might also entail explaining that there are no further treatment options available, ideally in a manner that patients can understand and accept. The existing model and the model proposed from the findings within this thesis, both propose that explicit reassurance directly impacts short-term outcomes. The model developed in primary care coded the association between explicit reassurance and medium- and long-term outcomes with dotted errors to denote that there is no robust evidence but as priority for research. Our results extend this knowledge by showing that explicit reassurance directly associated with short- term outcomes (satisfaction, enablement), medium- term outcomes (acceptance, catastrophizing), and long- term outcomes (disability, depression). However, the association is not straightforward and thus may

still require further research to provide clarification. Most importantly, we found that explicit validation of pain and suffering is necessary.

Generic Reassurance (GR)

The reassurance questionnaire assesses GR through 3-items: ‘telling you that everything would be fine’, ‘tell you that there is no need to worry’, and ‘reassure you that there is no serious concern about your back’. Evidence from primary care found that higher perceived levels of GR increased enablement, at short-term outcome, and low-risk patients who perceived more GR were less depressed, at long-term outcome, whereas for high-risk patients the opposite showed (Holt et al., 2018). In addition, in secondary care, we found that patients with a high-risk profile, who perceived more GR, lead to worst outcomes (more sick days). This suggests that optimistic generic statements may not work well for patients with a complex psychological risk profile. It also confirms theoretical proposals that at first, directly after the consultation, patients may experience a reduction in anxiety as a result of GR (e.g. ‘don’t worry I’ve seen this before’), but further down the line, when their pain returns and the reassuring practitioner is no longer present, patients have no new tools to manage their ongoing problem (Coia & Morely, 1998).

In secondary care, practitioners need to convey to LBP patients that surgery is not indicated because there is no serious underlying pathology existing in their spine, as evidenced by imaging results, and hence ‘there is nothing to worry about’ and patients can continue staying active without further damage (Braeuninger-Weimer et al., 2019). However, providing this type of GR to chronic LBP patients, who have consulted numerous times in the past with different practitioners who provided them with the same message (‘don’t worry, all good, you’ll be fine’), often lead to patients not being able to reconcile this message with their on-going and persisting pain experience. At worst, patients feel that their problem was undermined and dismissed, which resulted in increased worry. The results from our prospective cohort study that indicated perceived higher levels of GR were associated with increased satisfaction and enablement, at short-term outcome, whereas, at long-term outcome, it was associated with more reported sick days, which confirms Coia & Morley’s (1998) theoretical claims. On the other hand, for more complex pain patients (older, more

disabled & depressed), who perceived lower levels of GR (& more CR), it associated with more depression, at long- term outcome. This suggests that practitioners might purposely withhold their attempts to providing this type of GR, which might be false reassurance, because it feels wrong to tell persisting, long-term LBP patients ‘not to worry’ and that ‘everything will be fine’. One way to overcome this problem may be by teaching orthopaedic teams to withhold their attempts to provide positive, optimistic expectations to patients with complex chronic LBP (such as ‘there is nothing serious/to worry about’, ‘it’ll be fine’), but instead, teach them how to provide explicit, empathic validation of their pain and suffering (Braeuninger-Weimer et al., 2019; Edlund et al., 2015; Edmond & Keefe, 2015; Linton et al., 2012; Linton, 2015; Linton et al., 2017).

Cognitive Reassurance (CR)

In primary care, providing effective CR (education and information) has been linked to improved outcomes not only short-term but also long-term because it equips patients with tools to manage their condition later on (Coia & Morley, 1998; Pincus et al., 2013). Effective CR should result in a better understanding, better buy-in to clinical decisions and enhance self-efficacy, helping patients to control their anxieties and concerns even when the reassuring practitioner is no longer present. The consultation-based reassurance questionnaire assesses CR through 3-items: ‘they checked you understood the explanation you received for your symptoms’, ‘discuss how you could manage your problem’, ‘make sure you understood their decisions about management options’. In secondary care, patients felt that it was particularly important to get ‘peace of mind’ by knowing what their problem is and what they can do about it. In order to fully ‘get to grips with their problem, CR’ patients felt they needed consultants to provide information and explanations in simple terms and provide a follow-up letter with a summary of the consultation and outcomes. Especially for patients who are discharged, it is important to discuss a care plan with future management steps tailored to the patients’ needs and to employ an open- door policy that allows them to come back when their problems re-arises and feel they cannot manage by themselves (Braeuninger-Weimer et al., 2019). One patient stated she benefitted from having the option to email her consultant and stated it made her feel reassured knowing that there is one consistent person she can contact when in doubt about certain activities or management. Our qualitative study also suggests that

guidelines should not restrict the use of conservative treatment options, such as physiotherapy or massages, for patients with long-term LBP, since they felt helped for ‘short- term pain relief’, which they considered as necessary to ‘keep going’ with their enduring self- management journey of their persisting condition. A few patients in our qualitative work mentioned that they would be willing to pay as a contribution for the availability of services that offer physiotherapy, yoga, Pilates, and/or massages more readily available for their LBP.

Our study in secondary care extends the existing model by showing that effective CR does promote not only short-term outcomes, such as satisfaction, but also medium-term outcomes, such as acceptance of explanation and a reduction of catastrophizing beliefs. In primary care, for the patients of the high-risk profile group, CR was associated with worst outcomes at 3- month follow (Holt et al., 2018) and in secondary care, CR was associated with worst outcomes for LBP patients who were older, more disabled and distressed (Chapter 7). This shows that although theoretically it makes sense that CR is associated with better outcomes as the literature suggested, there is something going wrong in practice which makes practitioners deliver it poorly, and/or patients not understanding and/or accepting it. Our qualitative study suggests that it is the use of language in which CR is conveyed that may be difficult for complex patients to understand and comprehend, hence when their problem re-turned later they were unable to manage their anxieties and concerns in the absence of the reassuring practitioner. It is the health care providers’ responsibility to convey information so that patients can understand, accept and act on. Therefore, patients may benefit in the long run from trained practitioners who know how to effectively convey CR, especially when faced with uncertainty, and how to match and tailor this information appropriately to patients’ needs, capabilities and preferences. For example, training programmes may entail speaking slower with older patients (Gilbrandsen et al., 2010), using fewer complex terms (Cohen et al., 2017), tailoring information to the individual needs (Braeuninger-Weimer et al., 2019), enhancing shared-decision making (Verlinde et al., 2012), discussing personal circumstances (Farin et al., 2013), etc. Although in medical school pupils are taught how to use lay-person terminology, our evidence seems to suggest that especially the older generation orthopaedic practitioners seem to struggle to convey the complex non-specific explanation of LBP to patients. Future trials should test single consistent

message for explaining the biopsychosocial processes of LBP to patient with chronic LBP. Our qualitative work suggested that only older patients seemed to be accepting of ‘wear & tear, degenerative’, a more natural cause that is age related, whereas, younger patients who have a lot of pain might become very angry about this explanation. Thus, complex patients with persisting long-term LBP might require different types of explanations. It should be priority for future research to investigate what constitutes of effective CR, in terms of providing an explanation for their LBP that even complex patients with high levels of pain, disability and distress can understand and accept, leading to better health and management of their problem in the long-term.

Patient and problem characteristics

The existing model proposes that there is no robust evidence, denoted by dotted lines, for the associating between ‘patient and problem characteristics’ and reassurance, however, it indicates robust evidence for the association with medium- and long- term outcomes, as denoted by solid arrows (Figure 6). The work carried out within this thesis highlights the importance of this model element, because our findings show that there are certain characteristics that predict how reassurance is perceived and how they can interact with it in certain ways, leading to worst outcomes. As we have seen in the previous section, ‘complex patient characteristics’ that interacted with reassurance and were associated with worst outcomes, were older, more disabled and depressed, less educated, and high- risk profile patients. Those ‘complex patients’ may require practitioners to adopt a certain style of reassurance to meet their special needs and achieve optimized outcomes. In addition, in Chapter 6, the results indicate that different characteristics interacted with perceived reassurance, either through patients’ perceptions, or through practitioners changing their behaviours towards certain patient groups. For example, our results indicated patients who tried more previous types of different treatments perceived or received (not differentiable) more GR, and patients who were more educated perceived or received more CR. Therefore, our work provides evidence that certain patients’ characteristics are directly linked, both ways, with consultation-based reassurance.

One problem characteristic that may also play a key role in the whole process of care of chronic LBP patients, concerns the cartesian dualistic framework that is adopted not only by patients but also orthopaedic surgeons and their teams. According to Cohen et al. (2011) the subjective experience of pain (state of consciousness) is entirely in the brain, which doges the dualism perception that there must be functional separation between the body and the mind. Nonetheless, patients with chronic LBP are consulting in a medical domain, orthopaedic spinal departments, which is still primarily shaped by entrenched biomedical thinkers. Likewise, patients often expect clinical reasoning and physical treatment advice for their condition which has no identifiable organic pathology regardless of ongoing pain and disability. This leaves little room for negotiation between the two parties, unless a change of conceptual frame other than the dualistic one is being developed, one that allows to account for the complex interaction of ‘psychosocial’ factors (Cohen et al., 2011). Therefore, there is an urgent need to design far reaching public awareness interventions, across the UK, with the aim to educate and hence encourage the departure of the body and mind dualism in association with the treatment of chronic LBP and encouraging a ‘mind over matter’ approach for the management of this long-wearing condition.

Conclusion

In conclusion, the findings of this thesis suggest that the health care journey for patients with persisting, disabling MLBP, and the perceived reassurance they received in their discharging consultation once all other treatment options had been exhausted, is important but often not optimal. Patients often feel discouraged and dismissed, which also translated into poorer short- and long- term outcomes. They require comprehensive and specific reassurance to promote self-management. Validation was identified as a key to effective reassurance that may provide practitioners with a useful tool to address patients’ suffering and emotional distress. A small but potentially important effect was the association between reassurance and subsequent visits to the GP and mood at follow-up. This demonstrates the intersection of two very important but fairly neglected areas in pain research: provider communication and patient health care utilisation. The work carried out within this thesis provides sufficient data to demonstrate the need for training orthopaedic teams. However, our research also indicated that reassurance is a highly

complex phenomenon, which becomes more difficult still because of torturous care-seeking journeys, and complex patients with persisting, disabling MLBP.

Clinical implications

There are number of clinical implications from our findings. In reference to care pathways, our findings indicate a strong need for creating a consistent care journey for patients. The findings also suggest the need for training of clinicians to adjust their reassurance style to the specific needs of this group of patients. Of importance is our finding that suggests the biomedical focus employed in orthopaedic settings is too narrow to effectively address the pain problem presented by our participants. This might be because orthopaedic teams have minimal training, if any, in psychologically-informed practice, yet, our research suggested that they see some of the most challenging and complex patients with persistent MLBP. It could also be argued that our work indicated that some of our patients' experience pain that is so persistent and entrenched that it is too difficult for surgeons and their teams to attempt to unravel its complexities within a single 15-minute consultation. Instead, it might require experienced pain psychologists to work as a part of the orthopaedic team, or, as direct referral from orthopaedic settings. Psychologists might be appropriately equipped to handle and address the emotional and psychological aspects of pain that are neglected in orthopaedic consultations. Specialist pain management psychologists may be more experienced and skilled in developing management plans designed for that particular patient that helps them to adjust their coping with their pain. This may entail changing beliefs about pain, addressing accompanying co-morbidities (e.g. depression, anxiety) and equipping them with effective coping skills (e.g. relaxation techniques). Since, for the majority of this group, the physical aspects of pain management have been exhausted, patients need to adopt a new way of thinking about their pain and psychologists may be best equipped to find solutions that improve their coping and quality of life, despite living with pain.

Contribution and future research

The findings from this thesis provide an excellent starting point for proposing an intervention development, since they outline what patients think they require to feel

adequately and appropriately reassured despite being discharged without further treatment options. The evidence is of qualitative and quantitative nature, with sufficient data to demonstrate that there is a need for training to improve communication in consultations. However, what is missing is the practitioners' point of view about what is feasible. As a next step, a qualitative study with surgeons should be conducted to gain an understanding of the specific areas that require training and what training would be acceptable to them. Subsequently, the developing and testing of an effective training intervention is required to eventually support the notion for a full clinical trial in the future.

Considering our findings on CR, and, similar findings from previous research in primary care, it is still unclear why it leads to worse outcomes. Thus, there is a need for research to investigate what exactly entails effective CR. What are the key messages in terms of explanation and information that complex patients with persisting long-term LBP require to successfully self-manage and how should health care professionals best communicate those messages so that patients accept and act on it? This research should incorporate videotaping actual consultations, and asking patients to view these and comment on their responses and thoughts when they heard each message. Since verbal communication is not carried out in isolation there is also a need to explore how non-verbal communication enhance or detracts from patients' buy-in, comprehension and acceptance.

There is also a need for future research to further examine the concept of validation in consultations. How does it really work, which behaviours are influenced by it, what are the effects on short- and long-term outcomes, how is it best delivered? Future research should expand the range of outcomes that are examined in the context with validation and also assess its influence on non-verbal pain behaviours, since they might also predict other important outcomes. There it might be important to also use an extensive audio or video taping of the communication to conduct additional analyses on the content and compare to the self-reported feelings of validation from patients. Research is warranted to study to what extent self-reported validation correlated with observed validation and which one would be more predictive of outcomes.

Despite the importance of effective communication between patients and surgeons, there are relatively few studies addressing this, which may lead to applying information from primary care when it is not appropriate to this specific interaction (Levinson et al., 2013). The empirical work carried out within this thesis added to the synthesis of existing evidence by extending the models' known predictors of outcomes to patients consulting in orthopaedic secondary care settings. Our findings suggest that consultation-based reassurance requires to be adjusted to the specific needs of patients consulting in orthopaedic care. It provides speciality specific information to what patients want (qualitative study, Chapter 4) and need (prospective cohort, Chapter 5 & 6) to feel reassured and hence cope better with their condition after the consultation. Yet, it is still unclear how to best teach surgeons and their teams about effective reassurance.

Although this thesis highlighted the importance and urgency of effective consultation-based reassurance in orthopaedic care and may have helped to identify specific factors that are key to improving the communication and patients' outcomes, there is still a long way to go before administering effective communication training interventions for surgeons and their teams. Our secondary care adjusted reassurance model is complex, and interventions for enhancing reassurance will be too because they include practitioners and patient beliefs, values, behaviours and factors associated with quality of care. Therefore, more research is required to inform on how this new information can be translated into targeted training programs and how those can best be delivered to achieve improved interpersonal and communication skills for surgeons and their teams. An example of an effective training method that future research should explore is the use of audio-taped consultation interactions and feedback about their communication (Ambady et al., 2002). This may facilitate an enhanced awareness, making surgeons understand that patients may perceive them differently to how they perceive themselves. A systematic review of 36 RCTs that assessed the effectiveness of communication interventions with practitioners, patients or both, concluded that they make a difference in conversations between physicians and patients (Rao, Anderson, Inui, & Frankel, 2007). Results indicated that the interventions for physicians enhanced their reassurance behaviours leading to higher ratings of their communication style and the exhibiting of patient-centred communication behaviours, compared to controls. The intervention for patients, in nearly all studies, were delivered in the waiting room and yet led to patients

obtaining more information per question and expressing more involvement, compared to controls. This suggests that communication skills can effectively be taught. One domain of the reassurance model that seems to be particularly important for our cohort concerns teaching surgeons and their teams' effective RB skills.

While our extension of the consultation-based reassurance model to secondary care settings informs on training programmes for surgeons and their teams, it also suggested that patient's communication behaviours, such as not questioning the consultants' advice because they perceive them as too superior and believe in 'doctor knows best', impacts the transfer of information during a visit. Practitioner's consensus suggested that patients' expectations should be handled before the consultation by sending out pre-appointment letters informing them about who they are seeing. There might be a benefit to extend this information with communication intervention elements to enhance patient's involvement in the consultation or at least make them aware of elements that they should insist on taking away from their visit. This could be in the format of a A4 sheet which provides patients with a simple tick list of items that group within the four reassurance domains (e.g. DG: 'Prepare a short summary of bullet points of your previous pain history and treatments you received', CR: 'Ask consultant for 3 lifestyle changes and 3 new management recommendations', etc.). Although the consultation-based reassurance model mainly concerns optimizing the method of reassurance, which is in the behaviour of the health care provider (Linton et al., 2008), its domains were developed through associations with empirical evidence demonstrating their relationship with what patients feel they need and their outcomes. By urging patients to prepare questions for each domain, it not only helps patients to take home the information they need for recovery but might also help practitioners to stay focused on consultation contents that are relevant whilst being time-efficient. According to Rao et al. (2007) communication needs to be viewed holistically, as a reciprocal exchange between patients and practitioners that should be embedded in 'patient-centred communication' which requires both parties to participate. The authors argue that effective communication cannot be expected from *'anticipating an elegant waltz to emerge on the ballroom floor when only one partner has taken dance lessons'* (p.347). Future research should explore communication interventions based on the

consultation-based reassurance model that not only target practitioners' behaviours but also equip patients with tools that can facilitate the information exchange.

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APPENDICES

Appendix A: Honorary Contract

Committed To Excellence Working Together Facing The Future

Frimley Health **NHS**

NHS Foundation Trust

Resourcing Team (HR)
Frimley Health Foundation Trust
Wexham Park Hospital
Wexham Street
Slough
Berkshire
SL2 4HL

Date: 16th January 2017

Private & Confidential

Kathrin Louise Braeuninger-Weimer

Via email kathrin.weimer.2013@live.rhul.ac.uk

Tel: 01753 634340
Fax: 01753 849239

HONORARY CONTRACT

Dear Kathrin

I am pleased to offer you an honorary contract as **PhD Student** with **Frimley Health NHS Foundation Trust**. Two copies of the contract have been enclosed, which you should sign and date. Please keep one copy for yourself and return the other to me as acceptance of the terms in this contract.

This contract begins on **1st November 2016** and ends on **30th June 2019**, unless terminated earlier in accordance with the clauses in this contract.

If your circumstances change in relation to your health, criminal record, professional registration or any other aspect that may impact on your ability to undertake your role, you must inform your nominated manager at Heatherwood and Wexham Park Hospitals NHS Foundation Trust.

Yours sincerely,

Chi Ming Cheung (Mr)
Resourcing Administrator

Appendix B: GP letter

Committed To Excellence Working Together Facing The Future

Frimley Health **NHS**
NHS Foundation Trust



Wexham Park Hospital
Wexham Street
Slough
Berkshire
SL2 4HL
Tel: 01753 634191
Fax: 01753 634315

www.frimleyhealth.nhs.uk

Dear Sir/ Madam,

I am writing to inform you that your patient has very kindly agreed to take part in a study investigating consultation-based reassurance for people with lower-back pain for whom surgery has been ruled out as a treatment option. This patient has been asked to attend an interview and complete questionnaires about their experience of a consultation they received for their back pain. The study aims to gain an understanding that will inform the development of training surgeons and their teams to better support people who were advised not to have surgery for their back pain.

This research is funded by ~~EuroSpine~~ in collaboration with the NHS. Either myself, or any member of the research team would be very happy to discuss the study in greater detail with you by phone or email.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Tamar', with a long horizontal stroke extending to the right.

Professor Tamar Pincus (Chief Investigator)



In Partnership with the Ministry of Defence

Frimley Health incorporates Frimley Park Hospital, ~~Heatherwood Hospital~~ and Wexham Park Hospital
Headquarters: Portsmouth Road, Frimley, Camberley, Surrey, GU16 7UJ 01276 604604
26 April 2017, V1

Appendix C: Ethics documents

HRA approval letters



Health Research Authority

Professor Tamar Pincus
Dept of Psychology
Royal Holloway University of London
TW20 0EX

Email: hra.approval@nhs.net

13 December 2016

Dear Professor Pincus

Letter of HRA Approval

Study title:	Consultation-based reassurance for people with low back pain consulting about spine surgery
IRAS project ID:	214210
REC reference:	16/LO/1833
Sponsor	Royal Holloway University of London

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

REC approval


Health Research Authority
London - Bromley Research Ethics Committee
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 02071048152

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

12 October 2016

Professor Tamar Pincus
Dept of Psychology
Royal Holloway University of London
TW20 0EX

Dear Professor Pincus

Study title:	Consultation-based reassurance for people with low back pain consulting about spine surgery
REC reference:	16/LO/1833
IRAS project ID:	214210

Thank you for your correspondence of the 12th October 2016. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 10 October 2016

Sponsor letter



Royal Holloway
University of London
Egham, Surrey
TW20 0EX

Craig Bryce
Head of Research Services

Research & Enterprise
+44 (0)1784 443844
Craig.bryce@rhul.ac.uk
www.royalholloway.ac.uk

12th September 2016

To Whom it may concern

Research Sponsorship for research project "Effective reassurance to people with LBP" funded by Eurospine

This letter is to confirm that Royal Holloway, University of London is prepared to act as Research Sponsor for the research project "Effective reassurance to people with LBP" which is to be led by Professor Tamar Pincus.

Yours sincerely

A handwritten signature in black ink, appearing to be "C. Bryce", with a long horizontal flourish extending to the right.

Craig Bryce

Public liability indemnity



To Whom It May Concern

Our ref: SN/IND

19 May, 2016

Zurich Municipal Customer: Royal Holloway and Bedford New College

This is to confirm that Royal Holloway and Bedford New College have in force with this Company until the policy expiry on 31 July 2017 Insurance incorporating the following essential features:

Policy Number: NHE-01CA09-0013

Limit of Indemnity:

Public Liability:	£50,000,000	any one event
Products Liability:	£50,000,000	for all claims in the aggregate during any one period of insurance
Pollution:		any one event inclusive of costs

Employers' Liability: £50,000,000

Excess:

Public Liability/Products Liability/Pollution:	£250 any one event
Employers' Liability:	Nil any one claim

Indemnity to Principals:

Covers include a standard Indemnity to Principals Clause in respect of contractual obligations.

Full Policy:

The policy documents should be referred to for details of full cover.

Yours faithfully

Zurich Municipal
Farnborough

Zurich Municipal
Zurich House
2 Gladiator Way
Farnborough
Hampshire
GU14 6GB

Telephone: 0870 2418050
Direct Phone: 01252 387877
Direct Fax: 01252 375893
E-mail: claire.purdy@uk.zurich.com

Communications will be monitored regularly to improve our service and for security and regulatory purposes

Zurich Municipal is a trading name of Zurich Insurance Group Ltd

A public limited company incorporated in Ireland. Registration No. 13460
Registered Office: Zurich House, Ballsbridge Park, Dublin 4, Ireland.

UK branch registered in England and Wales
Registration No. 887985.
UK Branch Head Office: The Zurich Centre,
3000 Parkway, Whiteley, Fareham,
Hampshire PO15 7JZ

Authorised by the Central Bank of Ireland and subject to limited regulation by the Financial Conduct Authority. Details about the extent of our regulation by the Financial Conduct Authority are available from us on request

Appendix D: Study 1 (Qualitative Interview documents)

Invitation Letter (1)



You are invited to participate in a study about Low Back Pain.

Study title

Consultation-based reassurance for people with low back pain consulting about potential spine surgery.

Introduction

You recently saw a surgeon about your back pain. We are interested in interviewing you about your experience, and showing you a questionnaire we are developing. We would like to invite you to meet with our researcher at your convenience, to discuss your experience and ask for your advice about our questionnaire.

Before you decide if you want to take part, please take the time to carefully read this information and talk to others if you wish. This information will inform you of what will be involved.

What is the purpose of the study?

Persistent back pain can be very difficult to deal with, and many people are advised that surgery is not the right treatment for them. For some this is a relief while for others it is a terrible disappointment. Very little is known about how to support people with low back pain when surgery has been ruled out, or about how to explain to patients why surgery is not the advised treatment.

This study will help us gain understanding of what people need to be told, and how best to reassure patients, even when they are advised that they will not be offered surgery for their back pain.

Why have I been chosen?

Your name has been identified by the surgeon you consulted as someone who was seen recently for back pain, and who was not advised to undergo surgery. Only NHS staff have access to this information, and until you respond to this invitation, the research team will not know who you are.

Do I have to take part in the study?

No. It is up to you to decide if you want to take part. This information sheet outlines important information related to the study to help you make an informed decision. If you decide not to take part, the usual care you receive from your GP or other practitioners will not be affected in any way. If you agree to take part, you can withdraw from the study at any time without having to give a reason.

What will happen to me if I take part?

We are inviting you to take part in an interview. In this interview, we would like to learn more about your experience: What you expected before you saw the surgeon, what you were told by them, how you felt afterwards. We will also show you our questionnaire and ask you for your opinion about the questions.

You will be contacted by phone in about a week by NHS staff to find out if you are interested in being interviewed and to arrange a mutually agreeable time and place for the interview. Before the interview starts we will answer any further questions you may have about this part of the study and ask you to complete a consent form. The interview, with your permission, will be audio recorded and should take no longer than one hour.

What are the possible risks of taking part?

We do not think there are any risks with taking part in this interview study. The interview will last no longer than one hour and can be ended at any time you like.

What are the possible benefits of taking part?

Whilst there may not be any direct benefits to you, we hope that the information we gather will inform our development of training for surgeons and their teams to better support people living with chronic back pain for whom surgery is not recommended.

Will my details be kept confidential?

Yes. All information that is collected during the study will be kept confidential at all times and held in compliance with the Data Protection Act 1998.

The interviews will be transcribed by a ~~third party~~ transcription services contracted to work on the research project, who has signed a confidentiality contract with Royal Holloway University of London. For this study we use the transcripts to find out what worked and did not work for patients in the consultation, and whether our questionnaire captures all the important points that patients tell us about their consultation. In the future we may use the recordings, and transcripts, of the interviews for other research. We might agree to share these with other, carefully selected, researchers; any such sharing will be closely monitored by the University. We may use written quotations from your interviews to illustrate academic presentations or publications based on this research.

On all occasions, we will ensure that any material that may identify who you are is removed before there is any analysis of your interviews.

What if there is a problem?

This study is covered by Royal Holloway, University of London's insurance and indemnity cover. If you have any concerns about this study, please contact the Chief Investigator of the study:

Professor Tamar Pincus
Professor in Health Psychology
Department of Psychology
Royal Holloway University of London
Surrey TW20 0EX
t.pincus@rhul.ac.uk
01784443523

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Lucy ~~Caton~~
Administrator, college ethics committee,
Royal Holloway University of London
Egham, Surrey,
TW20 0EX
Lucy.caton@rhul.ac.uk
01784434455

Who can I contact for further information?

If you have any questions about the study, or your involvement in it, either now or in the future, do please contact the study team using the details below:

**Kathrin Braeuninger-Weimer,
Kathrin.Weimer.2013@live.rhul.ac.uk
Department of psychology
Royal Holloway University of London
Surrey
Tw20 0EX
TEL: 07958480185**

Who is organising and paying for the study?

The study is being co-ordinated by Royal Holloway, University of London, and is being led by Professor Tamar Pincus. The study is funded by the charity ~~EuroSpine~~.

Who has reviewed the study?

Any research that involves the NHS and patients is subject to review by an independent group of people, called a Research Ethics Committee. This committee is there to protect your interests. This study has been reviewed and given favourable opinion by **London - Bromley Research Ethics Committee**, Reference 16/LO/1833.

You can also get support and information from The Patient Advice and Liaison Service (PALS), which offers confidential advice, support and information on health-related matters. They provide a point of contact for patients, their families and their ~~carers~~. Details on this service and information on how to find your closest contact can be found on line: <http://www.nhs.uk/chq/Pages/1082.aspx?CategoryID=68>

Thank you for taking time to read this information leaflet and for considering the study.

Please call or text this number 07958480185 to participate.

Consent form (1)



CONSENT FORM – PHASE 1 - PROCESS INTERVIEWS

Ethics ID: 16/LO/1833

Study	Consultation-based reassurance for people with low back pain consulting about spine surgery	Name of Investigator	Prof Tamar Pincus
Clinic number		Participant ID number	

Please **initial** (do not tick) the boxes below if you agree

1. I confirm that I have read the information sheet dated for the above study. I have had the opportunity to consider the information and ask questions.	↓ <input type="checkbox"/>
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	<input type="checkbox"/>
3. I am happy for this interview to be audio recorded. Transcripts will be held securely and only accessed by authorised study personnel.	<input type="checkbox"/>
4. I understand that these interviews will be anonymised and transcribed for analysis, and that this may be shared with other carefully selected researchers for further analyses.	<input type="checkbox"/>
5. I understand that brief, anonymous, extracts from the interview may be reproduced in academic and non-academic presentations and publications.	<input type="checkbox"/>
6. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.	<input type="checkbox"/>
7. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals the sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	<input type="checkbox"/>

8. I agree to take part in the above study.	<input type="checkbox"/>
---	--------------------------

Name of Participant (PRINT NAME)		Signature of participant		Date signed	
--	--	---------------------------------	--	--------------------	--

Name of person taking consent (PRINT NAME)		Signature of person taking consent		Date signed	
--	--	---	--	--------------------	--

When completed:
 1 signed **original** for Investigator on site file (ISF)
 1 **copy** of signed original **to the participant**
 1 **copy** for participant Medical Record

Telephone screening questionnaire

Exclusion:

- English insufficient
☐
- Problems comprehending
☐
- Problems providing informed consent
☐
- Other serious health issues (e.g. cancer, severe diabetes, rheumatoid arthritis)
☐

Other.....

.....

- Pregnant
☐
- Any previous spine surgery?
☐
- Leg pain
☐
- Litigation or work-related injuries
☐
- Scan showing nerve root entrapment, stenosis, or other surgical pathology ☐

Patient characteristics

Age:

Gender: Male ☐ Female ☐

Level of Pain: In the last week, that is in the past seven days, on average, how INTENSE was your pain rated on a 0 to 10 scale where 0 is “no pain” and 10 is “worst possible pain?”

0 1 2 3 4 5 6 7 8 9 10

No Pain

Worst Possible Pain

Level of interference with daily activities: How much did your pain interfere with your daily activities?

0 1 2 3 4 5 6 7 8 9 10

No interference
due to pain

Daily activities limited

Qualitative Interview schedule

Background:

So, tell me about your back pain.

1. How long have you had it?
2. How does it affect you?
3. How does it affect your mood?
4. How well are you managing your back pain now?

Expectations before consultation:

I will now ask you about your thoughts directly before the consultation with the surgeon.

1. What were you hoping to get from the consultation?
2. Was there anything you were particularly keen to discuss?
3. What did you expect in terms of treatment options?
4. How did you expect them to be presented? (Multiple list, one single option, personalized?)

What happened in the consultation?

Please tell me as much as you can remember about your consultation.

1. When was your last consultation?

2. Who was it with?
3. What did the consultant/surgeon tell you?
4. What did the consultant say the problem was?
5. What did you think when they said that?
6. What did you say?
7. When you walked out of the consultation what were you thinking/feeling?
8. Did he/she discuss a management plan with you?
9. How satisfied are you with the information you received from the consultation about your treatment options?

10. What terminology did they use to describe your problem? How you google your problem?
11. What do you think of that?
12. Is there another label you'd prefer?
13. What do you think condition means?
14. In your whole time of care- did a consultant show you a leaflet about your condition?

After the consultation:

15. In retrospect, do you feel your expectation have been met?
16. What concerns were/ were not addressed in the consultation?
17. Was there something else you would have liked to ask?
18. What did you find most/least reassuring?
19. Is there something else he/she could have said?
20. In retrospect what do you think about the decision not to have surgery?
21. How do you feel about this decision now?
22. Are you still worried about your back pain?
23. Will you seek further consultations?

Questionnaire advice

Now, I would like your advice on a questionnaire that we developed. It aims to measure how practitioners reassure patients when they see them for low back pain.

1. Can we go through the items and see if they make sense to you?
2. Is there anything missing in the questionnaire, which you think, is important?
3. Are there questions you would not know how to answer?

Closing:

Is there SOMETHING else you would like to add in terms of reassurance in your experience with LBP consultations?

Appendix E: Coding Framework

Initial Coding Framework/Themes	Initial Coding Categories/Sub-themes	Final Coding Framework	Final Coding Categories/Sub-themes	Final Coding Elements
Pain Background	Estimated Pain Duration	Factors external to the consultation	Pain & Impact	Causes
	Co-morbidity			Symptoms
	High Pain Threshold			Co-morbidities
	Impact on Life (Psychological, Social, Physical)		Management & Coping	Management
Symptoms	Magical appearance of LBP			Coping strategies
	Triggers making it worse (e.g. chemo)		Expectations & Beliefs	Pre-conceptualized attitudes
	Chronic Pain (progression of pain & episodic, always)			Hopes & Expectations
	Description of agony		Previous health journey	Duration
				Inconsistency (diagnosis, advice, person)
Management	Medication (+ views about meds)			
	Home remedies			
	Exercise → Rest			
	Massages			
	Yoga, Pilates, Aquatic			
	Physiotherapist			
	Chiropractor, Osteopath			
	Acupuncture			
	Injections			
	Pain Management			
	Other			
	Psychological			

	Adjustment			
Hopes & Expectations	Alleviate Pain			
	Treatments (Surgery expectations)			
	Cure			
	Scan			
	Consultant to be Active			
Pre-conceptualized Ideas	Factual			
	Medical domain			
ESP vs Surgeon	Not expert			
	Lack of power (can't refer, wouldn't know)			
Barriers to recovery	Undermining own knowledge/capabilities			
	Fear avoidance			
Situational Aspects	Mediators in consultation			
	Pain level at consultation			
	Consultation length of time			
NHS Journey	Inconsistency of care			
	Duration of Journey			
	NHS needs cultural change			
Imaging	Scan clear	Consultation & reassurance	Know my whole story (DG)	Past History
	Reassured			Tests (Imaging & Hands on)
	Views about imaging			Me as a whole person
Consultants Characteristics	Negative		The right person	Knowing what
	Positive			
	Observations			
	'Vibe' between the			

	both parties		(RB)	they doing	
				Listening	
Affective Behaviour	Consultant listened			They get me & I get on with them	
What did they say the problem is?	Explanation			Nothing to worry about (GR)	Everything will be fine
	Options				Validation
				Getting to grips with my problem (CR)	Explain what problem is
					Language & Terms
					I have options
	Open door - follow up				
After Consultation	Discharged with care direction	Response to consultation	Feelings after consultation	Delayed processing	
	Feelings about NOT having surgery			Feeling dismissed into care void	
				No surgery	
	Coping Mechanisms			Intention to further consult	
	Search for cure- seeing consultants		Response to management advice	Disagreeing with proposed care	
			Worries	About health and future	

Appendix F: Study 2 (Prospective Cohort Documents)

Invitation Letter (2)



You are invited to participate in a study about reassurance for Low Back Pain.

Study title

Consultation-based reassurance for people with low back pain consulting about spine surgery.

Introduction

We are contacting you because you have an appointment to see a surgeon or one of their team members about your back pain. We are interested in questioning you about your experience before and after your appointment, and then contacting you in three months to see how your back pain is. We would like to invite you to meet with our researcher just before your appointment (15 minutes before the time you have been given). We are asking that you complete a short questionnaire before the appointment, directly after, and another questionnaire after three months.

Before you decide if you want to take part, please take the time to carefully read this information and talk to others if you wish. This information will inform you of what will be involved.

What is the purpose of the study?

Persistent back pain can be very difficult to deal with, and GPs refer people to consult with a surgeon if they feel that surgery might be appropriate. Some patients are advised by the surgeon that surgery is not the right treatment for them. This can happen for several reasons. Other patients are offered surgery but decide they would rather not undergo an operation. Very little is known about how to support people with low back pain when surgery has been ruled out, why people decide not to have surgery, or about how to explain to patients why surgery is not the advised treatment. This study will help us gain understanding of what people need to be told, and how best to reassure patients, even when they are advised that they will not be offered surgery for their back pain.

Why have I been chosen?

Your name has been identified by the NHS research nurse as someone who has been referred for consultation because of low back pain. Only NHS staff have access to this information, and until you respond to this invitation, the research team will not know who you are.

Do I have to take part in the study?

No. It is up to you to decide if you want to take part. This information sheet outlines important information related to the study to help you make an informed decision. If you decide not to take part, the usual care you receive from your GP or other practitioners will not be affected in any way. If you agree to take part, you can withdraw from the study at any time without having to give a reason. If you are offered spinal surgery and decide to have the operation you will no longer be part of the study, but will continue to receive treatment as usual.

What will happen to me if I take part?

We are inviting you to take part in a consultation-based reassurance study. In this research, before you see the surgeon, we would like to know more about your back pain and what you are hoping to get from the consultation. This will only take around 15 minutes and will not interfere with your appointment. After you have seen the consultant, we would kindly ask you to inform our researcher about the outcome of your consultation and to let us know when it is the best time for us to contact you per telephone in the following week. You will be contacted by our researcher to complete a short telephone questionnaire about the consultation, and how satisfied you are with how things went. Finally, we will contact you in three months to see how your back pain is. This will include questions about your back pain, your ability to do things and your mood. This final questionnaire can be completed by telephone, or by post, at your convenience. The NHS staff will ask you on the day of your appointment to find out if you are interested in taking part in the study. Before the study starts we will answer any further questions you may have about this part of the study and ask you to complete a consent form.

What are the possible risks of taking part?

We do not think there are any risks with taking part in this study. The questionnaires are short and have been completed by patients in the past. Completing them should not take more than 15 minutes. Some people find some items sensitive, for example, questions about depression or anxiety. If you do not wish to answer any questions you can skip them without having to give any explanations.

What are the possible benefits of taking part?

Whilst there may not be any direct benefits to you, we hope that the information we gather will inform our development of training for surgeons and their teams to better support people living with chronic back pain for whom surgery is not recommended.

Will my details be kept confidential?

Yes. All information that is collected during the study will be kept confidential at all times and held in compliance with the Data Protection Act 1998. The questionnaire data will be stored in a locked cabinet in the researcher's office. On the questionnaires, you will only be identified by a number. The data on the computer will not include any identifying features, and will be anonymised. In the future, we may use the anonymous data for other research. We might agree to share these with other, carefully selected, researchers; any such sharing will be closely monitored by the University. On all occasions, we will ensure that any material that may identify who you are is removed before analysis of data takes place.

Who can I contact for further information?

If you have any questions about the study, or your involvement in it, either now or in the future, do please contact the study team using the details below:

Kathrin Braeuninger-Weimer,
PhD Researcher
Department of Psychology
Royal Holloway University of London
Egham, Surrey
TW20 0EX
Kathrin.Weimer.2013@live.rhul.ac.uk
07958480185

What if there is a problem?

This study is covered by Royal Holloway, University of London's insurance and indemnity cover. If you have any concerns about this study, please contact the Chief Investigator of the study:

Professor Tamar Pincus
Professor in Health Psychology
Department of Psychology
Royal Holloway University of London
Egham, Surrey
TW20 0EX
t.pincus@rhul.ac.uk
01784443523

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the people below, who are from the Patient Advice and Liaison Service (PALS) at Royal Surrey County Hospital:

Patient Advice and Liaison Service (PALS),
Royal Surrey County Hospital,
Egerton Road,
Guildford, Surrey
GU27XX
rsc-tr.PALS@nhs.net
01483402757

Who is organising and paying for the study?

The study is being co-ordinated by Royal Holloway, University of London, and is being led by Professor Tamar Pincus. The study is funded by the charity ~~EuroSpine~~.

Who has reviewed the study?

Any research that involves the NHS and patients is subject to review by an independent group of people, called a Research Ethics Committee. This committee is there to protect your interests. This study has been reviewed and given favourable opinion by London - Bromley Research Ethics Committee, Reference 16/LO/1833.

You can also get support and information from The Patient Advice and Liaison Service (PALS), which offers confidential advice, support and information on health-related matters. They provide a point of contact for patients, their families and their ~~carers~~. Details on this service and information on how to find your closest contact can be found online: <http://www.nhs.uk/chq/Pages/1082.aspx?CategoryID=68>.

Thank you for taking time to read this information leaflet and for considering the study.

Consent form (2)



CONSENT FORM – PHASE 2 – PROSPECTIVE STUDY

Ethics ID: 16/LO/1833

Study	Consultation-based reassurance for people with low back pain consulting about spine surgery	Name of Investigator	Prof Tamar Pincus
Consultant ID		Participant ID	

Please initial (do not tick) the boxes below if you agree

1. I confirm that I have read the information sheet dated 11 th October 2018, V5 for the above study. I have had the opportunity to consider the information and ask questions.	↓ <input type="checkbox"/>
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	<input type="checkbox"/>
3. I am happy to be interviewed after my consultation and followed-up at three months.	<input type="checkbox"/>
4. I understand that all answers to the questionnaires will be anonymised, and that this may be shared with other carefully selected researchers for further analyses.	<input type="checkbox"/>
5. I understand that brief, anonymous, extracts from the questionnaires may be used in academic and non-academic presentations and publications.	<input type="checkbox"/>
6. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	<input type="checkbox"/>
7. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.	<input type="checkbox"/>
8. I agree to take part in the above study.	<input type="checkbox"/>

Name of Participant (PRINT NAME)		Signature of participant		Date signed	
-------------------------------------	--	--------------------------	--	-------------	--

Name of person taking consent (PRINT NAME)		Signature of person taking consent		Date signed	
---	--	------------------------------------	--	-------------	--


When completed:
 1 signed **original** for Investigator on site file (ISF)
 1 **copy** of signed original **to the participant**
 1 **copy** for participant Medical Record

Further contact details

In three months' time after your consultation, we will contact you for the final follow-up questionnaire. Completing the follow-up measures are crucial for the analysis of this study. Thus, we find it very useful to have several ways of contacting people.

Please provide as many of the contact information below:

Home number:

Mobile number: 

Baseline Questionnaires

Consultation-based reassurance for people with low back pain consulting about spine surgery - Version 5.0, 11/10/18.



Pre-Consultation Questionnaires

Dear Sir/ Madam,

You have recently agreed to take part in a study investigating your experience of your consultation for lower-back pain. Please note the first response that comes into your head when reading the questions. There are no right or wrong answers, and your first response is probably the most accurate. It should take you around 15 minutes to complete the questions. Please answer all questions as honestly as you can. If you do not want to answer any specific question, just skip it and move on to the next one. Remember that you can withdraw from this study at any given stage without giving an explanation, and that participating will not affect your treatment in any way.

We would also like to thank you for your participation.

Yours Faithfully,

The Royal Holloway Research Team

Consultant ID:

Participant ID:

1

Please answer the following questions about yourself. We would like to remind you that all answers will be confidential and this information will not be used to identify you at any stage of the research.

Age:

Gender: Female ☐ Male ☐

Are you currently pregnant? Yes ☐ No ☐

Marital Status: Single ☐ Cohabiting ☐ Married/Civil Partnership ☐
 Divorced ☐ Widowed ☐ Other ☐

Education: Left school at or before 16 ☐ Obtained A Levels or equivalent ☐
 Obtained higher education degree/certification ☐

Work Status (please select one answer only):

Employed (full or part time) ☐ Looking after home/family ☐ Retired ☐ Student ☐
☐ Unemployed (health reasons) ☐ Unemployed (other) ☐

Other serious health issues:

Cancer ☐ Rheumatoid arthritis ☐ Diabetes ☐ Parkinson's disease ☐

Other.....

Have you been told the cause of your low back pain? Yes ☐ No ☐

If yes, please specify:

Have you been told the diagnosis of your low back pain? Yes ☐ No ☐

If yes, please specify:

Please write in the box the number of imaging tests you have had in the past for your spine:

MRI X-rays CT

The Following questions concern your back pain.

Is this your first episode of back pain? (please circle)	Yes		No							
If no: How long since your last episode?	months									
How long have you had your current bout of back pain? Please circle	Less than 1 month	1 to 3 months	4 to 6 months	7 months to 3 years	More than 3 years					
Please estimate about how long you have had back pain all together?	years		months							
Excluding the consultation you about to have, how many consultations have you had overall with professionals for your low back pain (GP, physiotherapists, consultants, etc.)?										
1-2	3-5	5-10	10+							
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>							
Concerning your pain: In the last week, that is in the past seven days, on average, how INTENSE was your pain rated on a 0 to 10 scale where 0 is "no pain" and 10 is "worst possible pain?" (please circle)										
0	1	2	3	4	5	6	7	8	9	10
No Pain					Worst Possible Pain					

Please tick the statements true for your previous consultations about low back pain whether with the GP or specialist:

- ☐ I received a leaflet with information about my condition and treatment options
- ☐ I have been prescribed painkillers
- ☐ I have been advised to do Yoga or/and Pilates or/and Aquatics
- ☐ I saw an Osteopath or/and a Chiropractor
- ☐ I had Acupuncture
- ☐ I have received a series of/ an injection
- ☐ I have received physiotherapy
- ☐ I have been working with a pain specialist team
- ☐ I have seen a Psychologist
- ☐ I have had spinal surgery

Other:

Consultant ID:

Participant ID:

3

The following questions are about your expectations from the consultation you are about to attend. From a scale of 1 to 7, please rate each item in how much you expect it to be an outcome of this consultation.								
To what extent do I expect...		Not at all A great deal						
		1	2	3	4	5	6	7
1	A Diagnosis or an explanation so I can know what my problem is	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	A physical examination	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	To see my scan and have it explained	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Someone to listen to me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	A sense that the consultant cares about me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	A sense that they are qualified to know what they are talking about	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	To form a plan to improve my pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	To form a plan to exercise or participate in sport	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Surgery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Thinking about the last 2 weeks please tick your response to the following statements:		
	Agree	Disagree
It's not really safe for a person with a condition like mine to be physically active	<input type="checkbox"/>	<input type="checkbox"/>
Worrying thoughts have been going through my mind a lot of the time	<input type="checkbox"/>	<input type="checkbox"/>
I feel that my back pain is terrible and it's never going to get any better	<input type="checkbox"/>	<input type="checkbox"/>
In general, I have not enjoyed all the things I used to enjoy	<input type="checkbox"/>	<input type="checkbox"/>
<p>When your back hurts, you may find it difficult to do some of the things you normally do.</p> <p>Mark (with a tick next to it) only the sentences that describe you today.</p>		
I stay at home most of the time because of my back	<input type="checkbox"/>	
I change position frequently to try and get my back comfortable	<input type="checkbox"/>	
I walk more slowly than usual because of my back	<input type="checkbox"/>	
Because of my back I am not doing any of the jobs that I usually do around the house	<input type="checkbox"/>	
Because of my back, I use a handrail to get upstairs	<input type="checkbox"/>	
Because of my back, I lie down to rest more often	<input type="checkbox"/>	
Because of my back, I have to hold on to something to get out of an easy chair	<input type="checkbox"/>	
Because of my back, I try to get other people to do things for me	<input type="checkbox"/>	
I get dressed more slowly than usual because of my back	<input type="checkbox"/>	
I only stand for short periods of time because of my back	<input type="checkbox"/>	
Because of my back, I try not to bend or kneel down	<input type="checkbox"/>	
I find it difficult to get out of a chair because of my back	<input type="checkbox"/>	
My back is painful almost all the time	<input type="checkbox"/>	
I find it difficult to turn over in bed because of my back	<input type="checkbox"/>	
My appetite is not very good because of my back pain	<input type="checkbox"/>	
I have trouble putting on my socks (or stockings) because of the pain in my back	<input type="checkbox"/>	
I only walk short distances because of my back	<input type="checkbox"/>	
I sleep less well because of my back	<input type="checkbox"/>	
Because of my back pain, I get dressed with help from someone else	<input type="checkbox"/>	
I sit down for most of the day because of my back	<input type="checkbox"/>	
I avoid heavy jobs around the house because of my back	<input type="checkbox"/>	
Because of my back pain, I am more irritable and bad tempered with people than usual	<input type="checkbox"/>	
Because of my back, I go upstairs more slowly than usual	<input type="checkbox"/>	
I stay in bed most of the time because of my back	<input type="checkbox"/>	

Consultant ID:

Participant ID:

5

Read each item and circle the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

I feel tense or 'wound up':

- | | |
|----------------------------|--------------------------|
| Most of the time | <input type="checkbox"/> |
| A lot of the time | <input type="checkbox"/> |
| Time to time, occasionally | <input type="checkbox"/> |
| Not at all | <input type="checkbox"/> |

I feel as if I am slowed down:

- | | |
|------------------------|--------------------------|
| Nearly all of the time | <input type="checkbox"/> |
| Very often | <input type="checkbox"/> |
| Sometimes | <input type="checkbox"/> |
| Not at all | <input type="checkbox"/> |

I still enjoy the things I used to enjoy:

- | | |
|--------------------|--------------------------|
| Definitely as much | <input type="checkbox"/> |
| Not quite so much | <input type="checkbox"/> |
| Only a little | <input type="checkbox"/> |
| Not at all | <input type="checkbox"/> |

I get a sort of frightened feeling like 'butterflies in the stomach':

- | | |
|--------------|--------------------------|
| Not at all | <input type="checkbox"/> |
| Occasionally | <input type="checkbox"/> |
| Quite often | <input type="checkbox"/> |
| Very often | <input type="checkbox"/> |

I get a sort of frightened feeling like something awful is about to happen:

- | | |
|-----------------------------------|--------------------------|
| Very definitely and quite badly | <input type="checkbox"/> |
| Yes, but not too badly | <input type="checkbox"/> |
| A little, but it doesn't worry me | <input type="checkbox"/> |
| Not at all | <input type="checkbox"/> |

I have lost interest in my appearance:

- | | |
|---------------------------------------|--------------------------|
| Definitely | <input type="checkbox"/> |
| I don't take as much care as I should | <input type="checkbox"/> |
| I may not take quite as much care | <input type="checkbox"/> |
| I take just as much care as ever | <input type="checkbox"/> |

I can laugh and see the funny side of things:

- | | |
|----------------------------|--------------------------|
| As much as I always could | <input type="checkbox"/> |
| Not quite so much now | <input type="checkbox"/> |
| Definitely not so much now | <input type="checkbox"/> |
| Not at all | <input type="checkbox"/> |

I feel restless as if I have to be on the move:

- | | |
|------------------|--------------------------|
| Very much indeed | <input type="checkbox"/> |
| Quite a lot | <input type="checkbox"/> |
| Not very much | <input type="checkbox"/> |
| Not at all | <input type="checkbox"/> |

Worrying thoughts go through my mind:

- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

I look forward with enjoyment to things:

- As much as I ever did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

I feel cheerful:

- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

I get sudden feelings of panic:

- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

I can sit at ease and feel relaxed:

- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

I can enjoy a good book or radio or TV programme:

- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

Consultant ID:

Participant ID:

7

Post-consultation Questionnaire

Consultation-based reassurance for people with low back pain consulting about spine surgery,
Version 4.0, 11/10/18.

Have you been told the cause of your low back pain? Yes ☐ No ☐ NA ☐

If yes, please specify:

Have you been told the diagnosis of your low back pain? Yes ☐ No ☐ NA ☐

	Agree	Disagree	NA
I had the chance to voice my treatment preferences	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I received an explanation for my LBP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I agree with this explanation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I believe there is something else going on with my back, which has not yet been diagnosed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am considering seeking further consultations (GP/ specialists)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1. Private Physiotherapist/ Osteopath/ Chiropractor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. A different Orthopaedic consultant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specify:			

I was given advice to (you can tick more than one box):

- ☐ Go back to my GP
- ☐ Take time of work
- ☐ Do Yoga/Pilates/Aquatics
- ☐ Exercise regularly
- ☐ Rest when in pain

The outcome from my consultation is that (you can tick more than one box):

- ☐ I was sent to have an imaging test (e.g. bone, CT, MRI scan)
 - ☐ I was referred for another opinion with a specialist (e.g. hip-surgeon, vascular surgery, neurologist, etc....)
 - ☐ I received the chance for a 6-month open appointment
 - ☐ I was advised to continue taking my usual painkillers
 - ☐ I was prescribed new pain killers
 - ☐ I was referred to Yoga, Pilates or/and Aquatics
 - ☐ I will receive a series of/ an injection
 - ☐ I was referred to receive physiotherapy
 - ☐ I was referred to a pain specialist team
 - ☐ I was discharged without further treatment
 - ☐ I was recommended to undergo surgery For reason:.....
- I decided to have surgery Yes ☐ No ☐
- Why? (yes or no):

Other:

Consultant ID:

Participant ID:

1

To what extent did the physician ...		Not at all							A great deal	
		1	2	3	4	5	6	7		
1	Tell you that everything would be fine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2	Show that he/she understood your concerns	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3	Encourage you to voice your concerns regarding your symptoms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4	Check you understood the explanation he/she gave for your symptoms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5	Tell you that there is no need to worry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6	Listen attentively while you were talking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7	Discuss how you could manage your problem	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
8	Put you at ease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
9	Summarise what you had told them	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10	Show a genuine interest in your problem	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
11	Reassure you that he/she had no serious concerns about your back	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
12	Make sure you understood their decision about management options	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

Overall in your consultation, please indicate your agreement or disagreement with the following.

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	I am totally satisfied with my visit to this physician					
2	The physician told me everything about my treatment.					
3	Some things about my consultation with the physician could have been better					
4	The physician examined me very thoroughly					
5	This physician was interested in me as a person, not just my problem					
6	I understand my problem much better after seeing this physician.					
7	I felt this physician really knew what they were talking about.					
8	I wish it had been possible to spend a little more time with the physician.					
9	I would find it difficult to tell this physician about some private things					
10	I felt reassured by my consultation with this physician					

Recommendations for improved consultations:

.....

.....

Consultant ID:

Participant ID:

3

As a result of your consultation, do you feel you are ...

		Much Better	Better	Same	Worst	Not Applicable
1	Able to cope with life					
2	Able to understand your problem					
3	Able to cope with your problem					
4	Able to keep yourself healthy					
		Much More	More	Same	Worst	Not Applicable
5	Confident about your health					
6	Able to help yourself					

Follow-up questionnaire

Consultation-based reassurance for people with low back pain consulting about spine surgery - Version 4.0, 11/10/18.

The Following questions concern your back pain.

<p>Concerning your pain: In the last week, that is in the past seven days, on average, how INTENSE was your pain rated on a 0 to 10 scale where 0 is "no pain" and 10 is "worst possible pain?" (please circle)</p>											
0	1	2	3	4	5	6	7	8	9	10	
No Pain										Worst Possible Pain	
<p>How many days have you reported to be sick due to low back pain in the past 3 months?</p>											
<p>How many times have you been seeing your GP about your low back pain since your last specialist consultation?</p>											
<p>Have you seen anyone else from the NHS for your back pain since your last consultation? (please circle, and if yes please specify)</p>						<p>YES</p>			<p>NO</p>		
						<p>GP <input type="checkbox"/></p>			<p>Hospital visits <input type="checkbox"/></p>		
						<p>Surgeon <input type="checkbox"/></p>			<p>Pain Specialist team <input type="checkbox"/></p>		
						<p>Osteopaths <input type="checkbox"/></p>			<p>Physiotherapist <input type="checkbox"/></p>		
						<p>Other:</p>					
<p>Have you been seeing anyone privately for your back pain? (if yes please specify)</p>						<p>YES</p>			<p>NO</p>		
						<p>GP <input type="checkbox"/></p>			<p>Hospital visits <input type="checkbox"/></p>		
						<p>Surgeon <input type="checkbox"/></p>			<p>Pain Specialist team <input type="checkbox"/></p>		
						<p>Osteopaths <input type="checkbox"/></p>			<p>Physiotherapist <input type="checkbox"/></p>		
						<p>Other:</p>					

When your back hurts, you may find it difficult to do some of the things you normally do. Mark (with a tick next to it) only the sentences that describes you today.

I stay at home most of the time because of my back	
I change position frequently to try and get my back comfortable	
I walk more slowly than usual because of my back	
Because of my back I am not doing any of the jobs that I usually do around the house	
Because of my back, I use a handrail to get upstairs	
Because of my back, I lie down to rest more often	
Because of my back, I have to hold on to something to get out of an easy chair	
Because of my back, I try to get other people to do things for me	
I get dressed more slowly than usual because of my back	
I only stand for short periods of time because of my back	
Because of my back, I try not to bend or kneel down	
I find it difficult to get out of a chair because of my back	
My back is painful almost all the time	
I find it difficult to turn over in bed because of my back	
My appetite is not very good because of my back pain	
I have trouble putting on my socks (or stockings) because of the pain in my back	
I only walk short distances because of my back	
I sleep less well because of my back	
Because of my back pain, I get dressed with help from someone else	
I sit down for most of the day because of my back	
I avoid heavy jobs around the house because of my back	
Because of my back pain, I am more irritable and bad tempered with people than usual	
Because of my back, I go upstairs more slowly than usual	
I stay in bed most of the time because of my back	

Management:

.....

.....

Any suggestion to how reassurance could be improved?

.....

.....

Read each item and circle the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

I feel tense or 'wound up':

- Most of the time ☐
- A lot of the time ☐
- Time to time, occasionally ☐
- Not at all ☐

I feel as if I am slowed down:

- Nearly all of the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

I still enjoy the things I used to enjoy:

- Definitely as much ☐
- Not quite so much ☐
- Only a little ☐
- Not at all ☐

I get a sort of frightened feeling like 'butterflies in the stomach':

- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

I get a sort of frightened feeling like something awful is about to happen:

- Very definitely and quite badly ☐
- Yes, but not too badly ☐
- A little, but it doesn't worry me ☐
- Not at all ☐

I have lost interest in my appearance:

- Definitely ☐
- I don't take as much care as I should ☐
- I may not take quite as much care ☐
- I take just as much care as ever ☐

I can laugh and see the funny side of things:

- As much as I always could ☐
- Not quite so much now ☐
- Definitely not so much now ☐
- Not at all ☐

I feel restless as if I have to be on the move:

- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

Worrying thoughts go through my mind:

- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

I look forward with enjoyment to things:

- As much as I ever did ☐
- Rather less than I used to ☐
- Definitely less than I used to ☐
- Hardly at all ☐

I feel cheerful:

- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

I get sudden feelings of panic:

- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

I can sit at ease and feel relaxed:

- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

I can enjoy a good book or radio or TV programme:

- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐