# A Pilot RCT Assessing Feasibility and Acceptability of a Single Values-Based Versus Standard Goal-Setting Session for Community Dwellers with Acquired Brain Injury (ABI)

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# I. Lay Summary

## Why did we do this research?

Brain injury that happens after birth is common, and it can be caused by sudden trauma (like a road traffic accident), a stroke, (when blood to the brain gets interrupted), or an infection. Brain injury can cause physical, thinking, mood and behavioural difficulties which can make everyday life challenging, including continuing to work, taking part in activities in the community, doing things around the house, and maintaining social relationships. These difficulties can have a really big impact on the quality of life and wellbeing of people with a brain injury. For that reason, research is interested in finding helpful ways to improve wellbeing and other ‘positive’ psychological states.

## What is this research about?

This research took place in Royal Holloway University of London, and has two different parts that work together.

### *Systematic Review*

The first part is called a systematic review, which involves using two online libraries to search all published research about psychological interventions aiming to improve positive psychological states of people with a brain injury and provide a narrative summary. We did this because we wanted to know what these interventions are, and how good they are in improving positive states in brain injury. We only looked at studies that were available in English, and recruited brain injury survivors aged 18 or over.

## What did we find?

- We looked at 1,847 different published studies, and only 26 met our criteria.
- These studies recruited people with different kinds of brain injuries from hospitals, rehabilitation services or the community, and took place in many different countries.
- In total, 1,937 participants took part in these 26 studies and nine different interventions were assessed, most measuring the quality of life of participants.
- Using an available tool, we measured the quality of these studies. Half of them were low in quality, and only five studies were of high quality.

- Overall, we found that some interventions seem to be good at improving positive states, like third-wave (e.g., mindfulness), Positive Psychology, and counselling.
- The findings were less clear and more mixed for other interventions (e.g., Cognitive Behavioural Therapy and creative therapies).
- We did not find evidence that self-management or supportive psychotherapy were good at improving positive psychological states.
- Studies were too different to compare easily, and we need more studies that are of high quality and compare two active groups in order to make clearer conclusions.

### ***Research Study***

The second part is a research study that builds on the systematic review findings, which suggested that third-wave therapies seem to be good at improving positive states of brain injury survivors. Setting goals is a key part of neuro-rehabilitation for people with brain injury, but it's not always done in a helpful way. Research is interested in improving the goal-setting process to make it more helpful for people with a brain injury.

Acceptance and Commitment Therapy (abbreviated to ACT) is a type of third-wave therapy that is interested in values, which are life directions that give us a sense of purpose and meaning. ACT encourages us to act in a way that brings us closer to our values by setting meaningful goals, and could help improve the goal-setting process in brain injury. However, goal-setting based on values has not yet been compared to generic goal-setting for people with a brain injury.

This study asked the following questions:

- How acceptable and doable is goal-setting as standard and based on values for people with a brain injury living in the community?
- Is there a difference in wellbeing between participants engaging in the two different types of goal-setting two weeks later?
- Is there a difference between groups in:
    - how people feel about the goals they set in terms of confidence, motivation, and anticipated pleasure?

  - how much do people remember their goals?
  - how much have they progressed towards their goals?

To answer these questions, we recruited 24 brain injury survivors and randomly split them into two groups. Both groups were offered one 1:1 goal-setting session. For one group, people picked their most important values and set a goal based on those, while for the other group people thought about a goal they wanted to set without considering their values. I met with these participants two weeks later to follow up.

**What did we find?**

This study was called a "pilot" as its purpose was to see if a larger study should be done. Because of this, we could not compare the two groups using statistics. Here is what we found:

- It was possible to recruit people with a brain injury living in the community. Six people each month signed up to the study, and only two people dropped out. Both goal-setting sessions were rated as acceptable by participants, but these ratings were a little higher for the values group.
- Participants who set goals based on their values had slightly higher levels of wellbeing than those who set goals as standard.
- Participants from the values group had slightly higher levels of motivation to work on their goal, while participants from the standard goal-setting group had slightly higher levels of confidence and anticipated pleasure from working on their goal.
- No differences were found in terms of how much participants felt that they achieved their goal, or how well they remembered their goal. Participants from the values group felt closer to their values two weeks after their goal-setting session.

**What did we conclude?**

When goals were based on values, a modest improvement was found for the wellbeing of brain injury survivors living in the community. A larger study should take place, and future research could also take place in hospital or rehabilitation settings. Findings from this study will be shared with participants, brain injury organisations and other professionals.

# II. Paper 1. A Systematic Review of the Effectiveness of Psychological Interventions in Improving Positive Affect for People With an Acquired Brain Injury

## Abstract

Acquired brain injury (ABI) is known to have significant and complex long-term physical, cognitive and emotional impact on survivors and their social network (O'Rance & Fortune, 2007), often requiring the provision of psychological support (NICE, 2022). Previous systematic reviews largely focused on the effectiveness of therapeutic approaches on psychological distress (e.g., Little et al., 2021). However, ABI can have a significant impact on quality of life (QoL) and wellbeing even in the absence of a psychiatric diagnosis (Dijkers, 2004). This review presents a narrative synthesis of existing research evidence regarding the effectiveness of psychological interventions in improving positive affect in ABI. Studies were eligible if they were available in English, recruited adults with ABI and quantitatively evaluated the effectiveness of psychological interventions on QoL, wellbeing, happiness, life satisfaction or life meaning. From the 1,847 studies identified from two database searches, 26 studies were included in this review which varied in study setting, ABI type, country and sample size. The total sample size was 1,937 participants, with nine different types of psychological interventions represented and primarily measuring QoL. The quality of half of the studies (*n* = 13) was low, whereas only five studies were of high quality. Moderate evidence was found for the effectiveness of third-wave CBT, Positive Psychology and counselling interventions on positive affect, with effects ranging from small to large, although due to the small number of studies evaluating the same interventions and the heterogeneity of studies and types of comparators, the results are tentative. Evidence for CBT, creative art therapies, Narrative-Theory-based interventions and Neuro-Linguistic Processing was mixed, with small to large effect sizes, while little or no evidence was found for self-management interventions or supportive psychotherapy. Although initial findings appear promising, there is a need for more high-quality RCTs evaluating psychological interventions on positive affect.

## Introduction

Acquired brain injury (ABI) can be defined as injury to the brain that occurs since birth and is not degenerative (Department of Health and Social Care, 2022). Causes of injury can be traumatic, such as blunt force to the head from a fall, accident or assault; and non-traumatic, such as different types of strokes or brain tumours, infections that affect the brain (e.g., encephalitis), medical conditions or events that prevent oxygen from reaching the brain, and toxins that affect brain function (Giustini et al., 2013). ABIs can be classified as mild, moderate or severe according to various methods, such as the Glasgow Coma Scale (GCS; Menon & Maas, 2015). The total GCS score ranges 3-15 and consists of eye, motor and verbal scales, providing a quick estimate of ABI severity to be used in conjunction with imaging modalities (Najem et al., 2018). GCS scores of 13-15, 9-12, and ≤ 8 correspond with mild, moderate and severe injuries respectively (Bodanapally et al. 2015).

It is estimated that there are 69 million and 13.7 million individuals globally who sustain a Traumatic Brain Injury (TBI) and stroke respectively each year (Dewan et al., 2018; Saini et al., 2021). A recent systematic review estimated that TBI incidence rates ranged from 47.3 to 694 per 100,000 population per year in country-level studies in Europe (Brazinova et al., 2021), while the Stroke Association (n.d.) reports that there is currently a 1.81% stroke prevalence rate in England. Headway (n.d.) reported 356,699 ABI-related hospital admissions in the UK in 2019-20, a 12% increase since 2005-6, and the number of strokes in the UK is expected to more than double in the next two decades (King et al., 2020). ABI affects people of all ages; while TBI is most common for men and people aged 16-29, its prevalence has increased by 20% in women in 2019-20 since 2005-6 (Headway, n.d.) and it is estimated that about 40% of TBI-related hospital admissions in 2014-15 were for individuals aged 75 or over (Fryer et al., 2017). Stroke tends to affect older individuals, however about 20% of strokes occur in individuals younger than 65 (Yousufuddin & Young, 2019).

The impact of ABI is significant. It is the lead cause of death for those aged under 40 (National Institute for Health and Care Excellence; NICE, 2014) and more than 1.3 million survivors are living with its impact, which is estimated to cost about 10% of the National Health System (NHS) budget each year (UK Acquired Brain Injury Forum, 2019). Economic costs of ABI, resulting from health and social care costs, as well as premature death and lost work contributions (Centre for Mental Health, 2016), are estimated to have risen by 250% between 2015 and 2023 (King et al., 2020). However, the impact of ABI is much broader than economic costs and can be life-changing for survivors and their families. ABI can impact on all domains of life (e.g., physical, cognitive, emotional, behavioural and social functioning) and have a detrimental impact on individuals' quality of life and wellbeing (Goverover et al., 2017). Depending on the nature, location and severity of the injury, difficulties could last for a few weeks or be more long-term, and often life-long.

In terms of physical functioning, ABI can affect mobility and can cause spasticity, ataxia, weakness or limb paralysis, sensory impairment, hormonal imbalances, epilepsy, persistent fatigue, pain, and speech and sexual functioning difficulties (Headway, 2009). Disability caused by ABI can be more complex than disabilities caused by other conditions (O'Rance & Fortune, 2007) and activity levels often remain low even after physical rehabilitation (Driver et al., 2012). The cognitive impact of ABI can include memory, language, attention, information processing and visuo-perceptual changes, as well as difficulties with planning, problem-solving, inhibition, abstract reasoning, motivation and perseveration, among others (Headway, 2009). Changes in cognition can have a significant impact on individuals' behaviour and personality, which can create barriers to community reintegration and social functioning (Kelly et al., 2008). Behaviours that challenge include physical and verbal aggression, sexually and socially inappropriate behaviours and apathy (Fisher et al., 2015), and can have a higher impact on subjective caregiver burden than physical difficulties (Liss & Willer, 1990). This combination of physical, cognitive and behavioural difficulties can lead to major interpersonal role and relationship changes and can have a huge impact on individuals' ability to participate in work- and leisure-related activities (Roebuck-Spencer & Cernich, 2014), and engage in meaningful behaviours (Kangas & McDonald, 2011).

Unsurprisingly, the consequences of ABI can have a major impact on the mental health of survivors. In fact, depression (Riggio & Wong, 2009), anxiety (van Reekum et al., 2000) and other psychological disorders such as PTSD (Headway, 2009) are more common in this population up to 5.5 years post-ABI (Whelan-Goodinson et al., 2009). Research evaluating psychological interventions in reducing distress in ABI has been emerging over the last couple of decades, with a large number of systematic reviews evaluating the effectiveness of Cognitive Behavioural Therapy (CBT; e.g., Soo & Tate, 2007; Waldron et al., 2013). For example, CBT was found effective in reducing anxiety in TBI (Little et al., 2021), anxiety and depression in stroke (Ahrens et al., 2022), and sleep difficulties in TBI survivors (Ludwig et al., 2020). However, although CBT is used very widely and a large number of studies have evaluated its effectiveness, methodological limitations of the evidence base such as small sample sizes and few full-scale RCTs limit the conclusions that can be drawn. Recent research has started evaluating the effectiveness of other types of interventions (Gómez-de-Regil et al., 2019), such as third-wave CBT therapies like mindfulness (e.g., Bédard et al., 2014) or Acceptance and Commitment Therapy (ACT; e.g., Whiting et al., 2020), as well as Positive Psychology Interventions (PPI; e.g., Evans, 2011) and creative therapies (e.g., Kongkasuwan et al., 2016). Mindfulness, for example, was found to be moderately effective in reducing fatigue for individuals with stroke, TBI or Multiple Sclerosis (Ulrichsen et al., 2016) as well as fatigue and depression in mild TBI (Acabchuk et al., 2021) and depression in stroke (Tao et al., 2022), however the number of studies included was small and more high-quality research was recommended.

Although most published studies are interested in reducing symptoms of depression, anxiety and anger, the absence of clinically significant distress is not the same as positive psychological functioning and wellbeing (Keyes, 2002), which is certainly the case in ABI survivors. Even in the absence of clinical symptomatology, ABI can have a significant negative impact on the psychological wellbeing, life satisfaction and quality of life (QoL) of survivors (Dijkers, 2004), as these psychological states are related but unique to emotional distress (Williams et al., 2014). This impact on positive affect is often exacerbated by changes in social relationships and vocational roles (Jones et al., 2011), robbing people of a sense of meaning and identity as individuals struggle with adjusting to life limited by the injury and navigating the effects of limited social and activity participation (Carroll & Coetzer, 2011). Family and carers of people with ABI are also more likely to experience significant distress, anxiety, depression, isolation and a sense of loss stemming from relationship difficulties (Chan et al., 2009). Therefore, considering that low positive affect is common in ABI even in the absence of significant emotional distress (Damsbo et al., 2020), a broader understanding of psychological health and a transdiagnostic approach are important elements of psychological interventions (Robinson et al., 2019). In other words, it may be more pertinent to design interventions that support ABI survivors to “feel well” (Jumisko et al., 2009) and find meaning in life (Payne et al., 2018) despite their injury, than focusing on a disorder-specific approach that may only be relevant to a small percentage of individuals.

Although research in this field is still sparse, a small number of studies is starting to evaluate intervention effects on positive affect, such as QoL, hope, and life satisfaction (Gómez-de-Regil et al., 2019). Some recent systematic reviews have investigated the effectiveness of non-psychological interventions on positive affect (e.g., Domínguez-Téllez et al., 2020; Nindorera et al., 2022; O’Carroll et al., 2020). For example, Chang and colleagues (2023) found an overall moderate effect of exercise on QoL for TBI survivors, and Noukpo et al. (2022) found that community-based rehabilitation was superior to other protocols in enhancing QoL for chronic stroke survivors. Furthermore, one systematic review by Cheng et al. (2014) explored the effectiveness of psychosocial interventions on the wellbeing and QoL of the carers of stroke survivors, finding a small effect for psychoeducation programmes. However, to the author’s knowledge no previous systematic review evaluated psychological interventions that aim to enhance positive affect of brain injury survivors.

The purpose of this review is to narratively synthesise and critically evaluate the effectiveness of psychological interventions that aim to enhance positive affect for people with ABI. For the purposes of this review a broader view of psychological interventions than traditional “talking therapies" is taken, since interventions with a wider focus than talking (such as creative therapies) may be effective considering that language and cognitive difficulties are common difficulties following ABI (Lo et al., 2019).

## Methods

### Search Strategy

This systematic review was designed following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA; Moher et al., 2009; Page et al., 2021). The systematic review protocol was registered on PROSPERO (Booth et al., 2012; registration number: CRD42022345218), and the Population, Intervention, Comparison, Outcomes and Study (PICOS) tool was used to refine the research question (Centre for Reviews and Dissemination; 2009).

Studies of interest were identified from databases PubMed and PsychINFO on 5th August 2022, and repeated in January 2023 to identify any newly published papers. Although no other sources were systematically checked, additional studies were identified through in-text referencing. Boolean operators were used to develop search terms in relation to each construct of the research question (Table 1). The full search strategy can be found in Appendix A.

**Table 1**

*Search Terms for Each Construct of the Research Question*

| Population condition | Outcome measures | Study design |
|---|---|---|
| “Stroke” | “Wellbeing“ | “Experimental“ |
| “Cerebrovascular event” | “Quality of life“ | “Quasi-experimental“ |
| “Transient Ischaemic attack” | “Life satisfaction“ | “Randomised Controlled Trial“ |
| “Brain injury” | “Life meaning“ | “Intervention“ |
| “Head injury” | “Flourishing“ | |
| “Traumatic brain injury“ | “Happiness“ | |
| “Acquired brain injury“ | | |

A decision not to include any search terms in relation to psychological interventions was made by the research team and confirmed by an experienced librarian at Royal Holloway University London (RHUL), as it was felt this would limit the search and possibly exclude studies of interest. All searches were completed using the “Advanced Search” option, using language (English), age group (adults) and population group (humans) filters, with an additional filter for type (peer-reviewed articles) for PsychINFO. No publication date restrictions were applied. Titles and abstracts were searched for PubMed, whereas only abstracts were searched for PsychINFO.

### Study Eligibility Criteria

Studies were included as long as they met the following eligibility criteria: a) participants aged ≥ 18 diagnosed with ABI, with any level of injury severity or time post-injury; b) psychological interventions delivered on a 1:1 or group basis in any delivery modality and taking place in any setting; c) wellbeing, life satisfaction, life meaning, QoL, flourishing or happiness as one of the outcomes of interest; d) quantitative controlled or pre-test post-test experimental designs, or mixed methods designs with a quantitative element; and e) available in the English language.

Studies were excluded if they did not meet the above eligibility criteria. For example, participants with a progressive condition or a mixed population; samples of ABI caregivers; studies that primarily target caregiver burden or distress, or primarily aim at improving the participants’ health or cognition; psychological interventions delivered as part of wider multidisciplinary team interventions; studies with solely qualitative methodologies; study protocols; systematic reviews; case studies; single case designs; and grey literature or non-peer reviewed material (e.g., theses).

### Study Selection

All identified studies were imported to RefWorks ProQuest, a reference management software tool used to identify and remove duplicates. De-duplicated studies were imported onto Rayyan, an automated tool used for the initial title and abstract screen of studies.

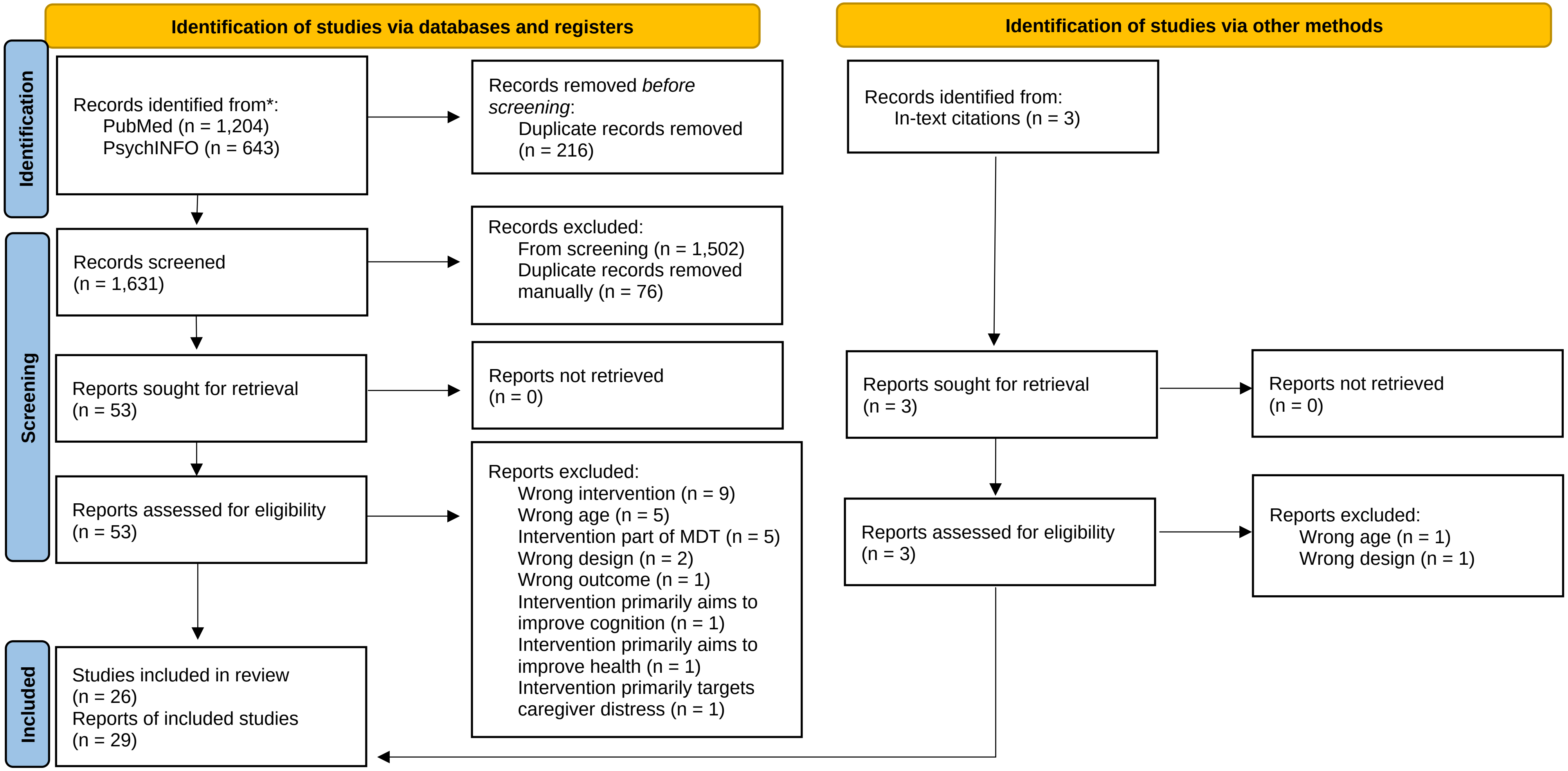
Figure 1 illustrates the selection process of identified studies. A total of 1,847 articles were initially identified from PsychINFO (*n* = 643) and PubMed (*n* = 1,204). A total of 216 duplicates were removed using RefWorks. Titles and abstracts of the remaining 1,631 papers were then screened by the first reviewer using Rayyan, with a second reviewer independently screening 10% of papers. While completing the first screen, another 76 duplicates were manually found and removed. A total of 1,502 studies did not meet the eligibility criteria and were removed. The percentage agreement between reviewers was 97.3%, *k* = .65, which can be interpreted as substantial (McHugh, 2012). A third reviewer was consulted and resolved decisions in the cases where eligibility was not clear.

The remaining 53 studies were retrieved in full text and screened against eligibility criteria using Microsoft Excel, with 20% of those being independently screened by the second reviewer. If a study was not accessible through the RHUL library or open source, the authors were contacted to request the full text. The percentage agreement between reviewers was moderate (80%, *k* = .60), with the third reviewer resolving disagreement. If age was not specified in the eligibility criteria or provided as an age range, the study was excluded (*n* = 5). Studies were also excluded if they did not measure the outcome of interest pre- and post-intervention (*n* = 2). Other reasons for exclusion can be seen in Figure 1. Three studies that were identified using in-text screening were also screened, and two were excluded.

A total of 29 empirical papers were deemed as meeting eligibility criteria after the full text screen and were included in the systematic review, 26 of these providing unique data sets.

**Figure 1**

*PRISMA Diagram Illustrating Study Selection Process*



## Quality Assessment

The Quality Assessment Tool for Quantitative Studies (2010) was selected to assess study quality for this review, developed by the Effective Public Health Practice Project (EPHPP) for public health research. It has been found to have adequate content and construct validity and interrater reliability (Thomas et al., 2004). It contains six components assessing selection bias: study design; confounders; blinding; data collection methods; and withdrawals and dropouts. Each of these components receives a ‘weak’, ‘moderate’ or ‘strong’ rating, with the number of ‘weak’ ratings for each study informing its overall rating. Two additional components (intervention integrity and analyses) do not contribute to the study’s overall scoring and have been omitted here due to the large number of studies included.

The tool contains a dictionary which sets out the criteria for each rating. Where there was need for clarification, the tool’s authors were contacted by email. An important clarification involves data collection methods, where authors suggest obtaining psychometric qualities of common tools through literature review if the study authors have not reported these. The first reviewer assessed all included studies for quality, with the second reviewer independently assessing 15%. The agreement between reviewers was substantial (83.3%, $k = .71$), with the third reviewer resolving any disagreements that arose.

## Data Extraction

Data was extracted according to (a) study characteristics: authors, publication year, country, setting, design, type of comparator(s), data collection time points, and study completion rate; (b) participant characteristics: population being studied, eligibility criteria, recruitment method, sample size recruited and analysed, age (mean, SD, range), gender, and ethnicity; (c) intervention characteristics: type, duration, delivery modality and clinician, and adherence evaluation methods; (d) outcome characteristics: outcome of interest, outcome measure used, and if it was primary or secondary; and (e) main findings: significance and effect size of outcomes of interest. If any information was missing or was unattainable from published data, it is marked as “not reported”.

## Data Synthesis

Where there is considerable clinical and methodological diversity of studies, presenting an average value for the intervention effect can be misleading (Deeks et al., 2022). Therefore, a narrative synthesis of results was completed given the heterogeneity of outcome measures, study designs and population of interest. Studies were grouped by brain injury type. When reporting on intervention effectiveness, data was sought only for outcomes of interest with all time-points considered.

Where possible, effect sizes were presented as Cohen's *d* and Hodge's *g*, the latter providing a correction for smaller samples (Hedges, 1981). For some studies, particularly when using Analysis of Variance (ANOVA), eta squared or partial eta squared were used to report effect size. An excel calculator by Beckham (2016) based on the calculations by Ellis (2010) available online, as well as formulas obtained from a supplementary document of the Cochrane Handbook (Deeks & Higgins, 2010) were used to estimate effect sizes when these were not directly reported. Although it can be helpful to consider Cohen's (1988) and Richardson's (2011) effect size classifications when interpreting results, presented in Table 2, it is important to emphasise that these need to be used with care, as it is often more meaningful to consider effect sizes in the context of related literature. For example, a small intervention effect against a robust disorder may be considered as highly important (Thompson, 2007).

**Table 2**

*Guidance for Interpretation of Effect Sizes (Cohen, 1988; Richardson, 2011)*

| Effect size measure | Small | Medium | Large |
|---|---|---|---|
| Cohen's *d* / Hedge's *g* | 0.2 | 0.5 | 0.8 |
| Eta Squared ($\eta^2$) | 0.02 | 0.13 | 0.26 |
| Partial Eta Squared ($\eta^2_p$) | 0.01 | 0.06 | 0.14 |

## Results

A total of 26 studies (29 empirical papers) were included in this systematic review for narrative synthesis. Papers were grouped together if the same dataset was used (Corsten et al., 2014 and Corsten et al., 2015; Bragstad et al., 2020 and Hjelle et al., 2019; Bédard et al., 2003 and Bédard et al., 2005). Study, population, sample, intervention and outcome characteristics and main findings are presented in Tables 3 and 4 and are grouped by brain injury type. Study completion rates refer to the number of participants completing the final data collection period in all groups.

### Participant Characteristics

As seen in Table 3, most studies (*n* = 16) recruited stroke survivors. There were a total of 1,937 participants across all included studies, ranging 10-322 in any one study (*M* = 74.5). 42% of studies (*n* = 11) had samples under *N* = 50, and only five studies had a sample size over *N* = 100. Participants' age ranged 22-89 in the studies that reported this (*n* = 12). For the majority of studies (*n* = 16) over 50% of participants were male, with proportions of female participants ranging 3-63% across all studies. Ethnicity was reported in fewer than half of the studies (*n* = 10), with at least nine different ethnicities represented.

### Study Characteristics

Studies predominantly took place in the USA (*n* = 5), the UK (*n* = 4), as well as a range of European countries (*n* = 9) and were published between 2003-2022 (*Mdn* = 2017), with the majority (*n* = 25) published between 2012-2022. The majority of studies took place in a community or outpatient setting (*n* = 16) and were described as RCTs (*n* = 14) or pilot / feasibility RCTs (*n* = 6). Most control groups had treatment as usual (TAU; *n* = 13) or were on a waitlist (*n* = 2). Five studies had a pre-post design with no control group, and one had a quasi-experimental design with dropouts acting as the control group. Study completion rates ranged 32%-100% (*M* = 77%) when these were reported (*n* = 23), and were < 80% for 10 studies. The majority of studies (*n* = 16) followed up past competition of treatment, with follow-up (FU) timings ranging from two to 12-months post-intervention.

**Table 3**

*Study, Participant, Intervention and Outcome Characteristics*

| Study & setting | Population (Inclusion criteria; Recruitment; Location) | Sample charac. (Size; Age (M, SD, range); % Females; Ethnicity) | Active intervention (Type; Duration & delivery modality; Clinician; Adherence tool) |
|---|---|---|---|
| | | Stroke | |
| Bragstad et al., 2020 & Hjelle et al., 2019<br>Community | Norwegian-speaking medically stable adults aged ≥ 18 who suffered a stroke ≤ 1 month ago, with sufficient cognitive functioning to participate and consent<br>Recruited from 11 acute stroke or rehabilitation units in South-Eastern Norway | *N* = 322<br>$^{a}M$ = 66.3, $^{a}SD$ = 12.7, range = NR<br>41% female<br>Ethnicity NR | Dialogue-based Intervention (Narrative Therapy)<br>8 1:1 F2F sessions lasting 1-1.5h<br>Delivered by Nurses or OTs who completed three-day training<br>Adherence measured using composite score based on number of sessions, timelines and duration |
| Chang et al., 2011<br>Inpatient | Hemiplegic stroke survivors with a score of ≥ 24 on MMSE<br>Recruited through a rehabilitation centre in Shandong Province, China | *N* = 77<br>*M* = 58.9, *SD* = 10.4, range = 34-84<br>31.8% female<br>Ethnicity NR | Psychoeducation & Behavior Therapy (Counselling)<br>Four weekly 1-2h F2F sessions<br>Delivered by trained psychology graduate student<br>Adherence measurement NR |
| Corsten et al., 2014 & Corsten et al., 2015<br>Setting NR | Stroke survivors with aphasia, without severely disordered speech perception or suspected depression according to the AAT and GDS-SF respectively<br>Recruited from rehabilitation units and aphasia support groups in Germany | *N* = 27<br>*M* = 60.85, *SD* = 7.75, range = 44-73<br>45% female<br>Ethnicity NR | Biographic-Narrative Intervention (Narrative Therapy)<br>Five 1:1 and seven group F2F sessions over 10 weeks for 90m max<br>Delivered by SLT and adult education professional specialized in biographical methods<br>Adherence measurement NR |

| Study & setting | Population (Inclusion criteria; Recruitment; Location) | Sample charac. (Size; Age (M, SD, range); % Females; Ethnicity) | Active intervention (Type; Duration & delivery modality; Clinician; Adherence tool) |
|---|---|---|---|
| Kerr et al., 2018<br>Inpatient | Adults aged ≥ 18 with an acute presentation after stroke (cerebral infarction or intracerebral haemorrhage)<br>Recruited from an acute tertiary adult health care organization across 3 acute hospital campuses in Melbourne, Australia | *N* = 48<br>$^{a}$*M* = 68.2, $^{a}$*SD* = 13.8, range = NR<br>47.4% female<br>55.3% Australian-born | Early Motivational Interviewing (Counselling)<br>Three 30-minute 1:1 F2F sessions<br>Delivered by Nurses or Social Workers who completed online training and two 8-hour workshops<br>Adherence measured by evaluator informally reviewing audio-recordings |
| Kongkasuwan et al., 2016<br>Inpatient | Stroke survivors aged > 50 who can communicate verbally<br>Recruited from a hospital rehabilitation ward in Bangkok, Thailand | *N* = 118<br>$^{a}$*M* = 66.3, $^{a}$*SD* = 9.5, range = NR<br>53.4% female<br>Ethnicity NR | Creative Art Therapy (Creative Therapy)<br>Eight F2F group sessions delivered twice weekly, lasting 1.5-2h<br>Delivered by Creative Art Therapist<br>Adherence measurement NR |
| Kootker et al., 2017<br>Outpatient | Adults aged ≥ 18 who suffered a stroke ≥ 3 months ago, score > 7 on the HADS-D, score > 27 on the MMSE, score positively on NIHSS communication-related items<br>Recruited from seven rehabilitation centres or hospital rehabilitation departments in the Netherlands | *N* = 61<br>*M* = NR, *SD* = NS, range = 25-76<br>37.7% female<br>Ethnicity NR | CBT + Occupational or Movement Therapy (CBT)<br>13-16 F2F sessions lasting 1h<br>Delivered by trained experienced Psychologist<br>Adherence measured but details NR |
| Majumdar & Morris, 2019<br>Community | Stroke survivors aged ≥ 18, discharged from hospital, without severe communication or cognitive impairments<br>Recruited from stroke clinical teams across three NHS sites in South Wales and one in South West England, UK | *N* = 53<br>*M* = 62.7, *SD* = 13.9, range = NR<br>39.6% female<br>Ethnicity NR | ACT-based Intervention (third-wave CBT)<br>Four weekly 2-hour F2F group sessions<br>Delivered by CP plus AP or stroke care coordinator who completed two-day training<br>Adherence not measured |

| Study & setting | Population (Inclusion criteria; Recruitment; Location) | Sample charac. (Size; Age (M, SD, range); % Females; Ethnicity) | Active intervention (Type; Duration & delivery modality; Clinician; Adherence tool) |
|---|---|---|---|
| Minshall et al., 2020<br>Community | Stroke survivors aged ≥ 18 who are able to communicate in English and their carers<br>Recruited from three metropolitan hospitals and community referrals in Melbourne, Australia | *N* = 73 stroke survivors; *N* = 64 carers<br>[ab]*M* = 67.8, [ab]*SD* = 12.9, [b]range = 27-88<br>[b]45.2% female<br>[b]71.2% Australian-born, [b]1.4% New Zealand/Asia Pacific-born, [b]8.2% Asia-born, [b]8.2% UK-born, [b]4.1% Europe-born, [b]6.8% not stated | Stroke Self-Management Intervention (self-management)<br>Eight 1:1 one-hour weekly sessions and a booster session at three months, delivered F2F, online or over the phone<br>Delivered by Psychologist<br>Adherence measurement NR |
| Peng et al., 2015<br>Inpatient | Adults aged 40-90 who suffered a stroke (hemispheric, brain stem or cerebellar ischemic) and score > 15 on GCS<br>Recruited from a hospital in Wuhan, China | *N* = 180<br>[a]*M* = 60, [a]*SD* = 10.2, range = NR<br>27.8% female<br>Ethnicity NR | Neuro-Linguistic Programming and Health Education (other)<br>Four 1:1 F2F sessions delivered twice weekly, lasting 1-2h.<br>Delivered by trained interventionists<br>Adherence not measured |
| Poćwierz-Marciniak & Bidzan, 2017<br>Inpatient | First stroke survivors, presence of motor disability, no evident cognitive difficulties, a score of ≥ 27 on MMSE and a score of ≥ 16 on FAB<br>Recruited from a rehabilitation centre in Gdynia, Poland | *N* = 61<br>*M* = 64, *SD* = NR, range = 44-84<br>52.5% female<br>Ethnicity NR | Music Therapy (Creative Therapy)<br>10 F2F twice-weekly 1:1 sessions<br>Delivered by trained Music Therapist and Researcher<br>Adherence measurement NR |
| Raglio et al., 2017<br>Inpatient | Stroke survivors aged ≥ 40 undergoing rehabilitation immediately after the acute phase, a score of ≥ 18 on MMSE, stable condition, no other neurologic and psychiatric diseases and sufficient autonomy in motor functions | *N* = 38<br>[a]*M* = 72.9, [a]*SD* = 8.5, range = 54-89<br>57.9% female<br>Ethnicity NR | Relational Active Music Therapy (Creative Therapy)<br>20 thrice-weekly 30-minute F2F sessions<br>Delivered by trained Music Therapist<br>Adherence measured by independent music therapist evaluating video- |

| Study & setting | Population (Inclusion criteria; Recruitment; Location) | Sample charac. (Size; Age (M, SD, range); % Females; Ethnicity) | Active intervention (Type; Duration & delivery modality; Clinician; Adherence tool) |
|---|---|---|---|
| | Recruitment NR, Italy | | recordings on the MTRS |
| Terrill et al., 2018<br>Community | English-speaking community-dwellers who suffered a stroke ≥ 6 months ago, score ≥ 19 on MoCA, cohabit with a partner who identifies as a carer and who is independent in ADLs and IADLs, and either partner score ≥ 5 on PHQ-9<br>Recruited through outpatient rehabilitation and neurology clinics and databases in Utah, USA | [b]*N* = 11 stroke survivors, 11 carers<br>[b]*M* = 56, [b]*SD* = 18.1, [b]range: 27-84<br>[b]55% female<br>Ethnicity NR | Dyadic PPI (PPI)<br>Eight-week 1:1 (couple) self-administered intervention with weekly check-in calls<br>Trained Research Assistants administered check-in calls<br>Adherence measurement NR |
| Thomas et al., 2019<br>Community | Adults aged ≥18 living in the community who suffered a stroke ≥ 3 months and ≤ 5 years ago, score ≥ 10 on PHQ-9 or ≥ 50 on VAMS ‘sad’ item<br>Recruited from acute and community stroke services in three sites in England, UK | *N* = 48<br>*M* = 65.6, *SD* = 13.6, range = NR<br>39.6% female<br>97.9% White, 2.1% Asian | Behavioural Activation (CBT)<br>Maximum of 15 one-hour 1:1 F2F sessions delivered over 4 months<br>Delivered by APs or PWPs who completed a two-day training<br>Adherence measured by independent researcher analysing video-recordings against manual |
| Visser et al., 2016<br>Outpatient | Stroke survivors aged 18-75, receiving outpatient rehabilitation and able to take part in group therapy<br>Recruited from a rehabilitation centre in the Netherlands and a hospital in Belgium | *N* = 166<br>*M* = 53.1, *SD* = 10.2, range = NR<br>47% female<br>Ethnicity NR | Problem-Solving Therapy (CBT)<br>Eight 1.5-hour group sessions<br>Delivered by trained Neuropsychologist<br>Adherence measurement NR |
| Wang et al., 2020<br>Inpatient | Chinese-speaking adults aged ≥ 40 who suffered an intracerebral hemorrhage 3-6 months ago, scored ≤ 20 on NIHSS<br>Recruited from a hospital in West China | *N* = 134<br>*M* = 59.9, *SD* = 10.7, range = 40-79<br>53.7% female | Mindfulness-Based Cognitive Therapy (third-wave CBT)<br>Eight 2-hour group sessions<br>Delivered by three professional |

| Study & setting | Population (Inclusion criteria; Recruitment; Location) | Sample charac. (Size; Age (M, SD, range); % Females; Ethnicity) | Active intervention (Type; Duration & delivery modality; Clinician; Adherence tool) |
|---|---|---|---|
| | | 98.5% Han, 1.5% Tibetan | Therapists<br>Adherence measurement NR |
| Wathugala et al., 2019<br>Community | Adults aged ≥ 18 who suffered a stroke > 1 year ago, with moderate to severe motor deficits and self-reported spasticity or hypertonia, and no prior mindfulness meditation experience<br>Recruitment NR, California, USA | *N* = 10<br>*M* = 59.8, *SD* = NR, range = 45-76<br>10% female<br>50% White, 30% Asian, 20% Hispanic | Mindfulness Meditation Training (third-wave CBT)<br>Two-week self-directed intervention with two F2F visits<br>Delivered by trained experimenters<br>Adherence measurement NR |
| | | Traumatic Brain Injury | |
| Ashman et al., 2014<br>Community | English-speaking TBI survivors aged 18-55, with DSM-IV diagnosis of depressive disorder or score of > 20 on BDI, access to a phone, residence within 1.5 hours of New York City; at least sixth-grade reading level and can provide informed consent<br>Recruited from advertisements, clinician referrals and word of mouth in New York, USA | *N* = 77<br>$^a$*M* = 47.6, $^a$*SD* = 10.3, range = NR<br>54.5% female<br>45.5% White, 22.1% Black / African American, 20.8% Hispanic / Latino, 10.4% Other | CBT (CBT)<br>16 1:1 sessions lasting 50-90 minutes and occurring twice weekly for the first month and once a week subsequently<br>Delivered by trained Postdoctoral Fellows in clinical neuropsychology and rehabilitation psychology with ≥ 2 years<br>Adherence measured by independent evaluator rating audio-recordings on CSPRS |
| Assonov, 2021<br>Setting NR | Currently demobilized veterans aged 18-64 who suffered TBI ≥ 3 years ago and score ≥ 14 on MMSE<br>Recruited from two hospitals in Ukraine | *N* = 70<br>*M* = 46.4, *SD* = 7.7, range = NR<br>3% female<br>Ethnicity NR | Two-step Resilience-Oriented intervention (CBT)<br>Six one-hour 1:1 F2F sessions<br>Delivered by Researcher<br>Adherence measurement NR |
| Azulay et | Medically stable adults aged 18-62 who | *N* = 22 | Mindfulness-Based Stress Reduction |

| Study & setting | Population (Inclusion criteria; Recruitment; Location) | Sample charac. (Size; Age (M, SD, range); % Females; Ethnicity) | Active intervention (Type; Duration & delivery modality; Clinician; Adherence tool) |
|---|---|---|---|
| al., 2013<br>Setting NR | suffered a mild TBI ≥ 3 months ago, can communicate in English and score ±1 SD from the mean on CVLT-II<br>Recruited from a post-acute brain injury rehabilitation center within a suburban rehabilitation hospital, USA | *M* = 48.9, *SD* = 8.3, range = NR<br>50% female<br>9.1% African American/Black, 4.5% Asian Pacific Islander, 68.2% White, 18.2% Hispanic/Latino | (third-wave CBT)<br>10 weekly 2-hour group sessions<br>Delivered by three trained neuropsychologists (two per group)<br>Adherence measurement NR |
| Bédard et al., 2003 & Bédard et al., 2005<br>Community | Mild/moderate TBI survivors aged 18-65 who can communicate in English and completed traditional rehabilitation<br>Recruited from a community-based rehabilitation programme, neuropsychologist referrals, the local brain injury association and media coverage in Ontario, Canada | *N* = 13; $^{c}$*N* = 7<br>$^{a}$*M* =42.1, *SD* = NR, range = 24-55; $^{c}$*M* = 45.6, $^{c}$*SD* = 11.2, range = NR<br>53.8% female; $^{c}$71.4% female<br>Ethnicity NR | Mindfulness-Based Stress Reduction (third-wave CBT)<br>12 weekly group sessions<br>Intervention delivery information NR<br>Adherence measurement NR |
| Gurr & Coetzer, 2005<br>Community | Patients who suffered TBI ≥ 6 months ago and experience headaches, with no severe cognitive or sensory impairments<br>Recruited from the database of a brain injury service in Poole, UK | *N* = 41<br>*M* = 44.1, *SD* = NR, range = 22-72<br>31.7% female<br>Ethnicity NR | CBT for CPTH (CBT)<br>Three weekly group relaxation sessions, six fortnightly 30-minute 1:1 sessions and one follow up session<br>Intervention delivery information NR<br>Adherence measurement NR |
| Hart et al., 2017<br>Outpatient | Adults aged 18-65 who suffered a moderate or severe TBI ≥ 6 months ago, experience new or worse problematic anger via self-, SO-, or clinician report, score ≥ 1 SD above the mean for age and gender on the TA or AX-O subscales of the STAXI-2, or score ≥ 9 on BAAQ, able to communicate in English, | *N* = 90<br>$^{a}$*M* = 32.3, $^{a}$*SD* = 11.6, range = NR<br>18.9% female<br>68.9% White, 23.3% Black, 7.8% Hispanic / Other | Anger Self-Management Training (self-management)<br>Eight 1:1 weekly sessions lasting up to 90 minutes<br>Delivered by one qualified trained Therapist per condition / site with ≥ 1 |

| Study & setting | Population (Inclusion criteria; Recruitment; Location) | Sample charac. (Size; Age (M, SD, range); % Females; Ethnicity) | Active intervention (Type; Duration & delivery modality; Clinician; Adherence tool) |
|---|---|---|---|
|  | able to travel independently in the community, and aged ≥ 16 at time of injury<br>Recruited from three outpatient treatment centers, USA |  | year experience in counselling for people with TBI<br>Adherence measured by author comparing audio-recordings to detailed checklists |
| Kjeldgaard et al., 2014<br>Outpatient | Adults aged 18-65 with CPTH due to a mild TBI without other neurological or psychiatric disorders, and interested in psychological headache treatment<br>Recruited from a multidisciplinary tertiary headache centre in Denmark | *N* = 90<br>*M* = 34, *SD* = 11.13, range = NR<br>56% female<br>Ethnicity NR | CBT for CPTH (CBT)<br>Eight 2-hour weekly group sessions<br>Delivered by experienced CP<br>Adherence measurement NR |
| Theadom et al., 2018<br>Community | Adults aged 18-60 who suffered mild/moderate TBI ≥ 3 months and ≤ 3 years ago with internet access, self-reported difficulty initiating or maintaining sleep for < 3 months and score of ≥ 5 on PSQI<br>Recruited from concussion services in Hamilton and Auckland in New Zealand | *N* = 24<br>*M* = 35.9, *SD* = 11.8, range NR<br>62.5% female<br>54.2% European, 45.8% Other | CBT for insomnia (CBT)<br>Six-week self-directed online module taking around 20 minutes each week<br>As intervention was delivered online, intervention delivery information NR<br>Adherence measurement NR |
| Acquired Brain Injury |  |  |  |
| Cullen et al., 2018<br>Outpatient | Medically stable adults aged ≥ 18 who suffered ABI 3-36 months ago, scored at least in the ‘moderate’ in one or more DASS-21 subscales, able to consent<br>Recruited from stroke outpatient clinics, the stroke psychology service outpatient waiting | *N* = 27<br>*M* = NR, *SD* = NR, range = NR<br>37% female<br>Ethnicity NR | Brief Positive Psychotherapy Intervention (PPI)<br>Eight weekly 1:1 F2F sessions<br>Delivered by PhD Research Psychologist with no formal therapy qualifications<br>Adherence measured by chief investigator rating audio-recorded |

| Study & setting | Population (Inclusion criteria; Recruitment; Location) | Sample charac. (Size; Age (M, SD, range); % Females; Ethnicity) | Active intervention (Type; Duration & delivery modality; Clinician; Adherence tool) |
|---|---|---|---|
| | list and a community brain injury service in Glasgow, UK | | sessions against treatment manual on three-point scale |
| Exner et al., (2022)<br>Outpatient | Adults aged 18-65 who suffered ABI ≥ 3 months ago and after age of 14, sufficient cognitive and language abilities, and a score SD ≥ 1 below population mean on cognitive tests or symptoms consistent with one or more psychological disorders from DSM-IV<br>Recruited from psychotherapy outpatient clinic in Marburg, Germany | *N* = 56<br>[a]*M* = 45.6, [a]*SD* = 11.1, range = NR<br>46% female<br>Ethnicity NR | CBT + Neuropsychology (CBT)<br>Maximum of 84 1:1 weekly F2F sessions<br>Delivered by three Trainee CPs<br>Adherence not measured |

*Note.* 1:1 = one-to-one; AAT = Aachen Aphasia Test; ACT = Acceptance and Commitment Therapy; ADLs = Activities of Daily Living; AP = Assistant Psychologist; AX-O = Anger Expression-Out; BDI = Beck Depression Inventory; CBT = Cognitive Behavioural Therapy; CP = Clinical Psychologist; CPTH = chronic post-traumatic headache; CSPRS = Collaborative Study Psychotherapy Rating Scale; CVLT-II = California Verbal Learning Test-II; DASS-21 = Depression Anxiety Stress Scales; DSM-IV = Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition; F2F = face-to-face; FAB = Frontal Assessment Battery; FU = follow-up; GCS = Glasgow Coma Scale; GDS-SF = Geriatric Depression Scale Short Form; HADS-D = Hospital Anxiety and Depression Scale- depression subscale; IADLs = Instrumental Activities of Daily Living; MMSE = Mini Mental State Examination; MoCA = Montreal Cognitive Assessment; MTRS = Music Therapy Rating Scale; NIHSS = National Institutes of Health Stroke Scale; NR = Not reported; OT = Occupational Therapist; PPI = Positive Psychology Intervention; PHQ-9 = 9-item Patient Health Questionnaire; PSQI = Pittsburgh Sleep Quality Index; PWP = Psychological Wellbeing Practitioner; RCT = Randomized Controlled Trial; SLT = Speech and Language Therapist; STAXI-2 = State-Trait Anger Expression Inventory-2; SO = Significant Other; TA = Trait Anger; VAMS = Visual Analogue Mood Scales.

[a]Calculated based on information available in full-text paper. [b]Only data for stroke survivors is presented. [c]Refers to participants followed-up.

## Intervention and Outcome Characteristics

Most of the interventions being evaluated can be categorised as CBT (*n* = 9) or third-wave CBT (mindfulness, *n* = 4; ACT, *n* = 1). Others consist of creative therapies (*n* = 3), self-management (*n* = 2), counselling (*n* = 2), narrative-theory-based therapies (*n* = 2), PPI (*n* = 2), and other non-specified (*n* = 2). Psychoeducation & Behaviour Therapy (Chang et al. 2011) was described as counselling and therefore was grouped with other counselling interventions. The total number of interventions (*n* = 27) is higher than the number of included studies (*n* = 26) because one RCT (Ashman et al., 2014) compared two experimental groups: CBT and Supportive Psychotherapy. Detailed descriptions of interventions and comparators can be found in Appendix B.

Two studies included carers of brain injury survivors (Minshall et al., 2020; Terrill et al., 2018). Number of sessions offered ranged 3-84, delivered individually (*n* = 11), as a group (*n* = 7), a combination (*n* = 2), or online / self-directed (*n* = 3) from those that reported delivery modality. Interventions were delivered predominantly by qualified psychologists or therapists (*n* = 12), pre-qualified, trainees or psychologists with no formal therapy experience (*n* = 4), and non-psychological professionals (*n* = 3), whereas almost one third of studies did not specify the role of those delivering the intervention (*n* = 7). Intervention adherence measurement was not reported or not completed by 70% of studies (*n* = 18). Most outcome measures assessed quality of life (QoL; *n* = 23), an equal amount measured life satisfaction (*n* = 3) and wellbeing (*n* = 3), and one measured happiness. These outcomes were mostly secondary (*n* = 14). Appendix C specifies how these outcome measures are scored and interpreted.

**Table 4**

*Study and Outcome Characteristics and Results*

| Study ID | Design; Comparators; Sample analysed | Timing of assessments; Completion rate | Outcome of interest; Outcome measure | Main findings (Reported $p$ and controlled or uncontrolled ES ($d$, $\eta^2$ or $\eta^2_p$), calculated $g$) |
|---|---|---|---|---|
| | | | Stroke | |
| BRA202 & HJE2019 | RCT<br>IG: Dialogue-based intervention + TAU ($N = 166$)<br>CG: TAU ($N = 156$) | Pre, post, FU (12 months)<br>282/322 (88%) | Secondary Outcome: QoL (SAQOL- 39g) | Paired-samples t-test (U): significant pre-post treatment improvement on SAQOL- 39g for CG ($p = .003$, [a]$d = .23$, [a]$g = .23$).<br>Independent-samples t-test (U; controlling for baseline): NS differences ($p > .05$) post-intervention or FU on SAQOL-39g. |
| CHA2011 | RCT<br>IG: Psychoeducation & Behavior Therapy + TAU ($N = 34$)<br>CG: TAU ($N = 32$) | Pre-post<br>66/77 (86%) | Outcome: QoL (SSQOL-Chinese) | ANOVA (C): Significant time*condition effects on SSQOL-Chinese ($p < .001$, $\eta^2_p = .40$) favouring IG. |
| COR2014 & COR2015 | Pre-post<br>Biographic-narrative intervention ($N = 27$) | Pre, post, FU (3 months)<br>[a]20/27 (73%) | Primary Outcome: QoL (ALQI)<br>Secondary Outcome: Life Satisfaction (SWLS) | Wilcoxon signed-ranks test (U):<br>Significant pre-post, pre-FU and post-FU treatment improvement on ALQI complaints ($p < .001$, [a]$d = .28$, [a]$g = .28$; $p < .001$, [a]$d = .43$, [a]$g = .42$; $p = .037$, [a]$d = .14$, [a]$g = .14$) and ALQI burden ($p < .001$, [a]$d = .27$, [a]$g = .26$; $p < .001$, [a]$d = .50$, [a]$g = .49$; $p = .015$, [a]$d = .20$, [a]$g = .20$) scores.<br>NS differences on SWLS pre-post or pre-FU ($p > .05$). |
| KER2018 | Pilot RCT<br>IG: Early Motivational Interviewing ($N = 18$) | Pre, post, FU (3 months)<br>38/48 (79%) | Secondary Outcome: QoL (QLI-Stroke | No statistical analysis done.<br>Within-group comparisons (U): Improvement pre-post treatment and pre-FU on QLI for both IG ([a]$d = 1.84$, [a]$g$ |

| Study ID | Design; Comparators; Sample analysed | Timing of assessments; Completion rate | Outcome of interest; Outcome measure | Main findings (Reported $p$ and controlled or uncontrolled ES ($d$, $\eta^2$ or $\eta^2_p$), calculated $g$) |
|---|---|---|---|---|
|  | CG: TAU ($N$ = 20) |  | version) | = 1.80; $^{a}d$ = 1.64, $^{a}g$ = 1.61) and CG ($^{a}d$ = 1.05, $^{a}g$ = 1.03; $^{a}d$ = 1.33, $^{a}g$ = 1.31).<br>Between-group comparisons (U): Improvement post treatment on QLI for IG ($^{a}d$ = .47, $^{a}g$ = .46), no differences at FU ($^{a}d$ = .06, $^{a}g$ = .06). |
| KON2016 | RCT<br>IG: Creative Art Therapy + TAU ($N$ = 54)<br>CG: TAU ($N$ = 59) | Pre-post<br>113/118 (96%) | Outcome: QoL (PTQL) | Independent t-test (U): Significant improvement on PTQL change scores for IG ($p < .001$, $^{a}d$ = .67, $^{a}g$ = .67). |
| KOO2017 | RCT<br>IG: CBT + OT or Movement Therapy ($N$ = 31)<br>CG: Computerised Cognitive Training ($N$ = 30) | Pre, post, FU (4 & 8 months)<br>44/61 (72%) | Secondary Outcomes: QoL (SSQoL); Life Satisfaction (LS2) | Linear mixed model (C; controlling for baseline): NS time*condition effects on SSQoL or LS2 ($p > .05$). |
| MAJ2019 | RCT<br>IG: ACT ($N$ = 26)<br>CG: TAU ($N$ = 27) | Pre, post, FU (2 months)<br>47/53 (89%) | Secondary Outcomes: QoL (EQ-5D-5L); Wellbeing (WEMWBS) | MANOVA (C): Significant time*condition effects on all secondary outcomes combined ($p = .003$, $\eta^2_p$ = .44) favouring IG. NS univariate time*condition effects on EQ-5D-5L or WEMWBS ($p > .05$).<br>ANOVA (C): Significant time*condition effects pre-post treatment on WEMWBS ($p = .047$, $\eta^2_p$ = .07) favouring IG; NS time*condition effects post-FU ($p > .05$), suggesting maintenance of gains. NS effects pre-post treatment on EQ-5D-5L ($p > .05$). |
| MIN2020 | RCT<br>IG: Stroke Self-Management intervention ($N$ = 77)<br>CG: TAU ($N$ = 60) | Pre, post, FU (2 months)<br>52/89 (58%) | Primary Outcomes: QoL (AQoL-6D; EQ-5D-3L) | Mixed effects model (C): NS time*condition effects on AQoL-6D and EQ-5D-3L for stroke survivors or carers ($p > .05$). |

| Study ID | Design; Comparators; Sample analysed | Timing of assessments; Completion rate | Outcome of interest; Outcome measure | Main findings (Reported *p* and controlled or uncontrolled ES (*d*, $\eta^2$ or $\eta^2_p$), calculated *g)* |
|---|---|---|---|---|
| PEN2015 | RCT<br>IG: Neuro-Linguistic Programming + health education + TAU (*N* = 90 post-intervention; *N* = 79 at FU)<br>CG: TAU (*N* = 90 post-intervention; *N* = 76 at FU) | Pre, post, FU (6 months)<br>155/180 (86%) | Secondary Outcome: QoL (QLI-index) | Wilcoxon rank-sum test (U): [b]Significant improvement post treatment on QLI-index (*p* = .01) and FU (*p* < .001) for IG. |
| POĆ2017 | RCT<br>IG: Music Therapy + TAU (*N* = 30)<br>CG: TAU (*N* = 31) | Pre-post<br>Completion rate NR | Primary Outcome: QoL (SF-36; SA-SIP30; The Cantril Ladder) | ANOVA (C):<br>Significant time*condition effects favouring IG on following SF-36 subscales: a) physical functioning (*p* = .05, $\eta^2$ = .06); b) general health (*p* < .001, $\eta^2$ = .22); c) vitality (*p* < .001, $\eta^2$ = .18); and d) mental health (*p* = .038, $\eta^2$ = .07). NS effects on all other subscales (*p* > .05).<br>Significant time*condition effects on SA-SIP30 (*p* = .006, $\eta^2$ = .12) and Cantril Ladder current (*p* < .001, $\eta^2$ = .21) and future (*p* = .008, $\eta^2$ = .11) scores, favouring IG. NS effects on before-illness scores (*p* > .05). |
| RAG2017 | Pilot RCT<br>IG: Relational Active Music Therapy + TAU (*N* = 19)<br>CG: TAU (*N* = 19) | Pre-post<br>Completion rate NR | Outcome: QoL (MQOL-It) | ANOVA (C): NS time*condition effects on MQOL-It (*p* > .05). |
| TER2018 | Pilot pre-post<br>Dyadic Positive Psychology Intervention | Pre, post, FU (3 months); comparisons | Primary Outcome: QoL (OPQOL) | No statistical analysis done.<br>Within-group comparisons (U):<br>Improvement pre-post treatment on following OPQOL |

| Study ID | Design; Comparators; Sample analysed | Timing of assessments; Completion rate | Outcome of interest; Outcome measure | Main findings (Reported *p* and controlled or uncontrolled ES (*d*, $\eta^2$ or $\eta^2_p$), calculated *g)* |
|---|---|---|---|---|
| | *(N* = 22) | did not include FU data<br>10/11 (91%) | | subscales: a) general ($^a$*d* = .48, $^a$*g* = .46); b) life overall ($^a$*d* = .34, $^a$*g* = .32); c) psychological ($^a$*d* = .38, $^a$*g* = .37); and d) finance ($^a$*d* = .40, $^a$*g* = .39). Decline pre-post treatment on following OPQOL subscales: a) social relationships ($^a$*d* = .46, $^a$*g* = .45); and b) leisure ($^a$*d* = .18, $^a$*g* = .17). |
| THO2019 | Feasibility RCT<br>IG: BA + TAU (*N* = 24)<br>CG: TAU (*N* = 23) | Pre, post, FU (6 months)<br>39/49 (80%) | Secondary Outcome: QoL (EQ-5D-5L) | No statistical analysis done.<br>Between-group comparisons (U): Improvement on EQ-5D-5L change scores ($^a$*d* = .39, $^a$*g* = .39) for CG. |
| VIS2016 | RCT<br>IG: Problem-Solving Therapy + TAU (*N* = 88)<br>CG: TAU (*N* = 78) | Pre, post, FU (6 & 12 months)<br>141/166 (85%) | Primary Outcome: QoL (SSQoL-12 psychosocial score)<br>Secondary Outcome: QoL (EQ-5D-5L utility score) | Linear mixed models (C): NS time*condition effects on SSQoL psychosocial score (*p* > .05). Significant time*condition effects on EQ-5D-5L utility score when considering the first three time-points (*p* = .034, *d* = .34) favouring IG. NS effects at 12-month FU (*p* > .05). |
| WAN2020 | RCT<br>IG: MBCT (*N* = 67)<br>CG: Stress Management Education (*N* = 67) | Pre-post<br>148/202 (73%) | Outcome: Wellbeing (FACT-Br) | Paired-samples t-test (U): Significant improvement pre-post treatment on FACT-Br total score (*p* < .05, *d* = .51, $^a$*g* = .51) for IG. |
| WAT2019 | Feasibility pre-post Mindfulness Meditation Training (*N* = 10) | Pre-post<br>10/11 (91%) | Outcome: QoL (SSQoL) | Paired-samples t-test (U): Significant improvement on following SSQoL domains: a) energy (*p* = .013, $^a$*d* = .34, $^a$*g* = .32); b) personality (*p* = .026, $^a$*d* = .82, $^a$*g* = .78); and c) work/productivity (*p* = .032, $^a$*d* = .37, $^a$*g* = .35). When correcting for multiple comparisons |

| Study ID | Design; Comparators; Sample analysed | Timing of assessments; Completion rate | Outcome of interest; Outcome measure | Main findings (Reported *p* and controlled or uncontrolled ES (*d*, $\eta^2$ or $\eta^2_p$), calculated *g)* |
|---|---|---|---|---|
| | | | | these were NS (*p* > .0042). NS effects on other SSQoL subscales (*p* > .05). |
| | | Traumatic Brain Injury | | |
| ASH2014 | RCT<br>IG: CBT (*N* = 24)<br>CG: Supportive Psychotherapy (*N* = 24) | Pre-post<br>43/77 (56%) | Secondary Outcome: QoL (Life-3) | Mixed effects model (C): NS time*condition effects on Life-3 (*p* > .05). |
| ASS2021 | Pilot RCT<br>IG: Two-step Resilience-Oriented intervention (*N* = 35)<br>CG: TAU + Waitlist (*N* = 35) | Pre-post<br>70/70 (100%) | Secondary Outcome: QoL (CQLS) | Multivariate linear regression (C): [b]Significant time*condition effects on CQLS (*p* = .017, *d* = .62), favouring IG. |
| AZU2013 | Pre-post<br>MBSR + concurrent rehabilitation (*N* = 22) | Pre-post<br>Completion rate NR | Primary Outcome: QoL (PQOL) | Paired-samples t-test (U): Significant improvement on PQOL (*p* = .003, *d* = .43, [a]*g* = .44). |
| BED2003 & BED2005 | Quasi-experimental<br>IG: MBSR (*N* = 10 at post-intervention; *N* = 7 at FU)<br>CG: Dropouts (*N* = 7) | Pre, post, FU (12 months)<br>10/19 (53%) | Primary Outcome: QoL (SF-36) | ANOVA (C) and post-hoc tests:<br>Significant time*condition effects favouring IG on following SF-36 subscales: a) mental component (*p* = .036, [a]*d* = 1.27, [a]*g* = 1.46); b ) vitality (*p* = .005, [a]*d* = 1.53, [a]*g* = 1.43); and c) mental health (*p* = .001, [a]*d* = 1.85, [a]*g* = 1.73).<br>Significant time*condition effects favouring IG that were significant pre-post treatment but became NS at FU were the SF-36 subscales of bodily pain (*p* = .034, [a]*d* = 1.42, [a]*g* = 1.33) and role-emotional (*p* = .028, [a]*d* = 1.75, [a]*g* = 1.64). |

| Study ID | Design; Comparators; Sample analysed | Timing of assessments; Completion rate | Outcome of interest; Outcome measure | Main findings (Reported $p$ and controlled or uncontrolled ES ($d$, $\eta^2$ or $\eta^2_p$), calculated $g$) |
|---|---|---|---|---|
| | | | | NS time*condition effects on all other subscales ($p > .05$). |
| GUR2005 | Pre-post<br>CBT ($N = 20$ post-intervention; $N = 13$ at FU) | Baseline, pre, post, FU (3 months)<br>13/41 (32%) | Outcome: QoL (NHP) | Wilcoxon signed-ranks test (U):<br>Significant improvement pre-post treatment on NHP pain scale ($p = .03$, [a]$d = .34$, [a]$g = .33$). NS differences when comparing baseline to FU ($p > .05$).<br>Significant improvement baseline to FU on NHP emotion scale ($p = .007$, [a]$d = .67$, [a]$g = .67$).<br>NS differences on all other scales and time points ($p > .05$). |
| HAR2017 | RCT<br>IG: Anger Self-Management Training ($N = 57$)<br>CG: Personal Readjustment and Education ($N = 27$) | Pre, post, FU (2 months)<br>84/90 (93%) | Secondary Outcomes: Life Satisfaction (SWLS); Wellbeing (Wellbeing Change Scale) | Mixed effects model (C): NS time*condition effects on SWLS ($p > .05$).<br>Mann-Whitney U test (U): NS differences on Wellbeing Change Scale rated by participants ($p > .05$); significant improvement for IG rated by carers ($p = .01$, [a]$d = .99$, [a]$g = .91$). |
| KJE2014 | RCT<br>IG: CBT ($N = 34$)<br>CG: Waitlist ([c]$N = 33$-$37$) | Pre, post, FU (26 weeks)<br>72/90 (80%) | Outcome: QoL (SF-36-Danish) | ANCOVA (C): [b]Significant time*condition effects on bodily pain subscale ($p = .02$) favouring CG. NS time*condition effects on other subscales ($p > .05$). |
| THE2018 | Pilot RCT<br>IG: CBT ($N = 9$)<br>CG: Education Programme ($N = 8$) | Pre-post<br>17/24 (71%) | Secondary Outcome: QoL (QOLIBRI) | Mann–Whitney U test (U): NS differences on QOLIBRI ($p > .05$). |
| | | | Acquired Brain Injury | |

| Study ID | Design; Comparators; Sample analysed | Timing of assessments; Completion rate | Outcome of interest; Outcome measure | Main findings (Reported *p* and controlled or uncontrolled ES ($d$, $\eta^2$ or $\eta^2_p$), calculated *g)* |
|---|---|---|---|---|
| CUL2018 | Pilot RCT<br>IG: Brief Positive Psychotherapy Intervention + TAU (*N* = 9)<br>CG: TAU (*N* = 8) | Pre, post, FU (3 months)<br>17/27 (63%) | Secondary Outcome: Happiness (AHI) | No statistical analysis done.<br>Between-group comparisons (U): Improvement pre-FU on AHI change scores ([b]*d* = 1.11) favouring IG. |
| EXN2022 | RCT<br>IG: CBT + Neuropsychology (*N* = 27)<br>CG: Waitlist (*N* = 29) | Pre, post, FU (6 months)<br>47/56 (84%) | Secondary Outcome: QoL (SEIQoL-DW; QOLIBRI) | Fixed effects regression (C): Significant time*condition effects on SEIQoL-DW (*p* =.018; [ab]*d* = .68) favouring IG. NS time*condition effects on QOLIBRI (*p* > .05). |

*Note*. Study ID: First three letters of first author surname and year of publication. ACT = Acceptance and Commitment Therapy; AHI = Authentic Happiness Inventory; ALQI = Aachen Life Quality Inventory; AQoL-6D = Australian Assessment of Quality of Life-6 Dimensions; BA = Behavioural Activation; C = Controlled Effect Size; CBT = Cognitive Behavioural Therapy; CG = Control Group; CQLS = Chaban Quality of Life Scale; EQ-5D-3L = 3-level EuroQoL 5-dimensions; EQ-5D-5L = 5-level EuroQoL 5-dimensions; ES: effect size; FACT-Br = Functional assessment of cancer therapy-brain; IG = Intervention Group; LS2 = Life Satisfaction questions; MBCT = Mindfulness-Based Cognitive Therapy; MBSR = Mindfulness-Based Stress-Reduction Therapy; MQOL-It = McGill Quality-of-Life Questionnaire- Italian version; NHP = Nottingham Health Profile; NS = Non-significant; OPQOL = Older People's Quality of Life Questionnaire; OT = Occupational Therapy; PQOL = Perceived Quality of Life scale; PTQL = Pictorial Thai Quality of Life questionnaire; QLI = Quality of Life Index; QLI-index = Spitzer's Quality of Life Index; QOLIBRI = Quality of Life after Brain Injury; RCT = Randomized Controlled Trial; SAQOL- 39g = Stroke and Aphasia Quality of Life Scale; SA-SIP30 = Stroke-Adapted 30-Item Version of the Sickness Impact Profile; SEIQoL-DW = Schedule for the Evaluation of Individual Quality of Life; SF-12 = Short-Form 12; SF-36 = Short-Form 36; SSQOL = Stroke Specific Quality of Life Scale; SWLS = Satisfaction with Life Scale; TAU = Treatment as usual; U = Uncontrolled Effect Size; WEMWBS = Warwick-Edinburgh Mental Well-being Scale. [a]Calculated based on information available in full-text paper. [b]Cohen’s *d* and/or Hodge’s *g* not calculated due to information not being available in full-text paper. [c]Value varies due to missing data.

## Quality Assessment

The quality assessment of studies by brain injury type is presented in Table 5. Half of the studies (*n* = 13) obtained a “weak" overall quality rating, with eight studies obtaining a “moderate” and five a “strong” overall rating.

Areas with the most “weak” ratings were blinding and confounders, with half (*n* = 13) or almost half (*n* = 12) of the studies obtaining a “weak” rating in each area respectively. Confounders were either rated as “weak” (46%; *n* = 12) or “strong” (54%; *n* = 14), with no studies scoring as “moderate” in this area. This means that studies either controlled for almost all confounders or less than 60% of those. Conversely, no study scored as “strong” for blinding, as there was no study reporting that participants were unaware of the research question.

Areas where the majority of the studies scored as “strong” consist of study design (77%; *n* = 20), with the majority of studies being RCTs or controlled trials, and data collection methods (80%; *n* = 21). For withdrawals and dropouts, 11 studies were rated as “strong” (42%) with eight rating as “moderate” and seven as “weak”. Finally, selection bias was an area with predominantly “moderate” scores (70%; *n* = 18) and no “strong” scores.

**Table 5**

*Quality Review Using the EPHPP Tool*

| Study ID | Selection bias | Study design | Confounders | Blinding | Data collection methods | Withdrawals and dropouts | Overall quality rating |
|---|---|---|---|---|---|---|---|
| | | | | Stroke | | | |
| BRA2020 & HJE2019 | Moderate | Strong | Weak | Moderate | Weak | Strong | Weak |
| CHA2011 | Moderate | Strong | Weak | Moderate | Strong | Strong | Moderate |
| COR2014 & COR2015 | Moderate | Moderate | Weak | Weak | Strong | Moderate | Weak |
| KER2018 | Moderate | Strong | Strong | Weak | Strong | Moderate | Moderate |
| KON2016 | Moderate | Strong | Strong | Moderate | Strong | Strong | Strong |
| KOO2017 | Moderate | Strong | Strong | Moderate | Strong | Moderate | Strong |
| MAJ2019 | Moderate | Strong | Weak | Weak | Strong | Strong | Weak |
| MIN2020 | Weak | Strong | Weak | Weak | Strong | Weak | Weak |
| PEN2015 | Moderate | Strong | Strong | Moderate | Weak | Strong | Moderate |
| POĆ2017 | Moderate | Strong | Strong | Weak | Moderate | Weak | Weak |
| RAG2017 | Moderate | Strong | Weak | Moderate | Strong | Weak | Weak |
| TER2018 | Weak | Moderate | Weak | Weak | Strong | Strong | Weak |
| THO2019 | Moderate | Strong | Strong | Moderate | Strong | Strong | Strong |

| Study ID | Selection bias | Study design | Confounders | Blinding | Data collection methods | Withdrawals and dropouts | Overall quality rating |
|---|---|---|---|---|---|---|---|
| VIS2016 | Weak | Strong | Strong | Moderate | Strong | Strong | Moderate |
| WAN2020 | Weak | Strong | Strong | Moderate | Strong | Moderate | Moderate |
| WAT2019 | Weak | Moderate | Weak | Weak | Strong | Strong | Weak |
| | | | Traumatic Brain Injury | | | | |
| ASH2014 | Moderate | Strong | Strong | Moderate | Strong | Weak | Moderate |
| ASS2021 | Moderate | Strong | Strong | Weak | Strong | Weak | Weak |
| AZU2013 | Moderate | Moderate | Weak | Weak | Moderate | Weak | Weak |
| BED2003 & BED2005 | Weak | Moderate | Weak | Weak | Strong | Weak | Weak |
| GUR2005 | Weak | Moderate | Weak | Weak | Strong | Moderate | Weak |
| HAR2017 | Moderate | Strong | Strong | Moderate | Strong | Strong | Strong |
| KJE2014 | Moderate | Strong | Strong | Weak | Moderate | Moderate | Moderate |
| THE2018 | Moderate | Strong | Strong | Moderate | Strong | Moderate | Strong |
| | | | Acquired Brain Injury | | | | |
| CUL2018 | Moderate | Strong | Weak | Moderate | Strong | Moderate | Moderate |
| EXN2022 | Weak | Strong | Strong | Weak | Strong | Strong | Weak |

*Note.* Study ID: First three letters of first author surname and year of publication. Overall Quality Score: Strong rating = no areas with “weak” ratings;

Moderate rating = one area with “weak” rating; Weak rating = 2 or more areas with “weak” ratings.

### Effectiveness of Interventions

Statistical significance and effect size for each outcome of interest are presented in Table 4. Only controlled comparisons are reported for RCTs when these were carried out, with within- and between-group comparisons reported in their absence. Results for subscales of outcome measures are only presented when a total score was not reported.

Out of the 28 measures of QoL in the included studies, positive effects were found for 54% (*n* = 15). No effect was found for any of the three measures of life satisfaction, while positive effects were found for all wellbeing (*n* = 3) and happiness (*n* = 1) measures.

#### ***CBT***

Nine studies in total evaluated CBT interventions across all brain injuries, all measuring QoL and one additionally measuring life satisfaction. Controlled comparisons were completed by six RCTs (one of which was described as a pilot). From these, only one study (Assonov, 2021) comparing a Two-Step Resilience-Oriented intervention to TAU pre- and post-treatment in TBI found significant medium-to-large effects on QoL favouring the intervention group (IG). However, the quality of this study was low. Two studies produced mixed findings: a study of moderate quality (Visser et al., 2016) found that Problem-Solving Therapy versus TAU for stroke survivors did not have significant effects on the psychosocial domain of a stroke-specific QoL measure, measured across four time-points (pre, post, six- and 12-month FU), however significant improvements for the IG were found for the utility score of another QoL measure for all time points apart from 12 months, with a small-to-medium effect size; and a low-quality study (Exner et al., 2022) evaluated CBT plus Neuropsychology against a waitlist control group (CG) in ABI, measuring QoL pre, post, and at 6 months, showing significant medium-to-large effects favouring the IG for a measure of individual QoL, and no significant effects for another measure of brain injury-specific QoL.

The remaining three studies making controlled comparisons found no effects or negative effects for the CBT group. For a high-quality study in stroke (Kootker et al., 2017), CBT plus Occupational or Movement Therapy did not have any significant effects on QoL or life satisfaction measured across four time-points (pre, post, four- and eight-month FU) compared to an active control group. Similarly, when CBT was compared to Supportive Psychotherapy in a moderate-quality study in TBI (Ashman et al., 2014), no significant effects were found on QoL pre- to post-intervention. Finally, a moderate-quality study (Kjeldgaard et al., 2014) in TBI compared CBT for post-traumatic headaches to a waitlist CG across three time-points (pre, post and 26-week FU), finding significant effects for the CG on the pain subscale of the QoL measure. Effect size was not reported and was unattainable.

From the remaining studies, a low-quality pre-post study (Gurr & Coetzer, 2005) evaluating CBT for post-traumatic headaches in TBI found significant pre-post differences on the pain scale of a QoL measure with small-to-medium effect sizes, as well as significant baseline to 3-month FU differences on the emotion scale with medium-to-large effect sizes, but no other differences on these or other subscales. In contrast, a high-quality feasibility RCT (Thomas et al., 2019) comparing Behavioural Activation to TAU in TBI completed between-group comparisons of change scores from baseline to six-month FU, and found a decline in QoL for the IG with a small-to-medium effect size; however, statistical comparisons were not done. Finally, a high quality pilot RCT in TBI (Theadom et al., 2018) did not find any significant differences when performing post-treatment between-group comparisons of online CBT for insomnia to an active CG.

### ***Third-wave CBT***

Two pre-post studies evaluated the effectiveness of mindfulness interventions on QoL, however both were of low quality and neither followed up past the end of the intervention. Wathugala et al. (2019) evaluated Mindfulness Meditation Training for stroke survivors and did not find any significant improvements on any of the scales of a QoL measure after controlling for multiple comparisons. In contrast, Azulay et al. (2013) evaluated Mindfulness-Based Stress Reduction (MBSR) for TBI survivors and found a significant improvement with a small-to-medium effect size.

MBSR in TBI was also evaluated by a low-quality quasi-experimental study (Bédard et al., 2003; Bédard et al., 2005) which showed significant controlled large effects favouring the IG versus dropouts on three out of eight subscales of a QoL measure across three time-points (pre, post, and 12-month FU). Significant effects on two additional subscales became non-significant at follow-up. Finally, a moderate-quality RCT (Wang et al., 2020) compared Mindfulness-Based Cognitive Therapy (MBCT) to an active CG measuring wellbeing in stroke. Pre-post within-group comparisons showed significant improvements for MBCT on wellbeing, with a medium effect size. In addition to mindfulness, a low-quality RCT (Majumdar & Morris, 2019) evaluated a didactic ACT intervention against TAU, measuring both QoL and wellbeing pre- and post-treatment. Controlled comparisons showed a significant medium intervention effect on wellbeing maintained at 2-months FU, however no significant effect on QoL.

### ***Creative Therapy***

Two RCTs and a pilot RCT evaluated creative therapies with mixed findings. All three studies recruited stroke survivors, measured QoL, compared only pre- and post-treatment time points, and had TAU CGs. Two studies evaluated music therapy and reported controlled comparisons, however were of low quality: the pilot RCT (Raglio et al., 2017) found that Relational Active Music Therapy did not have any significant effects on QoL; while the other RCT (Poćwierz-Marciniak & Bidzan, 2017) found significant improvements for music therapy on all three QoL measures (for one of these, significant effects were only found for three out of eight subscales). Effect sizes ranged from medium to medium-to-large. The final high-quality RCT (Kongkasuwan et al., 2016) made only between-group comparisons of pre-post change scores and found significant improvements for creative art therapy versus TAU, with a medium-to-large effect size.

### ***Counselling***

Two moderate-quality studies evaluated counselling interventions, both measuring QoL in stroke. The RCT by Chang et al. (2011) reported controlled comparisons pre- and post-treatment for Psychoeducation & Behaviour Therapy versus TAU, and found significant effects favouring the IG with a large effect size. The pilot RCT (Kerr et al., 2018) did not report on statistical significance but provided between- and within-group comparisons of Early Motivational Interviewing versus TAU for three time points (pre, post, 3-month FU).

Between-group comparisons showed an improvement for the IG with a medium effect size at post-treatment, which however disappeared at FU as the effect size became negligible. Furthermore, within-group comparisons showed that both IG and CG improved pre- to post-treatment as well as pre-treatment to FU, with large effect sizes.

### ***Narrative-Theory-Based Interventions***

Two low-quality studies evaluated narrative-theory-based interventions for stroke survivors. A RCT (Bragstad et al., 2020; Hjelle et al., 2019) compared a Dialogue-Based intervention to TAU measuring QoL across three time points (pre, post, and 12-month FU). Within-group comparisons showed a small significant pre- post-treatment effect on QoL for the CG only, while between-group comparisons showed no significant differences at any time-point. In contrast, a pre-post study (Corsten et al., 2014; Corsten et al., 2015) evaluated the effectiveness of a Biographic-Narrative Intervention on QoL and life satisfaction across three time points (pre, post, and 3-months FU) and within-group comparisons showed small but significant improvements on both QoL complaints and their burden pre-post and post-intervention to FU. No significant differences were found for life satisfaction across any time-points.

### ***Self-Management***

A low-quality RCT (Minshall et al., 2020) evaluated a self-management intervention for stroke survivors against TAU on two QoL measures across three time-points (pre, post, and 2-month FU). Controlled comparisons showed no significant intervention effects on either QoL measure. Similarly, a high-quality RCT (Hart et al., 2017) evaluating Anger Self-Management Training for TBI survivors against an active CG on life satisfaction and wellbeing found that controlled comparisons showed no significant effects on life satisfaction across three time-points (pre-, post-, 12-months). Between-group comparisons showed no significant effects on wellbeing change rated by TBI survivors, however there was a significant effect with a large effect size on participant wellbeing rated by carers, favouring the IG.

### ***Positive Psychology Interventions***

Two pilot studies measured the effectiveness of PPIs, however none completed statistical comparisons. A low-quality pre-post study (Terrill et al., 2018) evaluated the effectiveness of dyadic PPI on QoL in stroke, with descriptive pre-post within-group comparisons showing mixed findings: while small-to-medium improvements were found on four out of nine QoL domains, a small-to-medium decline was noted on another two. In contrast, a moderate-quality RCT (Cullen et al., 2018) evaluated the effectiveness of a brief Positive Psychotherapy intervention against TAU on happiness in ABI, with descriptive between-group comparisons of pre- to 3-month FU change scores showing a large improvement for the IG.

### *Other*

A moderate-quality RCT (Peng et al., 2015) compared Neuro-Linguistic Programming and health education against TAU in stroke, measuring QoL. Between-group comparisons at post-treatment and 6-month FU showed significant differences favouring the IG, however effect sizes were not reported and were unattainable. Lastly, Supportive Psychotherapy was compared to CBT for TBI survivors in a moderate-quality study (Ashman et al., 2014) with controlled comparisons showing no significant effects on QoL measured pre- and post-intervention.

## Discussion

The aim of this paper was to systematically review and present a narrative synthesis of psychological interventions that aim to increase positive affect, such as QoL, wellbeing and life satisfaction in ABI.

### Main Findings

Nine types of psychological interventions were evaluated in total, the majority targeting QoL. Out of 26 studies, 65% (*n* = 17) found intervention effects on positive affect measures. Specifically, these effects were found in 54% of QoL measures (*n* = 15) and all wellbeing (*n* = 3) and happiness (*n* = 1) measures, while no effects were found for life satisfaction measures (*n* = 3). Effects were found for eight intervention types: CBT; third-wave CBT; counselling; creative therapies; self-management; narrative-theory-based interventions; PPIs; and neuro-linguistic programming, however no controlled comparisons were available for the last three.

For CBT, all findings considered together give a mixed image of its effectiveness on outcomes of positive affect. Out of nine studies, only four found significant effects ranging from small to large and none were of high quality. However, three of these undertook controlled comparisons against TAU (Assonov et al., 2018; Exner et al., 2022; Visser et al., 2016), with only one providing pre-post comparisons (Gurr & Coetzer, 2005). Furthermore, three of the studies that did not find any controlled effects compared CBT to active control groups rather than TAU. Conflicting findings may in part be due to the range of different CBT interventions, ABI population, study designs and settings. For third-wave therapies, significant small to large effects on positive affect were found for four out of five studies, suggesting the effectiveness of mindfulness and ACT against TAU (Azulay et al., 2013; Bédard et al., 2003; Bédard et al., 2005; Majumdar & Morris, 2019) and stress management education (Wang et al., 2020). However, no studies were of high quality, only one study provided controlled comparisons. The study that did not find any effects was likely not powered due to small sample size (Wathugala et al., 2019).

In terms of creative therapies, two out of three studies found significant effects on positive affect against TAU, one of which being of high quality (Kongkasuwan et al., 2016) and one providing controlled comparisons (Poćwierz-Marciniak & Bidzan, 2017), which indicates mixed findings. Similarly, two moderate-quality studies evaluating counselling versus TAU found medium to large effects with only one study providing controlled comparisons (Chang et al., 2011), but these disappeared at FU for one of these studies (Kerr et al., 2018). Two pilots evaluating PPIs against TAU also showed mixed findings, with one study undertaking between-group comparisons finding large effects (Cullen et al., 2018) and another pre-post study finding improvements on some subscales and a decline on others (Terrill et al., 2018). However, none completed a statistical analysis or provided controlled comparisons. There are therefore promising findings supporting the effectiveness of creative therapies, counselling and PPIs on positive affect, although due to the variable study quality and lack of FU and controlled comparisons, no firm conclusions can be drawn. In contrast, none of the two studies evaluating self-management interventions found significant controlled effects in participant-rated positive affect, with one of these comparing self-management to an active control group. For narrative-theory-based interventions, one out of two studies found small to medium significant effects but these were only for one of two measures of positive affect and only pre-post comparisons were done (Corsten et al., 2014; Corsten et al., 2015). These conflicting findings may in part be due to variability in intervention content and delivery. Lastly, a study of moderate quality evaluating neuro-linguistic programming (NLP) found significant effects, although no effect size was available (Peng et al., 2015), and a moderate-quality study did not support use of Supportive Psychotherapy over and above CBT for enhancing QoL (Ashman et al., 2014).

### Findings in Relation to Previous Evidence

Although the effects of CBT on positive affect have not been previously reviewed for ABI survivors, they have for other types of long-term conditions. CBT has been found to be somewhat effective in enhancing QoL for cancer patients (Duncan et al., 2017), haemodialysis patients (Ling et al., 2020) and individuals with chronic back pain (Hajihasani et al., 2019), however the second review found CBT was only effective compared to usual care as opposed to antidepressant medication, and the final review could not tease out its effects from the effects of physical therapy. Similarly, the present review found some effectiveness of CBT in enhancing QoL, but only compared to usual care. Furthermore, similar to previously published research (e.g., Getu et al., 2021; Hajihasani et al., 2019), low-quality studies and lack of controlled comparisons limit the generalisations that can be made. It is perhaps unsurprising that evidence supporting the effectiveness of CBT in enhancing positive affect is not as strong as in reducing depression or anxiety (e.g., Ahrens et al., 2022), since CBT is known to be most effective when targeting a specific disorder (Waldron et al., 2013) rather than positive affect more generally.

The present review provides some support for the effectiveness of third-wave CBT interventions in ABI, which is not surprising considering that they tend to be appropriate for transdiagnostic difficulties (Robinson et al., 2019), as they are known to target common processes such as psychological flexibility (Whiting et al., 2017) that can lead to enhanced acceptance and wellbeing (Ciarrochi et al., 2013). A systematic review for stroke survivors (Lawrence et al., 2013) found benefits of mindfulness in QoL, however only one study measured this outcome. In contrast, Hearn and Cross (2020) found that only two mindfulness studies measured QoL and neither found improvements, however this was in spinal cord injury rather than ABI. In addition, ACT was found to be effective in enhancing wellbeing for non-ABI adults (Stenhoff et al., 2020). It is important to note that the quality of studies in the current review was low, and therefore more high-quality studies are needed to make firm conclusions regarding the effectiveness of third-wave therapies in enhancing positive affect.

This review found that evidence for creative therapies, although mixed, appears promising. This is in line with limited published research, for example music therapy (Li et al., 2020) and art therapy (Bosman et al., 2021) were found to be effective in enhancing QoL compared to usual care for cancer patients. However, similar to the current study, the low quality and methodological limitations of available studies are highlighted. Initial findings also appear promising for PPIs and counselling, however a small number of published reviews evaluated these interventions and even fewer investigated their effectiveness on positive affect. Counselling was found to have some effect on symptoms of anxiety and depression for older adults (Hill & Brettle, 2005) and in primary care (Bower et al., 2003), while PPIs were found to have a small to medium effect on wellbeing in mixed clinical and non-clinical populations (Carr et al., 2021), although they were not found more effective than active controls in enhancing happiness in depressed individuals (Lim & Tierney, 2022). A small number of self-management interventions were included in the present review, however no effect was found. In contrast, published literature suggests that these interventions are effective in improving QoL compared to usual care for stroke (Fryer et al., 2016) and cancer patients (van Dijck et al., 2016), although these reviews include non-psychological interventions.

The current review cannot draw conclusions for narrative-theory-based interventions due to mixed findings, and in fact a paucity of research is found in this area, with the only published review focusing on language difficulties in TBI (Steel et al., 2021). Similarly, it is not possible to draw conclusions for neuro-linguistic programming (NLP) from this study. A systematic review of NLP in organisational settings (Kotera et al., 2019) indicates that although improvements in outcomes such as self-esteem and occupational stress were seen, methodological limitations meant that benefits may not be as supported. Finally, there's a paucity of recent research on supportive psychotherapy, with an older review (Conte, 1994) recommending better specification and more use of objective measures.

### Strengths and Limitations of Studies

In terms of study design, there are a few strengths and limitations of the included studies. A strength is that 77% (*n* = 20) adopted a RCT design which can reduce bias, allowing cause-effect relationships to be examined (Zabor et al., 2020). In addition, most studies (*n* = 16) followed up past the end of intervention, allowing for an exploration of whether effects were maintained. In contrast, limitations include sample sizes of less than 100 participants for 81% (*n* = 21) of studies, limited controlled comparisons (*n* = 13) and comparisons to active control groups (*n* = 4). In fact, most control groups (*n* = 12) were labelled as “treatment as usual”, however usual care in rehabilitation settings can range widely between countries (Freedland et al., 2011) and even within countries due to healthcare disparities (Gross, 2008), limiting generalisations that can be made. Additionally, six studies adopted a pilot design, limiting conclusions that can be drawn. However, this reflects that research for some of these interventions applied to an ABI population is still in its infancy. In fact, all included studies were published in the last two decades with the vast majority (*n* = 25) coming from the last decade, demonstrating that this field is relatively new. Furthermore, study completion rates were low, with 38% (n = 10) of studies reporting completion rates under 80%. This is a methodological concern and lower than suggested in the literature; for example, Bell et al. (2013) found that, on average, only 18% of trials in medical journals investigating QoL outcomes reported a completion rate lower than 80%.

Finally, only a third of studies reported participant ethnicity and measured intervention adherence, highlighting this as an area of improvement for future studies.

As for the quality of included studies, there are a couple of limitations. Most importantly, only 19% (*n* = 5) were rated as “strong” and half were of low quality. Blinding is also an area of weakness, however as it is not common for pilots and pre-post studies to have the resources for a blinded independent assessor. Even in studies where the assessor was blinded, it was not clear if participants were aware of the research question, which is one of the blinding domain’s components. However, it would be unjustified to conceal the study aims when obtaining informed consent in this area of research. The overall quality of included studies may have therefore been underrated using the EPHPP quality assessment tool. In fact, if the blinding domain was removed, four studies would move from the low- to the moderate-quality categories. In contrast, data collection methods is an area of strength, as the measurement tools used by 80% of studies (*n* = 21) were widely used in ABI and had acceptable reliability and validity. Finally, while 70% of studies (*n* = 18) were of moderate quality in terms of selection bias, which is a relative strength, no study was able to demonstrate that participants were very likely to be representative of the target population, for example by using random selection from a comprehensive list, which can be an area of improvement for future studies.

A final limitation in the included studies is the measurement of constructs of interest. Although QoL was included as one of the constructs representing positive affect, a lack of clarity in its definition means that it may have been operationalised differently across studies. Research may use the terms “quality of life”, “health-related quality of life” (HRQoL) and “health status” interchangeably to refer to the domain of ‘health’ rather than positive affect (Guyatt et al., 1993). In fact, Karimi and Brazier (2016) suggest that many HRQoL measures such as SF-36 and the EQ-5D may actually be measuring health status rather than QoL. It therefore may be that conflicting findings of the effectiveness of psychological interventions on QoL could be in part due to this lack of agreement in the construct that tools actually measured.

## Strengths and Limitations of Current Review

A large number of studies was included in this review, which adds confidence that a representative sample of available studies was evaluated. However, grey and unpublished literature was not searched, which could have led to publication bias due to the tendency for studies to be published only when significant intervention effects are found (Boland et al., 2017). In addition, although there was an effort for the search terms to be worded in a way that captures all relevant research, some of the outcome-related search terms were less broad, which may have limited the number of studies included. Strengths of this review include reviewing the quality of included studies and having a proportion of papers assessed by two reviewers who were blinded to each other’s work for eligibility and quality, minimising researcher bias and methodological errors. A further strength is that the present review included studies with various designs, such as RCTs, pilots, pre-post and quasi-experimental, allowing for interventions where research is still at its infancy to be represented. However, making comparisons across different study designs limits conclusions that can be drawn. In addition, case studies were not included in the present review, however studies are increasingly taking on such designs when research of a specific field is still in its infancy. Future reviews could therefore include such designs to have a better representation of available research. Finally, although it was a strength of the review that only studies which clarified participants were aged 18+ were included, authors of studies where this was not clear were not separately contacted to clarify, which may have limited the number of studies included in this review.

A further strength is that this review included psychological interventions which were not in the form of “talking therapies" or delivered by non-psychologists, better reflecting clinical practice. Although this allowed for a wide range of psychological interventions to be included, some were only evaluated by a small number of papers, which makes it difficult to make conclusions on their effectiveness. In addition, the length and delivery modality of interventions varied, as well as where and how they were delivered. Again, while this captures the reality of clinical practice, it makes comparisons tentative. A further strength of this review is that when effect sizes were not initially reported in the studies, these were calculated where possible. Furthermore, calculating Hedge's *g* provided a small sample-size correction which enabled studies with varied sample sizes to be compared. As research has found that trials with small sample sizes often over-represent effect size (Kühberger et al., 2014), this also minimises the small sample size bias. However, when effect sizes for within-group comparisons were calculated, the correlation between the two variables was not taken into account, which could introduce bias to the results (Morris & DeShon, 2002).

## Conclusions and Recommendations

This review found: (a) some evidence for the effectiveness of third-wave CBT, PPIs and counselling interventions on positive affect, with effects ranging from small to large for the first two, and medium to large for the latter, although the quality of studies was generally low and the comparators not active; (b) mixed evidence for the effectiveness of CBT (although the lack of effects was most often observed against active comparators), creative therapies, narrative-theory-based interventions and NLP on positive affect, with effects ranging from small to large, medium to large, and small to medium respectively (effect sizes for NLP were not available); and (c) no evidence for the effectiveness of self-management interventions or supportive psychotherapy (over and above CBT) on positive affect.

Large variability in study designs as well as length and delivery of interventions jeopardise the generalisability of these findings to the larger ABI population. Furthermore, due to the small number of studies evaluating certain interventions, poor overall quality of studies, small sample sizes, low completion rates, and low number of controlled comparisons, any conclusions made need to be tentative as differences could be attributable to methodological issues rather than intervention effectiveness. Therefore, there is a need for more high-quality multi-centre RCTs reporting controlled comparisons for psychological interventions against (ideally) active control groups on positive affect. Specifically, the effectiveness of interventions such as third-wave CBT, PPIs and counselling on positive affect could be further evaluated as there appears to be a paucity of research but findings to this date appear promising. Finally, future studies could use measures of wellbeing and QoL when measuring positive affect, rather than measures of HRQoL or life satisfaction.

Overall, this study found evidence that psychological interventions have promising effects on enhancing positive affect for ABI survivors across different settings, findings which have implications for clinical practice. For example, services supporting ABI survivors could place a higher focus on providing wider psychological interventions that aim to enhance the quality of life and wellbeing of survivors, rather than solely targeting an improvement on clinical levels of distress. However, further high-quality research evaluating the effectiveness of specific types of interventions is necessary.

# III. Paper 2. A Pilot RCT Assessing Feasibility and Acceptability of a Single Values-Based Versus Standard Goal-Setting Session for Community Dwellers with Acquired Brain Injury (ABI)

# Abstract

Although goal-setting is a key part of recovery in Acquired Brain Injury (ABI), there is no consensus as to the most effective way to set goals. In Acceptance and Commitment Therapy, goals are embedded within an individual's values. The present pilot Randomised Controlled Trial examined the feasibility and acceptability of a single-session (T1) and two-week follow-up (T2) of values-based versus standard goal-setting for ABI community dwellers, and the size of the effect on wellbeing and other secondary outcomes. Twenty four participants (12 in each group) with ABI were recruited, 14 of which were male (age: *M* = 61, *SD* = 9.3). The recruitment rate was six participants per month, and completion rate was 92%. Both interventions were rated as acceptable (mean ratings ≥ 80%), with a small effect ($d = -0.19$) favouring the values group. Improvements in wellbeing were greater in the values group ($d_{ppc2} = 0.30$), while no differences between groups were found for goal attainment, memory of goals, or significance of new behaviours at T2. Regarding attitudes towards goals measured at T1, motivation was higher for the values group with a small-to-medium effect size ($d = -0.31$), while confidence and anticipated pleasure from working on the goal were higher for the standard goal-setting group with small-to-medium ($d = 0.28$) and small ($d = 0.17$) effect sizes respectively. Finally, the measure of value alignment that the values group completed showed higher value alignment at T2 with a large effect size ($d = -1.06$). The study found that when goals were embedded in values, a modest improvement was found for the wellbeing of ABI community dwellers, which does not appear to be due to better memory of goals or greater goal achievement. Study limitations and future recommendations are discussed.

## Introduction

Headway (n.d.) estimates that in 2019-2020 there was one head injury every three minutes and one stroke every four minutes in the UK. Around 1.4 million people are estimated to be living with an acquired brain injury (ABI) in the UK (UK Acquired Brain Injury Forum [UKABIF], 2019), although this number is likely an underrepresentation of the true prevalence of ABI (Bloom et al., 2022). Traumatic Brain Injury (TBI) is most common in younger men and older people (Biegon, 2021; Fryer et al., 2017), while risk of stroke is 1.5-2.5 times higher for Black than White people (Ali et al., 2021). The effects of ABI are significant not only for the economy, with ABI-related costs estimated as the equivalent of around 10% of the yearly NHS budget (UKABIF, 2019), but also for the individual, their family members, friends, and community (Milders et al., 2003).

The consequences of ABI can impact all areas of functioning. Physical difficulties such as loss of mobility and fatigue (Åkerlund et al., 2021), memory, attention, language and executive function impairments (van Rijsbergen et al, 2019), and psychological distress such as anxiety, depression and adjustment difficulties (Jorge et al., 2004) are all common. These can have a devastating, long-standing impact on the individual's functioning and, perhaps more importantly, on their quality of life and wellbeing (Hoofien et al., 2001). Wellbeing is normally fostered by a sense of belonging within one's self, others and the community (Wilkie et al., 2021), which can be severely disrupted due to the effects of ABI (Goverover et al., 2017). Interventions aiming to enhance wellbeing and quality of life for ABI survivors are therefore imperative.

### Goal-Setting

Neurorehabilitation is the multidisciplinary process of assessment, intervention and management that aims to enhance wellbeing and quality of life through the improvement of physical, cognitive and psychosocial functioning, and the increase of activity participation (UKAFIB, 2019). A key component of neurorehabilitation is identifying, setting and measuring clear goals (Wade, 2009) that target behavioural change through increasing persistence and goal-related attention, energising the individual, and passing on helpful knowledge and strategies (Locke & Latham, 2002). The aim of goal-setting in rehabilitation is for improved function to ultimately lead to better self-efficacy, wellbeing and life meaning, making goal-setting a therapeutic intervention in itself (Evans, 2012). For goals to be beneficial, literature suggests that they need to be SMART (Specific; Measurable; Achievable; Relevant; Time limited; Doran, 1981) and set according to the needs of the individual (Duncan et al, 2005). Effective goal-setting is thought to be client-centred, collaborative (Prescott et al., 2015), and negotiated between professionals and patients (Playford et al., 2009). In fact, when involved in the goal-setting process, patients tend to set more goals (Dalton et al., 2012) and these are perceived as more relevant (Holliday et al., 2007).

Although there is wide consensus that collaborative goal-setting is a core component of rehabilitation (Knutti et al., 2020), this is not often adhered to in practice, with ABI survivors largely reporting a lack of control or active involvement in setting goals (e.g., Lloyd et al., 2018; Rosewilliam et al., 2011). Barriers include conflicts between individual and team needs, as individuals' ambitions are not always perceived as achievable from the team (Playford et al., 2009), and differences in perspectives of what goal-setting involves (Plant et al., 2016). Even when patients are involved in setting goals, this does not always lead to a change in clinical reasoning and practice (Levack et al., 2011). As a result, goals tend to be largely formulated and prescribed by the individual's team (Playford et al., 2000) and usually focus on remediating impairments (Banja & Johnston, 1994) using a problem-oriented approach (Holliday et al., 2005), which may be helpful for daily functioning but may not contribute to an overall sense of meaning (Emmons, 2003). Current goal-setting methods are therefore not always effective in practice (e.g., Brown et al., 2023; Playford et al., 2009). While there is strong evidence that simple specific goals lead to improved performance in specific contexts, evidence that current goal-setting methods in rehabilitation improve patient outcomes is weak and inconsistent (Levack et al., 2006). In fact, current methods of goal-setting in inpatient and early-stage neurorehabilitation were found to be unsuitable (Plant et al., 2016).

It is not surprising, therefore, that recent literature has been concerned with improving the effectiveness of the goal-setting process for individuals with an ABI. For example, it has been recommended clinicians should engage patients through ‘being with’ rather than ‘doing to’ and support them to identify what is most meaningful to them (Bright et al., 2012). Hersh and colleagues (2012) also proposed that SMARTER (Shared; Monitored; Accessible; Relevant; Transparent; Evolving; and Relationship-centred) goals can facilitate collaborative goal-setting, especially for individuals with communication difficulties. Finally, a pilot Randomised Controlled Trial (RCT) compared a single goal-setting session using Positive Psychology principles to standard goal-setting in community ABI rehabilitation (Wainman-Lefley et al., 2022). Individuals were supported to identify personal character strengths through use of the Values in Action Inventory of Strengths (VIA-IS) questionnaire and use these strengths to inform and set rehabilitation goals, which was found to be feasible and acceptable, with two thirds of the VIA-IS group drawing on their questionnaire results when setting goals. No major differences in the types of goals or memory for goals were found between groups, although these findings should be interpreted with caution considering the study was a pilot.

### Acceptance and Commitment Therapy

To this date there is therefore no clear consensus as to the most effective method of goal-setting in ABI. A possible way of approaching goal-setting is through the lens of Acceptance and Commitment Therapy (ACT), a third-wave Cognitive Behaviour Therapy (CBT) intervention (Hayes et al., 1999). ACT proposes that distress arises from the way we relate to unwanted internal experiences, such as attempting to suppress or avoid them. Crucially, from an ACT perspective, this reduces the extent to which an individual’s behaviour is governed by their values, defined as chosen qualities that make life meaningful (Hayes, 2004). A key aim of ACT, therefore, is to support individuals in clarifying what their core values are and in setting and committing to behaviours that are consistent with those values.

In ABI, individuals' sense of meaning and identity can be significantly impacted (Carroll & Coetzer, 2011), as the change in life circumstances is likely to move individuals away from living a valued life (Soo et al., 2011). ACT could therefore help minimise the impact of brain injury on wellbeing, quality of life and valued living (Brown & Vandergoot, 1998; Pais et al., 2019) through connecting individuals with their values and supporting them to live a valued life even in the face of difficulties (Curvis & Methley, 2021). Specifically, the ACT processes of identifying and prioritising valued life-directions and setting goals to progress within these as a way to enhance a sense of meaning and identity can be a beneficial route to setting goals in ABI. Most importantly, embedding goals within an individual's values can fit well in a rehabilitation goal-setting context, having the potential of improving the goal-setting process by making it more collaborative, client-centred and meaningful for people with a brain injury. In fact, the National Institute for Health and Care Excellence (2022) recommends that goals in rehabilitation should take into account individual values, aspirations and meaningful and relevant activities of interest. ACT can therefore help ABI survivors clarify their values, set meaningful goals and engage in valued life-directions (Harris, 2009), ultimately enhancing wellbeing (Pais et al., 2019).

Goals that are embedded in values are expected to have different qualities to standard goals, which could mean they add more benefit. Generic goals focus on reaching a specific outcome which may or may not happen, and are therefore likely to only allow satisfaction if the outcome is successful (Villatte et al., 2016b), while goals embedded in values provide guiding principles of action (Hayes et al., 2011) that are broader than a singular goal. In addition, the primary source of reinforcement for value-based goals is that the individual's behaviour is coherent with their valued life direction (Wilson & DuFrene, 2008), which suggests that motivation will be higher for such goals than for generic goals. It can also be hypothesised that when values act as guiding principles, individuals will engage in more values-oriented behaviours in addition to their goal (Hayes et al., 2011). Furthermore, standard goals are often under aversive control, for example focusing on alleviating pain (Banja & Johnston, 1994), while developing goals in the context of values aims to bring them under appetitive control, for example focusing on engagement with meaningful behaviours (Catania, 2013), which would make them more likely to occur (Hebert et al., 2021). In fact, college students who engaged in values-based versus standard goal-setting achieved significantly improved academic performance (Chase et al., 2013). It is also possible that they are more likely to be remembered, since they are more collaborative (Wressle et al., 2002). Finally, values-based goal-setting is expected to increase how aligned individuals feel with their values after engaging in their clarification and committed action (Harris, 2006).

ACT as a therapeutic modality has shown significant benefits. In addition to its effectiveness for a variety of mental health conditions, such as anxiety, depression and transdiagnostic difficulties (e.g., Bai et al., 2020; Gloster et al., 2020; Ruiz, 2012), emerging evidence provides support for the effectiveness of ACT in long-term health conditions (Graham et al., 2016) and chronic pain (Feliu-Soler et al., 2018). Unsurprisingly, ACT has also been considered a good fit in ABI, with research showing benefits in reducing psychological distress. Symptoms of anxiety were reduced from moderate to mild in an acute stroke setting (Sianturi et al., 2018), and psychological distress was significantly reduced in TBI after an eight-week ACT intervention compared to a single needs-assessment session (Sander et al., 2021), and in stroke after a therapist-facilitated intervention involving a stroke-specific ACT book (Gladwyn-Khan & Morris, 2023). Benefits on quality of life have also been found (e.g., Gladwyn-Khan & Morris, 2023; Rauwenhoff et al., 2022). Furthermore, ACT delivered as a group therapy has been found to reliably improve wellbeing (Sathananthan et al., 2022) and hopefulness (Majumdar & Morris, 2019), and reduce psychological distress (Niu et al., 2022), although these effects were not always maintained at follow-up (e.g., Whiting et al., 2020). Although evidence shows great promise, it is clear that research is still in its infancy as most available studies are either single case designs or pilot RCT studies.

Research has more recently also started to investigate the utility of specific therapeutic elements of ACT, as following a standardised manual may not flexibly meet the needs of real-life individuals (Addis & Krasnow, 2000). In fact, modular treatment has led to significantly better clinical improvement rates and reduced number of diagnoses compared to both usual care and standardised manual-based interventions in a child population (Chorpita et al., 2013). Research evaluating the effectiveness of values identification and committed action specifically has shown promise, for example improvements in quality of life and symptom severity were found in a population of adults seeking support for depression and anxiety (Villatte et al., 2016a). In ABI specifically, two currently unpublished theses adopting a single-case experimental design investigated the effectiveness of the values and committed action components of ACT in inpatient neurorehabilitation, where there were high levels of disability and impairment. Sharma (2019) found that six sessions of individual values-based goal-setting led to improvements in depression, adjustment and values-based behaviour, while fewer than half of participants showed improvements in anxiety and quality of life. Importantly, all variables continued to improve at a two-week follow-up. Andrews (2021) examined the effectiveness of the same ACT components specifically for individuals with ABI and depression, and found that depression symptoms improved the most (although not always maintained two weeks later) and values-based behaviours increased for all participants, although adjustment and quality of life improved for fewer than half. In light of the promising initial findings, it appears that values identification and committed action could be utilised in and possibly improve goal-setting for ABI survivors, although values-based goal-setting has not been compared to standard goal-setting in ABI to date.

Although a focus has been placed in inpatient neuro-rehabilitation settings in ACT-related research thus far, considering ABI survivors residing in the community is equally important as individuals' changing needs require ongoing support as they adjust to life at home (Foster et al., 2021). However, provision for ongoing community support post-discharge from rehabilitation is limited due to the rationing of services (Knox & Douglas, 2018) despite almost half of stroke survivors reporting feeling abandoned in terms of support after leaving hospital (Stroke Association, 2013). This leads to a discrepancy between the need to continue working towards goals that reflect changing needs in terms of community integration and participation, and availability of continuing support to facilitate such goals (Foster et al., 2021). In fact, it has been argued that in order to have the biggest impact, ABI interventions should move away from individualised rehabilitation or psychotherapy, and take place in the environment where people live in order to consider the multiple factors that can impact on someone's life (Fisher et al., 2020).

**Current Study**

Using a pilot RCT design, this study was the first to examine the feasibility and acceptability of a client-centred one-session values-based goal-setting intervention versus standard goal-setting. The study also preliminarily examined the primary outcome of psychological wellbeing, as well as a range of secondary outcomes: participants' attitudes towards goals (such as confidence, motivation and anticipated pleasure), goal attainment, memory of goals, spontaneous action, and value alignment.

The RCT design was selected so that a strong methodological evaluation of the differences between these two interventions can be made. Comparing two interventions that are the same except for the addition of the values element allows for an investigation of whether the addition of values leads to a difference in a range of outcomes. Although both interventions could be thought of as novel, the goal-setting procedure is based on recommendations for standard goal-setting practice commonly used in both inpatient and community rehabilitation settings. Finally, a decision was made for an inactive control group not to be included in the design. This was made partly due to time limitations, as the recruitment of participants for an additional arm was not feasible in the time constrains of the Clinical Psychology Doctorate, and partly in an effort to offer an active intervention to all participants involved due to the lack of support normally available in the community.

**Research Questions**

1. Feasibility:
    a. Is it possible to recruit and engage community dwellers with ABI in a single values-based or traditional goal-setting session?
    b. Can two-week follow-up data be obtained?

2. Acceptability:
    a. Are the two types of goal-setting interventions viewed as equally acceptable?
    b. What is the qualitative feedback of participants regarding the interventions?
3. Effectiveness:
    a. What is the estimated effect size and confidence interval for the interventions on the primary outcome of psychological wellbeing?
    b. At the end of the goal-setting intervention session, what is the effect size of intervention type on anticipated pleasure, confidence in, and motivation to achieve the goal?
    c. At the follow-up session, what is the effect size of intervention type on memory for and progression towards the goal?

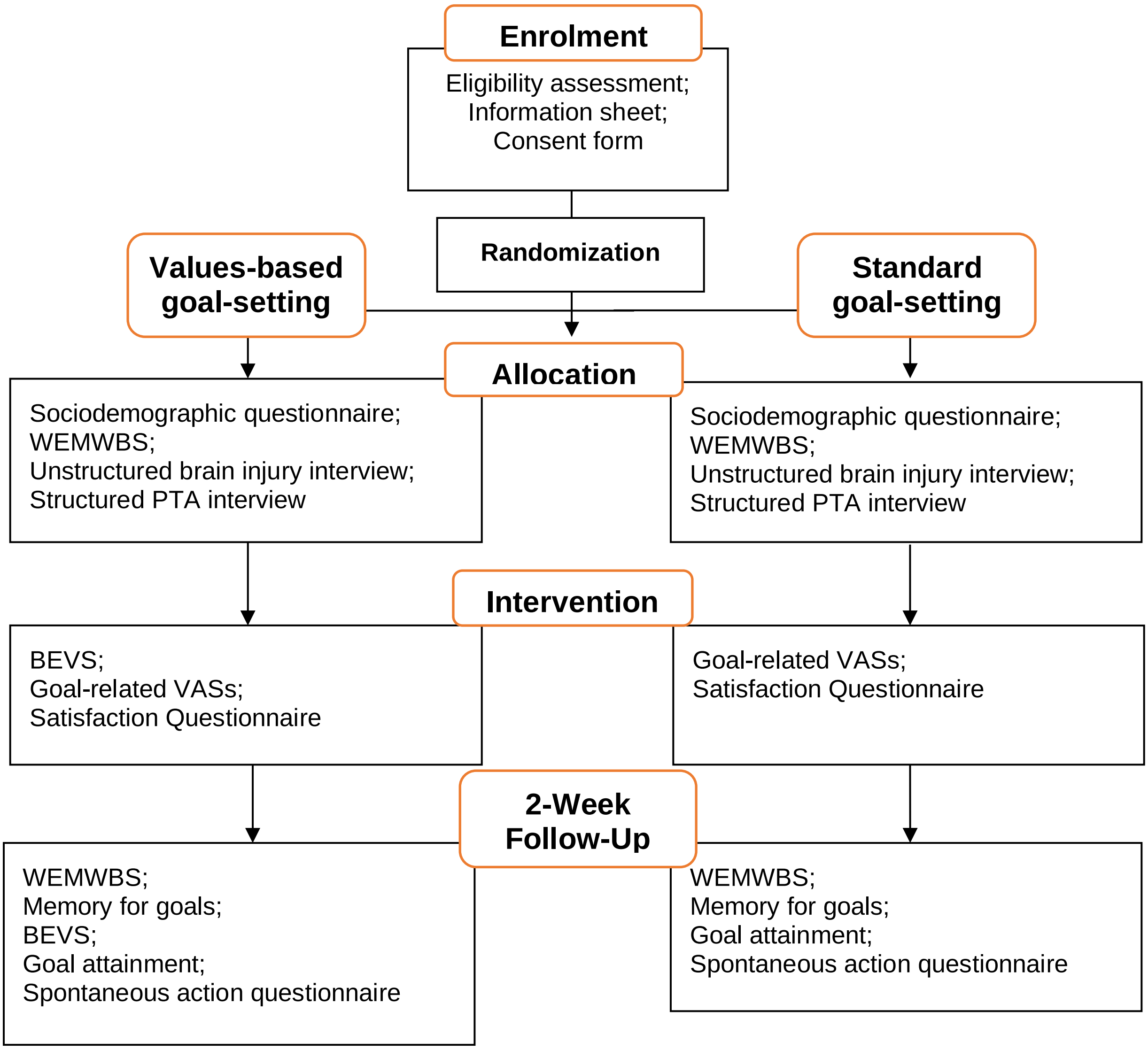
## Methods

### Study Design

This feasibility and acceptability pilot RCT was designed and reported in accordance with the CONSORT statement (Schulz et al., 2010). The between-group factor was condition (values-based goal-setting and standard goal-setting) and the within-group factor was time (T1 = baseline; T2 = 2-week follow-up). The primary outcome was psychological wellbeing, measured at T1 and T2. The secondary outcomes were ratings of participants' attitudes about goals, measured at T1; memory for goals, measured at T2; and goal attainment, measured at T2. In addition, exploratory analyses were conducted for how closely aligned participants from the values group felt to their values (value alignment) measured at T1 and T2, and spontaneous action, measured in both groups at T2. The stages in which outcome measures were completed for each group are illustrated in Figure 2.

**Figure 2**

*Diagram Depicting Timing of Outcome Measure Assessments*



*Note.* BEVS = Bulls-Eye Values Survey; PTA = Post-Traumatic Amnesia; VASs = Visual Analogue Scales; WEMWBS = Warwick - Edinburgh Mental Wellbeing Scale.

## Participants and Recruitment

Participants were recruited from community brain injury charity organisations in England (predominantly London), which advertised the study by including the recruitment poster (see Appendix D) in newsletters or putting up a physical copy in their locations, and/or inviting the researcher to deliver a PowerPoint presentation (see Appendix E) or a less formal question and answer session about the study. Recruitment took place from July to

November 2022. Individuals were included in the study if they were community-dwelling ABI survivors aged 18 or over, with adequate written and verbal understanding of the English language. Individuals were excluded if they had insufficient cognitive and/or communication abilities to participate in the intervention, or lacked capacity to consent. Cognitive and communication abilities were informally assessed during an initial conversation with the researcher, in which the information sheet was discussed and questions were answered. No formal measures were used to determine eligibility.

The sample size was not estimated from a power calculation due to this being a pilot study (Lancaster et al., 2004), which has the aim of estimating recruitment rate and other clinical parameters for a future full-scale trial (NIHR, 2013). There are various published "rule of thumb" recommendations for pilot RCT sample sizes, ranging from 24 (Julious, 2005) to 70 (Teare et al., 2014). Bell and colleagues (2018) recommend a sample size of 20-30 for a 80%-90% powered full-scale trial and medium effect size, which can be considered reasonable for the current study seeing as Dochat et al. (2021) found a medium pooled effect when reviewing single-session ACT interventions for long-term health conditions. Therefore, a sample size of 24 was selected which is similar to other pilot RCTs (e.g., 24 for Theadom et al., 2018; 22 for Wainman-Lefley et al., 2022).

## Measures

All measures were completed via Qualtrics, a secure web-based survey software.

### *Sociodemographic and Brain Injury Information*

The sociodemographic information collected included: age, gender, ethnicity, marital, education, and employment status (Appendix F). Brain injury type and time since injury were ascertained during an unstructured interview with participants (see procedures). For severity of brain injury, a proxy measure of self-reported post-traumatic amnesia (PTA) duration was estimated using a structured interview (Appendix G) designed by Brenner and colleagues (2012), since the information was not accessible through objective means such as hospital documentation. PTA estimates have been found to have a large correlation with actual measurements of PTA durations ($r$ = 0.68; Hart et al., 2010). However, Sherer and colleagues (2015) suggested that PTA estimates from individuals with TBI are not always accurate and brain injury classification based on this should be interpreted with caution.

### *Acceptability*

Acceptability of both interventions was assessed at the end of T1. Following methodology used by other similar studies (e.g. Jones et al., 2016; Sathananthan et al., 2022; Wainman-Lefley et al., 2022), a satisfaction questionnaire was designed to meet the needs of the study (Appendix H). Three visual analogue 10-point rating scales (1-not at all to 10-very much so) were used to assess satisfaction with the intervention (“How satisfied are you with today's session?”), time value (“Was today's session worth your time?”) and friend and family recommendation (“How confident are you in recommending this intervention to friends and family experiencing similar problems?”), with a mean value from these three ratings representing the total acceptability score. Finally, an open-ended question regarding any other feedback was used to collect qualitative feedback (“Please let us know if you have any other feedback from today’s session”).

### *Feasibility*

The feasibility of the intervention was measured by calculating participant recruitment and retention to follow-up rates.

### *Primary Outcome Measure*

**Warwick - Edinburgh Mental Wellbeing Scale (WEMWBS; T1 & T2)[1].** The WEMWBS (Tennant et al., 2007; Appendix I) is a 14-item questionnaire measuring psychological wellbeing over the last two weeks, scored on a 5-point Likert scale (“none of the time” to “all of the time”). Scores are summed to create a total (range 14-70) with higher scores indicating higher wellbeing. Established cut-offs are: 14-42 low wellbeing; 43-60 moderate wellbeing; and ≥ 61 high wellbeing. The scale was found to have good content validity, high internal consistency (Cronbach's alpha = .89 - .91) and test-retest reliability (.83), as well as high correlations with other wellbeing scales in the general population

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[1] A licence was obtained for use of the WEMWBS

(Tennant et al., 2007). Psychometric robustness was also found for minority ethnic groups (Stewart-Brown, 2013). Although the WEMWBS has not yet been validated for ABI populations, a recent US-based not-yet peer-reviewed study found that the scale has good item and person fit for a stroke population (Deng et al., 2023) and it has been found to be accessible and acceptable in UK stroke survivors (Majumdar & Morris, 2019).

### ***Secondary Outcome Measures***

**Goal-related visual analogue scales (VASs; T1).** Following previous research (e.g., Miragall et al., 2021; Salmela-Aro et al., 2012), four separate VASs were created (see Appendix J) to examine participants' confidence ("I feel able to do it"), motivation ("I am motivated to do it"), and anticipated pleasure for working on ("I look forward to working on it") and achieving ("I look forward to achieving it") their goal. Each VAS was rated on a 0-10 scale ranging from 0 = "not at all" to 10 = "very much so". VASs have been found to be adaptable, clear, quick and straightforward to complete (Stubbs et al., 2000), and more sensitive to small changes than Likert scales (Yusof et al., 2019). They have been used in ABI to measure a range of constructs such as quality of life and mood (e.g., Fourtassi et al, 2011; Gemmell & Leathem, 2006), and can be reliably completed by ABI survivors (Kinsella et al., 1988).

**Memory of Goals (T2).** Consistent with previous ABI research (Culley & Evans, 2010; Hart et al., 2002; Wainman-Lefley et al., 2022), memory for goals was measured by asking participants to recall their goal without looking at prompts or reminders. Responses were scored 0-3 according to content accuracy, with a higher score indicating higher accuracy (see Appendix K for scoring criteria).

**Goal Attainment (T2).** Goal attainment was measured using a 5-point Likert scale (Appendix L) as a response to the question "how much do you feel that you progressed towards this goal?". Options ranged from "not achieved" to "achievement plus", with the latter indicating that the goal was surpassed, as used in Hassett et al. (2015). This scale was chosen as it is a self-report measure that can be used directly by participants, rather than a therapist-rated tool (Evans, 2012) such as the Goal Attainment Scale (Turner-Stokes, 2009).

Furthermore, although the latter is commonly used, its reliability for use in RCTs has been questioned (Bovend’Eerdt et al., 2011).

**Bulls-Eye Values Survey (BEVS; T1 & T2).** The BEVS (Lundgren et al., 2012) was used to measure value alignment in the values group only, and was adapted to meet the needs of the study (see Appendix M). Individuals are asked to place an ‘X’ on an image of a dartboard; the closer the mark is to the centre of the dartboard, the more the person is living in a way that is fully consistent with the value they have chosen to work on. Lower scores signify higher value alignment, with scores ranging 1-7. A systematic review of values-based tools found that the BEVS was among the measures with the best psychometric properties (Barrett et al., 2019), while Reilly and colleagues (2019) found evidence demonstrating sensitivity to ACT interventions. It has been found to have high internal consistency, with a Cronbach's alpha of .95 (Villatte et al., 2016a), good content and construct validity and test-retest reliability (Barrett et al., 2019). It has been suggested that cognitive difficulties may impact use of values-based scales due to high abstract reasoning skills demands (Miller et al., 2022), however this scale has successfully started to be used in brain injury, for example in a single-case study that delivered a values-based intervention for inpatients with ABI (e.g. Sharma, 2019).

**Spontaneous Action (T2).** To the author’s knowledge, there is currently no established scale that measures the quantity and quality of engagement in new behaviours. Measurement of spontaneous action was therefore achieved by asking participants to list any new behaviours they engaged with since T1 in addition to goal-oriented behaviours. Importance was rated on a VAS that asked participants to select how important each behaviour was to them, with “not at all” on one side and “very much so” on the other, scored 1-5 (Appendix N).

### Conditions

The goal-setting element was the same for both conditions, and was adapted from a collaborative goal-setting process developed by Bovend'Eerdt et al. (2009) which is based on recommendations for standard goal-setting practice. During a one-hour session, a goal was identified solely by the participant so that it was relevant to them, with the researcher providing support in operationalising the goal: identifying available support; quantifying performance so that it is measurable; agreeing on a time period to achieve the desired target activity; and identifying possible barriers and ways of overcoming these. Strategies such as structured communication, slower pace and visual material were used to scaffold participants' cognition (Prescott et al., 2018). All participants received a copy of their goal in their preferred format (e.g., post-it note, text message, email).

The only difference between the two conditions was setting the context around goal-setting. For the standard goal-setting condition, the effects of brain injury on achievement and the importance of setting goals were initially discussed with participants. If participants struggled to identify a goal, their needs in different areas of life (e.g. personal, domestic, community, vocational) were collaboratively explored in order for a goal to be identified, as suggested by Prescott et al. (2018). For the values-based goal-setting condition, the context was set according to the values-based intervention for ABI piloted by Sharma (2019), which was found to be acceptable for individuals with ABI. The effects of brain injury on living a meaningful life were initially discussed and values were introduced using the compass metaphor (Harris, 2019). Participants then engaged in a values-clarification card sort exercise (Miller et al., 2001), where they were presented with 36 cards that depicted a unique written value alongside an image that best illustrated that value. These cards were developed for ABI specifically (Sathananthan et al., 2022), however a small number of images were replaced with a more diverse depiction in order to make these more relevant to the diverse population of the UK (see Appendix O). Participants were asked to sort each card into a "very important", "important", or "less important" pile, and were asked to decide which of the "very important" values they would like to work on. Prompting questions were used to support participants select a relevant value if needed. Once a value was identified, participants were encouraged to identify a goal that would enable them to feel more aligned to this value.

### Intervention Fidelity

Fidelity was measured based on criteria adapted from Carragher et al. (2019) to check protocol adherence for the delivery of a goal-setting session. The criteria were adapted to meet the needs of the present trial and illustrate differences between values and goals protocols (Appendix P). Scores ranged 0-5 for the values group, and 0-3 for the standard goal-setting group. A perfect score was needed to conclude sessions were delivered according to the protocol. A random 20% sample was selected and rated by the researcher’s supervisors.

## Procedure

Individuals who expressed interest to participate in the study met with the researcher either virtually using the platform MS Teams, or at a place convenient to them, which included their home and community venues. Where home visits were arranged, safety procedures were followed in order to mitigate risk. Through conversation with the researcher, individuals were assessed for eligibility using inclusion/exclusion criteria. Participants were given an accessible information sheet (see Appendix Q) and the opportunity to discuss and ask questions. Individuals were not blinded to the aims of the study, and ethical issues such as data protection and the limits of confidentiality in case of risk were highlighted. If individuals were eligible and interested to participate, the consent form (Appendix R) was signed physically or digitally via Qualtrics, and a copy was provided to the participant. Participants could opt in to having their research session audio-recorded for treatment fidelity assessment purposes, which was done using a password-protected device and immediately uploaded to Dropbox, a secure cloud service.

Participants completed the sociodemographic questionnaire and WEMWBS individually or with support from the researcher, which consisted of reading each question out loud and noting the responses. Following this, participants were randomised to the values-based or standard goal-setting conditions using the online platform Sealedenvelope.com, and were told of their allocation. Through use of the platform, it was not possible to predict which condition each participant would be randomised to. Participants then provided information about the type, severity and timing of their brain injury, and received the allocated intervention.

Interventions were delivered on a one-to-one basis as a single session by the researcher, who was not blinded to condition. The researcher followed the protocols developed by the research team (Appendix S), which were piloted to individuals without a brain injury prior to recruitment. The researcher was a Trainee Clinical Psychologist with experience in delivering therapeutic input to individuals with ABI as well as managing risk, and received regular supervision by a Clinical Psychologist. Although participants were not asked about suicidal ideation as standard, if participants appeared distressed during the intervention and required support for their mood, they were signposted to their GP. If suicidal ideation was raised, a standard risk assessment was conducted that includes assessment of intent, current plans, history of suicidality and protective factors. Crisis helplines were provided, and the participant’s GP was contacted if required and upon consent from the participant. Acute risk did not come up and confidentiality was not breached during the study.

Once participants identified a goal they wanted to work on over the next two weeks, they completed the VASs measuring motivation, confidence and anticipated pleasure for working on and achieving their goal. In addition, participants in the values-based goal-setting condition completed the BEVS, measuring how closely aligned they felt to the value they chose to work on. The satisfaction questionnaire was then completed by all participants, and a date for the follow-up session was agreed upon. The duration of each intervention session was not recorded, however sessions that were recorded ranged 30-60 minutes. In order to reduce confounding variables and enable participants to openly discuss personal experiences, it was preferred that participants were seen on their own. However, participants were encouraged to utilise significant others or carers as a source of support when working on their goal, as this can facilitate goal attainment (Behn et al., 2019).

The follow-up session took place two weeks later over the phone, online or face-to-face, according to participant preference. Participants completed the WEMWBS with or without assistance from the researcher followed by measuring memory for goals, recording responses verbatim. Participants were not told that they would be asked to remember their goals prior to the session so as not to prime them. Values-based goal-setting participants completed the BEVS to measure value alignment, and all participants completed the goal attainment and spontaneous behaviour measures. Participants were then thanked for their time and participation, and any questions were answered. This follow-up session was kept under 30 minutes to reduce burden for participants.

Participants were not expected to be burdened with any expenses due to the study, as the researcher was able to meet them at a convenient location. A prize draw was completed at the end of recruitment using an online integer generator (https://www.random.org/integers), and four participants were sent a shopping voucher valued at £50, £20 or £10.

### Ethical Approval

This research study was registered on the AsPredicted.org website (ID: 96731) and was approved by the Research Ethics Committee at Royal Holloway University of London (REC Project ID: 2971; see Appendix T).

### Data Analysis

Data was analysed using SPSS version 25 20.0.0.2 (IBM Corporation, 2017) for Mac. Missing data was minimised by alerting participants to any non-completed items either directly or via Qualtrics during data collection. If a participant dropped out, any collected data prior to drop out was included in the analysis and so T1 and T2 samples were unequal.

First, to assess whether randomisation was successful, data was examined using a descriptive approach due to the small sample size, as statistical tests are not recommended (e.g. Harvey, 2018; Morgan, 2017). Next, to answer the first research question regarding feasibility, recruitment and retention rates were calculated and presented using the CONSORT (2010) diagram. The second research question regarding acceptability was answered by calculating the between-groups effect size and confidence interval for the mean of the three satisfaction questions per group (see Appendix U for all effect size calculators).

Cohen's *d* and Hedge's *g* were both reported when calculating effect size, due to the latter being more appropriate for small sample sizes (Lin & Aloe, 2021). Effect sizes were interpreted as small (*d* = 0.2), medium (*d* = 0.5), and large (*d* = 0.8) for both *d* and *g* (Cohen, 1988). Finally, qualitative feedback was summarised and descriptively presented.

In terms of the third research question, effectiveness of psychological wellbeing was first measured by calculating the WEMWBS controlled effect size $d_{ppc2}$ for mean differences between groups with unequal sample size with a pre-post design based on calculations by Morris (2008), as well as the confidence interval. Within-group pre-post effect sizes $d_{av}$ for each of the two groups were also calculated. This is a pragmatic approach not taking into account intercorrelation, based on calculations by Cummings (2012). The effects on attitudes towards goals were then measured by calculating the between-groups effect size for each of the VASs. Next, memory for goals was first double rated by two blind raters independently. Since participants' recollections of their goals were scored on a continuous scale (0-3), the intraclass correlation coefficient (ICC) absolute-agreement, 2-way mixed-effects model was calculated. A third rater then resolved any disagreements. Finally, the goal attainment between-groups effect size for unequal sample sizes was calculated.

For the exploratory analyses, which were not pre-registered, the effect on value alignment was measured by calculating the pre-post within-group effect size $d_{av}$, and new behaviours were summed with means and standard deviations presented for the importance rating. In terms of estimating sample size for a full-scale trial, the standard deviation of WEMWBS change scores ($SD_{change}$) for the whole sample was calculated. The effect size was calculated by dividing the WEMWBS clinically meaningful change score by $SD_{change}$. The upper limit of the 80% Confidence Interval of $SD_{change}$ was also calculated using an excel formula provided from https://www.graphpad.com/support/faq/the-confidence-interval-of-a-standard-deviation/, and a new effect size was calculated in the same way as above. The software G*Power version 3.1 was used to run an a priori sample size power analysis using the ANOVA repeated measures, within-between interactions statistical test. Cohen's d effect sizes were converted into Cohen's f effect sizes using the online calculator https://www.escal.site/ to be used for the sample size power analysis. Finally, intervention fidelity was calculated by adding up the total of criteria present for each rated session.

## Results

### Missing Data

Two participants (one from each condition) dropped out, and one participant in the values-based goal-setting group did not complete all T2 outcome measures, with the goal attainment and memory, value alignment and spontaneous action outcome measures missing. No other participant data was missing.

### Sample Characteristics and Preliminary Analysis

Participant characteristics can be found in Table 6. Participants' age ranged from 43-73, while 77% (*n* = 8) of the values group and half (*n* = 6) of the standard goal-setting group were male. Three quarters of participants in each group (*n* = 9) were single (including divorced, widowed or separated) and 83% of all participants had a qualification at level two (i.e. GCSE) or above. In both groups almost all (*n* = 11) participants were seen face-to-face for the T1 session, with one participant in each group seen online. There was a broad representation of the brain injury recovery journey, with years since brain injury ranging 0.7 - 39.5, while four participants (21%) reported having two brain injuries, and one (8%) reported having three. TBIs were sustained due to a road traffic collision (*n* = 2), assault (*n* = 2) or a fall (*n* = 2). Participants who had more than one brain injury provided information regarding the brain injury they considered primary, while three participants (13%) were unable to provide information to calculate severity at all.

**Table 6**

*Participant Sociodemographic and Brain Injury Characteristics*

| Participant characteristics | Values-based goal-setting group | Standard goal-setting group |
|---|---|---|
| Age in years – *M* (*SD*) | 59.5 (11.3) | 62.4 (7.1) |
| Ethnicity – *n* (%) | | |
| Asian / Asian British | 1 (8%) | 0 (0%) |
| Black African / Caribbean / Black British | 6 (50%) | 4 (33%) |
| White British / Other | 5 (42%) | 8 (67%) |
| Education – *n* (%) | | |
| No qualifications / other | 3 (%) | 1 (%) |
| GCSE / A' level or equivalent | 1 (8%) | 2 (16%) |
| Undergraduate degree | 4 (33%) | 5 (42%) |
| Postgraduate degree(s) | 4 (33%) | 4 (33%) |
| Employment – *n* (%) | | |
| Employed full time | 1 (8%) | 0 (0%) |
| Other (e.g. disabled, carer) | 7 (58%) | 5 (42%) |
| Unemployed (not looking for work) | 0 (0%) | 2 (17%) |
| Retired | 4 (33%) | 5 (42%) |
| Years since injury – *M* (*SD*) | 12.4 (8.4) | 11.6 (10.9) |
| Type of Brain Injury – *n* (%) | | |
| Stroke | [a]11 (69%) | [b]7 (50%) |
| TBI | [a]2 (13%) | [b]4 (29%) |
| Other (e.g. brain tumour, encephalitis) | [a]3 (19%) | [b]3 (21%) |
| Brain Injury Severity – *n* (%) | | |
| Mild | 3 (25%) | 2 (17%) |
| Moderate | 0 (0%) | 5 (42%) |
| Severe / Very Severe | 3 (25%) | 1 (8%) |
| Very Severe | 6 (50%) | 1 (8%) |
| Unknown | 0 (0%) | 3 (25%) |

*Note*. Based on *n* = 12 unless specified otherwise.

[a]Based on *n* = 16, as some participants had more than one brain injury. [b]Based on *n* = 14, as some participants had more than one brain injury

Continuous values of participant characteristics for the values-based and standard goal-setting groups, such as age (*M* = 59.5, *SD* = 11.3; *M* = 62.4, *SD* = 7.1 respectively) and years since injury (*M* = 12.4, *SD* = 8.4; *M* = 11.6, *SD* = 10.9 respectively) all appear similar for the two groups. Baseline WEMWBS scores were *M* = 40.3 (*SD* = 11.2) for the values group and *M* = 41.3 (*SD* = 11.9) for the standard goal-setting group, which also appear similar. When descriptively examining if the two groups are similar in categorical variables, it can be noted that more White participants (*n* = 8) were in the standard goal-setting group compared to the values group (*n* = 5). Furthermore, participants in the values goal-setting group appeared to have a higher level of brain injury severity than the standard goal-setting group, with nine participants reporting a severe or very severe injury in the former, and only two in the latter.

### Research Question 1: Feasibility

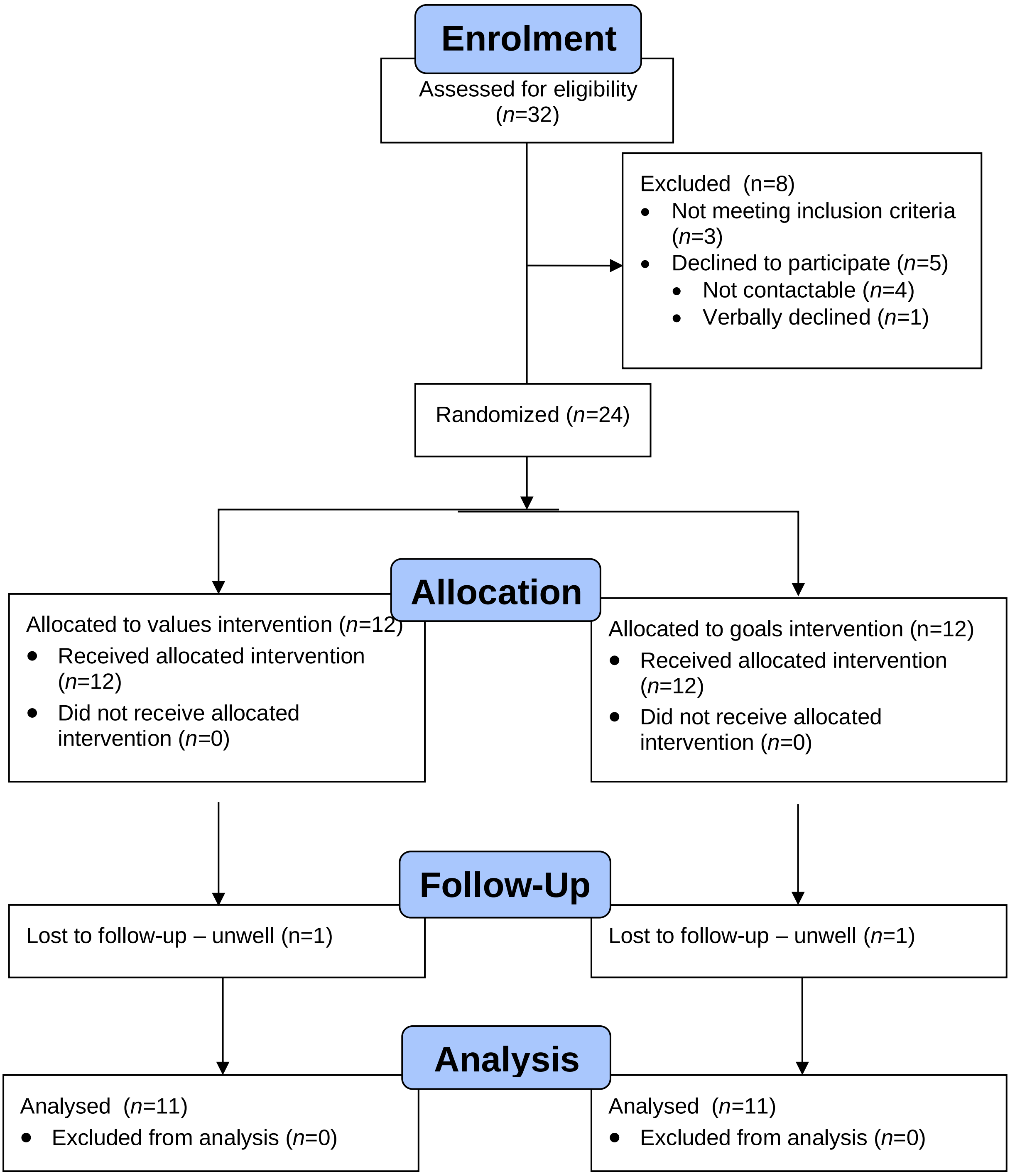
Enrolment and participant flow is represented in Figure 3 as a CONSORT diagram. Out of *n* = 32 people assessed for eligibility, *n* = 24 (75%) were randomised and recruited into the trial. Reasons for exclusion were not meeting the inclusion criteria for communication ability (*n* = 3), explicitly declining to participate (*n* = 1) or being uncontactable for unknown reasons (*n* = 4). The recruitment rate was 6 participants randomised per month. Participants were recruited equally from group injury charities Headway (*n* = 12) and the Stroke Project (*n* = 12). Most participants were recruited from the researcher visiting the group to present the research project (*n* = 21), while three participants responded to the research poster by contacting the researcher directly. Two participants (one in each group) did not complete the T2 follow-up, both due to feeling unwell. Datasets for 22 participants were analysed, which sets the retention rate as 92% for both groups. Time between T1 and T2 ranged 11-21 days, with most participants receiving a follow-up around the two-week target (*M* = 14.3; *SD* = 1.9).

### Research Question 2: Acceptability

The mean rating for the three satisfaction questions combined was *M* = 8.6 (*SD* = 1.4, range = 5-10) for the values and *M* = 8.3 (*SD* = 1.8, range = 5-10) for the standard goal-setting group, with a small effect size favouring the former (*d* = -0.19, 95% CI [-0.988 – 0.616], *g* = -0.18). Detailed descriptive statistics and frequencies for each satisfaction question can be found in Appendix V. Qualitative feedback was largely similar for the two groups (see Appendix W). Participants from both groups commented on the usefulness of the session (e.g., "*I'm very pleased and it has helped me a great deal*") and the value of it taking place at a convenient location (e.g., "*I am very appreciative for coming to my house […]")*. Some participants from the values group expressed surprise about how helpful the session was (e.g., "*it has opened my eyes to know that I still have achievements to make, I thought I knew it all before*"), while others commented on the extent of the support available (e.g., "*wish there was someone who could spoon feed me a bit [...]*") and what was offered during the session (e.g., "*a free cup of coffee would be nice*").

**Figure 3**

*CONSORT Diagram of Participant Flow*



Some participants from the standard goal-setting group commented on the motivational nature of the session (e.g., "*talking to different people about this is motivational to me*") and the acceptability of the session content (e.g., "*all the questions were thoughtful,* *didn't make me feel that I didn't want to answer them*"), while others expressed worry or hesitation about working on their goal (e.g., "*I'm worried I might make a big hash of it*").

## Research Question 3: Effectiveness

### ***Psychological Wellbeing***

The values group WEMWBS scores indicate a bigger wellbeing increase from T1 ($M$ = 40.3, $SD$ = 11.2, range = 19-56) to T2 ($M$ = 44.2, $SD$ = 10.5, range = 27-60), with a small-to-medium uncontrolled within-group effect ($d_{av}$ = .0.36, 95% CI [-.48 - 1.21], $g$ = 0.35), compared to the standard goal-setting group WEMWBS scores at T1 ($M$ = 41.3, $SD$ = 11.9, range = 25-61) and T2 ($M$ = 41.64, $SD$ = 11.43, range = 27-62), where the uncontrolled within-group effect is negligible ($d_{av}$ = 0.03, 95% CI [-.81 - .86], $g$ = 0.03). The controlled effect size indicated a small-to-medium effect in favour of the values group ($d_{ppc2}$ = 0.30, 95% CI [-.14 - .84]).

### ***Attitudes Towards Goals***

Descriptive statistics participants' attitudes towards goals are detailed in Table 7.

**Table 7**

*Descriptive Statistics for Goal-Related Visual Analogue Scales*

| Outcome measure | Values-based goal-setting group *M (SD),* range | Standard goal-setting group *M (SD),* range | Effect size *d*, (CI), *g* |
|---|---|---|---|
| Confidence | 7.2 (1.7), 4-10 | 7.7 (1.8), 5-10 | *d* = 0.28, CI (-.52 - 1.09), *g* = 0.27 |
| Motivation | 7.5 (1.5), 5-10 | 7 (1.8), 4-10 | *d* = -0.31, CI (-1.11 - .50), *g* = -0.30 |
| Anticipated pleasure from working on goal | 6.8 (3), 0-10 | 7.2 (1.8), 5-10 | *d* = 0.17, CI (-.63 - .97), *g* = 0.17 |
| Anticipated pleasure from achieving goal | 8.5 (2.1), 4-10 | 8.4 (1.7), 5-10 | *d* = -0.04, CI (-.84 - .76), *g* = -0.04 |

*Note*. Based on $n$ = 12. Effect size $d$ = Cohen's d, $g$ = Hedge's g, CI = 95% Confidence Interval.

Participants in the values group had higher ratings than participants from the standard goal-setting group for motivation to achieve their goal, with a small-to-medium between-groups effect in favour of the values group. Conversely, scores for confidence in and anticipated pleasure from working on the goal were higher in the standard goal-setting group, with small-to-medium and small effect sizes respectively. Lastly, scores for anticipated pleasure from achieving the goal were similar in the two groups, with a negligible effect size in favour of the values group.

### *Goal Attainment*

Goal attainment was rated at T2 by *n* = 10 and *n* = 11 participants in the values-based and standard goal-setting groups respectively, due to drop-outs and missing data. Ratings were similar in the values (*M* = 2.5, *SD* = 0.9, range = 1-4) and standard goal-setting group (*M* = 2.6, *SD* = 1.5, range = 1-5), with a negligible between-groups effect size in favour of the latter (*d* = 0.04, 95% CI [-.82 - .90], *g* = 0.04).

### *Memory of Goals*

Two independent raters scored participants' memory of goals collected at T2. In terms of inter-rater agreement, the ICC for single measures was found to be .91 (95% CI [.78 - .96]), which can be interpreted as good reliability (Koo & Li, 2016). A third rater resolved disagreements and agreed predominantly with the first rater. Scores for the values (*M* = 1.8, *SD* = 1.5, range = 0-3) and standard goal-setting groups (*M* = 1.9, *SD* = 1, range = 0-3) were similar, with a negligible between-groups effect size in favour of the latter (*d* = 0.07, 95% CI [-.73 - .87], *g* = 0.07).

## Exploratory Analyses

### *Value Alignment*

The BEVS, measuring alignment with values, was completed by *n* = 12 and *n* = 10 participants in the values group at T1 and T2 respectively. Scores decreased from T1 (*M* = 5.3, *SD* = 1.7, range = 1-7) to T2 (*M* = 3.6, *SD* = 1.5, range = 2-6), indicating an increase in how aligned participants felt with their chosen value. The within-group effect size was large ($d_{av}$ = -1.06; 95% CI [-1.95 - -0.16], $g$ = -1.01).

### *Spontaneous Action*

At T2, six participants from the values group reported eight new behaviours with rated importance ranging 2-5 ($M$ = 4, $SD$ = 1.07), and eight participants from the goals group reported 12, with rated importance ranging 1-5 ($M$ = 4, $SD$ = 1.3). Means were the same for the two groups, demonstrating that importance was rated similarly from participants in each group and so effect size was not calculated. The full list of new behaviours reported can be found in Appendix X.

### *Sample Size Calculation for Full-Scale Trial*

The primary outcome measure for a full-scale RCT would be wellbeing, measured by the WEMWBS, where the minimum clinically important difference is estimated as a change score of 3 points (Maheswaran et al., 2012). The standard deviation of the whole sample change scores was $SD_{change}$ = 9.2 ($d$ = .33, $f$ = .16). However, this can provide a misleading estimate as it is based on a small sample size. The upper limit of the 80% CI for $\mathrm{SD}_{\mathrm{change}}$ has been suggested as a more conservative option (Browne, 1995), which was $SD_{change}$ = 11.6 ($d$ = .26, $f$ = .13). Table 8 indicates varying sample sizes based on the different effect sizes at 90% and 80% power, as advised by Bell and colleagues (2018). A further trial might consider adding a waitlist control group, and therefore an estimation based on a three-armed RCT has also been included. Each sample size has been categorised or feasible or infeasible based on the monthly recruitment rate of the current pilot study.

### *Intervention Fidelity*

Intervention fidelity was rated for 20% of sessions for each condition by the study supervisors. 100% of the criteria were met for all four rated sessions, meaning that participants received the intervention they were randomised to.

**Table 8**

*Range of Sample Sizes Varying According to SD, Dropout Rate and Power*

| Arms | $SD_{change}$ | Dropout rate | 90% powered full-scale trial | | | 80% powered full-scale trial | | |
|---|---|---|---|---|---|---|---|---|
| | | | N (total) | Required recruitment rate | Feasible | N (total) | Required recruitment rate | Feasible |
| 2 | $9.2^a$ | 10% | 76 | 4.2 | Yes | 60 | 3.3 | Yes |
| | | 15% | 80 | 4.4 | Yes | 64 | 3.6 | Yes |
| | | 20% | 85 | 4.7 | Yes | 68 | 3.8 | Yes |
| 3 | $9.2^a$ | 10% | 74 | 4.1 | Yes | 60 | 3.3 | Yes |
| | | 15% | 78 | 4.3 | Yes | 64 | 3.6 | Yes |
| | | 20% | 83 | 4.6 | Yes | 68 | 3.8 | Yes |
| 2 | $11.6^b$ | 10% | 120 | 6.7 | No | 92 | 5.1 | Yes |
| | | 15% | 128 | 7.1 | No | 97 | 5.4 | Yes |
| | | 20% | 135 | 7.5 | No | 103 | 5.7 | Yes |
| 3 | $11.6^b$ | 10% | 117 | 6.5 | No | 94 | 5.2 | Yes |
| | | 15% | 124 | 6.9 | No | 99 | 5.5 | Yes |
| | | 20% | 132 | 7.3 | No | 105 | 5.8 | Yes |

*Note*. Recruitment rate per month is based on 1.5 years of recruitment (Bell et al., 2018); Feasibility is based on the pilot study recruitment rate of six participants per month. $^a$SD of change scores; $^b$Upper limit of 80% CI for SD of change scores

## Discussion

### Main Findings

This paper was the first of its kind to evaluate the feasibility and acceptability of a single-session values-based or standard goal-setting intervention for ABI survivors living in the community, assessing the impact on wellbeing, attitudes towards goals, goal attainment, memory of goals, value alignment, and new behaviours over a two-week period. No statistical analysis was done due to this being a pilot study, however effect sizes were examined.

### *Research Question 1: Feasibility*

Although studies have found that recruitment can be challenging for this population, for example struggling to recruit community dwellers with TBI for a pre-post evaluation of an aerobic exercise programme (Schwandt et al., 2012) or young men with TBI living in the community for a mindfulness-based intervention (Bédard et al., 2014), the present study found that it was feasible to recruit and retain ABI participants living in the community at a rate of six per month. This is perhaps due to reducing burden and time-commitment by evaluating a single-session intervention with a short follow-up session that took place only two weeks later. Another single-session intervention study (Wainman-Lefley et al., 2022) however found recruitment to be challenging, although individuals were solely recruited from a single community-based rehabilitation centre, limiting the pool of available participants. In contrast, multiple brain injury organisations were contacted as potential recruitment hubs for the present study. Similarly to Cullen et al. (2018), establishing good working relations with services and organisations was the most helpful recruitment strategy. The current study's dropout rate (< 10%) was lower than the acceptable cut-off of 20% for RCTs with a short-term follow-up (Furlan et al., 2009). An equal number of participants dropped out from each condition, both due to feeling unwell, which is unsurprising considering the high prevalence of disability (Thornhill et al., 2000) and fatigue (Åkerlund et al., 2021) in this population, which can disrupt daily functioning.

### *Research Question 2: Acceptability*

Participants from both conditions found the interventions acceptable, with mean ratings ≥ 80%, similar to other ACT-related studies in ABI (e.g., 81% in Gladwyn-Khan & Morris, 2023; 89% in Sathananthan et al., 2022). Although ratings from the values group were a little higher, the effect size was small. Qualitative feedback also highlighted the value of the interventions. For some participants in the values group there was an element of surprise that the intervention was found helpful, which may be indicative of less helpful experiences related to goal-setting in the past in neurorehabilitation (e.g., Rosewilliam et al., 2011). Less positive feedback concerned the limits of what the intervention could offer, such as the extent of support and incentives provided, which a full-scale trial with increased resources could address. Future research could also gain more qualitative feedback in order to understand how values-based goal-setting is perceived and which elements are found to be particularly helpful compared to past experiences of goal-setting.

### ***Research Question 3: Effectiveness on Clinical Outcomes***

For the primary outcome of psychological wellbeing, improvements were greater for the values group with a small-to-medium controlled effect size. In fact, the mean WEMWBS score at T2 moved to the ‘moderate wellbeing’ category in the values group, whereas in the standard goal-setting group it remained in the ‘low wellbeing’ category (Tennant et al., 2007). These findings suggest that embedding goals in one’s values can have a bigger impact on wellbeing compared to setting goals without exploring values. ACT interventions that include values clarification and committed action elements have found similar effects on wellbeing in this population. For example, Majumdar and Morris (2019) found that brief ACT group therapy for stroke survivors had a medium controlled effect on wellbeing ($\eta^2 = 0.07$) compared to treatment as usual, although this was not maintained at the 2-month follow-up. While the controlled effect size in the current study is smaller, this is expected considering that the intervention was delivered in one single 1-hour session rather than four 2-hour sessions, and the comparator was an active group rather than treatment as usual.

In terms of secondary outcomes, attitudes towards goals differed somewhat across conditions. Motivation was rated higher in the values group with a small-to-medium effect size, which is consistent with literature suggesting that actions coherent with values are expected to be reinforcing and intrinsically motivating (Wilson & DuFrene, 2008). In contrast, confidence and anticipated pleasure in working on the goal were rated higher in the standard goal-setting group, with small-to-medium and small effect sizes respectively. Values-based goals are more likely to focus on approach rather than avoidance (Hebert et al., 2021), however ACT literature highlights that such goals are not always pleasant or easy, and it is the willingness to tolerate these uncomfortable feelings and thoughts while still acting in line with values that can have a positive impact (Hayes et al., 2011). Therefore, it might be that approach-focussed goals are more challenging to work on and therefore evoke less confidence and anticipated pleasure. Future research can explore differences in types of goals set by the two groups, and whether they fall under approach or avoidance.

Differences in psychological wellbeing and attitudes towards goals did not seem to be attributable to differences in goal attainment or how well participants remembered their goals, as scores for these were similar in the two groups. Although goals embedded in values are expected to be more likely to occur (Hebert et al., 2021), goal-attainment has also been found to be higher when goals are client-centred (Prescott et al., 2019), which was the case for both conditions in this study and may explain goal attainment being similar for the two groups. Similarly, as participants in both conditions selected goals that were most relevant to them, this may explain why there were no differences in memory of goals between groups. The present study also found that clarifying values did not lead to an increase in new behaviours in addition to goal-oriented actions. In fact, more new behaviours were reported in the standard goal-setting group, although importance ratings were similar for the two groups. This is inconsistent with literature proposing that clarification of values may lead to an increase in more value-aligned behaviours (Hayes et al., 2011), whereas goals are expected to only be relevant for the specific context they were set for (Villatte et al., 2016b). However, participants in the current study only had two weeks to work on the goal they set, and it might be possible that a longer period is needed for the effects of values identification to generalise to other life contexts. Future studies could include a longer follow up to investigate the longer-term effects of values clarification and goal-setting.

Finally, it was unsurprising that values-based goal-setting participants reported feeling more aligned to their chosen value at T2 compared to T1, considering that they were encouraged to engage with committed action towards a valued life-direction. What was surprising, however, is the magnitude of the large effect achieved in a two-week time frame. A large effect size (*d* = 2.83) in value alignment was also found by Lundgren et al. (2008)

when comparing a nine-hour ACT intervention to an attention control group for people with epilepsy, however this was derived from comparing post-intervention BEVS scores between groups. In contrast, a four-hour telephone ACT intervention for advanced cancer patients (Plumb Vilardaga et al., 2020) led to non-significant pre-post value alignment changes with a small effect size (Hedge's $g$ = 0.17). In the current study, therefore, it is likely that enhanced value alignment led to higher improvements in wellbeing for the values group, although a direct comparison cannot be made as value alignment was not measured in the standard goal-setting group. Studies have indeed found a significant correlation between measures of valued living and wellbeing in ABI ($r$ = .63-.66 in Baseotto et al., 2022) and epilepsy ($r$ = .71 in Lundgren et al., 2008). It could be, therefore, that identification of the overarching guiding value and the act of moving towards a valued life-direction enhance wellbeing, whether or not a specific goal is achieved. A full-scale trial is needed to replicate these findings, and sample size calculations suggest that it can be feasible.

### Strengths and Limitations of Current Study

A key strength of this study is its design; randomisation minimised selection bias by allowing for the direct comparison of two relatively well-matched groups, at least upon descriptive examination. It was noted that participants from the values group appeared to have more severe brain injuries, although it is possible that participants who were not able to provide adequate information in regards to brain injury severity were limited by cognitive difficulties, and therefore may have met the criteria for severe ABI. Additional strengths of the study include the low (<10%) attrition rate, obtaining reasons for drop out, the excellent intervention fidelity suggesting that participants received the intervention they were randomised to, and the comparison of two active groups with the only difference between interventions being the addition of a values element for the values-based goal-setting group, minimising confounding variables such as history or maturation effects (Campbell et al., 1963). Comparing two active conditions also has advantages in ethical terms, such as not withholding support for some participants, and it minimises the possibility of effects being attributable to active input rather than the intervention specifically (Möller, 2011). However, the addition of the values element in this study did lead to longer input than the standard goal-setting group, although the length of sessions was not systematically recorded.

In addition, the study sample is representative of the ABI population in terms of ethnicity and education. Although Black people were over-represented in this sample (42% compared to 4%; Office of National Statistics, 2022) this ethnic makeup of participants better reflects the increased risk of stroke for Black people (Ali et al., 2021), and the education level is similar to the UK population, where it is estimated that 83% of people have a qualification of level 2 or above (Office of National Statistics, 2022). Furthermore, although it is a strength of the current study that the sample represented a wide range of brain injuries in terms of type, severity and time since injury, this heterogeneity may limit the interpretability and validity of findings to specific types of ABI. Finally, the primary measure of the WEMWBS has good known psychometric qualities in the general population, and even though it has not been validated yet in ABI, emerging studies suggest it is acceptable and a good item and person fit (Deng et al., 2023; Majumdar & Morris, 2019). However, it has also been suggested that cognitive difficulties may interfere with individuals' ability to interpret the scale and use the scoring system (Deary et al., 2013). Since the WEMWBS is being used increasingly in ABI, future research could validate its use in this population.

Key study limitations include the short follow-up of two weeks, which did not allow for any inferences to be made about the maintenance of effects, and the lack of blinding which potentially introduced examiner or acquiescence bias, especially due to some participants receiving support to complete questionnaires. The WEMWBS, for example, is designed to be completed independently, as supporting someone to complete this could risk participants responding more positively (Warwick Medical School, 2021). It was not possible to blind participants due to the intervention provided being obvious, however in the future a blinded researcher could collect outcome measures. Furthermore, psychological distress such as depression and anxiety was not measured in the current study, and therefore it is unclear if distress had an effect on any of the variables measured. For example, Rauwenhoff et al. (2022) did not find any effects of an ACT intervention on values-driven behaviour for individuals with ABI and anxiety or depression, although there were positive effects on psychological distress and quality of life. Finally, not measuring value alignment in both groups did not allow for a direct comparison, however priming participants from the standard goal-setting group to consider values may have led to intervention contamination.

Another limitation is that the self-selecting convenience sample of ABI survivors accessing charity organisations may have introduced sampling bias, since those individuals were likely already interested in community support and motivated to receive input. This recruitment method limits the generalisability of the study results, however not relying on online recruitment strategies likely made the study more accessible to those with limited cognitive ability or means to access the internet. Furthermore, since participants resided in the community, information regarding brain injury type and severity was self-reported, which may have not been reliable. However, approaching those accessing ABI organisations was a good way of confirming that they indeed had a brain injury. In addition, as cognitive and communication abilities were assessed informally, it is possible that the initial discussion was not thorough enough to determine if these abilities were sufficient for participation. Lastly, some of the measures used were created based on available literature or adapted to fit the needs of the current study. This reflects the novel nature of the current study, however poses questions of validity and reliability.

## Implications and Future Directions

The current study has provided preliminary evidence that goal-setting may be more effective in enhancing wellbeing of ABI community dwellers when goals are embedded in values. This can be important for services and organisations that support individuals with ABI set goals, since the addition of a values element in goal-setting is not labour-intensive, does not require extensive training and can be delivered by non-psychological professionals, but may have the potential to lead to enhanced wellbeing. It also highlights the need for continuous community support for ABI survivors, as a single values-based goal-setting session may be able to enhance wellbeing in this population.

It is recommended that in the future, a fully-powered single-blinded RCT should further investigate the effects of values-embedded goals and whether these are maintained after a longer follow-up. Future studies can also replicate findings in an inpatient rehabilitation setting, adding to the evidence base of improving the goal-setting process for individuals with ABI. Furthermore, the two groups can be even better matched in terms of input received, for example by having the standard goal-setting group engage in an unrelated sorting task, and a waitlist control can be added to the design as a baseline for comparison purposes.

It is also recommended that the single-session goal-setting interventions are expanded into multiple sessions. This would enable participants to receive support in setting and working on multiple goals, and the values-based goal-setting group would get the opportunity to develop the skill of committed action towards valued life-directions. This would also allow researchers to determine whether a longer intervention with higher levels of support can have a more meaningful impact on participants' wellbeing for both groups, and particularly whether the values-based group would benefit further. For example, Villatte et al. (2016a) examined the effects of an eight-week values clarification and committed action intervention for adults with clinically significant distress, and found session-by-session growth in values-based action.

Future studies could also investigate the mechanisms by which a change in wellbeing takes place. This could be achieved by using a process measure, such as the Process-Based Assessment Tool (PBAT; Ciarrochi et al., 2022), which allows for the selection of items that are relevant for the purpose it is being used. Future studies could include measures of psychological distress in order to examine whether clinically significant levels of depression or anxiety mediate the effectiveness of the values-based and standard goal-setting interventions. Finally, more objective measures could be employed to determine ABI severity, such as liaison with GPs to obtain GCS scores, and use of tools to measure cognitive and communication abilities in order to have a more standardised inclusion and exclusion methodology.

## Conclusion

This pilot study was the first to compare a single values-based versus standard goal-setting session for ABI survivors living in the community. It found that both single-session interventions were feasible and acceptable, and that psychological wellbeing was higher for the values-based group with a small-to-medium effect. Two weeks after setting a goal, participants from the values group felt more aligned to their value than before, with a large effect size. This did not translate to higher goal attainment, memory for goals or rated importance of new behaviours, which were similar for the two groups. Session satisfaction and motivation to work on the goal were rated higher in the values-based group, while confidence and anticipated pleasure were rated higher in the standard goal-setting group. Although findings from the current study should be interpreted with caution as the sample size was small and the findings require replication in a powered trial, preliminary evidence suggests that when goals are embedded in values, this can enhance the wellbeing of individuals with ABI living in the community. A fully-powered RCT appears to be feasible, with some suggested changes being a longer follow-up and investigating values-based goals in inpatient settings as well.

## IV. Integration, Impact, Dissemination

This chapter will first discuss the integration between my systematic review (SR) and empirical study (ES), how these are related conceptually, and reflections on the methodology, recruitment and service user involvement. The impact of my thesis will then be discussed before detailing plans for dissemination of my findings, with reflections and critical considerations provided throughout.

### Integration

My project consists of two interrelated pieces of work: the SR and the ES. The overall aim of my project was to investigate the effectiveness of psychological interventions in enhancing positive affect for Acquired Brain Injury (ABI) survivors, and further advance knowledge by specifically examining the effectiveness of the values-identification component of Acceptance and Commitment Therapy (ACT) when integrated into goal-setting, compared to standard goal-setting. Choosing this topic was largely driven by my past experiences of working with ABI survivors, as well as an interest in how ACT and third-wave CBT interventions more generally could enhance ABI survivors' wellbeing. The focus on positive affect (i.e., positive psychological states such as wellbeing) was driven by multiple motivations:

a. NICE (2022) guidelines stating that professionals should enquire about values and future aspirations as part of their neurorehabilitation assessment in ABI;
b. The UK Research Councils detailing that enhancing quality of life is a key part of research that contributes to society and the economy (National Coordinating Centre for Public Engagement, n.d.);
c. A move away from a 'deficit' approach, and a focus placed on promoting positive psychological states in the general population (Huppert, 2009), for example through campaigns such as "No Health Without Mental Health" (Department of Health, 2011) and "The Five Ways to Wellbeing" (Government Office for Science, 2008).

Furthermore, as psychological wellbeing is not merely the absence of distress (Keyes, 2002), interventions that only aim to reduce clinical symptoms of distress in ABI likely exclude a large number of survivors who experience lower positive affect as a response to the physical and cognitive effects of brain injury and their impact on independence, community participation and social relationships (Goverover et al., 2017), as they may not meet criteria for a psychiatric condition. Lastly, as ABI is more prominent in people who are likely to experience other health inequalities, increased risk of physical health conditions, homelessness and offending (Acquired Brain Injury Forum for London; ABIL, 2017), where the stigma associated with mental health is significant (Mejia-Lancheros et al., 2020), I hoped this research would feel relevant to all ABI survivors without introducing mental health condition labels that might be interpreted as unhelpful.

## Systematic Review

My SR specifically focused on psychological interventions aiming to enhance positive affect for ABI survivors. I was initially interested in the effectiveness of ACT interventions in ABI, however previous SRs have evaluated ACT for anxiety (Soo et al., 2011), preventing post-stroke depression (Niu et al., 2022), and enhancing wellbeing in adults (Stenhoff et al., 2020), as well as in long-term health conditions (Graham et al., 2016). A variety of theses have also reviewed the effectiveness of ACT (e.g., Sharma, 2019) and third-wave therapies more generally (e.g., Foreman, 2020) in ABI. No published SR has looked at the effectiveness of ACT in enhancing positive affect in ABI survivors, however after a quick literature search it emerged that there was a lack of available studies to synthesise, likely due to this field still being in its infancy. For that reason, I widened my scope to include all psychological interventions.

The SR evaluated a total of 26 studies and nine different types of psychological interventions. This wide range of interventions, as well as the heterogeneity in their delivery, posed a challenge in making comparisons and drawing firm conclusions about their effectiveness. However, the SR found evidence supporting the use of third-wave CBT interventions in enhancing positive affect in ABI, although only one study using ACT was included. Nevertheless, this group ACT intervention improved wellbeing in ABI with a medium effect size, which was maintained at two-months follow-up (Majumdar & Morris, 2019), suggesting that ACT and third-wave CBT therapies in general could have a role in enhancing positive affect for people with ABI. Based on this evidence, the rationale for using ACT components in ABI to enhance wellbeing for the ES was strengthened. However, the SR also highlighted the need for more studies with robust methodologies making controlled comparisons between active groups. In order to address these limitations, I decided to utilise a pilot Randomised Controlled Trial (RCT) design. Furthermore, the SR showed that measures of wellbeing, although not commonly used, were likely more able to capture positive affect than measures of life satisfaction or quality of life, the latter often using measures that tap into the domain of “health” rather than positive affect. The ES therefore used a measure of wellbeing to measure positive affect.

In general, conducting the SR was a time-consuming process due to the large number of studies involved, which did not allow me to follow the ideal methodology standards of having a second reviewer assess all identified studies for eligibility and quality, rather than a proportion of these. Furthermore, synthesising studies was challenging due to the heterogeneity of study methodologies, settings, and interventions being evaluated. Nonetheless, it was a very informative process as I enjoyed learning about the process of SRs, and gaining knowledge that will allow me to continue conducting research in the future. Additionally, it was informative and enjoyable to gain a deeper understanding of the literature, and explore some interventions such as those based on narrative theory and creative therapies, which have rarely been included in previous SRs due to psychological interventions taking on a narrow definition of “talking therapies”.

## Empirical Study

### *Methodology*

Since values-based goal-setting has not been previously compared to standard goal-setting in ABI, it was deemed appropriate to conduct a pilot RCT, which aims to calculate the required full-scale trial sample size and test out elements of the trial, such as the integrity of the study protocol and the acceptability of the interventions (Lancaster et al., 2004). Although conclusions made from this ES should be tentative, as pilot studies are not powered to make definitive conclusions about effectiveness (Williams, 2016), it is hoped that the results of this study will inform a fully-powered RCT, for example conducted by future trainees. A decision was made to conduct a follow-up only two weeks past the end of the intervention for this pilot, and although this prevents any conclusions about maintenance of effects to be made, it led to lower burden for participants and allowed for the study to be conducted within the time constraints of the Doctorate. It also may have contributed to the low drop-out rate of <10%, as I found that the two-week follow-up time allowed participants to hold the research in mind and it was less likely that they would be lost to follow-up. Additionally, I found that text reminders of our follow-up meetings, and flexibility in how these meetings were held (i.e., online or phone appointments if preferred) helpful in further reducing dropouts.

Additionally, both the values-based and standard goal-setting interventions took place in a single session, in line with other similar studies (e.g. Davies et al., 2021; Wainman-Lefley, 2022). Although it was sometimes challenging to build rapport and trust in a single session, the time commitment required from participants was low and satisfaction ratings showed that the intervention was deemed to be acceptable. However, in practice it was often the case that participants expressed the desire to receive more support in the form of multiple sessions, or be seen for longer. Unfortunately, this was not possible to do following a standardised methodology, and it often led me feeling disappointed in the extent of the input I was able to offer, considering that many ABI survivors expressed despondency in response to the lack of available support in the community.

In terms of measuring positive affect, it was initially planned to use the Flourishing Scale (FS; Diener et al., 2009), which is a global measure of psychological wellbeing asking participants to rate agreement with eight statements. However, this measure does not provide a timeline to guide participants when they complete it. For the purpose of this ES, it was necessary to specifically ask about wellbeing in the last two weeks, in order to measure the effects of the intervention, and so a different measure (WEMWBS) was selected that was better suited to this. Lastly, although there were benefits described above to focusing on positive affect in this study, the decision not to measure psychological distress did not allow for any investigation as to whether individuals with higher distress were less likely to benefit from values-based or standard goal-setting.

### ***Recruitment***

I started shaping the design of the ES with an awareness that recruitment was likely to be a challenge, in line with reports from previous similar studies (e.g., Wainman-Lefley et al., 2022) and due to the COVID-19 pandemic impacting on the recruitment of many projects from trainees in previous years (e.g., Andrews, 2021). A decision was therefore made early on to not seek ethical approval from the NHS, but to recruit from community charity organisations instead such as Headway. This was also driven by my past experiences of working with ABI survivors in the community, as I was aware that support and resources are often limited for this population and I hoped that my research would add value in this domain. I believe that this decision was helpful, as it allowed for recruitment to begin in July 2022 to allow for enough time in case it appeared to be as slow as expected. Recruitment was challenging at first, and although I initially reached out to a very large number of Headway branches across the UK, a very small number responded by circulating my recruitment poster to their members via a newsletter, and very few participants were recruited through this method. However, one Headway branch responded very positively as the topic of my research was in line with their efforts to improve the goal-setting process. Multiple in-person visits and online meetings allowed for strong relationships between myself and Headway staff to be created and nurtured, leading to this being a very successful recruitment strategy. Likewise, utilising existing relationships with a stroke-specific charity that I built in the past was another successful recruitment method. Both organisations allowed me to present my study and discuss it with their members in person, which made it significantly easier for ABI survivors to ask questions and express an interest than if my poster was shared in a newsletter, which would require access to the internet to access. This highlighted the importance of nurturing in-person relationships, and meant that it is likely that recruitment would have been significantly more challenging if it had taken place during the COVID-19 pandemic.

Another helpful recruitment strategy was making a conscious effort to be very flexible in terms of meeting participants to complete the study sessions, in order to reduce obstacles in participating. I offered to meet with participants in any venue that was most convenient to them, including their local community venues and even their home, if preferred. This was often mentioned as something that was particularly valued in the qualitative feedback participants gave about the study, and likely contributed to many individuals' decision to participate, as mobility difficulties would pose a challenge in getting to a pre-specified venue, and cognitive or communication difficulties may have created a barrier in engaging in the study online. Although I was glad I was able to provide this for participants in the London area, it required a significant amount of travel time and monetary contributions from my part, as well as a lot of planning and administration to ensure that I grouped participants by area so that I could visit more than one in a day, considering the time-constraints posed by the Doctorate.

## Service User Involvement

Service user involvement is an essential part of research and needs to be evidenced for funding to be awarded (National Institute of Health Research; NIHR, 2019), as it can have a wide impact and lead to better quality research (Staley, 2009). However, not all types of service user involvement are according to the values that have been highlighted as underlying good practice in public involvement in research (respect, support, transparency, responsiveness, fairness of opportunity and accountability; INVOLVE, 2013). A "Ladder of Participation" framework (Arnstein, 1969) demonstrates that involvement can range from simply informing service users, to giving the power of decision-making to them.

Regrettably, it was not possible to achieve true partnership in this ES, with the level of service user involvement perhaps sitting more in the "consultation" rung of the ladder, considered to be tokenistic. Service users shaped the design and content of the consent form and information sheet, originally used for Sharma (2019), as well as my recruitment poster, which was amended according to their contributions. Unfortunately, due to limited time and funding available, it was not possible to gain feedback on the measures or intervention of the ES, or more ideally have these elements co-designed by service users. Furthermore, the number of service users approached was small, limiting generalisation to the wider ABI population, and they were only approached after the documents had been designed, not allowing for true partnership between us. However, adding a qualitative element to the measure of satisfaction allowed study participants to contribute anything that they feel can be different in a full-scale RCT; for example, one participant noted that it would be good to be offered a free cup of coffee as part of the study. Furthermore, it is planned for service users to contribute to the dissemination of the ES findings by providing feedback on the findings summary that will be sent to participants and to brain injury organisations. Lastly, due to time limitations, it was not possible to involve service users in the SR process, and unfortunately the level of participation will be in the “informing” rung of the ladder. The lack of true partnership, and in some cases consultation, with service users is a significant weakness of this research project, and a disappointing one for me. I highly recommend that a future full-scale RCT rectifies this by involving service users in all aspects of the study, and I will ensure that I prioritise service user involvement in future research.

## Impact

The effects of ABI can have a long-term impact on survivors’ quality of life and wellbeing (Goverover et al., 2017), impacting on their social participation, ability to work, and need for continuous support, placing a significant economic burden on the National Health Service (UKABIF, 2019). Research focusing on enhancing positive psychological states therefore has the potential not only to improve the wellbeing of survivors, but also to have a positive impact on their social network and support engagement with meaningful activities and occupation. Findings from the ES are tentative, as the study was a pilot and not powered to make firm conclusions about effectiveness (Arain et al., 2010), however this is the first study directly comparing values-based to standard goal-setting for ABI survivors to my knowledge and the implications of these tentative findings are significant.

Both SR and ES findings contribute to evidence-based practice, which is essential in ABI neurorehabilitation (Barnes, 2003). As the interventions evaluated in the SR were not only delivered by psychological professionals or used a strict “talking therapies” approach, as is often the case in neurorehabilitation, findings may be of interest to clinicians from a wide variety of professions. Furthermore, several recommendations are made in the SR highlighting gaps in existing research, such as the lack of RCTs making controlled comparisons for certain types of interventions (e.g., Positive Psychology), the lack of comparisons to active control groups, and the need to further evaluate third-wave interventions in response to promising initial findings. These recommendations could be of use to future researchers interested in further developing the knowledge-base in this area.

Findings from the ES also contribute to the growing literature around goal-setting in ABI; although goal-setting is a key element of neurorehabilitation, existing methods are found to be largely unsuitable (Plant et al., 2016). This study explored the specific addition of the “behavioural” elements of ACT (values identification and committed action) in goal-setting, in line with NICE guidelines (2022) which recommend asking individuals about their values. These findings are promising, tentatively suggesting that the addition of these elements has the potential to make the goal-setting process more effective in enhancing wellbeing than the standard methods used currently. This is especially important considering that embedding goals in values adds little extra effort and time to existing goal-setting methods and can be done by non-psychological professionals, and could have wide implications in clinical settings. Firstly, these findings could contribute to raising awareness of values-based goal-setting as an alternative method to setting goals in ABI. Raising awareness and shifting attitudes is an important part of the impact that research can have (Research Excellence Framework, 2014). As there is one ABI admission in hospital every 90 seconds (Headway, n.d.) with goal-setting being an integral part of rehabilitation (NICE, 2022), it is important that professionals at different levels involved in neurorehabilitation are aware that values and committed action may be helpful approaches when supporting ABI survivors. Secondly, the findings could lead to behavioural changes. Staff members in neurorehabilitation and brain injury organisations could add these ACT elements into their existing goal-setting practices, and family and friends of ABI survivors, volunteers and befrienders could consider the benefits of discussing values when supporting individuals. Future iterations of the NICE guidelines could consider making a more explicit recommendation about embedding goals in values, if further evidence supports this. Furthermore, the findings highlighted that there is a need to continue providing support for ABI survivors in the community, evident in their willingness to participate in this study and in the disappointment towards the lack of support that was often expressed during their participation. This could strengthen rationale for wider access and funding for brain injury organisations, such as Headway. Lastly, these different levels of impact could be relevant for a wide audience, as they could be applicable to a variety of types of settings, services and organisations at a national level in the UK.

However, it is important to highlight that more research is needed before incorporating these ACT elements in clinical practice. Another pilot RCT could be conducted in inpatient rehabilitation settings, and services in different settings could run local Quality Improvement projects to explore the benefits of values-based goal-setting. Following this, a fully-powered RCT ideally co-designed with service users could test the effectiveness of values-based goal-setting in multiple settings and sites. Nonetheless, these initial findings contributed to the growing literature of ACT in ABI, and specifically utilising the “behavioural” elements of ACT, which is an area that is still in its infancy.

## Dissemination

The National Institute for Health and Care Research (NIHR) highlights that “research is of no use unless it gets to the people who need to use it” (Whitty, 2019, p.1). Effective research, academic, clinical and service user dissemination is therefore key in ensuring research is impactful and contributes to academic and clinical practice. With this in mind, a dissemination plan has been designed for this study in order to achieve wide reach and pass on relevant knowledge to those for whom it would be applicable.

In terms of clinical dissemination, several activities have been planned. Firstly, all brain injury organisations contacted will be sent a summary of the ES findings, whether they contributed to recruitment or not. Secondly, I have planned to deliver a presentation of relevant findings to staff members and volunteers from the two brain injury organisation branches that particularly supported recruitment, and provide a short training on how goals can be embedded in values, aiming to make this approach accessible to those working with ABI survivors in those branches so it can inform their practice if they choose so. Finally, I am becoming involved with Headway as trainer in order to help design a training course for those working with ABI survivors on goal-setting, which will include values-based goal-setting practices. I hope that this will be a way of further reaching those who may benefit from the ES findings, and as these trainings are delivered online they can be accessible from the whole of the UK.

I am also planning on disseminating the research findings to service users who participated in this ES, as recommended by the Health Research Authority (HRA; 2023) in their “Make it Public” strategy. Service users were asked whether they would like a copy of the findings when they consented to participate and how they would like for this to be presented, which will be considered when sharing findings with them. Another way of disseminating findings with service users more widely is via brain injury organisations. One of these is the Stroke Association, which often publishes relevant research on their website (Stroke Association, n.d.). Headway also tends to send out relevant research findings in the form of newsletters. These can be helpful ways to disseminate findings to staff, volunteers, service users and significant others as they are freely accessible.

Finally, I have planned on several different methods of disseminating my findings academically. Findings from this ES have already been disseminated to staff members and trainee Clinical Psychologists at Royal Holloway University London (RHUL) as part of a day of presentations from myself and fellow trainees. Findings were disseminated as part of a

PowerPoint presentation, with time to consider questions and feedback at the end. As well as providing different perspectives and reflections, this was helpful in making fellow trainees aware of this research in the hope that they might elect to participate in similar research that will further advance knowledge and literature. Furthermore, a submission to present a poster of my findings in the British Association for Behaviour and Cognitive Psychotherapies (BABCP) 51st Annual Conference, taking place in July 2023 in Cardiff, has been accepted. I hope that this will be a valuable opportunity to reach a wider audience of professionals who may use the findings to inform their clinical practice or conduct further relevant research, but also to consider a wide range of perspectives that professionals with different experiences may choose to share with me, and gain an understanding of other relevant research that is being conducted. Finally, I hope to publish my findings in a high-quality peer-reviewed journal so that other researchers and professionals are able to access and consider my findings when planning further research or informing clinical practice.

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# VI. Appendices

## Appendix A

Search Strategy

### PsychINFO search terms

AB ( Stroke OR “cerebrovascular accident” OR cva OR “cerebral vascular event” OR cve OR “transient ischaemic attack” OR “transient ischemic attack” OR tia OR “brain injury” OR “head injury” OR “traumatic brain injury” OR tbi OR “acquired brain injury” OR abi ) AND AB ( Wellbeing or “well-being” or “well being” or happiness or “life satisfaction” or “quality of life” or “life meaning” or flourishing ) AND AB ( Experimental OR quasi-experimental OR “randomised controlled trial” OR “randomized controlled trial” OR “randomised control trial” OR “randomized control trial” OR rct OR intervention OR “intervention design” )

### PubMed search terms

((Stroke[Title/Abstract] OR "cerebrovascular accident"[Title/Abstract] OR cva[Title/Abstract] OR "cerebral vascular event"[Title/Abstract] OR cve[Title/Abstract] OR "transient ischaemic attack"[Title/Abstract] OR "transient ischemic attack"[Title/Abstract] OR tia[Title/Abstract] OR "brain injury"[Title/Abstract] OR "head injury"[Title/Abstract] OR "traumatic brain injury"[Title/Abstract] OR tbi[Title/Abstract] OR "acquired brain injury"[Title/Abstract] OR abi[Title/Abstract]) AND (Wellbeing[Title/Abstract] OR "well-being"[Title/Abstract] OR "well being"[Title/Abstract] OR happiness[Title/Abstract] OR "life satisfaction"[Title/Abstract] OR "quality of life"[Title/Abstract] OR "life meaning"[Title/Abstract] OR flourishing[Title/Abstract])) AND (Experimental[Title/Abstract] OR quasi-experimental[Title/Abstract] OR "randomised controlled trial"[Title/Abstract] OR "randomized controlled trial"[Title/Abstract] OR "randomised control trial"[Title/Abstract] OR "randomized control trial"[Title/Abstract] OR rct[Title/Abstract] OR intervention[Title/Abstract] OR "intervention design"[Title/Abstract]

## Appendix B

Table Detailing Intervention and Control Group Details

| Study ID | Active intervention details | Control group details |
|---|---|---|
| | Stroke | |
| BRA2020 & HJE2019 | This Dialogue-Based intervention draws on narrative therapy and aims to improve wellbeing by facilitating a sense of coherence. Topics involve bodily changes, existential issues, coping with emotions, relationships, everyday issues, meaningful activities and values. | Usual care consists of standard acute stroke treatment, which includes home discharge and access to MDT services (e.g. PT, OT, SLT, nursing care) or inpatient rehabilitation, depending on need and availability. Psychosocial follow-up is rare. |
| CHA2011 | Knowledge & Behavior Therapy consists of counselling sessions that include a knowledge and a behavioural training component. The knowledge component involves psychoeducation around health and stroke recovery, and the behavioural training component involves skills training such as forgiveness training and anger management. | Usual care consists of medication and daily physical rehabilitation. |
| COR2014 & COR2015 | This Biographic-Narrative intervention consists of biographic–narrative interviews and group interventions. The interviews aim to facilitate identity renegotiation through narration of life stories and exploration of various issues. The group interventions aim to support peer learning, social contact and identity shaping. | No control group |
| KER2018 | Early Motivational Interviewing aims to facilitate adjustment to life after stroke. Participants are encouraged to explore issues such as stroke adjustment, realistic goals, barriers and ambivalence to working towards and achieving goals. | Usual care consists of support from nursing, medical, and allied health staff. Depending on need, psychiatric referral and Stroke Foundation brochures are provided. |
| KON2016 | Creative Art Therapy aims to stimulate and enhance cognition, physical functioning, emotions, communication, relationships and spiritual elements. Each session consists of music meditation, a warm-up | Usual care consists of daily 1-2h PT sessions over weeks that aim to enhance balance, strengthening, ambulation and motion. |

| Study ID | Active intervention details | Control group details |
|---|---|---|
| | activity, a main activity along with group singing, and a healing circle. | |
| KOO2016 | CBT aims to reduce depressive symptoms and consists of grief resolution, psychoeducation, goal-setting, recognizing and challenging cognitions and relapse-prevention.<br>The Occupational Therapy or Movement Therapy sessions aim to encourage participants establish and achieve goals around meaningful activities and social participation. | Computerised Cognitive Training consists of 13-16 one-hour sessions over months, largely self-administered via the Cogniplus program. The difficulty level is automatically adjusted for each training task. |
| MAJ2019 | This ACT-based intervention is delivered by PowerPoint and is didactic, manualized and psychoeducational in nature. It focuses on themes such as acceptance, thought diffusion and identification of values, and includes several ACT-based individual activities throughout, such as guided mindfulness practices. | Usual care consists of access to community services such as GP, charity support, or online resources. |
| MIN2020 | The Stroke Care Optimal Health Program aims to improve mental health by facilitating self-efficacy and self-management through developing skills and providing psychoeducation. Topics include optimal health, medication, strategies, goal-setting and developing health plans. Participants choose to take part on their own or with a partner. | Usual care consists of rehabilitation, which includes goal-setting, physical and cognitive work, as well as medical support (e.g., lifestyle modification, diabetes management) and community participation. |
| PEN2015 | Neuro-Linguistic Programming aims to shift negative beliefs, improve mood, increase mental energy, release pressure and enhance relaxation.<br>Health education aims to provide psychoeducation around stroke risk factors, warning signs and stroke prevention. | Usual care consists of medical, nursing, and therapy input and discharge coordination. There is no psychological support for stroke patients. |
| POĆ2017 | Music Therapy aims to improve mental health, joy and energy, and reduce psychophysical tension by facilitating adjustment, pain and emotion management, and a sense of control over health. | Usual care consists of PT, OT, a psychological diagnosis and maintenance psychotherapy. |

| Study ID | Active intervention details | Control group details |
|---|---|---|
| RAG2017 | Relational Active Music Therapy aims to improve mental health, motion, communication and relationships by facilitating emotional expression and regulation through non-verbal interactions between therapist and participants using rhythmical-melodic instruments. The intervention time was subtracted from usual rehabilitation care to balance time of interventions in the two groups. | Usual care consists of daily sessions of PT and OT. |
| TER2018 | Dyadic Positive Psychology aims to improve depressive symptoms and enhance wellbeing through encouraging couples to engage in at least two activities alone and two together each week. Activities include expressing gratitude, engaging with spirituality and fostering relationships, and couples can make use of a workbook and activity tracking calendar. | No control group. |
| THO2019 | Behavioural Activation aims to improve mood by increasing participants' enjoyable or valued activities. It consists of techniques such as activity monitoring, activity scheduling and graded tasks. | Usual care varied across settings as it was decided by local services, and included early supported discharge or community rehabilitation support. |
| VIS2015 | Problem-Solving Therapy aims to enhance coping strategies and improve quality of life. It consists of problem definitions, positive problem orientations and problem-solving, which includes generating multiple solutions, selecting a solution, implementing and evaluating. | Usual care consists of PT, OT, SPT, psychology and social work, according to individuals' needs. |
| WAN2012 | Mindfulness-Based Cognitive Therapy aims to reduce depressive symptoms and improve quality of life through improved attention control, enhanced emotion regulation and altered self-awareness. | Stress management education consists of eight 2-hour group sessions delivered in a group lecture format. Topics include stress psychoeducation, insomnia, exercise, and nutrition. |
| WAT2019 | This 2-week Mindfulness meditation training uses recordings from the first two weeks of the Mindfulness-Based Stress Reduction programme. Meditation recordings include the body scan, and a sitting and a breathing meditation. | No control group. |

| Study ID | Active intervention details | Control group details |
|---|---|---|
| | Traumatic Brain Injury | |
| ASH2014 | CBT involves cognitive restructuring techniques, socratic questioning and relaxation techniques. It is adapted to address cognitive difficulties by providing written handouts and embedding training of compensatory strategies within treatment sessions. | Supportive Psychotherapy aims to reduce symptoms, improve self-esteem, maximise adaptive coping and encourage functioning. It consists of techniques such as naming the problem, praise, reassurance, encouragement and psychoeducation. |
| ASS2021 | This Two-step Resilience-Oriented intervention aims to enhance veterans' resilience by addressing cognitive and emotional factors of resilience through psychoeducation, skills development and behavioural techniques. | Usual care consists of neuropsychological assessment, medication, social work, psychoeducation and counselling, depending on individual needs. |
| AZU2013 | Mindfulness-Based Stress Reduction is modelled after Kabat-Zinn's programme with some modifications to account for cognitive difficulties, such as expanded number of sessions, reduced group size, and modelling of techniques. | No control group. |
| BED2003 & BED2005 | Mindfulness-Based Stress Reduction aims to improve wellbeing and quality of life through present-moment awareness and acceptance. It includes techniques such as meditation, breathing exercises, guided visualization and group discussions. | The control group consists of participants who dropped out of the intervention. |
| GUR2005 | CBT for post-traumatic headaches aims to reduce the frequency, intensity and duration of headaches by facilitating new coping strategies to manage pain. It consists of strategies such as progressive muscle relaxation, psychoeducation, cognitive-behavioural strategies, lifestyle management and relapse prevention. | No control group. |
| HAR2017 | Anger Self-Management Training aims to provide psychoeducation about anger in TBI, and teach behavioural skills such as self-monitoring and problem-solving. | Personal Readjustment and Education aims to provide psychoeducation about the effects of TBI on personality, relationships and community roles |

| Study ID | Active intervention details | Control group details |
|---|---|---|
| | | through reflective listening and adjustment facilitation, delivered in eight 90-minute 1:1 weekly sessions. |
| KJE2014 | CBT for chronic post-traumatic headaches is based on the principles of Beck and aims to provide psychoeducation and strategies that facilitate primarily cognitive change and increase activity. It includes relaxation strategies such as autogenic training and progressive muscle relaxation. | Waiting list control group. |
| THE2018 | CBT for insomnia aims to improve sleep. It consists of sleep psychoeducation, relaxation training, sleep restriction, cognitive strategies and mindfulness meditation, and includes video presentations and interactive tasks. | The Education Programme offers psychoeducation around brain injury, sleep and fatigue, routine and effects of environment and exercise on sleep. It does not contain interactive features or advice on implementing behaviour change strategies. Participants were asked to complete a module each week for six weeks, lasting around 20 minutes each. |
| | Acquired Brain Injury | |
| CUL2018 | Brief Positive Psychotherapy is a manualized programme based on Seligman’s PERMA framework. It consists of psychoeducation, facilitating use of signature character strengths, reflecting on positive events and relapse prevention. | Usual care is not standardised and input varies between services. Psychological input is available if required. |
| EXN2022 | Integrated Neuropsychology and CBT aims to improve function and wellbeing by teaching cognitive and emotional compensation and regulation strategies. It consists of a variety of modules offered according to needs: adjustment, cognitive remediation, attention, memory, executive functions, self-concept, management of negative emotions, and reformulation of life goals. | Waiting list control group. |

*Note.* Study ID: First three letters of first author surname and year of publication. OT = Occupational Therapist. PT = Physiotherapist. SLT = Speech & Language Therapist.

## Appendix C

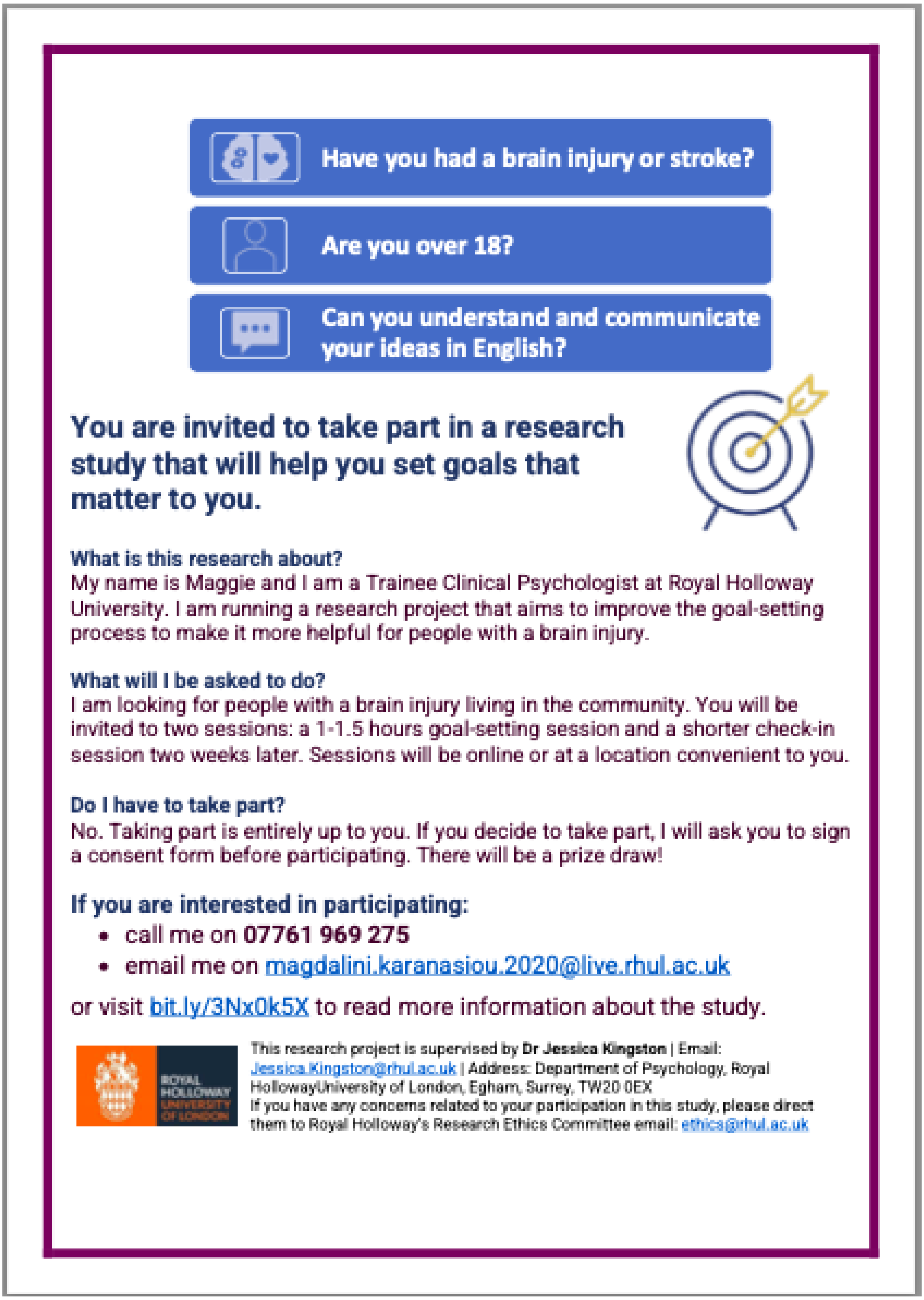
Table of Outcome Measures and Measurement Details

| Outcome Measure | Measurement Details |
|---|---|
| | Quality of Life |
| Aachen Life Quality Inventory (ALQI) | 117 items judged true or false and burden evaluated on a three-step scale. Higher scores indicate worse QoL. |
| Australian Assessment of Quality of Life-6 Dimensions (AQoL-6D) | 20 items rated on 4-6-point Likert scales. Higher scores suggest better QoL. |
| Chaban Quality of Life Scale (CQLS) | 10 items rated on an 11-point Likert scale. Higher scores indicate better QoL. |
| Five Dimensions EuroQoL-Five Levels (EQ-5D-5L) | Five items rated on a five level scale, and a visual analogue 0-100 scale. Higher scores indicate better QoL. |
| Five Dimensions EuroQoL-Three Levels (EQ-5D-3L) | Five items rated on a 3-point Likert scale, and a visual analogue 0-100 scale. Higher scores suggest better QoL. |
| Life-3 | 1 item rated on a 7-point Likert scale. Higher scores indicate better QoL. |
| McGill Quality-of-Life Questionnaire-Italian version (MQOL-It) | 16 items rated on a 11-point Likert scale. Higher scores indicate better QoL. |
| Nottingham Health Profile (NHP) | 38 items rated as ‘true’ or ‘false. Higher scores indicate worse QoL. |
| Older People's Quality of Life Questionnaire (OPQOL) | 35 items encompassing 9 domains, rated on a 5-point Likert scale. Higher scores indicate better QoL. |
| Perceived Quality of Life scale (PQOL) | 20 items rated on a 10-point scale. Higher scores indicate better QoL. |
| Pictorial Thai Quality of Life questionnaire (PTQL) | 25 items rated on a 3-point Likert scale. Higher scores indicate better QoL. |
| Quality of Life after Brain Injury (QOLIBRI) | 37 items rated on a 5-point Likert scale. Higher scores indicate better QoL. |
| Quality of Life Index (QLI) -Stroke version | 38 items rated on a 6-point Likert scale. Higher scores indicate better QoL. |
| Schedule for the Evaluation of Individual Quality of Life (SEIQoL-DW) | 5 areas rated on a scale of 1-100 for functioning and importance. Higher scores indicate better QoL. |
| Short-Form 12 (SF-12) | 12 items rated as true or false, or on a 5-point Likert scale, and are combined into eight domains. |

| Outcome Measure | Measurement Details |
|---|---|
|  | Higher scores indicate better QoL. |
| Short-Form 36 (SF-36) | 36 items rated as true or false, or on a 5-point Likert scale, and are combined into eight domains. Higher scores indicate better QoL. |
| Spitzer's Quality of Life Index (QLI-index) | 5 items rated on a 3-point Likert scale. Higher scores indicate better QoL. |
| Stroke-Adapted 30-Item Version of the Sickness Impact Profile (SA-SIP30) | 30 items rated as true or false. Higher scores indicate worse QoL. |
| Stroke and Aphasia Quality of Life Scale (SAQOL- 39g) | 39 Items rated on a 5-point Likert scale. Higher scores indicate better QoL. |
| Stroke Specific Quality of Life Scale (SSQoL) | 49 items encompassing 12 domains, rated on a 5-point Likert scale. Higher scores indicate better QoL. |
| Stroke Specific Quality of Life Scale-12 (SSQoL-12) | 12 items rated on a 5-point Likert scale. Higher scores indicate better QoL. |
| Stroke Specific Quality of Life Scale - Chinese Version (SSQOL - Chinese) | 62 items rated on a 5-point Likert scale. Higher scores indicate better QoL. |
| The Cantril Ladder | 3 items rated on a 11-point Likert scale. Higher scores indicate better QoL. |
| Life Satisfaction |  |
| Life Satisfaction questions (LS2) | 2 items rated on a 6-point and 7-point Likert scale respectively. Higher scores indicate better LS. |
| Satisfaction with Life Scale (SWLS) | Five items rated on a 7-point Likert scale. Higher scores indicate better LS. |
| Wellbeing |  |
| Functional assessment of cancer therapy-brain (FACT-Br) | 50 items rated on a 5-point Likert scale. Higher scores indicate better WB. |
| Warwick-Edinburgh Mental Well-being Scale (WEMWBS) | 14 items rated on a 5-point Likert scale. Higher scores indicate better WB. |
| Wellbeing change scale | 1 item rated on a 7-point Likert scale. Higher scores indicate lower WB. |
| Happiness |  |
| Authentic Happiness Inventory (AHI) | 24 items rated on a 5-point Likert scale. Higher scores indicate better happiness levels. |

# Appendix D

Recruitment Poster



**Have you had a brain injury or stroke?**

**Are you over 18?**

**Can you understand and communicate your ideas in English?**

## You are invited to take part in a research study that will help you set goals that matter to you.

**What is this research about?**
My name is Maggie and I am a Trainee Clinical Psychologist at Royal Holloway University. I am running a research project that aims to improve the goal-setting process to make it more helpful for people with a brain injury.

**What will I be asked to do?**
I am looking for people with a brain injury living in the community. You will be invited to two sessions: a 1-1.5 hours goal-setting session and a shorter check-in session two weeks later. Sessions will be online or at a location convenient to you.

**Do I have to take part?**
No. Taking part is entirely up to you. If you decide to take part, I will ask you to sign a consent form before participating. There will be a prize draw!

**If you are interested in participating:**

- call me on **07761 969 275**
- email me on magdalini.karanasiou.2020@live.rhul.ac.uk

or visit bit.ly/3Nx0k5X to read more information about the study.

ROYAL
HOLLOWAY
UNIVERSITY
OF LONDON

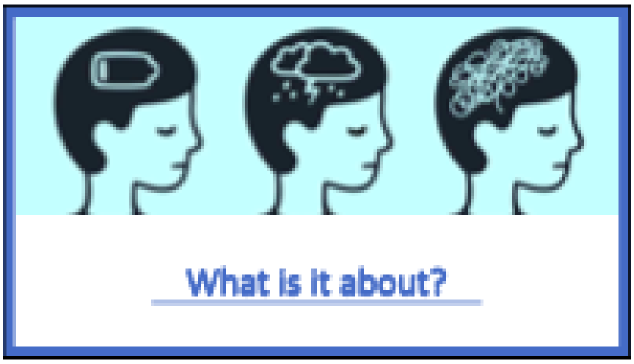
This research project is supervised by **Dr Jessica Kingston** | Email: Jessica.Kingston@rhul.ac.uk | Address: Department of Psychology, Royal HollowayUniversity of London, Egham, Surrey, TW20 0EX
If you have any concerns related to your participation in this study, please direct them to Royal Holloway's Research Ethics Committee email: ethics@rhul.ac.uk

## Appendix E

Recruitment Presentation

Welcome to my Research Study

Maggie Karanasiou
Royal Holloway University London
REC Project ID: 2071



What is it about?

Can I take part?

What do I need to do?

What's in it for me?

How do I take part?

Call 07761 969 275

Email

magdalini.karanasiou.2020@live.rhul.ac.uk

Book your session now!

# Appendix F

## Sociodemographic Questionnaire

Start of Block: Default Question Block

Type in your Research ID

________________________________________________________________

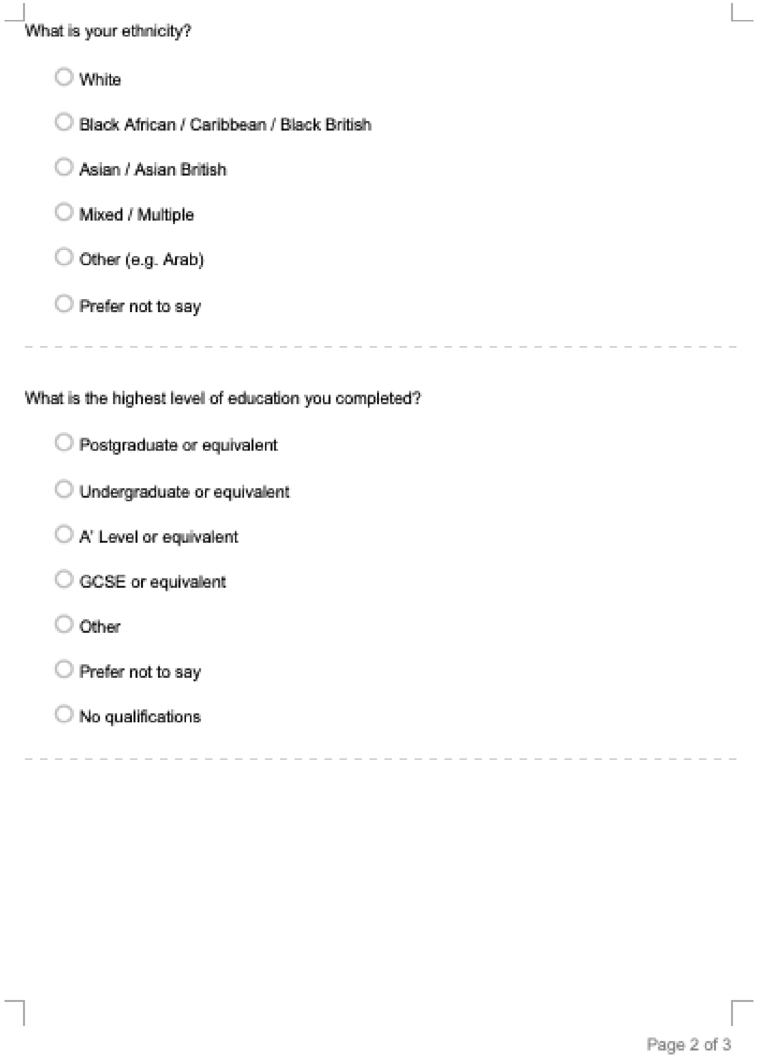
What is your age?

________________________________________________________________

What is your gender?

- ○ Male
- ○ Female
- ○ Non-binary / third gender
- ○ Prefer not to say

Page 1 of 3



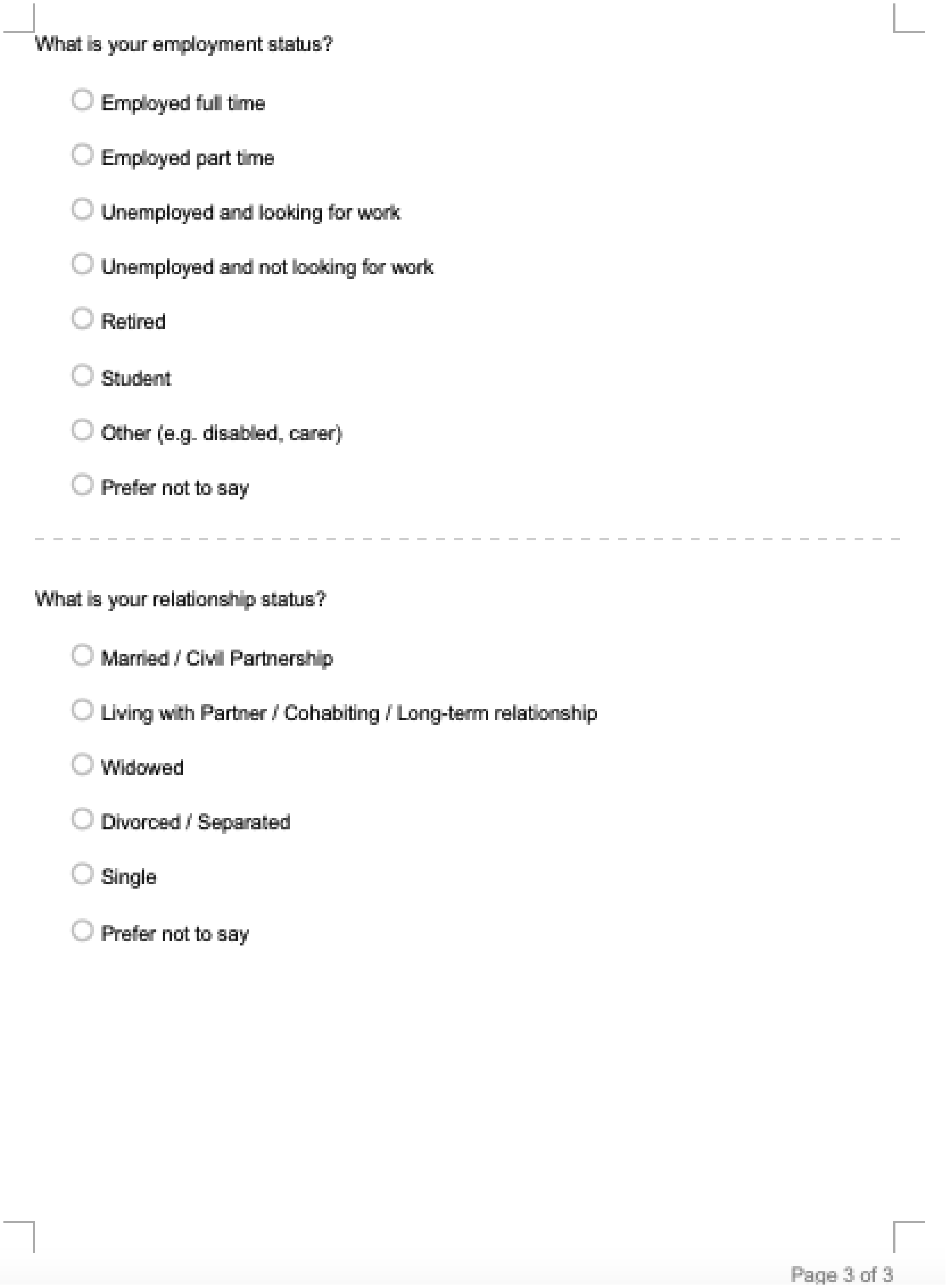
What is your ethnicity?

- ○ White
- ○ Black African / Caribbean / Black British
- ○ Asian / Asian British
- ○ Mixed / Multiple
- ○ Other (e.g. Arab)
- ○ Prefer not to say

What is the highest level of education you completed?

- ○ Postgraduate or equivalent
- ○ Undergraduate or equivalent
- ○ A' Level or equivalent
- ○ GCSE or equivalent
- ○ Other
- ○ Prefer not to say
- ○ No qualifications

Page 2 of 3



What is your employment status?

- ○ Employed full time
- ○ Employed part time
- ○ Unemployed and looking for work
- ○ Unemployed and not looking for work
- ○ Retired
- ○ Student
- ○ Other (e.g. disabled, carer)
- ○ Prefer not to say

What is your relationship status?

- ○ Married / Civil Partnership
- ○ Living with Partner / Cohabiting / Long-term relationship
- ○ Widowed
- ○ Divorced / Separated
- ○ Single
- ○ Prefer not to say

Page 3 of 3

## Appendix G

Post-Traumatic Amnesia Interview and Scoring Criteria

### Post-traumatic amnesia interview

*Now I am going to ask you when you started remembering things again after your brain injury.*

*When people have a brain injury, there's often a period of time afterwards when they can't remember anything at all, and the memory never comes back (e.g. because you were unconscious, or in a coma). Then when you wake up, it's common to still be confused for a while and during that time, you still can't remember anything from one day to the next, or you may remember just bits and pieces.*

*How long it was between your injury and the time when you felt like you started remembering things continuously again, from one day to the next?*

*This does not mean that your memory was back to normal, but rather when you started remembering day to day events in a consistent way.*

[Prompts: "Was it a day? A week, shorter, longer? A month, shorter, longer?"]

### Post-traumatic amnesia scoring criteria

Mild brain injury: < 1 hour
Moderate brain injury: 1 hour - 24 hours
Severe brain injury: 24 hours - 7 days
Very severe brain injury: > 7 days
other / unsure

## Appendix H

Satisfaction Questionnaire

### Satisfaction

How satisfied are you with today's session?

| Not at all ☹ | | | | | | | | | | Very much so ☺ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

### Time value

Was today's session worth your time?

| Not at all ☹ | | | | | | | | | | Very much so ☺ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

### Friends & Family test

How confident are you in recommending this intervention to friends and family experiencing similar problems?

| Not at all ☹ | | | | | | | | | | Very much so ☺ |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

### Optional Feedback

Please let us know if you have any other feedback from today's session:

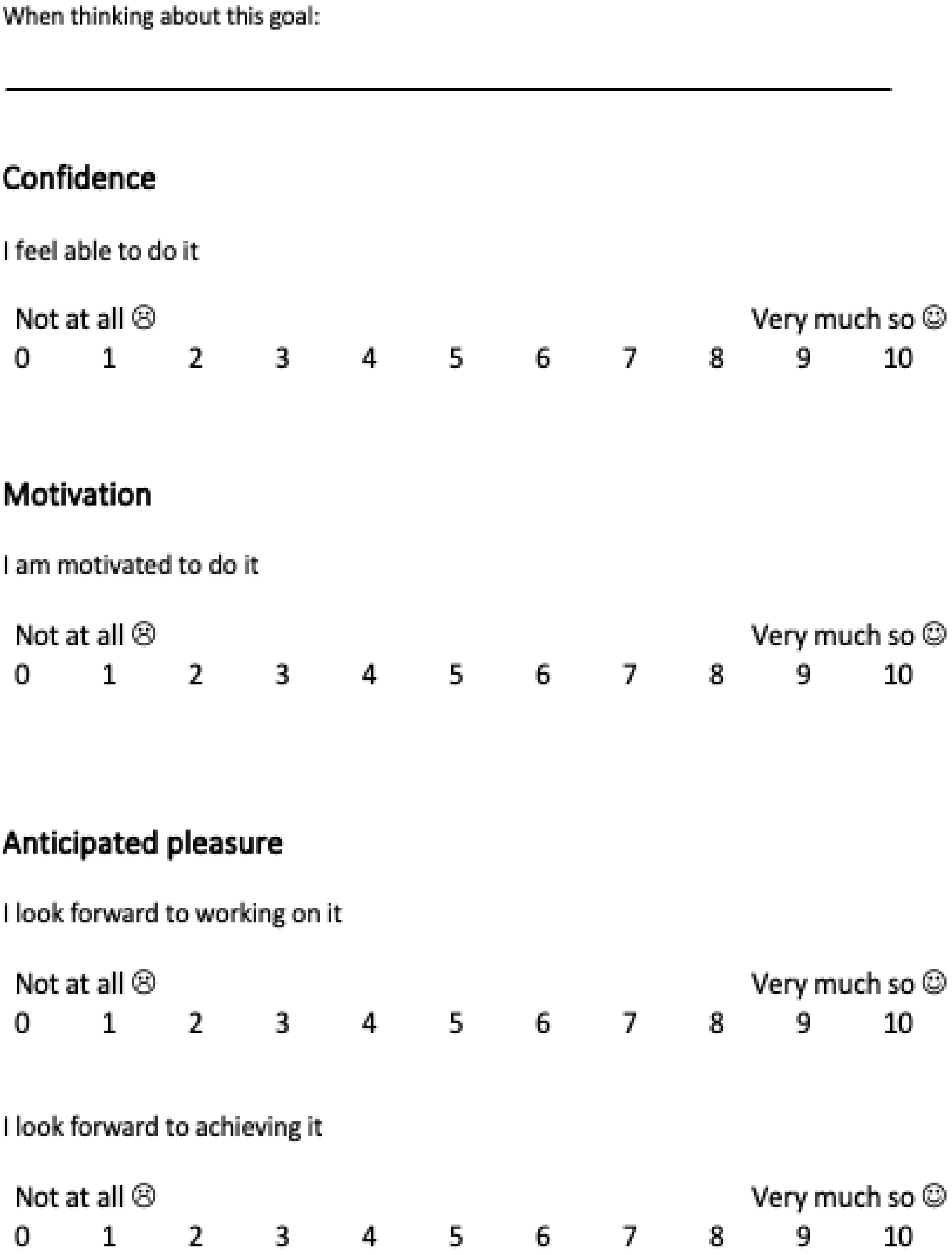
# Appendix I

Warwick - Edinburgh Mental Wellbeing Scale (WEMWBS)

Not included due to copyright restrictions. A copy can be provided upon request.

## Appendix J

Goal-Related Visual Analogue Scales (VASs)



When thinking about this goal:

______________________________________________

### Confidence

I feel able to do it

Not at all ☹ Very much so ☺
0 1 2 3 4 5 6 7 8 9 10

### Motivation

I am motivated to do it

Not at all ☹ Very much so ☺
0 1 2 3 4 5 6 7 8 9 10

### Anticipated pleasure

I look forward to working on it

Not at all ☹ Very much so ☺
0 1 2 3 4 5 6 7 8 9 10

I look forward to achieving it

Not at all ☹ Very much so ☺
0 1 2 3 4 5 6 7 8 9 10

# Appendix K

## Memory for Goals Script and Scoring Criteria

### Memory for goals script

*Two weeks ago, we set a goal together.*

*Without looking at your reminder, can you recall the goal we set? Anything else you can remember about your goal?*

### Memory for goals - scoring criteria (Wainman-Lefley et al., 2022).

a. Zero points: no recall, or participant’s recall was not representative of their goal in any way
b. One point: recall indicted a basic awareness of the goal, however there was a lack of specific details or the content was significantly distorted
c. Two points: the goal’s basic theme was recalled, but there was a lack of further details, or some evidence of content distortions or intrusions
d. Three points: recall was an accurate representation of the goal’s content

# Appendix L

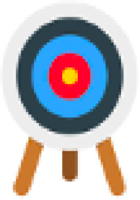
## Goal Attainment Question

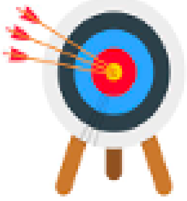
When thinking about this goal:

________________________________________________________________

**How much do you feel that you progressed towards this goal?**

| Not achieved | Partially achieved | Mostly achieved | Achieved | Achievement plus |
|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 |

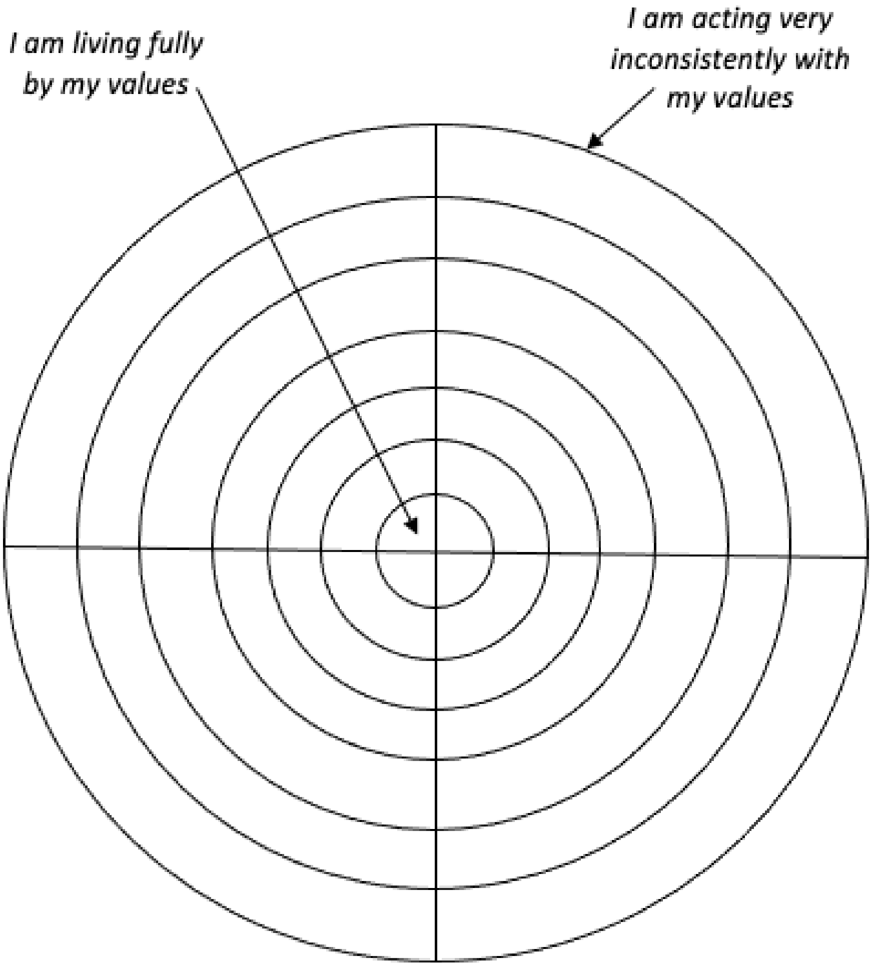




# Appendix M

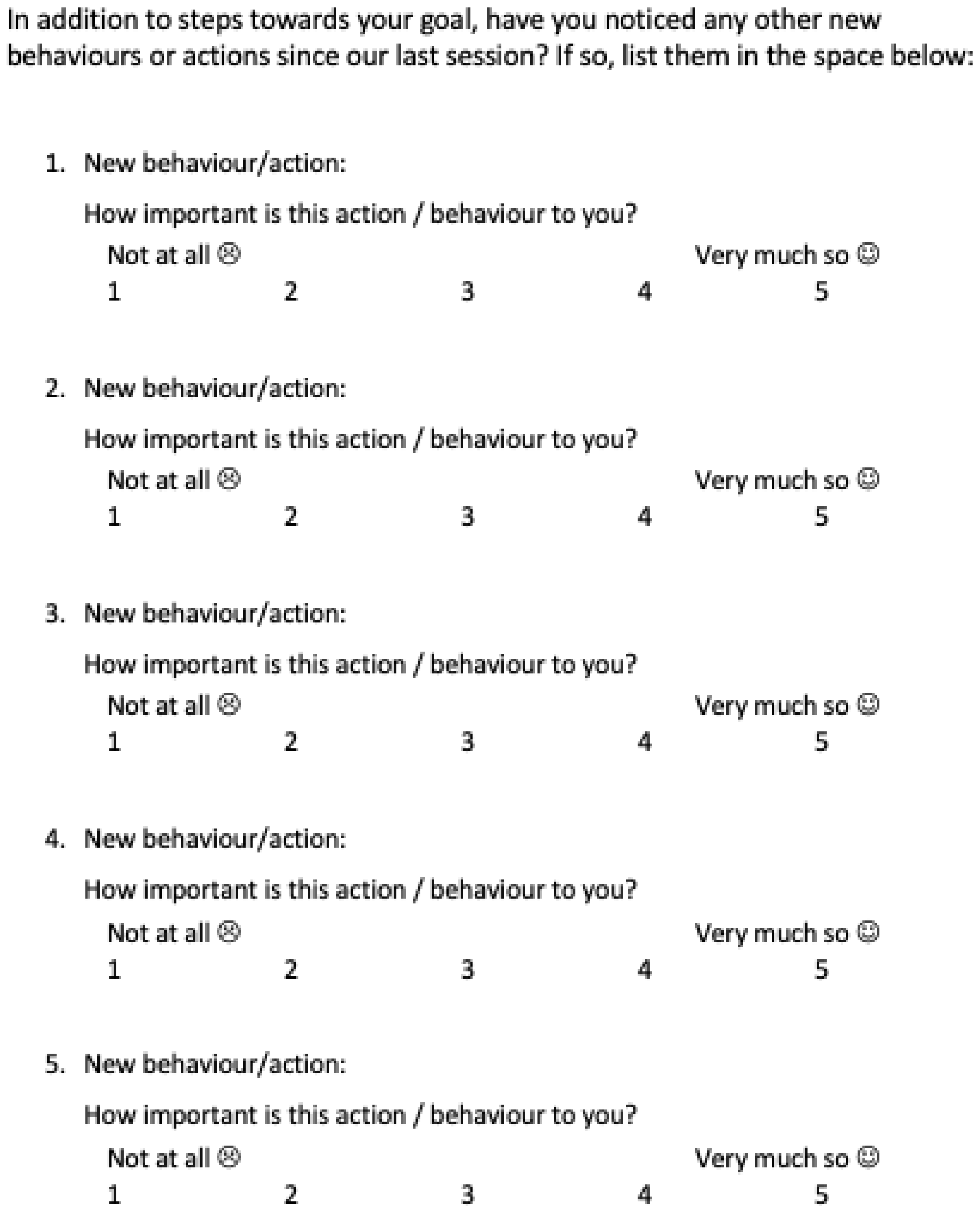
Bulls-Eye Values Survey (BEVS)

Instructions:
Make an X in the dart board to represent where you are today.



## Appendix N

Spontaneous Action Questionnaire



In addition to steps towards your goal, have you noticed any other new behaviours or actions since our last session? If so, list them in the space below:

1. New behaviour/action:

   How important is this action / behaviour to you?

   Not at all ☹ Very much so ☺

   1 2 3 4 5

2. New behaviour/action:

   How important is this action / behaviour to you?

   Not at all ☹ Very much so ☺

   1 2 3 4 5

3. New behaviour/action:

   How important is this action / behaviour to you?

   Not at all ☹ Very much so ☺

   1 2 3 4 5

4. New behaviour/action:

   How important is this action / behaviour to you?

   Not at all ☹ Very much so ☺

   1 2 3 4 5

5. New behaviour/action:

   How important is this action / behaviour to you?

   Not at all ☹ Very much so ☺

   1 2 3 4 5

## Appendix O

Values Clarification Card Sort Exercise

| | |
|---|---|
| To give love to others  | To help others  |
| To be reliable and trustworthy  | To be a loving spouse/partner  |
| To earn respect from others  | To be honest and truthful  |
| To be a good parent  | To be a loyal friend  |

| | |
|---|---|
| To be a loving family member  | To connect with nature  |
| To have joy in life  | To fill my time with interesting activities  |
| To travel and see the world  | To be imaginative  |
| To relax and enjoy myself  | To play and have fun  |

| |
|---|
| To look after my physical health  |
| To be easy going and calm  |
| To feel good about myself  |
| To have meaning and direction in my life  |

| | |
|---|---|
| To carry out my duties and obligations<br> | To make important personal achievements<br> |
| To master challenges<br> | To look after the environment<br> |
| To be organised<br> | To have a sense of humour<br> |
| To be independent<br> | To look after my mental health<br> |

| | |
|---|---|
| To seek adventure<br> | To participate in hobbies that I enjoy<br> |
| To continually learn and grow<br> | To be curious<br> |
| To practice my faith/religion<br> | To work towards something even when it's hard<br> |
| To be a hard-worker<br> | To do something good for the world<br> |

## Appendix P

Adapted Fidelity Criteria

**Presence of essential criteria for fidelity rating.**

| **Values-based goal-setting group** | | **Standard goal-setting group** | |
|---|---|---|---|
| **Competence** | **Rating** | **Competence** | **Rating** |
| A goal was agreed upon after discussion with the participant | Present / Absent | A goal was agreed upon after discussion with the participant | Present / Absent |
| A target value was agreed upon from completing a values-clarification exercise with the participant | Present / Absent | N/A | N/A |
| Gave a rationale for goal-setting | Present / Absent | Gave a rationale for goal-setting | Present / Absent |
| Gave a rationale for focusing on and clarifying values | Present / Absent | N/A | N/A |
| The therapist delivered ONLY the target treatment as described in the protocol; *For example, values / areas of importance were ONLY mentioned for the values-based goal-setting participants* | Present / Absent | The therapist delivered ONLY the target treatment as described in the protocol; *For example, values / areas of importance were ONLY mentioned for the values-based goal-setting participants* | Present / Absent |
| **Total competences present:**<br>*Possible total: 5* | | **Total competences present:**<br>*Possible total: 3* | |

# Appendix Q

## Participant Information Sheet

PARTICIPANT INFORMATION SHEET

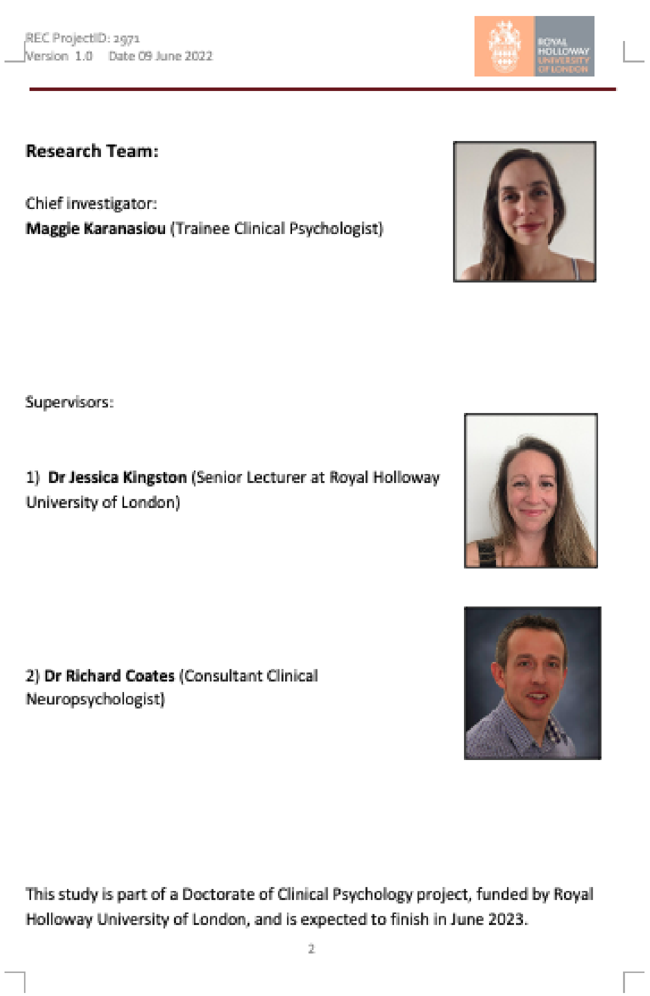
**Goal setting for people with an acquired brain injury: a research study.**

**We are inviting you to take part in a research study and would like you to know:**

Yes ✓ | No ⊘

- Taking part is entirely up to you
- Before you decide, it is important for you to understand why the project is being done and what it will involve for you
- Together, we will go through this information sheet. This may take around 25 minutes

  You can ask me questions at any point
- You do not have to decide today. Please feel free to talk to others about the study if you wish



**Research Team:**

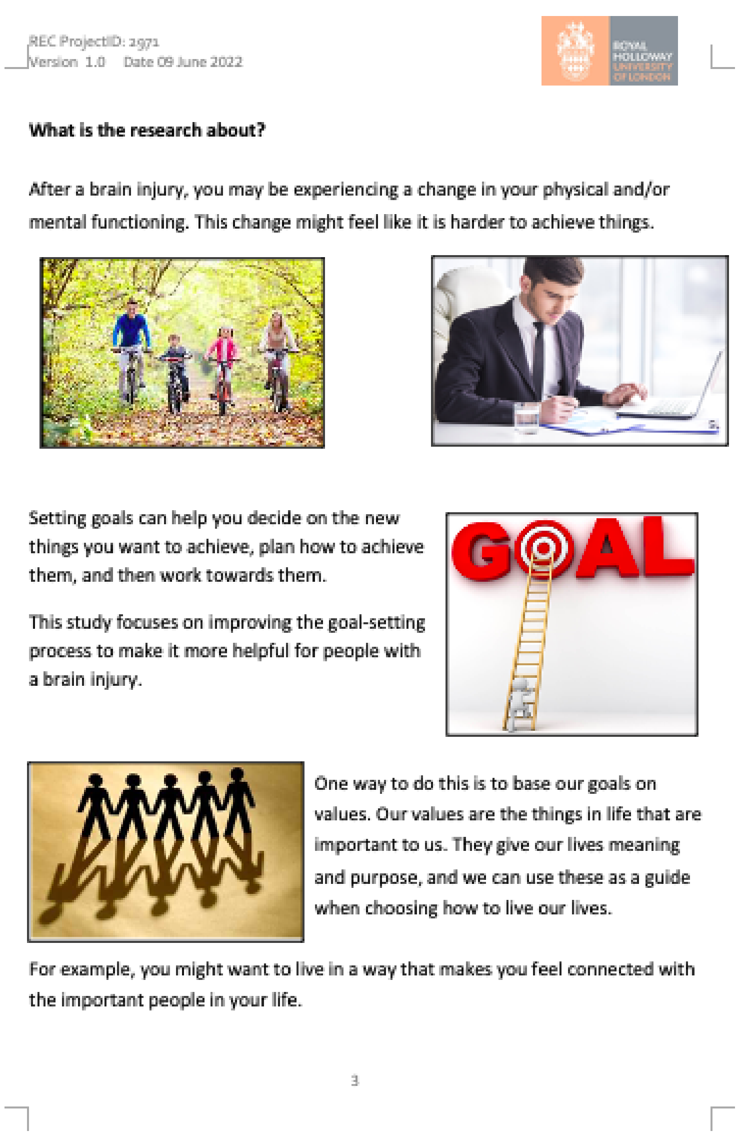
Chief investigator:
**Maggie Karanasiou** (Trainee Clinical Psychologist)

Supervisors:

1) **Dr Jessica Kingston** (Senior Lecturer at Royal Holloway University of London)

2) **Dr Richard Coates** (Consultant Clinical Neuropsychologist)

This study is part of a Doctorate of Clinical Psychology project, funded by Royal Holloway University of London, and is expected to finish in June 2023.



REC ProjectID: 2971
Version 1.0 Date 09 June 2022

**What is the research about?**

After a brain injury, you may be experiencing a change in your physical and/or mental functioning. This change might feel like it is harder to achieve things.

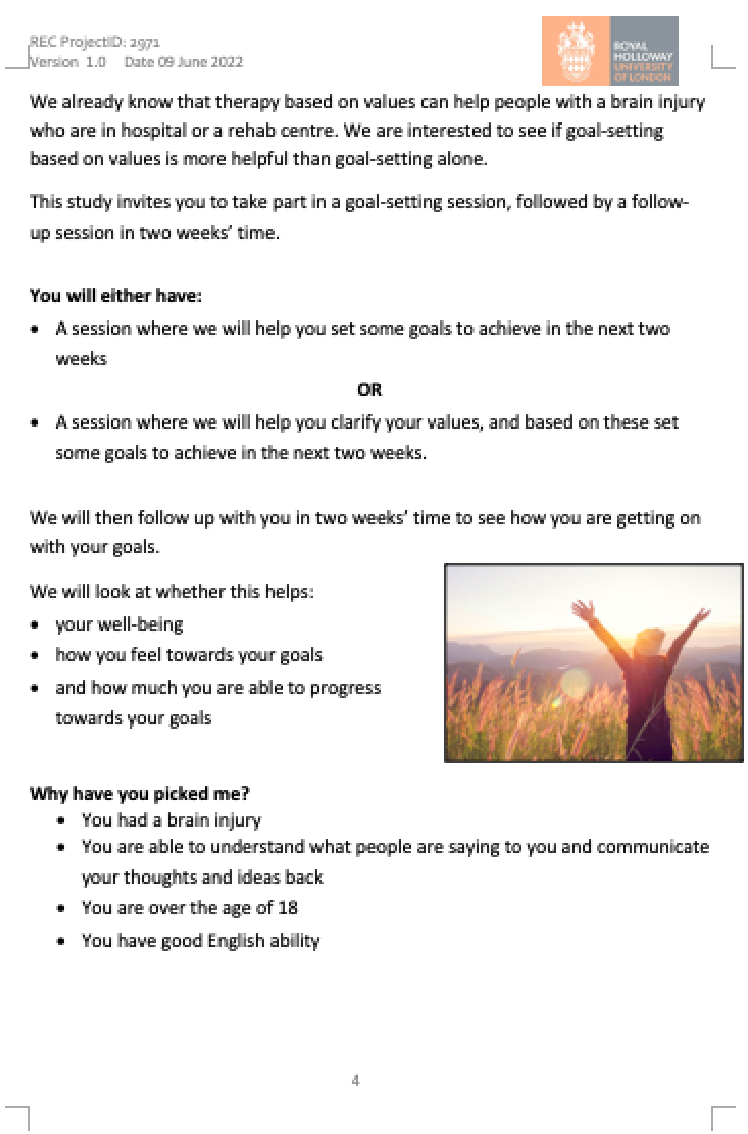
Setting goals can help you decide on the new things you want to achieve, plan how to achieve them, and then work towards them.

This study focuses on improving the goal-setting process to make it more helpful for people with a brain injury.

One way to do this is to base our goals on values. Our values are the things in life that are important to us. They give our lives meaning and purpose, and we can use these as a guide when choosing how to live our lives.

For example, you might want to live in a way that makes you feel connected with the important people in your life.

3



REC ProjectID: 2971
Version 1.0 Date 09 June 2022

We already know that therapy based on values can help people with a brain injury who are in hospital or a rehab centre. We are interested to see if goal-setting based on values is more helpful than goal-setting alone.

This study invites you to take part in a goal-setting session, followed by a follow-up session in two weeks' time.

**You will either have:**

- A session where we will help you set some goals to achieve in the next two weeks

**OR**

- A session where we will help you clarify your values, and based on these set some goals to achieve in the next two weeks.

We will then follow up with you in two weeks' time to see how you are getting on with your goals.

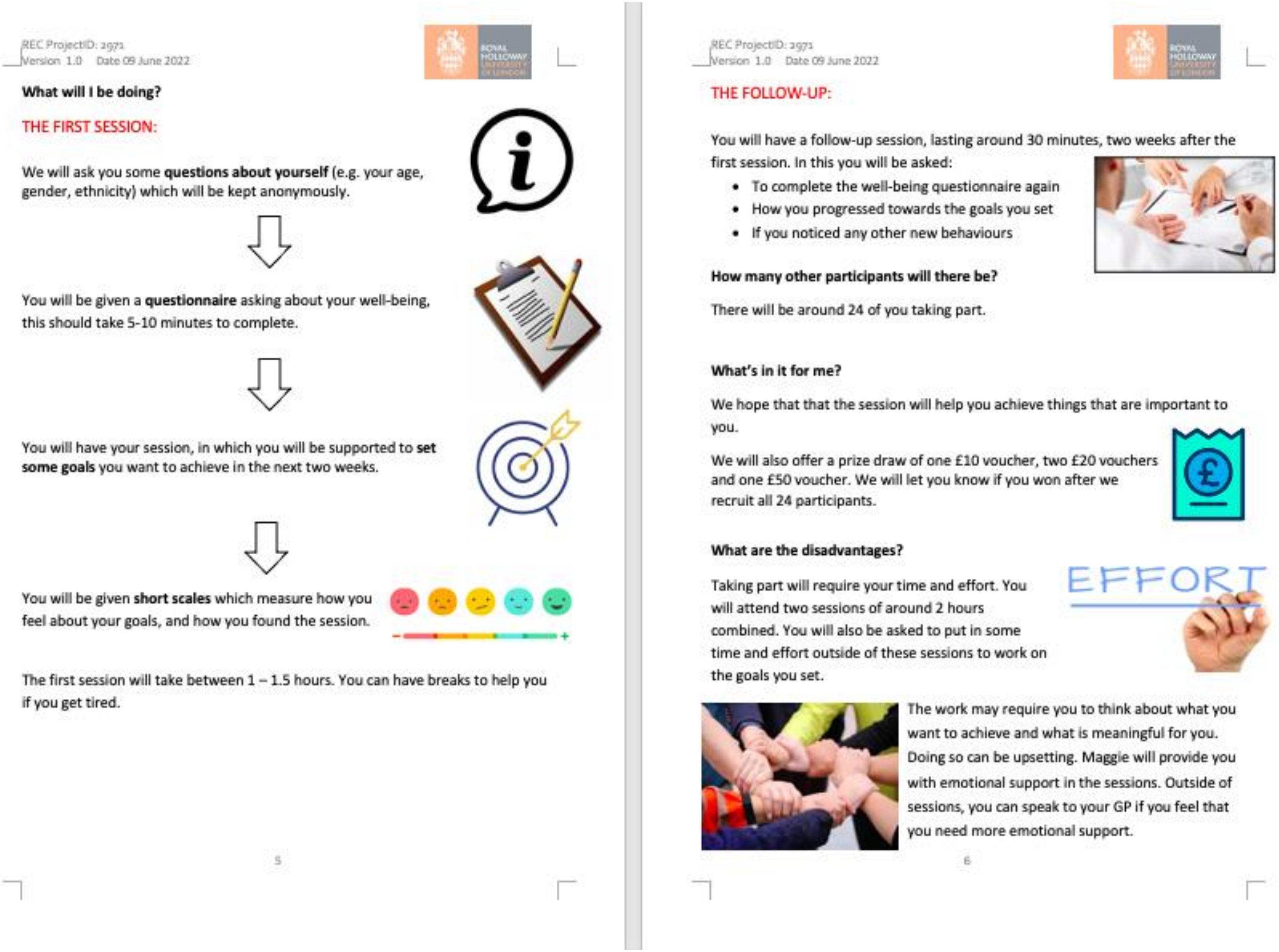
We will look at whether this helps:

- your well-being
- how you feel towards your goals
- and how much you are able to progress towards your goals

**Why have you picked me?**

- You had a brain injury
- You are able to understand what people are saying to you and communicate your thoughts and ideas back
- You are over the age of 18
- You have good English ability

4



**What will I be doing?**

THE FIRST SESSION:

We will ask you some **questions about yourself** (e.g. your age, gender, ethnicity) which will be kept anonymously.

⇩

You will be given a **questionnaire** asking about your well-being, this should take 5-10 minutes to complete.

⇩

You will have your session, in which you will be supported to **set some goals** you want to achieve in the next two weeks.

⇩

You will be given **short scales** which measure how you feel about your goals, and how you found the session.

The first session will take between 1 – 1.5 hours. You can have breaks to help you if you get tired.

THE FOLLOW-UP:

You will have a follow-up session, lasting around 30 minutes, two weeks after the first session. In this you will be asked:

- To complete the well-being questionnaire again
- How you progressed towards the goals you set
- If you noticed any other new behaviours

**How many other participants will there be?**

There will be around 24 of you taking part.

**What's in it for me?**

We hope that that the session will help you achieve things that are important to you.

We will also offer a prize draw of one £10 voucher, two £20 vouchers and one £50 voucher. We will let you know if you won after we recruit all 24 participants.

**What are the disadvantages?**

Taking part will require your time and effort. You will attend two sessions of around 2 hours combined. You will also be asked to put in some time and effort outside of these sessions to work on the goals you set.

The work may require you to think about what you want to achieve and what is meaningful for you. Doing so can be upsetting. Maggie will provide you with emotional support in the sessions. Outside of sessions, you can speak to your GP if you feel that you need more emotional support.

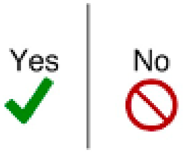
**What if I start, but want to stop later?**

You can stop at any time. You do not have to tell us why.

You can also ask Maggie to delete your data any time before January 2023. After that, it will not be possible to delete your data.

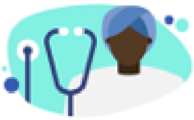
**Do I have to take part?**

No, you don't have to take part. Taking part is entirely up to you.



**Who will know that I am taking part?**

We will not let anyone know that you are taking part. However, we will need to contact your GP if there is a risk to you or anyone else at any point.

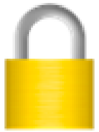


**How will my data be protected?**

As the study's sponsor, Royal Holloway University of London is responsible for looking after your information and using it properly at all times. Royal Holloway needs to manage your information in specific ways in order for the research to be reliable and accurate.

Some of your personal information data will be under the GDPR 'special category' (for example your ethnicity and information about your brain injury), because it is sensitive. A plan is put in place to properly and securely manage this data.

The research team will have access to your research data (the questionnaires you complete). This data and your Consent form will be stored securely at Royal Holloway University of London for 5 years until 2028. All data will be handled according to the General Data Protection Regulations and will be kept anonymous (your name will not appear in any publication related to this study and will not be shared with any other parties).



Since your Consent form will have your name on it, it will be stored separately from the research data so that the documents cannot be linked. Only Maggie and Dr Jess Kingston will have access to data files containing identifiable information.

To check that Maggie is following the guidelines, sessions may be audio recorded with your consent. These recordings could be stored for up to 5 years at Royal Holloway University of London for audit purposes. These will be stored securely, labelled only by your anonymous code rather than your name or any other identifiable details.

If you decide to leave the study, we will make sure that the information kept about you is as minimally identifiable as possible.

For more information, you can refer to the General Data Protection Regulation Statement below. You can also contact Dr Jess Kingston at Royal Holloway University of London on 01784 414105 if you have any questions.

**Ethical Approval**

This study has received ethics approval from Royal Holloway University of London, with the ID approval of [ID no].

**What happens after?**

Research data will be analysed and typed into a report as part of a Clinical Psychology Doctorate programme. The report will include information relating to our sessions, and any relevant details about you (for example your gender, ethnicity, type of brain injury). All information will be anonymous, so nobody will be able to identify you from this information. Even if the study is published, people will not know that the information is about you.

If you are interested, you can request to see a summary of the results, or to have the results explained to you.

We would also like your permission to use this data in future studies, and to share this with other researchers. **Data shared will be completely de-identified**.

**Data protection**

This research commits to abide by the Data Protection Act (2018). For detailed information about what this means for research participants, please visit the Research Participant Privacy Notice: *https://intranet.royalholloway.ac.uk/research/documents/researchpdf/new-intranets/research-participant-privacy-notice.pdf*

**Is this everything I need to know?**

This is all of the important information. If you have any questions, please ask!

If new information about the study emerges at any time we will let you know immediately.

**Who can I contact if I have more questions after this, or want to participate?**
Please contact **Maggie Karanasiou** on **07761 969 275 or** **magdalini.karanasiou.2020@live.rhul.ac.uk**.

---

**What if I have concerns or want to make a complaint about the study?**

If you have a concern about any aspect of this study, you can contact:

- Dr Jessica Kingston at Jessica.Kingston@rhul.ac.uk or 01784 414105
- Royal Holloway's Research Ethics Committee via ethics@rhul.ac.uk
- integrity@rhul.ac.uk to make a formal complaint

Thank you for taking the time to read this. ☺

Please keep a copy for your records, along with the consent form.

**General Data Protection Regulation Statement**
Important General Data Protection Regulation Information (GDPR). Royal Holloway, University of London is the sponsor for this study and is based in the UK. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Any data you provide during the completion of the study will be stored securely on hosted on servers within the European Economic Area'. Royal Holloway is designated as a public authority and in accordance with the Royal Holloway and Bedford New College Act 1985 and the Statutes which govern the College, we conduct research for the public benefit and in the public interest.

Royal Holloway has put in place appropriate technical and organisational security measures to prevent your personal data from being accidentally lost, used or accessed in any unauthorised way or altered or disclosed. Royal Holloway has also put in place procedures to deal with any suspected personal data security breach and will notify you and any applicable regulator of a suspected breach where legally required to do so.

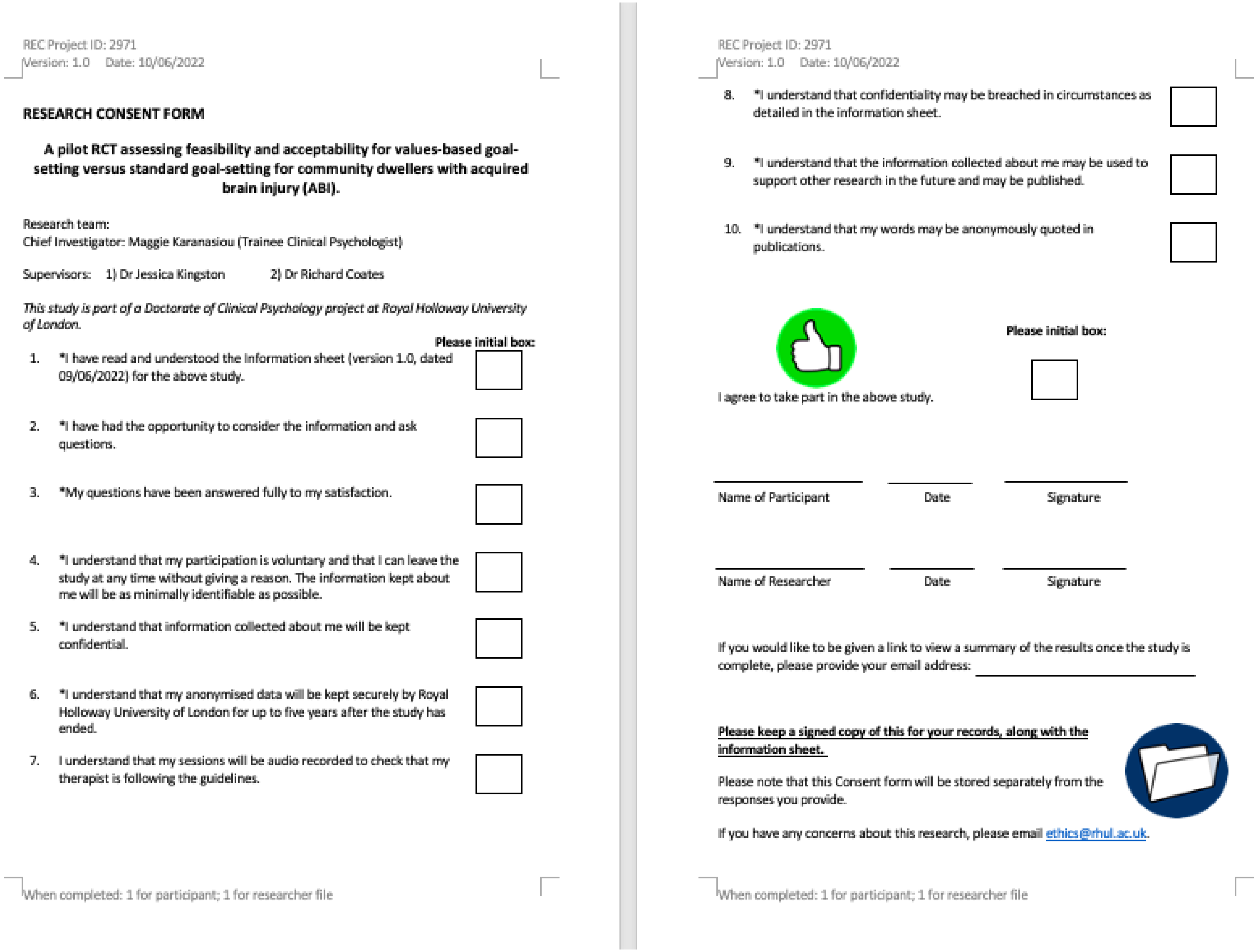
To safeguard your rights, we will use the minimum personally-identifiable information possible (i.e., the email address you provide us). The lead researcher will keep your contact details confidential and will use this information only as required (i.e., to provide a summary of the study results if requested and/or for the prize draw). The lead researcher will keep information about you and data gathered from the study, the duration of which will depend on the study.

Certain individuals from RHUL may look at your research records to check the accuracy of the research study. If the study is published in a relevant peer-reviewed journal, the anonymised data may be made available to third parties. The people who analyse the information will not be able to identify you.

You can find out more about your rights under the GDPR and Data Protection Act 2018 by visiting https://www.royalholloway.ac.uk/about-us/more/governance-and-strategy/data-protection/ and if you wish to exercise your rights, please contact dataprotection@royalholloway.ac.uk

# Appendix R

## Participant Consent Form



REC Project ID: 2971
Version: 1.0 Date: 10/06/2022

**RESEARCH CONSENT FORM**

**A pilot RCT assessing feasibility and acceptability for values-based goal-setting versus standard goal-setting for community dwellers with acquired brain injury (ABI).**

Research team:
Chief Investigator: Maggie Karanasiou (Trainee Clinical Psychologist)

Supervisors: 1) Dr Jessica Kingston 2) Dr Richard Coates

*This study is part of a Doctorate of Clinical Psychology project at Royal Holloway University of London.*

| | | **Please initial box:** |
|---|---|---|
| 1. | *I have read and understood the Information sheet (version 1.0, dated 09/06/2022) for the above study. | ☐ |
| 2. | *I have had the opportunity to consider the information and ask questions. | ☐ |
| 3. | *My questions have been answered fully to my satisfaction. | ☐ |
| 4. | *I understand that my participation is voluntary and that I can leave the study at any time without giving a reason. The information kept about me will be as minimally identifiable as possible. | ☐ |
| 5. | *I understand that information collected about me will be kept confidential. | ☐ |
| 6. | *I understand that my anonymised data will be kept securely by Royal Holloway University of London for up to five years after the study has ended. | ☐ |
| 7. | I understand that my sessions will be audio recorded to check that my therapist is following the guidelines. | ☐ |

When completed: 1 for participant; 1 for researcher file

REC Project ID: 2971
Version: 1.0 Date: 10/06/2022

| | | |
|---|---|---|
| 8. | *I understand that confidentiality may be breached in circumstances as detailed in the information sheet. | ☐ |
| 9. | *I understand that the information collected about me may be used to support other research in the future and may be published. | ☐ |
| 10. | *I understand that my words may be anonymously quoted in publications. | ☐ |

**Please initial box:**

I agree to take part in the above study. ☐

| Name of Participant | Date | Signature |
|---|---|---|
| Name of Researcher | Date | Signature |

If you would like to be given a link to view a summary of the results once the study is complete, please provide your email address: ______________

**Please keep a signed copy of this for your records, along with the information sheet.**

Please note that this Consent form will be stored separately from the responses you provide.

If you have any concerns about this research, please email ethics@rhul.ac.uk.

When completed: 1 for participant; 1 for researcher file

## Appendix S

Values-Based and Standard Goal-Setting Protocols

### Values-Based Goal-Setting Protocol

***Step 1***

Provide context:

- We all have areas in our lives that are important to us and these typically differ across people. We might call these are values – the things that are most important to us.
- After a brain injury, the things that are most important to you might change or they may stay the same. What we know is that having a brain injury can make it difficult at times to feel able to do the things that are most important to us and/or to live up to the qualities we most want to have in our lives.
- Today, we will spend some time thinking together about what is most important to you and thinking of goals that help you to move you in the direction of these values over the next two weeks.

***Step 2***

Clarifying values exercise:

- Start by explaining what values are using the compass metaphor, and by clarifying the qualities of values if needed.
- “Let’s now take some time to think about your own values. Once we’ve worked out your top values, we can help you think of ways to have more of that value in your day-to-day life”.
- We use a values card sort exercise to think about what’s important to you. You might already have a good idea about what’s important to you, this is something we do with everyone to clarify what’s most important
    - Ensure there are also some blank cards to include values not on the list
    - Taking each card and sorting it by how important it is to you. Then, we’ll pick 1-2 values from the Very Important pile
    - Use prompting questions during exercise if needed.
- Complete the BEVS to measure value-based living

***Step 3***

Set the actions / goals based on values:

- Now that we know what values are important to you, you have the choice to work towards them to make life more meaningful.
- Introduce goals / actions, explaining that they are stepping stones that lead us to the path of our values.

- Thinking about [value A, value B], what goal do you think you can set that will help you behave in a way that gets you closer to that value?
- The behaviour should be specified as clearly and explicitly as possible.
    - For example, 'walking indoors' rather than 'mobilizing', and 'cooking a three-course meal' rather than 'preparing food'. Phrases such as 'using left hand in functional tasks' are too vague and need more detail such as 'brushing teeth using left hand'.

***Step 4***

Measurable & realistic:

- Helping the participant narrow down the action into a behaviour that is measurable (e.g. 'how would you know if you achieved this action/goal?')
    - If the action can be measured by distance, time taken or frequency, this can be helpful in ensuring the action is measurable
- Specify that the action is to be achieved within the next two weeks
    - However, these actions can be short-term goals that form part of other, longer-term goals.

***Step 5***

Think about barriers and ways of overcoming these (inc. support):

- Is there anything that may get in the way of achieving the goal/s?
- Can you think of ways to overcome these barriers?
- Here we can consider enlisting support of others and objects that may be helpful, as well as problem-solving.

***Step 6***

Measure quality of goals and satisfaction of goal-setting:

- Provide the confidence, motivation and anticipated pleasure VAS for participants to complete for each of their goals, if more than one was set.
- Provide the satisfaction questionnaire for participants to complete.

***Step 7***

Wrap up:

- Write down the values and goals, and leave these with the participant so that they have a written prompt.
- Schedule the two-week follow-up appointment.

## Supplementary Material

### ***Compass Metaphor***

Values are like a compass. A compass gives you direction and keeps you on track when you're travelling. And our values do the same for the journey of life. We use them to choose the direction in which we want to move and to keep us on track as we go.
So when you act on a value, it's like heading west. No matter how far west you travel, you never get there, there's always further to go. But goals are like the things you try to achieve on your journey, they're like the sights you want to see or the mountains you want to climb while you keep on travelling west.

### ***Qualities of Values***

Values are:

- very personal
- freely chosen (what you choose, not what your partner or parents would choose)
- life directions (they guide what we do in our day-to-day life)
- what you want to live by
- the things that matter to you deep down
- the things that still matter even if no one knows about them
- what you want to stand for in life, even in the face of difficulty
- how you would want to be described by others.

### **Prompting Questions**

- Would you want your life to be about that?
- Would you want this to be a value we work on together over the next few weeks?
- Even if you don't feel you are doing much of this right now, is it still important to you?
- Is this something you would like to develop?

**Standard Goal-setting protocol**

***Step 1***

Provide context:

- Achieving things can really give us a sense of enjoyment in life and contribute to our happiness. Setting goals helps you decide on the new and realistic things you want to achieve, plan how to achieve them, and then progressively work towards them in a structured way that puts you in charge. Setting goals also guides our focus and motivates us to behave in new ways.
- After a brain injury, there may be a lot of things that are harder than before
- Goals can help us re-engage in day-to-day activities by helping us achieve things despite limitations.
- Here we want to spend some time thinking about your goals, and by the end we will come to decide on some goals that you want to achieve over the next two weeks.

***Step 2***

Specify the target area/s & identify the goals:

- Can start by asking open questions such as:
    - Do things you want to achieve in the next two weeks already come to mind?
    - If we fast forward to two weeks from now, is there anything you'd like to have achieved?
    - Is there anything you would like to do that you are not doing at the moment?
    - Is there anything you are finding difficult at the moment?
- Examples could include participation in the home and community and activities of daily living (personal, domestic, community, vocational, etc.).
- Then, ask questions to help identify the target behaviour (e.g. 'what is it that you would like to achieve?', 'how do you think you may be able to get there?').
    - The behaviour should be specified as clearly and explicitly as possible.
    - For example, 'walking indoors' rather than 'mobilizing', and 'cooking a three-course meal' rather than 'preparing food'. Phrases such as 'using left hand in functional tasks' are too vague and need more detail such as 'brushing teeth using left hand'.

***Step 3***

Measurable & realistic :

- Helping the participant narrow down the goal into a behaviour that is measurable (e.g. 'how would you know if you achieved this goal?')

    - If the goal can be measured by distance, time taken or frequency, this can be helpful in ensuring the goal is measurable
- Specify that the goal is to be achieved within the next two weeks (e.g. is this a realistic goal you are able to achieve in the next two weeks?)
    - However, these goals can be short-term goals that form part of other, longer-term goals.

***Step 4***

Think about barriers and ways of overcoming these (inc. support):

- Is there anything that may get in the way of achieving the goal/s?
- Can you think of ways to overcome these barriers?
- Here we can consider enlisting support of others and objects that may be helpful, as well as problem-solving, such as:
    - hands-on, practical or physical assistance (such as assisting in a transfer, cutting food, doing up shoelaces)
    - emotional and stand-by support to increase self-confidence
    - cognitive, structural support such as prompting and reminding
    - specific items that can be moved around (such as a walking stick)
    - adaptation to personal items (such as clothing or cutlery)

***Step 5***

Measure quality of goals and satisfaction of goal-setting:

- Provide the confidence, motivation and anticipated pleasure VAS for participants to complete for each of their goals, if more than one was set.
- Provide the satisfaction questionnaire for participants to complete.

***Step 6***

Wrap up:

- Write down the goals and leave these with the participant so that they have a written prompt (or email / text reminder).
- Schedule the two-week follow-up appointment.

## Appendix T

Ethical Approval from the Royal Holloway University of London Research Ethics Committee

*From: Ethics Application System <ethics@rhul.ac.uk>*

*Date: Wednesday, 30 March 2022 at 12:35*

*To: Karanasiou, Magdalini (2020) <Magdalini.Karanasiou.2020@live.rhul.ac.uk>, Kingston, Jessica <Jessica.Kingston@rhul.ac.uk>, Ethics <Ethics@rhul.ac.uk>*

*Subject: Result of your application to the Research Ethics Committee (application ID 2971)*

*PI: Dr Jessica Kingston*

*Project title: A pilot RCT assessing feasibility and acceptability for values-based goal-setting versus standard goal-setting for community dwellers with acquired brain injury (ABI)*

*REC ProjectID: 2971*

*Your application has been approved by the Research Ethics Committee.*

*Please report any subsequent changes that affect the ethics of the project to the University Research Ethics Committee ethics@rhul.ac.uk*

## Appendix U

Online Calculators Used to Calculate Effect Sizes and Confidence Intervals

| Outcome Measure | Online Calculator Link | Calculator number | Type of effect size |
|---|---|---|---|
| Satisfaction Questionnaire | https://www.psychometrica.de/effect_size.html | 1 | Between-groups for equal sample sizes |
| Goal-related VASs | https://www.psychometrica.de/effect_size.html | 1 | Between-groups for equal sample sizes |
| Goal Attainment | https://www.psychometrica.de/effect_size.html | 2 | Between-groups for unequal sample sizes |
| WEMWBS | https://www.psychometrica.de/effect_size.html | 4 | Within-groups for equal sample sizes[a], not taking intercorrelation into account, based on calculations by Cummings (2012) |
| BEVS | https://www.psychometrica.de/effect_size.html | 4 | Within-groups for equal sample sizes[a], not taking intercorrelation into account, based on calculations by Cummings (2012) |
| WEMWBS | https://www.psychometrica.de/effect_size.html | 3 | Controlled effect size for mean differences between groups with unequal sample size with a pre-post design, based on calculations by Morris (2008) |
| All measures | https://georgebeckham.com/2016/cohens-d-and-hedges-g-excel-calculator/ | N/A | Hedge's g |

[a] Effect size was also calculated without participants with missing data, and the difference was negligible. Therefore, only the within-groups calculator for equal sample sizes was used.

## Appendix V

Descriptive Statistics and Frequencies of Satisfaction Ratings

| Ratings | Values condition<br>*M (SD)* | Goals condition<br>*M (SD)* |
|---|---|---|
| Satisfaction | 8.7 (1.1) | 8.3 (2) |
| *n* (%) | | |
| 5 | 0 (0%) | 1 (8%) |
| 6 | 0 (0%) | 2 (17%) |
| 7 | 2 (17%) | 2 (17%) |
| 8 | 3 (25%) | 0 (0%) |
| 9 | 4 (33%) | 1 (8%) |
| 10 | 3 (25%) | 6 (50%) |
| Intervention worth participant’s time | 9.3 (1) | 8.8 (1.1) |
| *n* (%) | | |
| 7 | 1 (8%) | 1 (8%) |
| 8 | 1 (8%) | 5 (42%) |
| 9 | 4 (33%) | 1 (8%) |
| 10 | 6 (50%) | 5 (42%) |
| Friends and family recommendation | 8 (1.7) | 7.8 (2.2) |
| *n* (%) | | |
| 5 | 1 (8%) | 3 (25%) |
| 6 | 1 (8%) | 1 (8%) |
| 7 | 3 (25%) | 1 (8%) |
| 8 | 3 (25%) | 2 (17%) |
| 9 | 0 (0%) | 0 (0%) |
| 10 | 4 (33%) | 5 (42%) |

*Note*. Based on n=12

## Appendix W

Qualitative feedback from satisfaction questionnaire

| Values-based goal-setting group quotes | Standard goal-setting group quotes |
|---|---|
| *“I came into it with a sense of I know what I'm doing and this will help others, but actually I found things that might be helpful for me.”*<br>*“it was okay”*<br>*“It helped me feel that I can do more than I'm doing at present.”*<br>*“I am very appreciative for coming to my house and for asking me all these questions. Thank you for your time”*<br>*“Wish there was someone who could spoon feed me a bit, although I know this will not be helpful. I know I need support, whatever that may be. But actually I'm doing this on my own and that feels difficult.”*<br>*“A free cup of coffee would be nice!”*<br>*“It has opened my eyes to know that I still have achievements to make, I thought I knew it all before. It has encouraged me to the point that I now have a goal that I am aiming towards and quite happily looking forward to doing.”*<br>*“Thank you for finding a time to come over here. This is helpful, to try to help people to try and remember things.”*<br>*“I'm sorry about the inconvenience to you, glad you were able to come* | *“I'm very pleased and it has helped me a great deal, thank you.”*<br>*“Researcher is very motivating. But I don't like promises.”*<br>*“I was very satisfied with today, mainly due to the fact that we're in a room privately. This makes me able to concentrate more on the answers and keeps your mind more on the answers.”*<br>*“All the questions were thoughtful, didn't make me feel that I didn't want to answer them, felt comfortable. You treated me well, it was respectful and considered. And delivered in a sympathetic / thoughtful and caring manner.”*<br>*“It was good that you came to my house to see exactly my situation, that was good for me.”*<br>*“I was able to help the interviewer achieve her goals.”*<br>*“Are you able to share any of other people's insights with me? Or are people in different contexts that we are not comparable?”*<br>*“Today, I liked having someone to talk to. It's not something I want on my medical record - they gossip! It felt easy.”*<br>*“It's been really interesting. However I didn't know what it was going to be like, and I'm worried I might make a big hash of it.”* |

| Values-based goal-setting group quotes | Standard goal-setting group quotes |
|---|---|
| *to do the session. Thank you very very much. I hope I was a good candidate for you. You helped me see things differently.”* | *“It was useful for me to get some goals moving forward. Talking to different people about this is motivational to me.”* |
| *“You've been very helpful, I'm very grateful to you.”* | *“It's been positive, I've enjoyed it, it has given me the motivation to start putting it into practice now that I've spoken about it. You've been very helpful and understanding and given me a positive vibe, and I'll try my best to kick it off tonight. I'll try to go away and give this energy you've given me going.”* |

## Appendix X

Full List of New Behaviours Reported

| Values-based goal-setting group behaviours | Standard goal-setting group behaviours |
|---|---|
| *“I noticed that I am doing a lot more of the tidying up. I don't do it because I like it, I do it because I like order”* | *”Taking sodium tablets”* |
| *”I've been sleeping better”* | *”Went to the cinema”* |
| *”I'm feeling more alert during the day because I'm reading more”* | *”Went to Wagamama”* |
| *”I cooked a meal for the whole family”* | *”Went to B&Q and IKEA”* |
| *”Sorted out some things about moving house”* | *”Making some dinners”* |
| *”Looking after my daughter”* | *”Doing some yoga and tapping”* |
| *”I have been applying new music to my relaxing and doing daily things”* | *”I had acupuncture”* |
| *”My nephew has been taking me for short walks and to the local shops”* | *”Did some gardening today at church”* |
|  | *”I went to my GP to talk to them about my mood, and got referred for mood support”* |
|  | *”I tried phoning the GP service to get some support with my leg”* |
|  | *”Increased volunteering to take up more responsibility”* |
|  | *”I started clearing up things in the living room, and now I can sit on my sofa again”* |