Development and Pilot Testing of an Online Mindfulness-based Intervention for Improving Fear of Hypoglycaemia, Well-being and Self-management Behaviours in Adults with Type 1 Diabetes.

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May 2022

Research submitted in partial fulfilment of the requirements for the degree of Doctor in Clinical Psychology (DClinPsy), Royal Holloway, University of London.

Acknowledgments

I would firstly like to thank Dr Michelle Taylor for providing a constant source of support throughout this process. I've appreciated her wisdom which guided the project, as well as her kindness and compassion. I would also like to thank Professor Dawn Langdon and Dr Jane Vosper for their guidance and encouragement.

I would like to express my gratitude to the external collaborators, Dr Nick Oliver and Dr Vicky McKechnie from Charing Cross Hospital and Dr Sonya Frearson from Barts NHS Trust, who generously provided their knowledge and expertise. I am very grateful for their help in the recruitment process.

I am also grateful to all the local diabetes support groups who helped raise awareness of the study, and to those in the Facebook diabetes support groups who spread the word and cheered the project on.

I am immensely grateful to all the participants who offered their time to this study. Your enthusiasm and dedication made this a rewarding endeavor, and it wouldn't have been possible to achieve without you.

Thank you to my family, partner and friends for all the encouragement, moral support and joy you have given me over the past few years of the training course.

I would finally like to say thank you to my dad for the strength he has shown me throughout his journey with type 1 diabetes. Thank you for also always encouraging me to work hard and strive for my goals.

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I. Lay Summary

Type 1 diabetes (T1D) is a long-term health condition affecting approximately 1 in 250 people. In this condition, the body produces little or no insulin, which is a hormone used to break down sugar (or 'glucose') in the blood. People with T1D therefore need to self-administer insulin. If blood glucose levels drop to low, a reaction known as 'hypoglycaemia' can take place. Hypoglycaemia can lead to physical symptoms such as shakiness, sweating and fatigue. It can also lead to difficulty thinking clearly which can result in individuals making mistakes, having accidents or getting physical injuries. In response to the risk of hypoglycaemia, some people with T1D reasonably develop a fear towards this reaction, known as 'fear of hypoglycaemia' (FOH). They may do certain behaviours to avoid hypoglycaemia such as eating sugary snacks or taking too little insulin so that there is more glucose in the bloodstream. This can be harmful as high blood glucose levels can lead to long-term health complications caused by damage to the person's blood vessels and nerves which can particularly affect the heart, eyes, feet and kidneys.

There are different education courses to support people with T1D. Courses include Blood Glucose Awareness Training (BGAT) and Dose Adjustment for Normal Eating (DAFNE). These are normally run in groups and help to educate people on how to manage their diabetes and to keep blood glucose at ideal levels. People with T1D can also access psychological interventions such as Cognitive Behavioural Therapy (CBT) which can help to reduce anxiety by challenging negative thoughts and changing behaviours. Research has shown educational and psychological interventions have positive impacts on well-being and blood glucose

management. However, there is little research which has looked into the impact of these interventions on FOH.

The systematic review presented in this thesis aimed to explore this literature gap. An online search found research papers which have investigated the impact of educational (BGAT, DAFNE) and psychological (CBT) interventions on FOH in adults with T1D. It aimed to assess the effectiveness of these approaches and compared them by mode of delivery, format and duration.

It was found that:

- Current psychological and educational interventions are limited in reducing FOH.
- BGAT was the most promising approach showing some reductions in worries associated with FOH.
- There were no clear differences between interventions by delivery mode, intervention format and duration.
- There is limited research which has explored DAFNE as an intervention to reduce FOH.
- There were no studies which have investigated the use of third wave psychological interventions such as Acceptance and Commitment Therapy and mindfulness-based interventions (MBIs) to reduce FOH.

It was therefore recommended that future research should develop and test new approaches to help people with FOH. BGAT may be effective because it helps people to be more in tune with their body and therefore understand the difference between symptoms of hypoglycaemia, symptoms of anxiety and normal bodily sensations. Interventions which also target the mind-body link could be effective.

Building on this finding, an online mindfulness-based intervention (MBI) was developed and assessed in an experimental pilot study. Mindfulness supports people to be more aware of what they're sensing and feeling in the moment, without interpretation or judgment. Research has found it is associated with FOH in parents of children with T1D. MBIs have also been found to improve well-being and diabetes-self management in people with T1D. The aims of the project were to assess whether an online MBI targeted at FOH could (1) help to reduce FOH, (2) improve well-being and diabetes self-management, and (3) be acceptable and feasible for use in a T1D population.

The course was delivered online and was co-developed with two experts by experience. Six volunteers with T1D, who were experiencing FOH were recruited through two NHS diabetes services, charity support groups and social media. They were randomly assigned to a wait time of 1, 2 or 3 weeks before accessing the online course. The volunteers completed four modules of the mindfulness course over four weeks and were encouraged to practice mindfulness in between modules. At the end there was a 4-week period to see if improvements were maintained over time.

Throughout their involvement, participants were asked to complete simple daily questions which asked about FOH, diabetes self-management behaviours and well-being. They were also asked to complete longer questionnaires at the start, after the course and after the 4-week wait. Their answers were analysed to see if there were any differences in outcomes before and after the course.

It was found that:

- Of the people who were eligible and signed up for the study, 43% completed it, suggesting that the online course may not be feasible for everyone.

- Completers gave feedback to say that the course was user-friendly and that it helped them effectively deal with their problems.
- Most participants found they had less anxiety about hypoglycaemia after doing the course, with changes maintained at follow-up.
- Most participant's well-being also improved after engaging in the mindfulness course.
- Mindfulness increased for most participants during the course.
- Self-management behaviours did not improve overall, although there were positive changes in blood glucose management for some participants.

Altogether both the systematic review and experimental study suggest that research investigating how to support people with FOH is growing, although current interventions are quite limited in effectiveness. Online MBIs may offer a low-cost way to support people with T1D. This could help to fill a gap in services, as there are currently no targeted interventions for this presentation. It is recommended that future research builds on these results by testing the online MBI in a larger trial with more participants. In order for results to reach a wide audience, they will be made available to participants, shared on social media accounts of diabetes support groups and published in a scientific journal.

II. A Systematic Review of the Effectiveness of Psychological and Educational Interventions in Reducing Fear of Hypoglycaemia in People with Type 1 Diabetes

Abstract

Background: There is a growing evidence base on the impact of psychological, educational and technological interventions on fear of hypoglycaemia (FOH) in people with type 1 diabetes (T1D). The current review aims to evaluate the effectiveness of psychological and educational interventions in reducing FOH and to compare by mode of delivery, format and duration of intervention.

Methods: A systematic literature search using two electronic databases, Web of Science [v.5.35] and PubMed, was performed and reference lists were examined in October 2021. Full-texts of papers written in English that examined the efficacy of psychological or educational interventions on FOH (using a validated measure) in adults with a diagnosis of T1D were included. Papers were screened for eligibility criteria by (1) title and abstract, and (2) full-text. Final papers were extracted by study characteristics and study findings.

Results: Fifteen studies met inclusion criteria, assessing various interventions such as Cognitive Behavioural Therapy (CBT), Blood Glucose Awareness Training (BGAT) and Dose Adjustment for Normal Eating (DAFNE). Interventions varied in mode of delivery, format and duration. The main outcomes measured were worries and behaviours related to FOH.

Narrative synthesis found that BGAT showed the most consistent improvements in FOH worries and behaviours, with small-moderate effect sizes. Outcomes for other interventions were inconsistent with mainly non-significant or small effects. Overall, there were no clear differences between interventions by delivery mode, intervention format and duration.

Conclusions: These findings suggest that psychological and educational interventions have limited effectiveness in reducing FOH, although BGAT is a promising approach. Future research should develop and test novel approaches to target FOH, which may be guided by mechanisms of change underpinning BGAT. The review also found limited research into the effectiveness of DAFNE, ACT and mindfulness on FOH. A recommendation is therefore for future research to focus on these areas.

Introduction

The aim of the current review is to understand the effectiveness of psychological and educational interventions in reducing fear of hypoglycaemia (FOH) in adults with type 1 diabetes (T1D). The following provides an overview of diabetes, the impact of hypoglycaemia, and the potential consequences in terms of FOH and other diabetes-related outcomes. Previous literature on the effectiveness of technological, psychological and educational interventions in improving diabetes-related outcomes is summarised.

Diabetes

Diabetes mellitus is a chronic health condition characterised by high blood glucose (BG) levels. It occurs when the body produces little or no insulin or when the body does not respond to insulin that is produced (Atkinson et al., 2014). There are different types of diabetes, including T1D, type 2 diabetes (T2D), latent autoimmune diabetes in adults (LADA) and gestational diabetes and diabetes caused by rare syndromes (Royal College of Nursing [RCN], 2021). T1D and T2D are the most common forms with T1D affecting 8% of cases in the UK and T2D affecting 90% (Diabetes UK, 2020).

T1D presents with symptoms of extreme thirst, weight loss, urinating more than usual and tiredness (Diabetes UK, 2020). In T1D the body attacks the cells which produce insulin due to the autoimmune destruction of β cells of the endocrine pancreas (Atkinson et al., 2014). Prevalence varies greatly by geographical region however, overall approximately 1 in 250 people present with T1D (Redondo, 2001). The condition is most often diagnosed in childhood and adolescence, and is slightly more common in males (Diaz-Valencia et al., 2015). The exact cause of T1D is

unknown however, research suggests that both genetic and environmental factors contribute to development. Lifetime risk significantly increases in relatives, as approximately 30-70% of monozygotic twins (Redondo et al., 2008) present with T1D compared with 0.4% prevalence in the general population. Environmental and behavioural factors including diet, early life exposure to viruses which lead to islet inflammation and obesity are also associated with increased T1D presentations (Ferrara et al., 2017; Rewers & Ludvigsson, 2016).

Diabetes and Hypoglycaemia

Hypoglycaemia is the most common adverse event associated with insulin treatment in T1D and occurs when BG levels drop too low (BG level <4.0mmol/l; Diabetes UK, 2021). The main reasons for hypoglycaemia include excessive insulin doses, and low glucose levels due to missed or low-carbohydrate meals, and over-exertion during exercise (International Hypoglycaemia Study Group, 2015). Symptoms of hypoglycaemia can be broadly categorised as neurogenic, caused by activation of the autonomic nervous system (e.g. sweating, shakiness) and neuroglycopenic, caused by glucose deprivation in the brain (e.g. confusion, speech/coordination difficulties) (Frier, 1993). However, the hypoglycaemic profile for each individual is idiosyncratic (Cox, 1985; Zammitt et al., 2011). Episodes can result in negative consequences for the individual including loss of control and cognitive impairment that may result in socially unacceptable behaviour, interruption of daily activities and physical injuries, coma and, rarely, death (Hendrieckx et al., 2019).

To prevent a hypoglycaemic episode, people with T1D rely on self-monitoring of BG levels and of bodily sensations to detect early warning signs of lowering BG

levels. Individuals can respond by increasing intake of glucose (e.g. taking oral carbohydrates). Other preventative methods include eating regular meals and reducing insulin doses or taking carbohydrates prior to exercise. However, excessive counteractive behaviours used to prevent hypoglycaemia, can also result in poor glycaemic control and prolonged hyperglycaemia (excess of glucose in bloodstream). The National Institute for Health and Care Excellence (NICE) guidance recommends target BG levels of between 5-7 mmol/l before breakfast ('fasting' level) and between 4-7 mmol/l before meals at other times of day (NICE, 2021). Poor metabolic control and prolonged hyperglycaemia can have long-term implications such as microvascular and macrovascular complications, including retinopathy, neuropathy, nephropathy, impaired cognitive function and cardiac problems (Diabetes Control and Complications Trial Research Group [DCCT], 1993; Nathan, 2014).

Fear of Hypoglycaemia (FOH)

In response to the negative physiological, cognitive and social impacts of hypoglycaemia, people with T1D are at risk of developing FOH. FOH is defined as "the degree of fear associated with episodes of hypoglycaemia and their negative consequences" (Gonder-Frederick, Cox & Vajda, 2011, pp. 12). FOH can be conceptualised as worries related to having a hypoglycaemic episode (e.g. fearing social embarrassment), and engaging in behaviours to avoid hypoglycaemia or its negative consequences (Surwit et al., 1982). Common avoidance behaviours include increasing glucose intake by frequently snacking, reducing insulin doses and avoiding situations such as driving, socialising or looking after others (e.g. children) (Brod et al., 2012; Leiter et al., 2005). Wild et al. (2007) suggest an over-compensation theory whereby high levels of hypoglycaemia worry lead to "over-compensating"

management behaviours intended to maintain high glucose levels. In this way, FOH can be framed theoretically within a cognitive-behavioural model of anxiety and avoidance (Hendrieckx et al., 2019). Negative experiences of hypoglycaemia can lead to avoidance of a repeat episode which consequently increases anxiety as feared thoughts are not disconfirmed, or the individual does not learn that they can cope with a feared consequence. Avoidance behaviours are reinforced as they are associated with a reduction in anxiety.

As FOH is not a diagnosable condition, it is difficult to ascertain prevalence of FOH within a T1D population. It has been postulated that approximately 1 in 7 people with type 1 diabetes experience FOH (Diabetes UK, n.d.). Although it should be noted that this number may be higher in groups of people who have a higher risk of hypoglycaemia or who have impaired hypoglycaemia awareness. For example, a systematic review analysing 34 papers found that FOH is associated with more frequent hypoglycaemia and risk factors for severe hypoglycemia, such as BG variability (Wild et al., 2007). In addition to this, Costea et al. (1993) found that 74% of participants who had frequent hypoglycaemic events had exacerbated anxiety about hypoglycemia, indicating that prevalence may be higher in subgroups of the diabetes population.

Research on the predictors of FOH can assist in understanding why fear develops in some people and not in others. A relatively consistent relationship has been found between clinical variables and FOH including previous negative experiences of hypoglycaemia (Polonsky et al., 1992), frequency of hospitalisation due to hypoglycemia, and impaired hypoglycaemia awareness (Wild et al., 2007). FOH has also been found to be associated with psychological traits (e.g. trait anxiety),

psychological symptoms (e.g. depressive symptoms), as well as personality factors (e.g. neuroticism) (Wild et al., 2007).

Technologies in T1D

Over the past three decades, newer BG and insulin infusion technologies have been developed to support patients to manage BG levels e.g. continuous glucose monitoring (CGM) systems and continuous subcutaneous insulin infusion (CSII) pumps (Ramchandani & Heptulla, 2012). These allow for continuous monitoring of glucose concentration in interstitial fluid over time, and some systems provide a warning for when glucose values are dropping too low or increasing too high. In hybrid closed-loop insulin-pump systems, pumps are able to respond to detection of lowering BG levels by adjusting insulin secretion accordingly (Weaver & Hirsch, 2018).

Research has found such technologies can reduce the number of hypoglycaemic episodes (e.g. Davey et al., 2012) and shorten hypoglycaemic episodes (Battelino et al., 2011). However, despite improved glucose control and reduction in the risk of hypoglycaemia, FOH has not been found to reduce (Adams et al., 2018; Davey et al., 2012; Hermanides et al., 2011). For example in Davey et al. (2012), CGM led to reduced incidence of hypoglycaemic episodes but did not alter self-reported FOH. The authors state this may be due the observation that not all episodes of hypoglycaemia were prevented by the CGM alarm system due to inaccuracies of CGM at low interstitial glucose levels. Additionally, using CGM systems may have made patients more aware of how variable their BG levels were, which could have inadvertently increased their anxiety. Conversely, other studies have found significant reductions in FOH-behaviours in response to CSII pumps

(Barnard & Skinner, 2008), and CGM in children (Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, 2010). However, it should be noted that worries related to FOH were not significantly reduced in either study suggesting technologies do not address the underlying cognitive aspects of FOH.

Educational Interventions in T1D

Blood Glucose Awareness Training (BGAT) is a psychoeducational course for people with T1D which is typically delivered in a group format over eight sessions. It aims to support participants to better detect internal cues to identify and respond to extreme BG levels (e.g. neurogenic and neuroglycopenic symptoms). Research suggests BGAT can improve BG estimation accuracy, detection of hypoglycaemia and hypoglycaemia awareness across the USA and Europe (Cox et al., 2006).

Dose Adjustment for Normal Eating (DAFNE; DAFNE Study Group, 2002) is another educational course which teaches participants the necessary skills to administer the right amount of insulin based on carbohydrate intake. Courses last 5 days and are offered to groups of 6-8 people by DAFNE Educators. The course has been found to significantly reduce the proportion of participants experiencing severe hypoglycaemia (Elliott et al., 2014) and is associated with improvements in diabetes-related quality of life (QoL) (DAFNE Study Group, 2002).

Interventions such as BGAT and DAFNE support individuals to improve their recognition of the warning signs of hypoglycaemia. By lowering this risk, they may also indirectly reduce FOH.

Psychological Interventions in T1D

Psychological interventions have been adapted for use in a diabetes population including Cognitive Behavioural Therapy (CBT), and third-wave models such as Acceptance and Commitment Therapy (ACT; Hayes, 1999) and mindfulness.

CBT is a widely used psychological approach which aims to alleviate distress by reframing maladaptive cognitions and changing behaviours using behavioural experiments (Beck, 2011). Research on its use in diabetes is limited and has produced mixed findings. A recent systematic review suggests that CBT is effective in improving short-term and medium-term glycaemic control as well as reducing levels of anxiety and depression (Uchendu & Blake, 2017). However, a second systematic review found that despite reducing depression and increasing QoL among patients with co-morbid depression, CBT did not improve diabetes-related distress or glycaemic control (Li et al., 2017).

There is growing literature on the use of ACT in diabetes. This is a "third wave" CBT model based on functional contextualism and Relational Frame Theory. It moves away from attempts to change negative thoughts or emotions, and instead aims to change the way an individual relates to difficult internal experiences (i.e. reducing experiential avoidance). Key processes underpinning ACT include acceptance, defusion and valued living which can increase psychological flexibility. There is growing literature on the use of ACT in diabetes, with a number of trials reporting improvements in self-management, glycaemic control and anxiety in adults with T2D (Fayazbakhsh & Mansouri, 2019; Ghasemlou et al., 2018; Gregg et al., 2007). Acceptance has been identified as a mechanism of change, mediating the impact of

treatment on changes in glycaemic control among adults with T2D (Gregg et al., 2007).

Mindfulness is another "third wave" approach which cultivates the use of *attention* to monitor one's present moment experiences with an orientation of *acceptance* to these experiences (Bishop et al., 2004). Mindfulness-based interventions (MBIs) have been shown to have positive effects for people with physical health conditions (i.e. cancer, fibromyalgia, epilepsy, heart disease, tinnitus, acquired brain injury), on outcomes such as pain acceptance, coping and depressive symptoms (Toivonen et al., 2017). This may indicate how changing the way an individual relates to health-related cognitions using third-wave approaches, may be more helpful than challenging the content of cognitions (Hofmann et al., 2010). In diabetes-related research, a recent meta-analysis found that MBIs significantly improved diabetes-related distress in patients with T1D and T2D, and were most effective for patients with elevated baseline distress levels (Guo et al., 2019).

Current Review

Whilst research exploring the impact of educational (BGAT, DAFNE) and psychological (CBT, ACT, MBIs) interventions on FOH is in its infancy, the literature in this area is growing. There have been two published systematic reviews exploring prevalence and predictors of FOH, and provide summaries of therapeutic advancements in reducing FOH (Martyn-Nemeth et al., 2016; Wild et al., 2007). Findings indicated that technological advancements did not consistently reduce FOH, although the most promising advancement was sensor-augmented insulin pumps (Rubin & Peyrot, 2012). There were mixed findings regarding the effectiveness of educational and psychological interventions in reducing FOH. BGAT was identified

as the most promising in reducing FOH-worries (Boyle et al., 2004; Cox et al., 2008; Cox et al., 2001; Schachinger et al., 2005), whilst CBT had some reductions in FOH-behaviours, but not in worries (Amsberg et al., 2009; Ismail et al., 2008; Snoek et al., 2001). There were no DAFNE studies which included a validated FOH measure.

The current review aims to build on these summaries to explore the effectiveness of psychological and educational interventions on reducing FOH. It will include research published since both publications including DAFNE trials (Cooke et al., 2015; de Zoysa et al., 2014) and follow-up studies to consider long-term treatment effects (e.g. Little et al., 2018). Technological interventions were not included as there is already a Prospero registered systematic review in progress which is focusing specifically on the influence of technologies on FOH.

The review will consider the effectiveness of interventions on emotional and behavioural aspects of FOH in adults with T1D, providing a comparison of interventions by format, mode of delivery and duration. It will also explore whether these interventions can provide a viable additive effect to diabetes technologies in reducing FOH.

Methods

Search Strategy

The Preferred Reporting Items for Systematic reviews and Meta-Analyses guidelines (PRISMA; Moher, 2009) were followed when conducting the literature search and reporting the systematic review. A systematic review protocol was initially developed outlining the proposed process and study eligibility criteria.

After conducting scoping searches, two bibliographic databases (PubMed and Web of Science [WoS; v.5.35]) were searched for relevant published literature. The search syntax was devised in collaboration with a librarian based at Royal Holloway, University of London. Table 1 contains the search syntax used for each database. The searches contained no methodological search filters that would limit results.

Table 1

Search Syntax for PubMed and Web of Science (v.5.35)

Database	Search syntax
PubMed	(hypoglycemia OR hypoglycaemia) AND (fear OR anxiety OR worry OR concern) AND adults AND type 1 diabetes
Web of Science (WoS)	ALL=((hypoglycemia OR hypoglycaemia) AND (fear OR anxiety OR worry OR concern) AND adults AND type 1 diabetes)

Study Eligibility Criteria

The eligibility criteria was developed in accordance with PICOS guidelines (Methley et al., 2014) (Table 2). These guidelines are an adaption to Miller & Forrest's (2001) 'PICO' guidelines and provide five areas of inclusion/exclusion; Population, Intervention, Comparison, Outcomes, Study type.

Table 2

Eligibility Criteria

Criterion	Description
Population	Include: adults; type 1 diabetes. Exclude : gestational diabetes, diabetes insipidus, steroid-induced diabetes, Type 2, Type 3 diabetes, children/adolescents, parents of children with diabetes.
Intervention	Include: studies examining the impact of psychological and educational interventions (CBT, ACT, Dose Adjustment For Normal Eating (DAFNE), Blood Glucose Awareness Training (BGAT) on fear of hypoglycaemia (FOH). Individual, group, self-guided, workshop, online/app based. One intervention or comparing multiple interventions. Exclude: blood glucose technologies, exercise strategies.
Comparator	Comparison of multiple interventions on FOH. Comparison of interventions across timepoints or single intervention across timepoints.
Outcome	FOH as measured by a validated outcome measure.
Study Type	Include: quantitative, experimental, correlational/longitudinal, randomised controlled trial (RCT). Exclude: qualitative designs, study protocols, systematic reviews, meta-analyses, single case studies and editorial letters.

There were no restrictions on date of publication or country of origin, however papers were required to have been published in a peer-reviewed journal and available in English.

Study Selection

The main searches were conducted on 29th October 2021 (PubMed) and on 31st October 2021 (WoS), generating 499 and 391 results respectively. All searches were conducted using the "Advance Search" option, with no restrictions on publication date and language. Search terms were applied "in all fields". All search results were exported to RefWorks ProQuest reference management software. An additional paper was identified via discussion with an expert in the field. Duplicates (n=215) were removed and remaining records were transferred onto a spreadsheet in Microsoft Excel.

The remaining 676 papers were screened by title and abstract to determine if PICOS eligibility criteria were met and 642 papers were consequently excluded. Relevant systematic reviews were also screened for additional literature. Several protocols were identified for potentially relevant projects and authors were contacted to request unpublished manuscripts if available. Of the six contacted, one provided a manuscript.

The remaining 34 full-text papers were screened by eligibility criteria. Papers were excluded due to the design being a single case study or the paper being written as an editorial letter (n=3), the sample including people under 18 years of age (n=1), including an exercise- or technology-based intervention (n=2), including comparators which were not relevant (n=5), using a non-validated measure of FOH (n=4), and written as a protocol (n=5). To reduce publication bias, citation chaining was

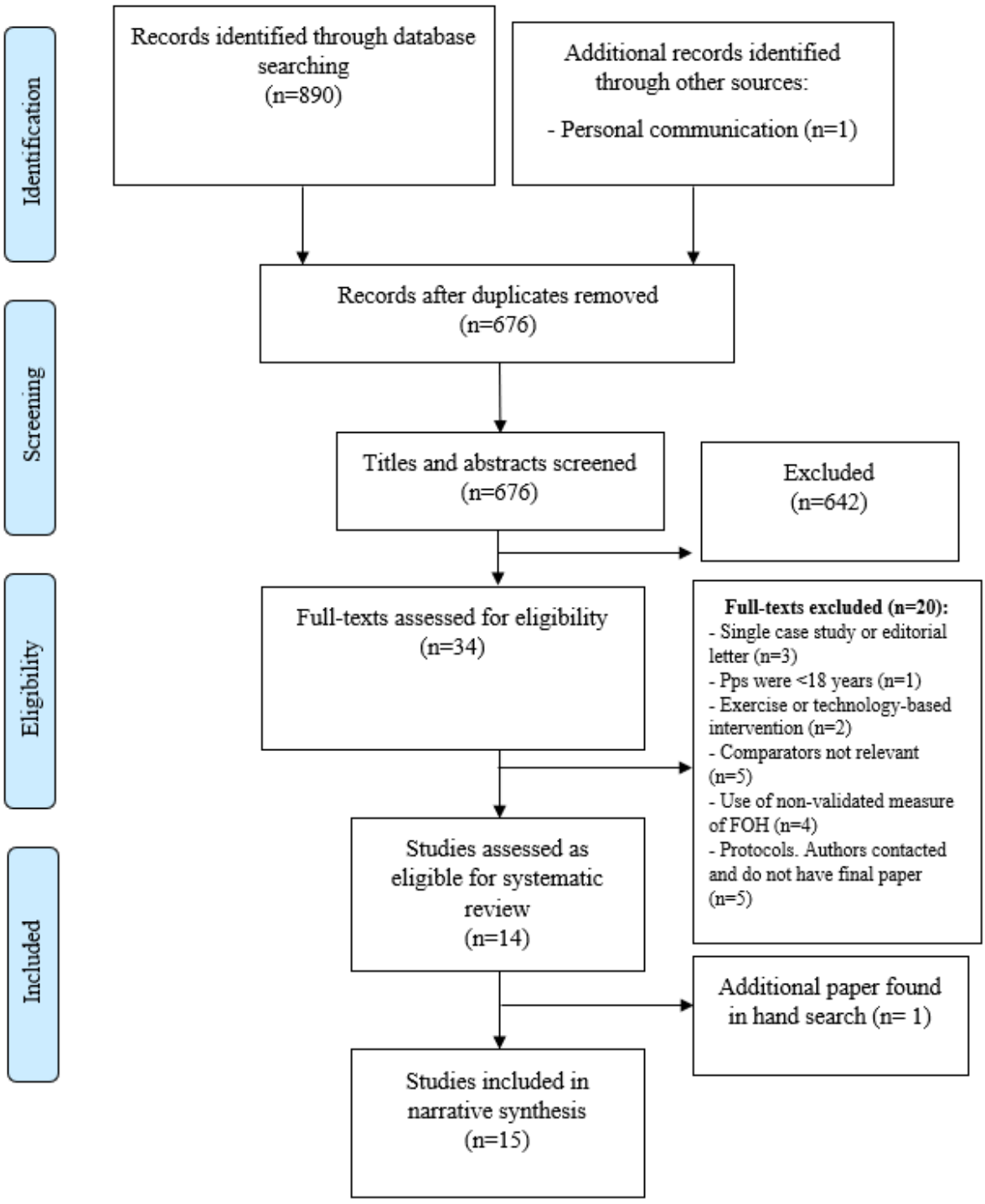
conducted in December 2021, whereby reference lists of full-texts were screened for additional literature (n=1). After exclusion of papers, and with the addition of the hand-searched paper, the total number of papers for inclusion in the review was 15.

An independent second reviewer screened 10% of titles and abstracts with a percentage agreement of 49%, k=.49, indicating moderate agreement. Any disagreements over inclusion were resolved through discussion.

The study selection process is illustrated in Figure 1.

Figure 1

PRISMA Diagram



Quality Assessment

To assess the quality of papers included, the Quality Assessment Tool for Quantitative Studies developed by the Effective Public Health Practice Project (EPHPP; 1998) was used. This is a standardised assessment tool used to evaluate quantitative studies. It has demonstrated good content validity and test-retest reliability (Thomas et al., 2004). A number of factors are considered when assessing the quality of a study including selection bias; study design; confounders; blinding; data collection methods; withdrawals and dropouts. Each of these factors were assessed on a methodological rating scale and graded as either "strong", "moderate" or "weak". The global quality rating is dependent on the number of sections rated as "weak". Each study included was assessed by the primary researcher, with 10% of the studies assessed by a second reviewer with a percentage agreement of 60%, k =.6. Disagreements over quality rating were resolved through discussion.

Data Extraction

Data for each paper were extracted onto individual 'Data Extraction Forms' (see Appendix A) which were developed with guidance from Boland et al. (2017). Data were extracted according to: (a) Publication details: first author, publication year, country; (b) Study Characteristics: study design, number of participants in each condition, aims, type of comparator(s); (c) Participant information: sample size, age (mean, SD), gender (% female), inclusion criteria, recruitment site, study completion rate (n and percentage); (d) Intervention characteristics: model, format, components, duration, delivery provider, adherence (completion of all sessions), control description; (e) Outcomes: primary and secondary outcomes, standardised measures, data collection timepoints; (f) Main findings: statistical analyses, descriptive data

(means and SDs) of intervention (and control if applicable) at baseline, post-intervention and follow-up, including statistical significance and effect sizes as reported by authors.

Data Synthesis

Data from the final studies were analysed through narrative synthesis following guidance from the Centre for Reviews and Dissemination (CRD; 2009) and reported following the PRISMA checklist (Moher, 2009). A meta-analysis was not performed due to the heterogeneity of the studies in terms of design, type of comparators and outcome measures not meeting the criteria required for quantitative synthesis (Boland et al., 2017). Effect sizes (ES) according to Cohen's *d* and statistical significance (*p*) were calculated where sufficient data was provided in the full-text. Additionally, to facilitate comparison between studies, Hedge's *g* was computed in order to adjust for small sample size bias. Computations of *d* and *g* were conducted based on the calculations described in Ellis (2010).

Results

In total, fifteen published studies were included in the narrative synthesis. The main characteristics of eligible studies are presented in Table 3 and categorised according to type of intervention (CBT, BGAT, DAFNE and other).

Table 3

Study Characteristics

First Author, Year, Country	Sample Characteristics % Female Age: *M (SD)*	Intervention Characteristics Model, Format, Components, Duration/Number of Sessions, Delivery Provider, Adherence (% treatment completers)	Study Completion Rate
CBT interventions			
Amsberg, 2009 Sweden	*N*=94 52% 41.2 (12.3) Adults (18–65 years) with diagnosis of T1D, duration of at least two years, BMI < 30 kg/m2, HbA1c > 7.5% during the last year	CBT F2F group (*n*=4-6) with additional 1:1 support. Manualised Components: challenging negative beliefs, self-care, behavioural education (e.g. insulin technique) 8 weekly 2-hour sessions Diabetes specialist nurse and psychologist 87% Control: routine diabetes care	24-week FU: 73/94 (78%) 48-week FU: 69/94 (73%)
Ismail, 2008 England	*N*=344 60% *M*=36.1 Adults (18-65 years) with T1D for >2 years, with persistent, suboptimal glycaemic control	Motivational enhancement Tx (MET): 1:1 F2F Components: identifying behavioural goals, formulating of plan to change and problem-solving barriers. Homework between sessions 4 x 50 minute sessions over 2 months Nurse-delivered 83% attended all 4 sessions	HFS-W: full baseline and follow-up data for 176/344 (51%)

	(HbA1c levels of 8.2% to 15%), and without complications or severe comorbid disease	MET plus CBT Tx: 1:1 F2F Components: MET content plus CBT strategies (challenging NATs, BEs, activity scheduling, assertiveness training). 4 MET sessions plus 8 sessions of CBT over 6 months Nurse-delivered 55.7% attended all 12 sessions. 29 (27%) attended 3 or less Sample of session recordings formally rated for model fidelity. Weekly individual and group supervision for nurses delivering both interventions. Control: Minimum standards of diabetes care for patients with suboptimal glycaemic control on the basis of national guidelines. This included a minimum of 2-4 clinic appointments per year. 2 hospitals also offered structured education programs as part of this care.	HFS-B: full baseline and follow-up data for 241/344 (70%)
Snoek, 2001 Netherlands	*N*=24 62% 35.2 (11.1) Adults (18-50 years) diagnosed with T1D for ≥12 months, persistent poor control defined at two consecutive HbA1c values ≥8%, no severe medical or psychiatric co-morbidity	CBT F2F groups (n=6-8). Homework between sessions Components: Cognitive restructuring, behavioural strategies (e.g. cueing and self-rewarding), stress management techniques, challenging rationality of beliefs 4 x 1.5 hour weekly sessions Diabetes nurse specialist and psychologist 23/24 (96%) completed On average, patients spent 30 minutes per week on homework	Not reported
BGAT interventions			

Broers, 2005 Netherlands	*N*=59 32% Group: 43.7 (9.2). Individual: 42.5 (11.1) Adults (18-65) diagnosed with T1D before the age of 40 and for at least 2 years; had become insulin dependent within 18 months after diagnosis; used multiple injections a day or (CSII), and no serious physical or psychological comorbidity	Group BGAT-III. F2F groups (*n*=5-9) 6 weekly sessions x 1.5-2 hours Diabetes educator and psychologist Individual BGAT-III: F2F, 6 x 30-minute sessions Diabetes educator	Current FU study: 49/59 (83%) Completion since original study 49/123 (48%)
Cox, 2001 USA	*N*=73 65% 38.3 (9.1) Patients with diabetes for ≥2 years, have taken insulin since the time of diagnosis, routinely measure BG ≥2/day, and no history of severe depression or substance abuse	BGAT-2 F2F groups (*n*=5-15) Components: identifying internal cues (autonomic, neuroglycopenic, affective symptoms) of extreme levels of BG and anticipating extreme BG levels using external cues 7 x 1.5-hour classes. Classes followed a standardised training manual.	6-month FU: 76/78 (97%) 12-month FU: 73/78 (94%)
Rondags, 2016a Netherlands	*N*=137 46% 52 (13) Patients with T1D or T2D performing at least 3 daily insulin injections per day and had experienced one or more severe hypoglycaemia in past 2 years	HypoAware (adapted version of Dutch BGAT) F2F group (*n*=8) and partly web-based. Homework element Components: education on improving symptom recognition, risk awareness, preventive and problem-solving strategies, and coping with risk of hypoglycaemia 3 x 2.5 hours over 4 weeks, combined with two online modules in the weeks between meetings. Paper doesn't state duration of modules	2-, 4- and 6-month FU: 118/137 (87%)

	T1D = 88%	2 trained diabetes professionals 96% participating in two or more group sessions. 90% completing two online sessions.	
Rondags, 2016b Netherlands	*N*=37 40% 54.4 (12.6) Adults with T1D and insulin-treated T2D and IAH, frequent hypoglycaemia and/or FOH T1D = 85%	HypoAware (adapted version of Dutch BGAT) F2F group (*n*=8) and partly web-based. Homework element Components: education on improving symptom recognition, risk awareness, preventive and problem-solving strategies, coping with risk of hypoglycaemia 3 x 2.5 hours over 4 weeks, combined with two online modules 2 trained diabetes professionals Trainer manual to guide group process and ensure fidelity 37/40 (92%) completed intervention 50% of participants completed all assignments	37/40 (92%)
Schachinger, 2005 Switzerland and Germany	*N*=138 42% Tx: 45 (14.4) Control: 47.9 (13.1)	BGAT F2F group (*n*=5-12) 8 weekly 2-hour sessions Physician-psychologist team 14/138 (10%) attended less than 50% of sessions Control: A physician GSH group (n=5-12), 3 monthly sessions x 2 hours	6- and 12-month FU: 111/138 (80%)
DAFNE interventions			

Cooke, 2015 England	*N*=262 Equal no. of males and females. Number not provided in full-text 40 (14)	DAFNE F2F groups of up to 8 Components: carbohydrate counting and dose adjustment, managing hypoglycaemia and illness 5-day course (total=38 hours) with booster session after 6 weeks 2 trained diabetes educators 97%	6- and 12-month FU: 194/262 (74%)
De Zoysa, 2014 England	*N*=23 50% of original sample (n=24) 54.4 (7.9) Adults ≥18 diagnosed T1D, with persistent IAH (assessed clinically and scoring ≥4 on the Gold score)	DAFNE-HART (adapted to include MI and CBT strategies) F2F group with additional individual F2F and telephone support. Homework between sessions Educational material structured within MI framework. Included CBT strategies (e.g. cognitive restructuring, body scan) 6 weekly sessions Diabetes educators (specialist nurses and dieticians) 100% course completion Diabetes educators had weekly supervision with CP to facilitate model fidelity	12-month FU: 23/24 (96%):
George, 2008 England	*N*=114 55% *Tx:* 41 (10)	BITES (Brief version of DAFNE) F2F group (*n*=8-10)	3- and 12-month FU: 102/114 (89%)

	Control: 41 (12) Adults ≥18 diagnosed with T1D for >12 months, multiple injection therapy for ≥2 months, and ability to read and write	Components: education on carbohydrates and diet; understanding insulin adjustment; skills and confidence to self-manage. Included CBT techniques (e.g. challenging NATs) 2.5 days Diabetes specialist nurse and dietician 100% completed intervention Control: routine care in diabetes clinic	
Other interventions			
Linden, 2018 Sweden	*N*=174 100% Tx: 31.4 (4.8) Control: 30.2 (4.2) Adults >18 years and literate with a diagnosis of T1D and registered at one of the six participating study centres	Person-centred support (education and peer support) delivered alongside standard care (frequent contact with midwives, obstetricians and endocrinologists) Web-based Components: (1) educational information on pregnancy and life as a new mother with diabetes; (2) a self-care diary; (3) peer support in a discussion forum Access to programme during pregnancy, childbirth and immediately after Web-support developed by experts, patient representatives and researchers 67/78 (86%) completed intervention. Median no of logins per participant =91 Control: standard care	FU in late pregnancy = 131/174 (75%) 6-month post-childbirth FU=137/174 (79%)

Little, 2014 England	*N*=96 64% 48.6 (12.2) Adults (18–74 years) with T1D and IAH confirmed by Gold score ≥4	Structured education which focused on hypoglycaemia assessment/management and use of BG monitoring and CSII F2F. 1:1 or small groups (*n*=4) Components: facilitator-guided discussions on recognising symptoms of hypoglycaemia and advice on self-adjustment of insulin doses according to carbohydrate intake, SMBG and planned activity One 3-hour education session Trained research fellow, specialist nurse or dietician	6-month FU: 87/96 (91%)
Little, 2018 England	*N*=76 63% 49.4 (12.3) Adults (18–74 years) with T1D and IAH confirmed by Gold score ≥4	Structured education which focused on hypoglycaemia assessment/management and use of BG monitoring and CSII F2F. 1:1 or small groups (*n*=4) Components: facilitator-guided discussions on recognising symptoms of hypoglycaemia and advice on self-adjustment of insulin doses according to carbohydrate intake, SMBG and planned activity One 3-hour education session Trained research fellow, specialist nurse or dietician	24-month FU: 76/96 (91%)
Weinger, 2001 USA	*N*=55 56% 34 (8)	Medical/education clinic F2F group and 1:1 telephone appointments Components: groups focused on either cholesterol education or BGAT. Appointments focused on improving glycaemic control and following a specific meal plan	52/55 (95%)

		Groups: 8 x weekly sessions Additionally, monthly appointments with nurse educators, physicians and a nutritionist and weekly telephone contact with nurse educator (4-5 months of appointments) Nurse educators, physicians and a nutritionist 55/61 (90%) completed intervention	

Key. BE=behavioural experiment; BG=blood glucose; BGAT=Blood Glucose Awareness Training; BGAT-2=revised version of original BGAT; BGAT-III: Third version of BGAT (Dutch adaptation); BITES=Brief Intervention in Type 1 diabetes, Education for Self-efficacy; BMI=Body Mass Index; CBT=cognitive behavioural therapy; CP=clinical psychologist ; CSII=continuous subcutaneous insulin infusion; DAFNE=Dose Adjustment for Normal Eating; DAFNE-HART=DAFNE-Hypoglycaemia Awareness Restoration Training; F2F=Face-to-face; FOH=fear of hypoglycaemia; FU=Follow-up; GSH=guided self-help; HbA1c=Glycosylated haemoglobin A1c; HFS=Hypoglycaemia Fear Survey; HFS-B=Hypoglycaemia Fear Survey - behaviour subscale; HFS-W=Hypoglycaemia Fear Survey - worry subscale; IAH=impaired awareness of hypoglycaemia; MET=motivational enhancement therapy; MI=motivational interviewing; NAT=negative automatic thoughts; SMBG=self-monitoring of blood glucose; T1D=Type 1 diabetes; T2D=Type 2 diabetes; Tx=treat

Study Characteristics

The publication year of included studies ranged between 2001 and 2018. The studies were conducted in a variety of countries: England (n=6), Netherlands (n=4), Sweden (n=2), USA (n=2), Switzerland and Germany (n=1). The study designs employed are shown in Table 4: pre-test post-test (within-subjects) experimental design (n= 6); two-armed RCT (n= 6); 2 x 2 Factorial RCT (n=2); three-armed RCT (n=1). Of these, three were described as pilot studies. Four studies had two or more experimental conditions and six included a control group. Regarding type of intervention, three studies included a CBT intervention, five included BGAT, four included DAFNE and four assessed interventions which were not categorised as a specific approach (named 'other' for the purpose of the review).

Of the two papers that provided completion rates directly post-treatment, the percentage of completers ranged from 92 to 95%, with a mean rate of 93.5%. Of the thirteen studies that reported completion rates at follow-up, the range was between 48% to 97%, with a mean rate of 79%. Two studies obtained measures of outcomes at pre- and post-intervention, while thirteen studies recorded outcomes at pre-intervention and follow-up only. Nine studies had multiple follow-up measurements, varying between 2- and 24-months.

Variations of the Hypoglycaemia Fear Survey (HFS) were used to measure the outcome FOH. Eight studies used the original version (HFS; Cox et al., 1987), six used the revised version (HFS-II; Gonder-Frederick et al., 2011), and one used the Swedish HFS (SWE-HFS; Anderbro et al., 2008). The HFS and HFS-II includes two subscales; (1) the worry subscale (HFS-Worry) measuring worries related to hypoglycaemia, and (2) the behaviour subscale (HFS-Behaviour) measuring

behaviours which are aimed at avoiding hypoyglycaemia. Nine studies measured both worries and behaviours and five measured worries only. One study used the SWE-HFS which provides one total score and has items relating to behaviour/avoidance, worry and aloneness.

Participant Characteristics

The total number of participants across fifteen studies was 1706, with a range of sample sizes between 23 and 344. All participants were aged 18 years and above, with a mean age range of 31 to 54 years. Nine of the fifteen studies had majority women however, the ratio of males to females tended to be relatively equal. There was an average across studies of 53% female cases, and additionally one study in which only women took part.

Inclusion criteria varied across studies. All studies required a diagnosis of T1D with a duration of at least one or two years. Two studies also included people with T2D which was treated with insulin. In these cases the majority of both samples had T1D (87% of both samples combined). Four studies also required participants to have impaired hypoglycaemia awareness which was assessed using a self-report measure, the Gold Score (Gold et al., 1994). Two studies had inclusion criteria of persistent subobtimal glycaemic control (measured using recent HbA1c levels), and two studies required participants to have experienced frequent or severe hypoglycaemia in the past two years. Exclusion criteria for all studies included comorbidity with severe mental and physical health difficulties that would limit the person's ability to partake in the intervention. Seven studies recruited through self-referrals in diabetes clinics, six recruited opportunity samples through physician referrals, and two through self-referrals in response to adverts circulated online.

Table 4

Study Results

First author, year, Country	Design	Outcome (FOH measure) Timing of assessments	Main intervention findings (reported *p* and ES (*d*), calculated *g*) *Where it was not possible to calculate effect size the main reported findings are presented.
CBT Interventions			
Amsberg, 2009 Sweden	RCT Tx: F2F Group CBT (*n*=46) Control: routine care (*n*=48)	HFS-W & HFS-B Baseline 6-month FU 12-month FU	[a]Sig difference in HFS-Behaviour between groups at 12-month FU (CBT group mean=15.3; control group mean=17.94; p=.006). [a]NS difference in HFS-Behaviour between groups at 6-month FU (*p*=.08). [a]NS difference in HFS-Worry between groups at 6-month FU (*p*=.35) and 12-month FU (*p*=.79).
Ismail, 2008 England	RCT (3 arm) 1:1 F2F MET plus CBT (*n*=106) 1:1 F2F MET (*n*=117) Control (*n*=121)	HFS-II W & HFS-II B Baseline 12-month FU	[a] [b]NS difference between MET plus CBT and usual care: behaviour subscale mean=-0.35, CI=-1.56-0.85; worry subscale, mean=-1.79, CI=-4.31-0.72. [a] [b] [c] NS difference between MET and usual care: behaviour subscale mean=0.07, CI=-1.21-1.35; worry subscale, mean=0.66, CI=-1.90- 3.22.
Snoek, 2001 Netherlands	Pre-post, one arm. Pilot F2F Group CBT (*n*=24)	HFS-W Baseline 3-month FU	[b]NS difference in HFS-Worry from baseline to 6-month FU (*d*=.13, *g*=.13; S).

		6- month FU	No statistics were presented for 3-month FU but the authors state that there was no significant change in outcomes during this period.
BGAT Interventions			
Broers, 2005 Netherlands	Non-randomised controlled trial F2F Group BGAT (*n*=37) F2F Individual BGAT (*n*=22)	HFS-W Baseline 12-month FU	NS difference in HFS-Worry between both conditions (*p*=0.29, *d*=.09, *g*=.09; S).
Cox, 2001 England	Pre-post, one arm F2F Group BGAT (*n=73*)	HFS-W Baseline 6-month FU 12-month FU	Significant reduction in HFS-Worry from baseline to 6-month FU (*p*<.001, *d*=.44, *g*=.44; S-M). Significant reduction in HFS-Worry from baseline to 12-month FU (*p*<.001, *d*=.47, *g*=.47; S-M).
Rondags, 2016a Holland	RCT Tx: HypoAware (BGAT; blended F2F & web-based; group) (*n*=66) Control: Routine care (*n*=71)	HFS-II W & HFS-II B Baseline 2-month FU 4-month FU 6-month FU	[a] [c] Using Generalized estimation equation (GEE) analyses, participants in the intervention group experienced a borderline significant 20% reduction in worries, as measured with the Worry scale of the HFS-II (relative risk [RR] 0.80 [95% CI 0.64–1.01], *p* = 0.06). [a] [c]NS effect on HFS-II Behaviour for participants in the intervention condition (*p*=0.08).
Rondags, 2016b Holland	Pre-post, one arm. Pilot HypoAware (BGAT; blended F2F & web-based; group) (*n*=37)	HFS-II W & HFS-II B Baseline Post	Significant reduction in HFS-II Worry from baseline to post-BGAT (*p*=0.03, *d*=.24, *g*=.24; S). NS difference in HFS-II Behaviour from baseline to post-BGAT (*p*=0.13, *d*=.21, *g*=.21; S).

Schachinger, 2005 Switzerland and Germany	RCT Tx: F2F Group BGAT (*n*=56) Control: Group Guided self-help group (*n*=55)	HFS-W & HFS-B Baseline 6-month FU 12-month FU	Significant difference in HFS-Behaviour between Tx and control at 12-month FU (*p*=0.03, *d*=.08, *g*=.08; S). NS difference in HFS-Behaviour between Tx and control at 6-month FU (*p*=0.62, *d*=.29, *g*=.28; S). NS difference in HFS-Worry between Tx and control at 6-month FU (*p*=0.93, *d*=.05, *g*=.05; S). NS difference in HFS-Worry between Tx and control at 12-month FU (*p*=0.24, *d*=.13, *g*=.13; S).
DAFNE Interventions			
Cooke, 2015 England	Pre-post, one arm F2F Group DAFNE (*n*=262)	HFS-W Baseline 3-month FU 6-month FU 12-month FU	Significant reduction in HFS-Worry from baseline to 3-month FU (*p*<0.01, *d*=.17, *g*=.17; S). [b]NS difference in HFS-Worry from baseline to 6-month FU (*d*=.17, *g*=.17; S). [b]NS difference in HFS-Worry from baseline to 12-month FU (*d*=.18, *g*=.18; S).
De Zoysa, 2014 England	Pre-post, one arm. Pilot F2F group with 1:1 support DAFNE-HART (*n*=23)	HFS-II W & HFS-II B Baseline 12-month FU	NS difference in HFS-II Worry between baseline and 12-month FU (*p*=0.1, *d*=.21, *g*=.21; S). NS difference in HFS-II Behaviour between baseline and 12-month FU (*p*=0.39, *d*=.46, *g*=.46; M).

George, 2008 England	RCT Tx: F2F group DAFNE course (*n*=54) Control: Routine care (*n*=60)	HFS-W & HFS-B Baseline 3-month FU 6-month FU 12-month FU	[a]NS difference in HFS-Worry between groups at 3-month (*p*=.15), 6-month (*p*=.33) or 12-month (*p*=.57) FU. [a]NS difference in HFS-Behaviour between groups at 3-month (*p*=.85), 6-month (*p*=.99) or 12-month (*p*=.45) FU.
Other Interventions			
Linden, 2018 Sweden	RCT Tx: web-based person-centred web-based support (*n*=78) Control: standard care (*n*=80)	SWE-HFS Early pregnancy (1st or 2nd trimester) FU 1: late pregnancy (third trimester) FU 2: 2-months after childbirth FU 3: 6-months after childbirth	[b]NS difference in SWE-HFS between Tx and control at FU 1 (*d*=.07, *g*=.07; S). [b]NS difference in SWE-HFS between Tx and control at FU 2 (*d*=.06, *g*=.06; S). [b]NS difference in SWE-HFS between Tx and control at FU 3 (*d*=.23, *g*=.23; S).
Little, 2014 England	2 x 2 Factorial RCT Insulin Delivery groups: - MDIs - CSII Monitoring Regimen groups: - SMBG - RT All pps received education intervention (F2F 1:1 or group)	HFS-II W & HFS-II B Baseline 6-month FU	Significant reduction in HFS-II Worry from baseline to 6-month FU (*p*<.001, *d*=.65, *g*=.65; M). Significant reduction in HFS-II Behaviour from baseline to 6-month FU (*p*<.001, *d*=.38, *g*=.38; S).
Little, 2018	2 x 2 Factorial RCT	HFS-II W & HFS-II B	Significant reduction in HFS-II Worry from baseline to 24-month FU (*p*<.001, *d*=.76, *g*=.76; L).

England	Insulin Delivery: - MDIs - CSII Monitoring Regimen: - SMBG - RT All pps received education intervention (F2F 1:1 or group)	Original study (Little et al., 2014; Baseline & 6-month FU) Current study: 12-month FU 18-month FU 24-month FU	Significant reduction in HFS-II Behaviour from baseline to 24-month FU (p<.001, d=.4, g=.4; S). [b]Reduction in HFS-II Worry from baseline to 6-month FU (d=.6, g=.6; M). [b]Reduction in HFS-II Worry from baseline to 12-month FU (d=.9, g=.9; L). [b]Reduction in HFS-II Worry from baseline to 18-month FU (d=1, g=1; L). [b]Reduction in HFS-II Behaviour from baseline to 6-month FU (d=.3, g=.3; S). [b]Reduction in HFS-II Behaviour from baseline to 12-month FU (d=.3, g=.3; S). [b]Reduction in HFS-II Behaviour from baseline to 18-month FU (d=.6, g=.6; M).
Weinger, 2001 America	Pre-post, one arm Education clinic (F2F group & 1:1 telephone; n=55)	HFS-W Baseline Post	Significant reduction in HFS-Worry from baseline to post education clinic (p<0.01, d=1.73, g=1.73; L).

Note. [a] effect size not calculated as information not available in full-text paper and no response from authors upon request of supplementary information. [b]p-value not available in full-text. [c] statistics for control group not available in full-text paper.

S, M, L indicate respectively small, medium and large effect sizes.

Key. CI=confidence interval; BG=Blood Glucose; CSII=Continuous subcutaneous insulin infusion; d =Cohen's d; ES = Effect Size; g = Hedge's g; HFS=Hypoglycaemia Fear Survey; HFS-B=Hypoglycaemia Fear Survey - behaviour subscale; HFS-II=revised version of HFS; HFS-

W=Hypoglycaemia Fear Survey - worry subscale; MDIs=Multiple daily injections; NS=non-significant; RCT=Randomised Controlled Trial; RT: Real-time continuous glucose monitoring; SMBG=self-monitoring of blood glucose; SWE-HFS=Swedish Hypoglycaemia Fear Survey

Study Results

The main findings for the included studies are presented in Table 4, with effect sizes (ES) as calculated using means, standard deviations (SD) and sample sizes when available in the full-texts. ES of 0.2 are considered small, 0.5 medium, and 0.8 large according to Cohen's classification (1988). The impact of each intervention, as arranged by effect size, is provided in Tables 5 and 6, for HFS-Worry and HFS-Behaviour respectively.

Intervention Models

Various models were investigated including CBT (n=3), BGAT (n=5) and DAFNE (n=3). Of these studies, one included a motivational enhancement (ME) experimental condition and another was structured within a motivational interviewing (MI) framework. Four studies investigated newly developed psychological and/or educational interventions adapted for use alongside medical appointments or the provision of diabetes technology ('other').

CBT

There were mixed findings on the impact of CBT interventions on FOH, with predominantly non-significant effects on emotional and behavioural aspects of FOH. All three papers found no significant impact of CBT on HFS-Worry (Amsberg et al., 2009; Ismail et al., 2008; Snoek et al., 2001). Amsberg, (2009) and Snoek (2001) found no significant difference in worries after a CBT intervention at follow-up. Ismail (2008) investigated CBT plus Motivational Enhancement Therapy (MET) and also found no significant difference between the intervention and routine care on worries at 12-month follow-up. These findings suggest that a CBT model does not significantly reduce FOH-worries in adults with T1D.

Two CBT papers analysed the behavioural subscale of the HFS. Amsberg (2009) found a significant difference in HFS-Behaviour between CBT and a control group at 12-month follow-up (unable to calculate effect size). However, it should be noted that this difference was not found at 6-month follow-up. Conversely, Ismail (2008) found no significant difference between a CBT (plus MET) intervention and routine care on HFS-Behaviour.

BGAT

Studies investigating BGAT interventions provided mixed findings (n=5). A pilot and follow-up study of a BGAT group found a borderline significant and significant reduction in HFS-II Worry between baseline and follow-up, respectively, with small effect sizes (Rondags et al. 2016a, Rondags et al., Rondags et al., 2016b). However, there were no significant differences in HFS-II Behaviour in either study. Cox (2001) corroborates this finding and found a significant reduction with a small-medium effect size in HFS-Worry from baseline to 6- and 12-month follow-up.

Conversely, Schachinger (2005) found the reverse effect. A significant difference with a small effect size was found in HFS-Behaviour between a BGAT group and a guided self-help control group at 12-month follow-up, but not at 6-month follow-up. However, there was no significant reduction in HFS-Worry. These findings indicate that BGAT is a promising intervention as most studies found a significant effect on some aspect of FOH. However, there are inconsistencies indicating that further research is needed.

DAFNE

There were three studies investigating the impact of DAFNE courses on FOH. Conflicting evidence emerged for the effectiveness of DAFNE on worries related to FOH, with the majority reporting non-significant or small effects. One study found a significant reduction in HFS-Worry from baseline to 3-month follow-up, with a small effect size (Cooke et al., 2015). However, a reduction in HFS-Worry was not sustained at later follow-ups (6- or 12-month). A further two studies found no significant impact of DAFNE on HFS-Worry. De Zoysa, (2014) found no significant difference pre and post DAFNE-HART in HFS-worry. Similarly, George (2008) found no significant difference between group DAFNE and control on HFS-Worry at any of the follow-up time points (3-, 6, 12-month).

Two DAFNE studies measured the behavioural subscale of the HFS. Both found that DAFNE interventions led to no significant reduction on this outcome (De Zoysa et al., 2014; George et al., 2008). Overall, findings suggest that DAFNE courses do not lead to any sustainable reduction in FOH worries or behaviours.

Motivational Enhancement

Two studies assessed interventions which included motivational enhancement components. Ismail (2008) found no significant difference between MET and usual care on HFS-II worry or behaviour subscales. Similarly, De Zoysa (2014) investigated a DAFNE intervention structured within an MI framework and found no significant difference in FOH worries and behaviours between baseline and 12-month follow-up. Findings are limited but indicate interventions which included motivational enhancement components have no significant impact on FOH.

Other Interventions

There were four studies which investigated newly developed psychological and/or educational interventions, which were delivered alongside 1:1 medical appointments or provision of diabetes technology. Linden (2018) investigated the impact of a person-centred web-based intervention which provided educational modules and a peer support forum. Findings indicated no significant difference in FOH (worries and behaviour) between treatment and control conditions at multiple follow-up periods (early pregnancy; third trimester; 2-months after childbirth; 6-months after childbirth).

Two studies investigated the impact of a structured F2F programme focused on hypoglycaemia assessment/management as well as BG monitoring (Little et al., 2014; 2018). Findings indicated a significant reduction in HFS-II Worry (medium and large ES) and Behaviour scores (small and medium ES) from baseline to 6-, 12, 18- and 24-month follow-up. However, all participants were randomised to different insulin delivery and monitoring regimen groups and it is difficult to discern the impact of these groups, separate to that of the educational programme. Similarly, an education clinic which included 4-5 months 1:1 medical/educational support and an 8-week group (cholesterol education or BGAT) found a significant reduction in FOH-worries with a large effect size from pre- to post-intervention (Weinger & Jacobson, 2001). Overall, findings indicate that structured educational programmes may be effective in reducing FOH worries and behaviours when delivered alongside medical and technological support.

Table 5

Intervention Impact on FOH-Worries as Arranged by Effect Size

Effect size	Author	Model	Intervention
Large	Little, 2018	Other intervention	Education intervention (F2F 1:1 or group)
	Weinger, 2001	Other intervention	Education clinic (F2F group & 1:1 telephone support)
Medium	Little, 2014	Other intervention	Education intervention (F2F 1:1 or group).
Small to medium	Cox et al., 2001	BGAT	F2F Group BGAT
Small	Rondags, 2016b	BGAT	F2F and web-based BGAT
	Cooke, 2015	DAFNE	F2F group DAFNE Please note: effect was not sustained at 6- or 2-month FU
Sig effect but insufficient data to calculate effect size	Rondags, 2016a	BGAT	F2F group and partly web-based with homework Please note: effect was borderline significant
NS effect	Snoek et al., 2001	CBT	F2F group CBT
	Amsberg et al., 2009	CBT	F2F group with additional 1:1 support
	Ismail et al., 2008	MET plus CBT	1:1 F2F MET plus CBT sessions
	Ismail et al., 2008	MET	1:1 F2F motivational enhancement sessions
	Schachinger, 2005	BGAT	F2F group BGAT
	De Zoysa, 2014	DAFNE	F2F group with 1:1 support
	George, 2008	DAFNE	F2F group DAFNE
	Linden, 2018	Other intervention	Web-based person-centred support (psychoeducation and peer forum) Please note: scored as total worries and behaviour

Note: Broers (2005) was not included because data was not analysed across the whole sample.

Table 6

Intervention Impact on FOH-Behaviours as Arranged by Effect Size

Effect size	Author	Model	Intervention
Large	n/a		
Medium	n/a		
Small to medium	n/a		
Small	Schachinger, 2005	BGAT	F2F group BGAT Please note: Significant at 12-months but NS at 6-months
	Little, 2014	Other intervention	Education intervention (F2F 1:1 or group)
	Little, 2018	Other intervention	Education intervention (F2F 1:1 or group)
Sig effect but insufficient data to calculate effect size	Amsberg et al., 2009	CBT	F2F group with additional 1:1 support Please note: Significant at 12-month, but NS at 6-month FU
NS effect	Ismail et al., 2008	MET plus CBT	1:1 F2F MET plus CBT sessions
	Ismail 2008	MET	1:1 F2F motivational enhancement sessions
	Rondags, 2016b	BGAT	F2F group and partly web-based with homework
	Rondags, 2016a	BGAT	F2F group and partly web-based with homework
	De Zoysa, 2014	DAFNE	F2F group with 1:1 support
	George, 2008	DAFNE	F2F group DAFNE
	Linden, 2018	Other intervention	Web-based person-centred support (psychoeducation and peer forum). Please note: scored as total worries and behaviour
Did not measure	Snoek et al., 2001	CBT	F2F group CBT
	Cox et al., 2001	BGAT	F2F Group BGAT
	Cooke, 2015	DAFNE	F2F group DAFNE Please note: effect was not sustained at 6- or 12-month FU
	Weinger, 2001	Other intervention	Education clinic (F2F group & 1:1 telephone support)

Note: Broers (2005) was not included because data was not analysed across the whole sample.

Intervention Format

Interventions included in the studies were delivered in various formats such as group (n=8), individual (n=2), and group with additional 1:1 support (n=2). All DAFNE courses were delivered in a group format and therefore cannot be compared by format (Cooke et al., 2015; George et al., 2008; DeZoysa, 2014).

CBT

CBT was delivered in various formats across the included studies, including group (Snoek et al., 2001), individual (Ismail et al., 2008) and group plus 1:1 support (Amsberg et al., 2009). Both groups were delivered in relatively small sizes (Snoek et al., 2001: 6-8 participants; Amsberg et al., 2009: 4-6 participants). All three studies found no significant difference in HFS-Worry, suggesting that intervention format did not influence efficacy of CBT.

Furthermore, two studies analysed the impact of individual CBT (Ismail et al., 2008) and group CBT plus 1:1 support (Amsberg et al., 2009) on behaviours related to FOH. Findings were mostly non-significant. Ismail (2008) found no significant change, and Amsberg (2009) found one significant effect at 12-month, but not at 6-month follow-up. Overall, findings suggest that format did not influence on efficacy of the intervention in reducing FOH-related behaviours.

BGAT

The majority of BGAT interventions were delivered in a group format with large course sizes of 5-15 attendees (Cox et al., 2001; Rondags, 2016a; 2016b; Schachinger et al., 2005). One paper analysed the difference in effect between group BGAT and individual BGAT (Broers et al., 2005). Findings showed no significant

difference in HFS-Worry between both conditions when compared between baseline and 12-month follow-up. HFS-Behaviour was not included. Results suggest that intervention format does not impact on efficacy of BGAT in reducing FOH-worries.

Delivery Mode

Interventions had various modes of delivery such as F2F (n=11); a blended approach of F2F plus telephone/web-based support (n=3); and online delivery (n=1). All CBT (Amsberg et al., 2009; Ismail et al., 2008; Snoek et al., 2001) and DAFNE interventions (Cooke et al., 2015; de Zoysa et al., 2014; George et al., 2008) were delivered F2F and therefore cannot be compared by mode of delivery.

BGAT

Included BGAT studies assessed two F2F interventions (Cox et al., 2001; Schachinger et al., 2005) and one F2F plus web-based support (Rondags et al., 2016a; 2016b). Regarding HFS-Worry, there were conflicting findings between the two F2F interventions. Cox et al. (2001) found a significant difference in HFS-Worry from baseline to 6- and 12-month follow-up, with a small-medium effect size. Whereas, Schachinger (2005) found no sustainable reduction in FOH-worries when comparing a F2F intervention with control at follow-up. Comparatively, a F2F BGAT with web-based support had a borderline significant and significant reduction in worries related to FOH between baseline and follow-up, respectively, with small effect sizes (Rondags et al., 2016a; 2016b). Overall, findings suggest no clear differences between mode of delivery in efficacy of intervention.

Regarding FOH-related behaviours, both F2F and F2F with web-based support found mainly non-significant effects. One F2F BGAT found a significant difference

with a small effect size in HFS-Behaviour at 12-month follow-up, but not at 6-month follow-up (Schachinger et al., 2005). Similarly, a pilot and follow-up study of a F2F BGAT with web-based support found no significant changes in HFS-II Behaviour in either study (Rondags et al. 2016a; 2016b). Findings therefore suggest no discernible differences in outcomes between formats.

Duration

Various intervention lengths were analysed including relatively long- (≤15 hours; n=4), moderate- (6-10 hours; n=5) and brief-durations (3-3.5 hours; n=4). Three papers provided insufficient information on intervention duration and are therefore not discussed (Weinger & Jacobson, 2001; Linden et al., 2018; De Zoysa et al., 2014). All DAFNE interventions (Cooke et al., 2015; George et al., 2008) were prolonged interventions and therefore cannot be compared by length of delivery.

CBT

Included studies assessed CBT interventions which were prolonged in length (≤15 hours; Amsberg et al., 2009) and moderate in length (Ismail et al., 2008: 10 hours; Snoek et al., 2001: 6 hours). All three studies found no significant reduction in HFS-Worry. Therefore, there were no clear differences between levels of duration, indicating that length did not impact on efficacy of CBT.

Regarding FOH-related behaviours, one prolonged- (Amsberg et al., 2009) and one moderate-length intervention (Ismail et al., 2008) was included. Amsberg (2009) found a significant difference between CBT and a control group in HFS-Behaviour at 12-month follow-up (data not available to calculate effect size). However, it should be noted that this difference was not found at 6-month follow-up. Conversely, Ismail (2008) found no significant difference between a moderate length

CBT (plus MET) intervention and routine care on the behavioural subscale. Therefore, both levels of duration found majority non-significant effects indicating that length does not impact on intervention efficacy.

BGAT

There was one prolonged BGAT intervention lasting 16-hours (Schachinger et al., 2005) and two moderate length interventions lasting 6-10 hours (Cox et al., 2001; Rondags et al., 2016a; 2016b). The prolonged intervention found no significant reduction in HFS-Worry (Schachinger et al., 2005). In comparison, both moderate length interventions significantly reduced worries at follow-up. A pilot and follow-up study of a moderate length BGAT group found a borderline significant and significant reduction in worries related to FOH between baseline and follow-up, respectively (Rondags et al., 2016a; 2016b). Both had small effect sizes. Similarly, Cox (2001) found a significant reduction with a small-medium effect size in HFS-Worry scores from baseline to 6- and 12-month follow-up. This indicates a pattern whereby moderate length interventions were more effective in reducing HFS-Worry.

Conversely, neither of the moderate length BGATs which measured FOH-behaviour found a reduction on this outcome (Rondags et al., 2016a; 2016b). Similarly, the prolonged intervention found majority non-significant effects (Schachinger et al., 2005). Results therefore indicate that variations in length did not influence intervention efficacy in reducing behavioural aspects of FOH.

Quality Assessment

The quality assessment of each study is shown in Table 7, of which seven studies obtained a “weak” quality rating, four obtained a “moderate” rating and four obtained a “strong” rating. Common strengths included the use of valid and reliable data collection methods, clear descriptions of the randomisation procedure, control for confounders (due to no significant differences between groups at baseline or adjustment for baseline differences), and clarity on number of drop-outs and reasons for drop-out. Common areas of weakness included lack of information on blinding procedures and lack of data on numbers of potential participants approached to indicate selection bias. It is worth noting that the majority of studies scored as “weak” were pre-test post-test (within-subjects) designs, where double blinding is not a routine procedure. Therefore the rating on the blinding criteria may have skewed the overall ranking. To address this, an extra column was added, reporting the overall quality excluding the blinding criteria. This showed that of the seven studies initially rated as “weak”, six then obtained a “moderate” rating and one remained “weak”.

Table 7

Quality Assessment

First Author, Year	Selection Bias	Study Design	Confounders	Blinding	Data Collection Method	Withdrawals and Dropouts	Overall Quality Rating	Overall Quality Rating Excluding Blinding
Amsberg, 2009	Weak	Strong	Strong	Moderate	Strong	Moderate	Moderate	Moderate
Broers, 2005	Weak	Weak	Strong	Moderate	Strong	Strong	Weak	Weak
Cooke, 2015	Moderate	Moderate	Weak	Weak	Strong	Strong	Weak	Moderate
Cox, 2001	Moderate	Moderate	Weak	Weak	Strong	Moderate	Weak	Moderate
De Zoysa, 2014	Weak	Moderate	Weak	Weak	Strong	Strong	Weak	Weak
George, 2008	Moderate	Strong	Strong	Moderate	Strong	Strong	Strong	Strong
Ismail, 2008	Moderate	Strong	Strong	Weak	Strong	Moderate	Moderate	Strong
Linden, 2018	Moderate	Strong	Strong	Moderate	Strong	Moderate	Strong	Strong
Little, 2014	Strong	Strong	Strong	Moderate	Strong	Strong	Strong	Strong
Little, 2018	Strong	Strong	Strong	Moderate	Strong	Strong	Strong	Strong
Rondags, 2016a	Moderate	Strong	Strong	Weak	Strong	Strong	Moderate	Strong
Rondags, 2016b	Moderate	Moderate	Weak	Weak	Strong	Strong	Weak	Moderate
Schachinger, 2005	Weak	Strong	Strong	Moderate	Strong	Strong	Moderate	Moderate
Snoek, 2001	Moderate	Weak	Moderate	Weak	Strong	Strong	Weak	Moderate
Weinger, 2001	Moderate	Moderate	Weak	Weak	Strong	Weak	Weak	Moderate

Note: Overall quality rating: ‘Strong’ = 0 weak ratings; ‘Moderate’ = 1 weak rating; ‘Weak’ = ≥2 weak ratings

Discussion

This review aimed to systematically review literature examining the effectiveness of psychological and educational interventions on worries and behaviours associated with FOH.

Summary of Findings

Intervention Models

Included studies investigated the impact of CBT, BGAT and DAFNE on FOH. There were mixed findings on the impact of CBT, with predominantly non-significant effects on FOH worries and behaviours (Amsberg et al., 2009; Ismail et al., 2008; Snoek et al., 2001). Amsberg et al. (2009) found a significant reduction in FOH-behaviours, however, this should be interpreted with caution as it was found at 12-month, but not at 6-month follow-up and may be the result of familywise error. Overall, it is difficult to interpret the impact of CBT on FOH due to the limited number of studies. However, findings of those studies which have taken place suggest effects are limited.

Following BGAT interventions, FOH-worries reduced in two interventions with small to medium effect sizes (Rondags et al., 2016a; 2016b; Cox et al., 2001). There were less consistent effects for FOH-behaviours, with only one study finding a significant reduction with a small effect size (Schachinger, 2005). Overall, findings indicate that BGAT is a promising intervention as most studies found a significant effect on some aspect of FOH. However, inconsistencies between studies indicate that further research is needed.

Studies investigating DAFNE suggest no long-term impacts on FOH worries or behaviours. Studies found either no significant effect of DAFNE on FOH-worries (De Zoysa et al., 2014; George et al., 2008) or a small effect which was not sustained at follow-up (Cooke et al., 2015). Two DAFNE studies measured HFS-Behaviour with both finding no significant reduction on this outcome (De Zoysa et al., 2014; George et al., 2008).

Two papers investigated the impact of motivational enhancement strategies on FOH (Ismail et al., 2008; De Zoysa et al., 2014). Both found no significant reduction in HFS-II Worry or Behaviour. Overall, it is difficult to infer conclusions as results are limited however, findings tentatively suggest that MET strategies do not lead to significant reductions in FOH.

Interventions which were most effective in reducing FOH were those that were delivered alongside 1:1 medical appointments or provision of diabetes technology. One intervention was a structured educational programme on hypoglycaemia management and BG monitoring (Little et al., 2014; 2018), and a second was an education group delivered alongside 4-5 months of individual medical/educational support (Weinger & Jacobson, 2001). Both found significant effect sizes with large reductions in worry scores. One also found significant reductions in FOH-behaviours with small to medium effect sizes (Little, 2014; 2018). Conversely, an intervention providing educational online support for pregnant women with T1D did not impact on FOH (Linden et al., 2018). Overall, findings suggest that educational group interventions may provide an additive effect to medical treatment and diabetes technology.

Intervention Format

Findings indicated there were no significant differences between intervention formats on FOH. CBT delivered in groups (Snoek et al., 2001), individually (Ismail et al., 2008) and group plus 1:1 support (Amsberg et al., 2009), each had no significant impact on FOH-worries. Reductions in behaviours were also mostly non-significant. A study comparing different BGAT formats corroborate this finding. Broers et al. (2005) found no significant difference between individual and group BGAT in reducing FOH-worries. Therefore, findings suggest that intervention format did not impact efficacy of educational or psychological interventions in reducing FOH.

Delivery Mode

Interventions had various modes of delivery such as F2F, F2F plus telephone/web-based support, and online delivery. All CBT and DAFNE courses were delivered F2F and were not compared by delivery mode. BGAT interventions were delivered either F2F (Cox et al., 2001; Schachinger et al., 2005), or F2F plus web-based support (Rondags et al., 2016a; 2016b). Both delivery modes were found to reduce FOH-worries with small-medium effect sizes, and no discernable differences. Regarding FOH-related behaviours, both F2F and F2F with web-based support found mainly non-significant effects. Therefore, results indicate there were no differences in BGAT treatment effectiveness by delivery mode.

Duration

Various intervention lengths were analysed including relatively long- (≤15 hours), moderate- (6-10 hours) and brief-durations (3-3.5 hours). CBT interventions were either prolonged (n=1) or moderate in length (n=2). Both levels of duration

found majority non-significant effects in reducing FOH-worries and behaviour, suggesting that length did not impact on efficacy of CBT.

Similarly, BGAT interventions were either prolonged (n=1) or moderate in length (n=2). There was a difference in effectiveness as two moderate-length interventions significantly reduced worries at follow-up, whereas a longer course found no reduction. Conversely, both prolonged- and moderate-length BGATs had majority non-significant effects for FOH-behaviours. Findings indicate a pattern whereby moderate-length interventions were more effective in reducing worry. However, as research was limited to a small number of interventions, these findings should be interpreted with caution.

Findings in Relation to Existing Evidence and Theory

In the current review evidence emerged to suggest that psychological and educational interventions have a limited impact in reducing FOH-worries and behaviour. Those that were significant tended to have small effect sizes or effects which were not sustainable in the longer term.

Included studies suggested tentative support for the efficacy of BGAT in reducing FOH worry and behaviours. BGAT aims to support participants to better detect internal cues to identify and respond to extreme BG levels. Anderbro (2015) found that fear of anxiety symptoms was the psychological factor most strongly associated with FOH. The authors consider that because anxiety symptoms overlap to a large extent with autonomic hypoglycaemia symptoms, people with T1D may misinterpret anxiety symptoms to be those of hypoglycaemia. By supporting individuals to become more aware of their bodily sensations, and better able to

discriminate between symptoms of hypoglycaemia and those of anxiety, BGAT may support individuals to reduce misinterpretation of anxiety symptoms.

The current review also found that CBT and DAFNE were less effective in reducing FOH. This may be explained by the content of these interventions not targeting the underlying mechanisms of FOH. A discrepancy has been observed between actual risk of hypoglycaemia and level of fear in people with T1D (Anderbro et al., 2015; Irvine et al., 1992). Some adults experience high fear which is disproportionate to their low risk of hypoglycaemia (and have high trait and general anxiety), whereas others have low fear despite a higher risk (and low trait and general anxiety). These findings have implications for the types of interventions appropriate for different subgroups of people with T1D. Those with high risk should first receive educational and technological interventions aimed at reducing the occurrence of severe hypoglycaemia (e.g. DAFNE; Choudhary et al., 2015). Alternatively, those with high fear but low risk may benefit more from interventions to reduce anxiety (e.g. CBT, ACT; Vallis et al., 2014). This may explain why DAFNE and CBT were less effective with certain groups of people if interventions were not targeting the underlying factors contributing to FOH. Further research is required to explore this association.

Furthermore, CBT may have been less effective because it aims to alleviate distress by targeting maladaptive cognitions and behaviours (Beck, 2011). Whilst effective in improving anxiety where health fears are irrational (Taylor et al., 2005), it can be less effective in reducing anxiety when thoughts are more realistic. Therefore, challenging these inner experiences can have limited effectiveness for people with long-term health conditions, as worries are often linked to the possibility of realistic

consequences (e.g. fear of having hypoglycaemia) (Hofmann et al., 2010). In line with this dilemma, CBT has evolved and a "third wave" of CBT interventions (e.g. ACT and MBIs) aim to target individuals' relationships with their thoughts rather than thought content (Hayes & Hofmann, 2017). MBIs for example, have been found to have positive effects for people with physical health conditions (i.e. cancer, fibromyalgia, epilepsy, heart disease, tinnitus, acquired brain injury), on outcomes such as pain acceptance, coping and depressive symptoms (Toivonen et al., 2017). This may indicate how changing the way an individual relates to feared cognitions using third-wave approaches may be helpful for people with long-term health conditions (Hofmann et al., 2010).

Overall, findings indicated no clear differences in intervention effectiveness on FOH worries or behaviours by delivery mode. BGAT interventions were delivered either F2F or F2F with web-based support, with no clear differences in outcome. The review did not include web-based BGAT which would have been interesting, particularly as web-based interventions have a growing literature base (Mehta et al., 2019) and offer a low-cost alternative to F2F delivery. There is some evidence to suggest that online BGAT may be effective in reducing FOH (Cox, 2008). Results showed that 'Improved Functioning Score' (a composite score of FOH and diabetes knowledge) increased for participants after engaging in online BGAT. Further research is required in this area to explore web-based interventions as these are economical alternatives to F2F delivery.

Findings indicated no significant differences in FOH between prolonged or moderate durations in CBT. However, regarding BGAT studies, there was some preliminary evidence to suggest that moderate-length BGAT was more effective in

reducing worries than prolonged-length. However, this should be interpreted tentatively owing to low number of interventions investigated (n=3). Generally, findings corroborate a study which found similar treatment recovery rates regardless of treatment duration across 50 psychological services in the UK for domains of subjective well-being, functioning and risk (Stiles et al., 2015). This has practical implications as it counters the 'dose-effect' relationship whereby more therapeutic support equates to better psychological outcomes.

Evaluation of the Current Review

This review had several strengths. The search strategy was purposefully broad to ensure a comprehensive review of the literature. To reduce publication bias, citation chaining was conducted and authors of several protocols were contacted to request unpublished manuscripts of the completed study. The use of a second reviewer in the screening and quality assessment phase minimised the risk of methodological errors and researcher bias. Furthermore, a fairer comparison of treatment effects between studies with varied sample sizes was ensured through the use of small sample bias-correction.

There are also several weaknesses of the review. A common criticism of narrative synthesis as an approach is that conclusions are largely subject to the author's interpretation which may be biased in favour of pre-determined views or expectations (Campbell et al., 2018). Furthermore, comparison of findings within each intervention group (CBT, BGAT, DAFNE) were limited by the heterogeneity of delivery modality. The content of these interventions differed even in those delivering the same model which limits study generalisability. Despite including a broad search strategy there were few papers investigating DAFNE and no papers investigating

ACT or mindfulness. This reflects a deficit in the wider literature but also indicates that the conclusions drawn may be limited.

Evaluation of the Included Studies

The majority of included studies were graded as either moderate (n=7) or strong (n=6) after the 'blinding' criterion was removed. Common strengths included the use of valid and reliable data collection methods, clear descriptions of the randomisation procedure and control for confounders. Psychometric evaluation of the measures indicates that (1) the HFS has high construct validity, internal consistency and test-retest stability (Cox et al., 2001 et al., 1987); (2) the HFS-II has good internal, test-retest reliability as well as convergent validity (Gonder-Frederick et al., 2011); (3) the SWE-HFS has high content validity and convergent validity (Anderbro et al., 2008). Another common strength was that studies were clear and transparent in treatment engagement and completion rates. It is important to understand participants' adherence to the intervention, so that the adequate 'dose' of therapy to result in psychological benefit can be evaluated, as well as establishing acceptability and feasibility of interventions.

However, there were also limitations within studies. Most studies were conducted with primarily White European participants with often higher educational levels reported. Higher educational levels have been negatively correlated with FOH (Gonder-Frederick et al., 2011). Regional differences in FOH have also been found with lower levels of FOH and utilisation of healthcare resources in Northern Europe and Canada compared with South East Asia (Khunti et al., 2017). Further research is therefore required with inclusion of diverse samples to enhance generalisability. Additionally, two studies included participants with T2D which may have

contaminated results as evidence suggests differences in behavioural responses to FOH between T1D and T2D (Khunti et al., 2017).

The most effective interventions were those that offered educational or psychological groups alongside medical support or provision of new diabetes technology (Little et al., 2014; 2018; Weinger & Jacobson, 2001). While such interventions reflect realistic clinical practice, the combination of psychoeducational groups with other treatments made it difficult to draw firm conclusions on the unique contribution of the psychological/educational interventions. Furthermore, despite the use of validated measures, the SWE-HFS measures experiences of 'aloneness' as an additional construct to worries and behaviours (Anderbro et al., 2008). There is therefore some inconsistency in how FOH was operationalised and this may have impacted on comparability of studies. Most papers also did not provide clear descriptions of the interventions and whether FOH was explicitly targeted in therapy. This is important as two case studies have found that a participant's FOH significantly reduced when CBT was adapted to target FOH specifically (Boyle et al., 2004; O'Donnell et al., 2019). Regarding the analysis, several studies may have been at risk of familywise error as they measured FOH at multiple follow-up points. For example, two papers found significant effects at 12-month, but not at 6-month follow-up (Amsberg et al., 2009; Schachinger et al., 2005). As there were multiple opportunities for the hypothesis to be tested, there was a higher probability of making a type I error.

Conclusions and Recommendations

In line with similar previous systematic reviews (Wild et al. 2006; Martyn Nemeth, 2016), findings indicated that current educational and psychological interventions have limited effectiveness on worries and behaviours associated with

FOH. The most effective group of interventions were BGAT and interventions delivered alongside additional medical and technological support. There were no clear differences in intervention efficacy by format, mode of delivery or duration.

Findings imply that novel approaches to target FOH should be developed and tested. As BGAT was the most promising model, a direction for future interventions may be to focus on increasing patient awareness of bodily sensations to reduce over-interpretation of perceived hypoglycaemia symptoms. It also indicates that further research is necessary in exploring third-wave approaches (e.g. ACT and mindfulness) which considers the mind-body connection. These findings have clinical practice implications, that generally educational and psychological interventions may have an additive effect to medical treatment and diabetes technology.

Additionally, as many studies were pilots, future research could include RCTs or patient preference trials to improve the quality of research in this area and overcome methodological issues associated with pilots (e.g. no randomisation or blinding). Several studies in the review were also limited as they did not measure the behavioural outcome of FOH and therefore it is difficult to draw conclusions on this aspect of the construct. A recommendation is for future studies examining FOH to use both worry and behaviour subscales to facilitate comparison.

III. Development and pilot testing of an online mindfulness-based intervention for improving fear of hypoglycaemia, well-being and self-management behaviours in adults with Type 1 diabetes.

Abstract

There is preliminary evidence to suggest that mindfulness is associated with reduced fear of hypoglycaemia (FOH) in people with T1D. This project examined the preliminary effectiveness of an online mindfulness-based intervention (MBI) on FOH, as well as on well-being and diabetes self-management behaviours. Acceptability and feasibility of the MBI were also investigated. A single-case experimental design (SCED) was adopted using an ABa multiple-baseline design. Six participants were recruited from two NHS diabetes care services, or via diabetes support groups. Participants were randomised to a baseline length (1-3 weeks), before accessing a four-week online MBI, followed by a one-month follow-up. Idiographic measures were recorded daily. Standardised diabetes-specific measures of FOH, well-being and self-management behaviours, and a trait mindfulness measure were completed at pre-, post-intervention and follow-up. A process measure of state mindfulness was completed weekly during the intervention phase. Idiographic data were analysed using visual and Tau-U analysis. Standardised and process measures were analysed using reliable and clinically significant change. Findings suggested that the intervention was acceptable for people with T1D. FOH-worries reduced for the majority (n=4), and FOH-behaviours reduced for half of participants at post-intervention and follow-up compared to baseline. Diabetes-specific well-being improved for most participants (n=5). Self-management behaviours did not significantly improve. Half of participants improved in state mindfulness and half improved in one facet of trait mindfulness: 'non-judging of inner experiences'. The findings support the acceptability of an online MBI for adults with T1D and its preliminary effectiveness on reducing FOH and improving diabetes-related well-being. Study limitations and recommendations for future research are discussed.

Introduction

Diabetes mellitus is a chronic health condition characterised by high glucose levels in the blood and occurs when the body produces little or no insulin, or when the body does not respond to insulin that is produced (Atkinson et al., 2014). Type 1 (T1D) and type 2 (T2D) diabetes are the most prevalent forms with T1D affecting 8% of cases in the UK, and T2D affecting 90% (Diabetes UK, 2020). Common symptoms of T1D are extreme thirst, weight loss, urinating more than usual and tiredness (Diabetes UK, 2020).

The NHS England Five Year Forward View for Mental Health (2015) highlighted as a priority the importance of integrating mental health and physical health approaches, acknowledging the impact of psychological difficulties on the health of people living with diabetes. However, many NHS diabetes services do not include access to diabetes-specific psychological support due to funding limitations (Trigwell et al., 2008). It is important to target this gap by developing tailored interventions which are financially feasible and accessible. Web-based therapies represent an economical approach with the potential to enhance availability of psychological input. A brief online mindfulness-based intervention (MBI) was developed in this study, to support people with T1D with fear of hypoglycaemia and other diabetes-related outcomes. Accessibility and feasibility was assessed as well as preliminary effectiveness.

Impact of Hypoglycaemia

Hypoglycaemia is the most common adverse event associated with insulin treatment in T1D and occurs when blood glucose (BG) levels drop too low (BG level <4.0mmol/l; Diabetes UK, 2021). Hypoglycaemic symptoms can be categorised as

neurogenic, caused by activation of the autonomic nervous system (e.g. sweating, shakiness) and neuroglycopenic, caused by glucose deprivation in the brain (e.g. confusion, speech/coordination difficulties; Frier, 1993). Hypoglycaemia can result in negative cognitive, social and psychological consequences for the individual (Hendrieckx et al., 2019). Hypoglycaemia unawareness occurs when an individual with diabetes is frequently unable to detect the warning signs of hypoglycaemia and their judgement to self-treat is reduced (Cryer et al., 2003).

Fear of hypoglycaemia (FOH) is a common response to the risk of hypoglycaemia. It can be conceptualised as worries related to having a hypoglycaemic episode (e.g. fearing embarrassment in a social situation) and engaging in behaviours to prevent a hypoglycaemic episode (e.g. snacking before bed; Davis & Alonso, 2004). Wild et al. (2007) suggest an over-compensation theory whereby high levels of hypoglycaemia worry lead to "over-compensating" management behaviours intended to maintain high BG levels. Whilst these behaviours may prevent hypoglycaemic episodes, over time they can lead to sustained high BG levels which can result in long-term microvascular and macrovascular complications (Diabetes UK, 2020). It has been postulated that approximately 1 in 7 people with type 1 diabetes experience FOH (Diabetes UK, n.d.) although this number may be higher in groups of people who have a higher risk of hypoglycaemia or who have impaired hypoglycaemia awareness (Costea et al. 1993; Wild et al., 2007).

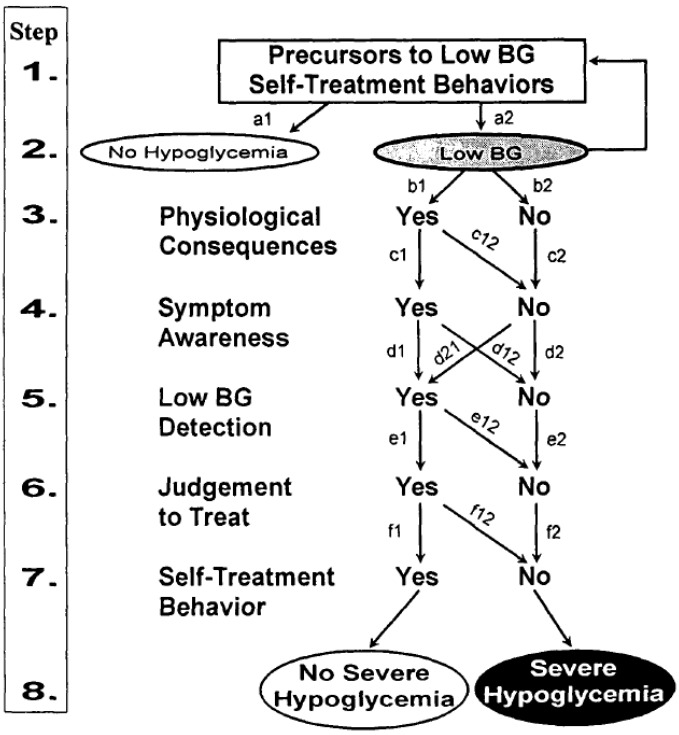
Risk of Hypoglycaemia

The biopsychobehavioural model of risk (Gonder-Frederick et al., 1997; Figure 2) is a theoretical framework which describes the biological, psychological and behavioural processes that interact to determine risk of hypoglycaemia. It is based on

somatic self-regulation theory (Meyer et al., 1985, Pennebaker, 1982) and emphasises the role of symptom *perception* and *attribution* in determining self-treatment behaviour. The model posits that when behavioural and/or biological precursors (step 1) lead to low BG (step 2), physiological responses either occur or do not occur (step 3). If physiological responses occur and cause symptoms, a person may or may not become aware of them (step 4) and even if symptom awareness does occur, detection of hypoglycaemia may or may not occur (step 5). If hypoglycaemia is recognised, then a patient may or may not make appropriate decisions (step 6). Additionally, even if they do decide to take action, behavioural implementation may or may not occur (step 7). Furthermore, the model assumes that FOH can influence risk at several steps of the model. Notably, FOH can influence hypoglycaemia symptom awareness and low BG detection (steps 4 and 5). For example, patients who worry more have more difficulty distinguishing symptoms of anxiety from those caused by low BG, and may overtreat which can lead to an excess of glucose in the bloodstream, known as 'hyperglycaemia' (steps 6 and 7) (Hepburn et al., 1994).

Figure 2

The Biopsychobehavioural Model of Risk



Underlying Mechanisms of FOH

There are several proposed underlying mechanisms for FOH with differences found between men and women (Hendrieckx et al., 2019). For women, FOH is associated with an over-interpretation of hypoglycaemic symptoms (Anderbro et al., 2010). This can be exacerbated by difficulty in distinguishing between the symptoms of hypoglycaemia and symptoms of anxiety as both include physiological sensations such as shaking, sweating, nausea and mental confusion (Green et al., 2000). Feeling anxious and experiencing anxiety-related sensations may increase over-interpretation of hypoglycaemic levels at the point of detecting symptoms (step 5).

For men, FOH is associated with hypoglycemia unawareness and frequency of hypoglycaemia (Anderbro et al., 2010). Thus, in line with the biopsychobehavioual

model, those who struggle to detect and respond to (steps 5 and 6) early symptomatic warning signs of hypoglycaemia are at a higher risk of having a hypoglycaemic episode. Similarly, risk may appear higher for those who have a history of frequent hypoglycaemic episodes. In line with Padesky's formula for anxiety, higher perceived risk can understandably lead to increased anxiety (Greenberger & Padesky, 2015).

Educational Interventions

Diabetes educational interventions may support people with FOH. Blood Glucose Awareness Training (BGAT; Gonder-Frederick et al., 2000) was developed to support participants to better detect and respond to internal cues of low BG levels. BGAT has been found to improve BG estimation accuracy, detection of hypoglycaemia and hypoglycaemia awareness (Cox et al., 2006). It is also one of the most promising interventions in reducing FOH-worries (Rondags, 2016a; 2016b; Cox, 2001) and behaviours (Schachinger, 2005) (see Systematic Review). This may be because BGAT targets the proposed underlying mechanisms of FOH by increasing hypoglycaemia awareness and enabling people to be more in tune with the early physical signs of hypoglycaemia, which in turn enables them to respond appropriately (e.g. taking oral glucose).

Dose Adjustment for Normal Eating (DAFNE; DAFNE Study Group, 2002) is another educational programme which teaches participants the necessary skills to administer the right amount of insulin based on carbohydrate intake. The course has been found to significantly reduce the proportion of participants experiencing severe hypoglycaemia (Elliott et al., 2014) and has been demonstrated to improve diabetes-specific quality of life (QoL) (DAFNE Study Group, 2002). Research also suggests the course can result in improved self-management behaviours (Murphy et al., 2011),

and increased well-being at one-year follow-up (Hopkins et al., 2012). However, despite this, literature suggests this intervention has no long-term impacts on FOH-related worries or behaviour (Cooke, 2015; De Zoysa, 2014; George, 2008).

Technological Interventions

In addition to educational programmes, over the past three decades, newer BG and insulin infusion technologies have been developed to support patients to manage their BG levels and reduce the risk of hypoglycaemia e.g. continuous glucose monitoring (CGM) systems and continuous subcutaneous insulin infusion (CSII) pumps. Research has found such technologies can reduce the number of hypoglycaemic episodes (e.g. Davey et al., 2012) and shorten hypoglycaemic episodes (Battelino et al., 2011). However, despite improved BG control, self-management behaviours and well-being, as well as a reduction in the risk of developing hypoglycaemia, FOH has not been found to reduce significantly (Adams et al., 2018; Boaz et al., 2009; Davey et al., 2012; Hermanides et al., 2011; Lawton et al., 2018).

Psychological Interventions

Psychological interventions have been adapted for use in diabetes populations including Cognitive Behavioural Therapy (CBT) and third-wave models such as Acceptance and Commitment Therapy (ACT; Hayes, 1999). CBT is a widely used psychological approach which aims to alleviate distress by reframing maladaptive cognitions and changing behaviours using behavioural experiments (Beck, 2011). A recent meta-analysis has shown that CBT can lead to improvements in diabetes self-management and emotional well-being, although effects tend to reduce in the medium- and long-term (Uchendu & Blake, 2017). However, CBT has not been found

to be effective in reducing FOH-worries and behaviours (Amsberg, 2009; Ismail, 2008; Snoek, 2001). Notably, case studies which have investigated CBT focusing specifically on challenging FOH-worries (e.g. “I will have a seizure if my blood sugar is low”) have had more promising findings in reducing FOH (Boyle et al., 2004; O’Donnell et al., 2019).

There is growing literature on the use of ACT in diabetes. This is a “third wave” CBT model which is increasingly being used clinically to support individuals with health conditions. It moves away from attempts to change negative thoughts or emotions, and instead aims to change the way an individual relates to difficult internal experiences (i.e. reducing experiential avoidance using mindfulness, thought defusion and encouraging valued living). Literature suggests that ACT can lead to improvements in self-management, glycaemic control and anxiety in people with T2D (Fayazbakhsh & Mansouri, 2019; Ghasemlou et al., 2018; Gregg et al., 2007). There is less research on people with T1D who have more intensive insulin regimes and therefore more self-management requirements. However, two recent pilot studies found that web-based ACT showed preliminary effectiveness in improving diabetes self-management and well-being outcomes (Somaini, 2021; Logeswaran, 2020). There have been no studies which have explored the impact of ACT on FOH. This is an important avenue for future research.

Need for Further Research

The systematic review presented in this thesis found that current educational and psychological interventions have limited effectiveness in reducing worries and behaviours associated with FOH. BGAT was the most promising intervention. This may be because it targets the proposed underlying mechanisms of FOH, namely (1)

BGAT increases hypoglycaemia awareness and thus reduces risk of hypoglycaemia, and (2) it supports people to be more in tune with their physical sensations and therefore learn to better discriminate between symptoms of anxiety and those of hypoglycaemia, thus reducing misinterpretation of anxiety symptoms. However, despite promising findings, effect sizes were small-medium at best and there were inconsistencies across studies.

Mindfulness-based Interventions

Evidence suggests mindfulness-based interventions (MBIs) may be a promising avenue for future research to improve outcomes for people with T1D. Mindfulness can be defined as "the self-regulation of one's attention focusing on direct experience, while adopting a curious, open, and accepting attitude toward these experiences" (Bishop et al., 2004). Therefore, rather than challenging thoughts, the individual learns to allow for and accept unpleasant internal experiences. The concept of 'mindfulness' is informed by the 'inner science' developed by centuries of Buddhist traditions (Cabezón, 2003).

Whilst there are many conceptualisations of the theoretical underpinnings of mindfulness, there are two components which are commonly described: (1) the use of *attention* to monitor one's present moment experiences, and (2) cultivating an orientation of *acceptance* to these experiences (Bishop et al., 2004). Monitor and Acceptance Theory (Lindsay & Creswell, 2017) posit that these two mechanisms of attention monitoring and acceptance lead to positive cognitive, emotional and physical outcomes. For example, attention monitoring can explain how mindfulness improves cognitive functioning (e.g. selective attention, working memory), with research showing that increased mindfulness leads to reduced cognitive reactivity and

reduced thought suppression (Keyworth et al., 2014; Raes et al., 2009). This process can however, increase emotional reactivity as the individual starts to pay attention to negative thoughts and emotions. With practice, the second mechanism of 'accepting' difficult internal experiences can develop and reduce emotional reactivity as well as improve affect regulation (Lindsay & Creswell, 2017).

MBIs have been found to improve psychological and physical outcomes among people with T1D and T2D. Studies have shown MBIs to improve emotional well-being (i.e. reducing anxiety, depression) when compared with a control (Armani Kian et al., 2018; Keyworth et al., 2014; Rosenzweig et al., 2007; Tovote et al., 2013, 2014; van Son et al., 2013; Whitebird et al., 2018). Increased mindfulness has also improved behavioural outcomes such as less emotional and environment-influenced eating patterns (Tak et al., 2015). However, there are mixed findings on the impact of MBIs in improving glycaemic control, with some literature suggesting improvements (Armani Kian et al., 2018; Rosenzweig et al., 2007), and others finding no significant effects (Tovote et al., 2013, 2014; van Son et al., 2013).

Web-based therapies, such as online MBIs, represent an economical platform to deliver psychological interventions. A recent meta-analysis on the effectiveness of online MBIs reviewed 15 randomised controlled trials (RCTs) and found online formats have significant small to moderate effects on mental health outcomes (depression, anxiety, stress, well-being) (Spijkerman et al., 2016).

Mindfulness and FOH

Research examining the impact of MBIs on FOH in T1D is limited. However, a cross-sectional study by Aalders et al. (2018) found that lower mindful parenting was related to greater FOH in parents of children with T1D. A narrative review of the

effects of mindfulness on diabetes outcomes demonstrated that increased mindfulness reduced anxiety, worry and depression (Medina et al., 2017) which are factors associated with FOH (Nefs et al., 2015).

Theoretically, it may be argued that adopting a mindfulness approach can reduce FOH by supporting individuals to cultivate a stance of acceptance to unwanted bodily sensations, thoughts and emotions. This approach differs to CBT which aims to reframe negative thoughts. Challenging these inner experiences can have limited effectiveness for some individuals as thoughts are often linked to the possibility of realistic consequences e.g. experiencing hypoglycaemia (Hofmann et al., 2010). It is hypothesised that, by reducing thought suppression and cultivating acceptance of FOH-related worries, the negative thoughts and associated emotions can paradoxically dissipate.

Mindfulness may also target the underlying mechanisms of FOH in line with the biopsychobehavioural model by supporting individuals with symptom *detection* and *attribution* (Figure 2). As mindfulness increases present moment focus of bodily sensations, it may help individuals to distinguish between neutral bodily sensations, those which are indicative of low BG levels, and those of anxiety. Despite there being similarities between hypoglycaemia and anxiety symptoms, there are also differences which can be considered. For example, hypoglycaemia does not cause a person to have dry mouth, tightness or pain in the chest, muscle tension, or frequent urination (Green et al., 2000). Learning to distinguish between symptoms of hypoglycaemia and anxiety may reduce over-interpretation of bodily sensations.

Mindfulness and Long-term Health Conditions

There are connections between this area of research and those which are investigating MBI treatment outcomes in other physical health conditions. Toivonen et al. (2017) conducted a systematic review of 16 studies analysing the impact of web-based MBIs for people with cancer, chronic pain or fibromyalgia, irritable bowel syndrome (IBS), epilepsy, heart disease, tinnitus, and acquired brain injury. Findings showed that overall, most studies reported positive effects of MBIs compared with usual care on a variety of outcomes including pain acceptance, coping measures, and depressive symptoms. Furthermore, a systematic review investigating the effectiveness of MBIs for people with epilepsy, found preliminary evidence that these interventions reduce anxiety (Wood et al., 2017).

It may be useful to have treatments which are tailored to target specific aspects of a long-term health condition so that the intervention is pertinent to the experience of the condition e.g. cultivating acceptance and non-attachment to the experience of pain in fibromyalgia (Kozasa et al., 2012). In the current project, an online mindfulness course was adapted specifically for people with Type 1 diabetes to focus on areas of mindfulness associated with anxiety in diabetes e.g. mindful eating.

The Present Study

To date, there is only one cross-sectional study which has explored the relationship between FOH and mindfulness. This was explored in parents of children with T1D (Aalders et al., 2018). The present study aimed to investigate the preliminary effectiveness of a web-based MBI on FOH in adults with T1D.

The principal aim of the study was to investigate whether the MBI led to improvements in self-reported FOH. Secondary aims were to (1) investigate the

acceptability and feasibility of the MBI for use with adults with T1D; (2) investigate whether the MBI led to improvements in self-management behaviour and well-being.

The following hypotheses were proposed:

1. The online MBI will be feasible and acceptable for adults with T1D.
2. The MBI will lead to significant changes in idiographic data for FOH, well-being and diabetes self-management behaviours during the intervention and follow-up phases compared to baseline.
3. Scores on standard measures for FOH, well-being and diabetes self-management will be reliably different at post-intervention and follow-up, compared to baseline.
4. State mindfulness will increase during the intervention.

Method

Ethical approval was obtained from the Wales 3 NHS Research Ethics Committee and from the Research Ethics Committee at Royal Holloway University of London (Appendix B).

Design

A single-case experimental design (SCED) was adopted in the form of ABa multiple-baseline design. Participants were randomly allocated to baseline of either 1, 2 or 3 weeks in line with recommendations for a minimum of three baselines (Barlow et al., 2009; Kazdin, 2011; Kratochwill et al., 2010). “A” represented the baseline phase; “B” represented the intervention phase consisting of the four-week web-based mindfulness course; “a” was a four-week follow-up phase to monitor outcomes at post-intervention.

The independent variable was an online MBI which was developed with reference to published mindfulness texts (outlined below, under 'Intervention Development'), and through consultation with one of the project supervisors (Dr Michelle Taylor) and two clinical psychologists from diabetes services at Charing Cross Hospital (Dr Vicky McKechnie) and Barts NHS Trust (Dr Sonya Frearson). The dependent variables were FOH, well-being and diabetes self-management behaviours. Evaluation took place across three levels of measurement in accordance with Morley's (1996) assessment funnel: (1) standardised measures, (2) process measure, and (3) idiographic measures. Sociodemographic information and feedback on intervention feasibility and acceptability were also collected.

Participants

In total, nine participants (7 females, 2 males) completed all phases of the study. The first six people to complete the follow-up phase were analysed for inclusion in this thesis due to time constraints. Participants were recruited from NHS diabetes care services at Charing Cross Hospital (n=2) and Barts Health NHS Trust (n=2). A further five participants were recruited from diabetes support groups. The recruitment period was November 2021–January 2022.

Power

In SCED designs the number of participants is determined through the requirements of effect replication, that is a minimum of three effects replications across either participants, behaviours or settings are required to demonstrate experimental control (Horner et al., 2005). This study used replication across participants, therefore a minimum of three participants were needed to produce three effect demonstrations (Kratochwill et al., 2010). To consider these recommendations,

allowing for attrition and considering feasibility within the study time limits, the study aimed to recruit 6 participants.

Eligibility

All participants met the inclusion criteria of being aged 18 or over, being fluent in English, having a diagnosis of T1D for at least one year, and having access to the internet. They were also screened for experiencing FOH (measured using the worry subscale of the HFS-II; Gonder-Frederick et al., 2011) and having hypoglycaemia awareness (measured using The Gold Score; Gold et al., 1994).

Individuals were excluded if they did not meet the inclusion criteria. Further exclusion criteria included: diagnosis of a severe and enduring psychiatric disorder or significant cognitive impairment; accessing psychology therapy; having a history of severe hypoglycaemia due to rapid and unpredictable declines in BG levels; having FOH which meets diagnostic criteria for PTSD; having risk concerns to self or others; routinely practicing mindfulness (at least twice per week).

Recruitment

Participants were recruited via three channels; (1) diabetes care services at Charing Cross Hospital, (2) diabetes care services at Barts Health NHS Trust and (3) diabetes charity support groups.

Members of the Diabetes Care Team at Charing Cross Hospital identified patients in clinic who appeared to meet eligibility criteria and exhibited FOH based on patient self-report and clinician judgement. Patients were identified during multi-disciplinary team (MDT) reviews and new referrals on the waitlist for psychological support. The principal investigator (PI) attended a team meeting at the diabetes service to promote the project to the wider team. Two NHS project collaborators

(Consultant Endocrinologist and Clinical Psychologist) compiled a list of potentially eligible participants and sought consent from these patients to pass their contact details to the research team. A total of 9 eligible participants were identified with 5 recruited to the project.

Recruitment via Barts Health NHS Trust was conducted via an email advert (Appendix C) circulated by a project collaborator (Clinical Psychologist) to a mailing list of service users who had opted to receive service-user involvement opportunities (n=approximately 700). The advert was also placed in the service newsletter. Additionally, the PI attended an online pump support group to advertise the study to 5 attendees. Service-users who were interested in participating contacted the PI via email. A total of 5 participants were recruited through this service.

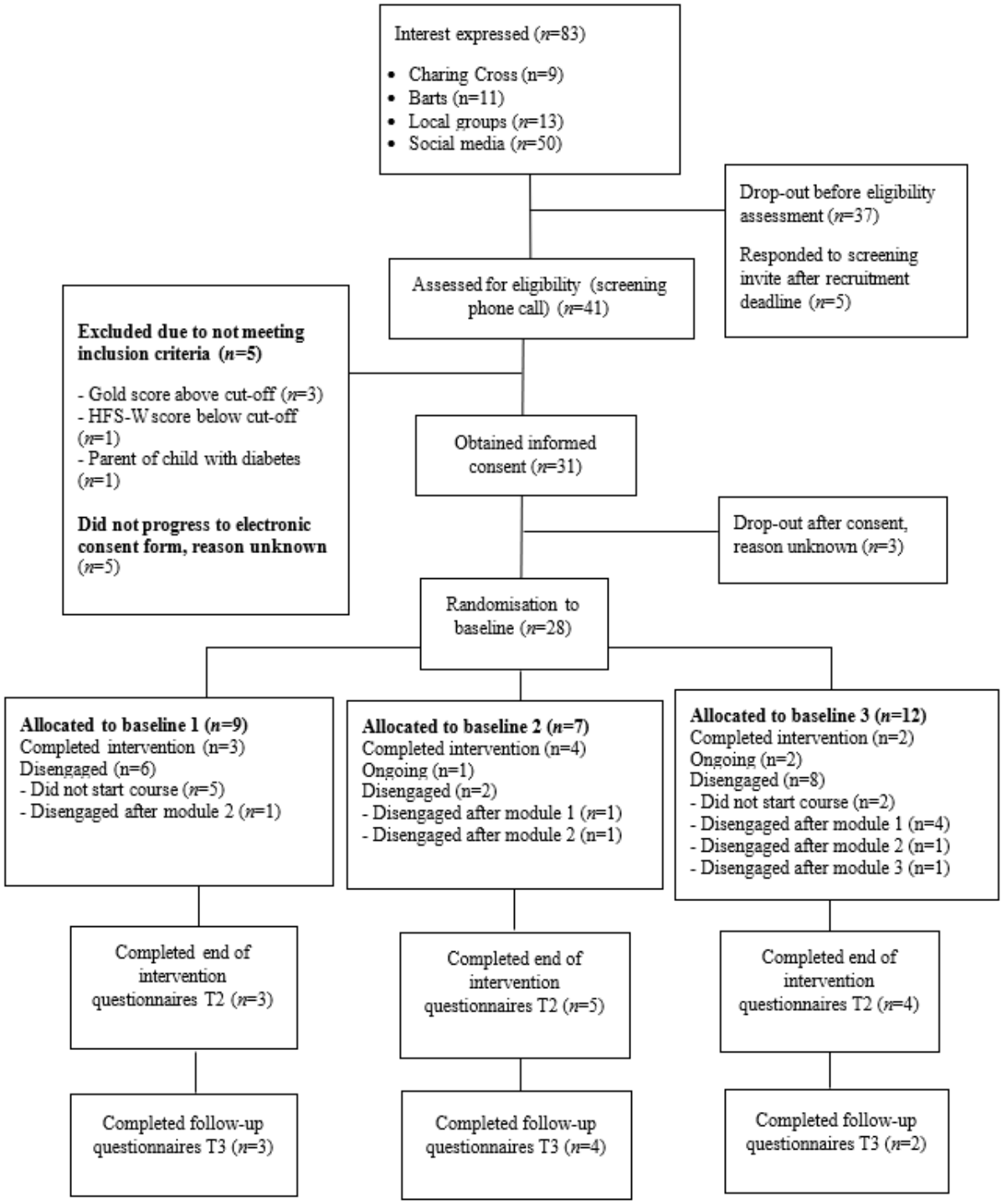
For recruitment via diabetes charities, 76 support groups were contacted and asked to promote the project to their members by email circulation of a recruitment poster (Appendix D), or by sharing the advert on their social media channels. Four groups agreed to forward the material to their members, a further four advertised on social media channels (Facebook group; charity website) and one advertised in their group newsletter. Service-users who were interested in participating contacted the PI via email. A total of 6 participants were recruited via diabetes support groups.

To supplement recruitment, from November 2021 the advertisement materials were posted on T1D Facebook groups based in the UK (e.g. *Type 1 Diabetes in Scotland*). A total of 12 people expressed interest to partake in the study through recruitment via social media.

In total, 83 people were sent an electronic copy of the Participant Information Form (Appendix E), out of whom 41 (49%) proceeded to arrange a screening phone call. Of those who attended screening, 5 (12%) were excluded due to not meeting eligibility criteria and 31 (76%) went on to provide electronic consent (Appendix F) to partake in the study. Twenty-eight completed the first set of measures and were allocated to a baseline phase. Figure 3 provides a description of the recruitment process.

Figure 3

Diagram Illustrating Participant Flow Through the Study

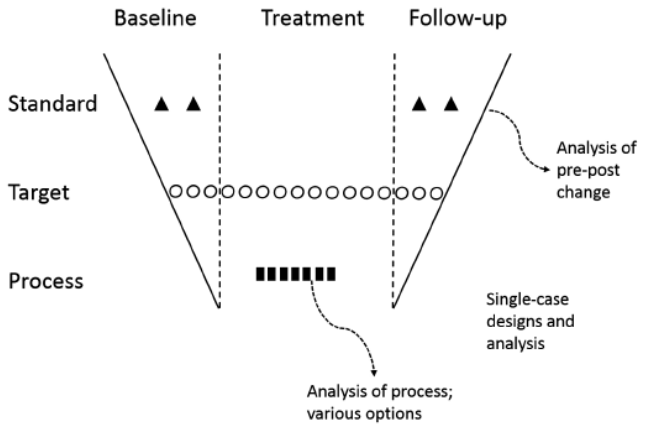


Measures

Six types of outcome measures were collected: socio-demographics, screening, idiographic, standardised, process and feedback. Psychological outcomes consisted of measures of FOH and well-being. Behavioural outcomes included diabetes self-management behaviours. The primary outcome (FOH) and secondary outcomes (well-being, self-management behaviours) were measured through standardised measures and idiographic visual analogue scales (VAS). Using both types of measurements for the same construct was chosen to enable better understanding of change at an individual level (through idiographic measures which are more sensitive to change) and in a wider context in comparison to population norms (through standardised measures). Idiographic, standardised and process measures were used in accordance with Morley's (1996) assessment funnel (Figure 4). All measures were completed online using electronic copies. Permission to use measures were requested and granted by authors, with licenses provided for use in the project.

Figure 4

Morley's (1996) SCED Assessment Funnel



Socio-demographics and clinical information

Sociodemographic and clinical information was collected at baseline including age, gender, ethnicity, diabetes duration, medication, complications and history of severe hypoglycaemia (Appendix G). The questionnaire was adapted from a tool used in previous research with a diabetic population (Taylor et al., 2019), and revised using feedback from NHS collaborators on the project.

Screening measures

The Gold score (Gold et al., 1994) is a 1-item measure commonly used in clinical practice and as a screening tool in diabetes research to assess whether participants feel they are able to recognise the warning signs of hypoglycaemia. It is a subjective rating on a scale from 1 (always) to 7 (never) in response to the question 'Do you know when your hypos are commencing?'. Individuals were required to have a score of ≤4, suggesting hypoglycaemia awareness.

The worry subscale of the Hypoglycaemia Fear Survey II (HFS-II; Gonder-Frederick et al., 2011 Appendix H) is an 18-item self-report measure of worries related to FOH in adults with T1D, describing concerns that respondents may have about hypoglycaemic episodes. Items are measured using 5-point Likert scales. The HFS-II has found good internal and test-retest reliability as well as convergent validity (Gonder-Frederick et al., 2011). Individuals were required to have a score of 3 or 4 on at least one of the HFS-W items, which indicates they experience FOH-related worry (Hajós et al., 2014).

Idiographic measures

Idiographic measures were developed to collect information on self-reported psychological and behavioural outcomes. Measures consisted of seven non-

standardised visual analogue scales (VAS) and one item asking for number of insulin injections in the past 24-hours (Appendix I). Participants were encouraged to complete idiographic measures as close to daily as possible. VAS are commonly used in SCEDs as they are simple and appropriate for repeated use to measure individual behaviours or subjective states. As they focus on singular variables of interest as opposed to constructs, they are assumed to have acceptable construct validity (Morley, 2017) and have known sensitivity to change within individuals across short periods of time (McCormack et al., 1988).

Outcomes included FOH-worries (To what extent have you been concerned or worried about the possibility of having an episode of hypoglycaemia?), FOH-behaviour (To what extent have you actively taken precautions to prevent hypoglycaemia in the past 24 hours?), well-being (To what extent have you felt low, stressed or anxious in the past 24 hours?) and four self-management behaviours including dietary adherence, blood glucose monitoring, medication adherence and exercise (e.g.To what extent did you follow your diet regime in the past 24 hours?). All scales were rated on a 0-10 score range (whereby 0= 'Not at all' and 10 ='Completely').

Standardised Measures

The HFS-II (Gonder-Frederick et al., 2011) is a revision of the Hypoglycaemia Fear Survey I (HFS-I; Cox et al., 1987) and includes 33 items across two subscales. It measures both behaviours (Behaviour subscale; HFS-B) and worries (Worry subscale; HSF-W) related to FOH in adults with T1D. The HFS-B has 15-items describing behaviours people may engage in to avoid hypoglycaemic episodes. The HFS-W includes 18-items describing concerns that respondents may have about

hypoglycaemic episodes. Items are measured using 5-point Likert scales. The HFS-II has found good internal and test-retest reliability as well as high construct and convergent validity (Gonder-Frederick et al., 2011).

The Well-being Questionnaire (W-BQ28; Speight et al., 2000; Appendix K) is a 28-item measure of diabetes-specific and general well-being developed for people with diabetes. Diabetes-specific items measure the cognitive impact of diabetes and diabetes self-management which includes depression, anxiety and positive well-being (e.g. 'Because of my diabetes I get depressed'). Items are scored on a 4-point Likert scale indicating how often each item applies to the respondent, ranging from 'not at all' (0) to 'all the time' (3). Speight & Bradley (2002) found the scale to have excellent internal validity for each subscale (alpha coefficients: 0.80-0.87); test-retest reliability (0.79) as well as construct validity and sensitivity to change.

The Diabetes Self-Management Questionnaire (DSMQ; Schmitt et al., 2013; Appendix L) is a 16-item measure assessing self-care activities associated with glycaemic control. The measure is composed of four subscales: 'Glucose Management', 'Dietary Control', 'Physical Activity' and 'Health-Care Use'. Items are scored on a 4-point Likert scale from 'applies to me very much' (3) to 'does not apply to me' (0). This measure has been found to have good internal consistency (0.84) and significant convergent correlations with parallel scales of self-management and HbA1c levels (Schmitt et al., 2013).

The Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006; Appendix J) is a 39-item scale which was used to gain an understanding of baseline trait mindfulness and explore intervention specific changes in mindfulness. It identifies five independent facets of mindfulness: observing, describing, acting with

awareness, non-judging of inner experience and non-reactivity to inner experience. Items are rated on a five-point scale ranging from 'Never or rarely true' (1) to 'Very often or always true' (5). The total score ranges from 39 to 195, with higher scores indicating greater mindfulness. The scale has demonstrated adequate to good internal consistency for all five facets (α = .75 – .91; Baer et al., 2006, 2008). Baer et al. (2006) have found the mindfulness facets were differentially correlated in expected ways with several other constructs and found the measure to have incremental validity in the prediction of psychological symptoms.

Process measure

The State Mindfulness Scale (SMS; Tanay & Bernstein, 2013; Appendix M) is a 21-item questionnaire which measures both mental (15 items) and physical (6 items) objects of state mindfulness. Respondents consider items within the context of the past 15 minutes e.g. 'I noticed emotions come and go'. Tanay & Bernstein (2013) demonstrated strong internal consistency (α = .90–.95) of the mental and physical factors, as well as high convergent, discriminant and construct validity. Furthermore, the scale has incremental sensitivity to change in state mindfulness over time. Among a mindfulness intervention group the measure demonstrated strong 1-week (mean r = .64, p < .01) and 2-week (mean r = .63, p < .01) test-retest reliability following weekly mindfulness meditation sessions (Tanay & Bernstein, 2013).

Feasibility and Acceptability

Feasibility and acceptability of the intervention was measured using the 'Client Satisfaction Questionnaire' (CSQ-8; Larsen et al., 1979), alongside additional items that aimed to obtain feedback on the user-friendliness and appropriateness of the intervention for the target population (Appendix N). The CSQ-8 is an 8-item self-

report measure of satisfaction with the service received. Each item is rated on a 4-point Likert scale with a total score range of 8-32. Higher scores indicate greater client satisfaction. The CSQ-8 has shown excellent reliability (α=.83-93) and good validity (*r*=.60-.80; Larsen et al., 1979). Feasibility was also assessed through recruitment and retention rates.

Intervention Development

The web-based MBI (Appendix O) was a 4-week modular intervention developed based on adaptations of mindfulness scripts from *'The mindful way through depression: Freeing yourself from chronic unhappiness'* (Teasdale & Segal, 2007) and '*Diabetes and well-being: managing the psychological and emotional challenges of diabetes types 1 and 2'* (Nash, 2013). Additionally, methods of building self-compassion based on Neff and Knox's (2016) approach was integrated into the script for Module 4. This was informed by the 'Turning Toward Difficult Emotions' guide for informal practice by Burch (2013). Each mindfulness exercise was preceded by brief psychoeducational material on the topic for the week. The project supervisor and NHS professionals from Charing Cross and Barts diabetes services reviewed the intervention materials and provided feedback to guide project development.

The intervention included four modules and was hosted on Qualtrics, a secure online platform widely used in psychology research, accessible from any electronic device. Each module included a new mindfulness exercise lasting 5-10 minutes which participants were encouraged to practice twice more over the week.

Module 1 provided an introduction to the concept of 'mindfulness', and the notion that developing a non-judgmental present moment awareness of difficult internal experiences (thoughts, emotions, sensations), can dissipate their strength.

Barriers to practicing mindfulness were also outlined, alongside proposed solutions. Participants were subsequently invited to practice a mindful breathing exercise. This involved attending to the movements of breath and gently pulling thoughts back to the task if they started to wander.

The focus of Module 2 was introducing participants to the body scan. Psychoeducational material at the start of the module outlined how paying attention to bodily sensations can indicate health difficulties such as hypoglycaemia however, concern about hypoglycaemia can lead to hypervigilance and misinterpreting otherwise normal bodily sensations. The exercise therefore focused on noticing ongoing bodily sensations in a non-judgemental manner and to reframe from labelling them with feared thoughts.

Module 3 focused on developing the skill of mindful eating. The psychoeducational material considered how eating can be a response to external and internal cues which can sometimes be unhelpful (e.g. FOH). The exercise encouraged participants to eat a piece of food mindfully and bring more purpose to the act of eating, rather than in response to an unhelpful cue.

Module 4 focused on mindfulness with difficult emotions. Participants were invited to think of a difficult recent situation in relation to diabetes. The exercise focused on cultivating mindful awareness of internal experiences the memory evoked, and to practice making room for any difficult emotions, thoughts and physical reactions.

Audios of mindfulness exercises were recorded by the PI. Exercises were followed by four questions to promote reflection on the experience, and the

transferability of the skill to day-to-day diabetes management. Tasks for each week were to practice the mindfulness exercise an additional two times and to practice being mindful in everyday life, including with aspects of their diabetes regime. Recordings and scripts were sent via email upon completion of each module. Following each module, participants were provided with contact details for the Diabetes UK helpline and encouraged to speak to their diabetes team or GP, in the event that they felt they needed additional support.

Procedure

Participants who expressed an interest in the study were sent an electronic Participant Information Form via email which included an overview of the project with eligibility criteria. Screening telephone calls were set up with those who felt they were eligible. During the phone call, a more detailed summary of the research process was provided and two screening questionnaires were completed. Eligible participants were then emailed a link to the electronic consent form. After consenting to partake in the project, participants were sent a second link to complete sociodemographic and standardised measures (T1). Once measures were completed, participants were allocated to a baseline phase of 1, 2 or 3 weeks, using a randomiser function embedded in the survey flow, to control for extraneous threats to internal validity such as maturation. A letter was sent to participants' General Practitioner informing of their patient's participation in the study (Appendix P).

Baseline (A): the baseline phase started with completion of the sociodemographic/clinical information questionnaire and standardised measures (T1), followed by allocation to baseline length. Participants were asked to complete idiographic measures as close to daily as possible through an online form sent via

email. An automatic reminder to complete VAS recordings was sent automatically every other day.

Intervention (B): at the end of the baseline period, an email with a link to the online MBI was automatically sent to participants. Upon completion of each module, participants received an email with a reminder of the task for the week. A link for the following module was also sent automatically after seven days. Following each module, participants were asked to complete the process measure. To assess fidelity to the intervention, participants completed a brief questionnaire before starting each week's module to evaluate how often they practiced exercises over the past week. Although participants were invited to complete each module in one sitting on the same day each week, they had the flexibility to choose when to complete it (e.g. evenings, weekends). Therefore, for some participants the completion of the intervention took longer than the planned four weeks. Participants continued to complete idiographic measures as close to daily as possible and re-completed standardised measures and at the end of the intervention (T2). The feedback questionnaire was sent upon completion of the final module.

Follow-up (a): throughout the four-week follow-up phase participants completed idiographic measures as close to daily as possible. Standardised measures were completed a final time at the end of the follow-up period (T3). At this stage participants were sent £10 Amazon vouchers as a thank you for their involvement.

Please refer to Figure 5 for a visual representation of the procedure.

Figure 5

Administration of Measures Across Phases

	A	B	a
Standardised measures	T1	Pre-intervention | Post-intervention T2	T3
Mindfulness Process Measure		Weekly	
VAS	Daily	Daily	Daily

Participants were sent check-in emails every two weeks during their participation and check-in phone calls were provided mid-way through, and at the end of their involvement. This was in line with a blended approach to lower drop-out rates and support engagement with the online intervention (Erbe et al., 2017). Check-in phone calls lasted 5-15 minutes and were used as opportunities to receive feedback on the accessibility of Qualtrics and to support with any technological issues. Barriers to practicing mindfulness were also considered and problem-solved (e.g. planning a regular time in the day to practice).

Service-User Involvement

Two service-users from Barts NHS Trust were recruited to review the intervention scripts and provide feedback. Their comments were used to adapt the materials to increase user-friendliness and accessibility. For example, wording was changed to provide examples of difficulties with food or anxiety that are pertinent to people with diabetes. Furthermore, one of the services users had attended group mindfulness sessions at her diabetes clinic and was able to consider barriers to engaging in exercises. Feedback was integrated into the final materials. Services users who took part in the study also provided feedback on how they found the intervention in terms of acceptability, user-friendliness and relevance. This information was

obtained via completion of feedback questions (CSQ) and by qualitative comments provided in check-in phone calls with the PI.

Data Analysis

Idiographic data

Visual Analysis. Visual analysis of time-series graphs was used to evaluate idiographic VAS data as this is the principal method for identifying relations between independent and dependent variables in SCED research (Bourret & Pietras, 2013). In visual analysis, the effects of the intervention are examined at different points over time, with a consideration for data trend, level and variability. This data are visually inspected to infer reliability or consistency of intervention effects and ascertain whether patterns are replicated across participants (Kazdin & Tuma, 1982). The more stable the change is in each phase and the larger the magnitude of change, the greater the internal validity of the design (Morley, 2017).

In order to reduce subjectivity in the interpretation and enhance replicability, the following criteria for visual inspection were adopted (Kazdin, 2011):

a) Variability: change in the variability of the data indicating stability of symptom change.
b) Change in central tendency: visually detectable differences in the average VAS score across phases. The broadened mean (BMed) was used to calculate central tendency in each phase to prevent the impact of extreme scores on the mean. Rosenberger & Gasko (1983) suggest BMed as a solution whereby a small group of middle datapoints are assigned most weighting. BMed was computed according to Rosenberger & Gasko's (1983) rules.

c) Change in level: differences in the pattern of data from the end of one phase (e.g. baseline) to the beginning of the adjacent one (e.g. intervention).
d) Change in trend: upward or downward changes in the slope of the trend line.

In order to meet the study hypothesis, the following changes would be expected between adjacent phases: (1) a decrease in central tendency and downward trend in FOH-worries and behaviours; (2) a decrease in central tendency and downward trend in low mood and anxiety; (3) an increase in central tendency and an upward trend in self-management behaviours (diet, BG management, medication, exercise). To substantiate the hypothesis at least three effect replications across three participants which meet the above criteria would be required (Kratochwill et al., 2013). Demonstration of effect in a multiple-baseline design is inferred at the point of introduction of the intervention.

Tau-U Analysis. Statistical analysis was also used to corroborate findings attained from visual analysis. This process is important as it removes observer bias from visual judgments (Jones et al., 1978) and can also reliably detect smaller effects disregarded by visual analysis (Kazdin & Tuma, 1982).

Tau-U computes the proportion of data non-overlap between phases while controlling for the presence of a baseline trend (i.e. the direction a person's symptoms were taking prior to intervention) (Morley, 2017). The test is a combination of Mann-Whitney U and Kendall's rank correlation (Tau) and reflects the proportion of data that is different (or non-overlapping) between adjacent phases (Willson et al., 2016). It considers all the data points, not only summary statistics (i.e., mean or median). Tau-U test statistic was calculated using an online calculator: (www.singlecaseresearch.org/calculators/tau-u).

Tau-U comparisons were made between adjacent phases, including (1) baseline phase compared with intervention phase (A x B) to examine whether significant changes occurred after the introduction of the mindfulness course; (2) intervention compared with follow-up phase (B x a) to find whether there was a further change in scores with continued practice of mindfulness exercises during follow-up; (3) baseline phase compared with a combined intervention and follow-up phase (A x [B+a]), in order to determine the overall impact of the intervention over time compared to baseline (Parker & Vannest, 2012). A significant negative Tau-U value indicated a negative trend and a positive value indicated a positive trend (Morley, 2017).

After considering VAS for individual participants, single omnibus Tau-U effect sizes were calculated using weighted averages for variables where at least three significant effect replications were found. Effect sizes reflected the proportion of data non-overlap across participants for each variable.

Standardised data

For standardised measures, Reliable Change Index (Jacobson et al., 1984, 1999; Jacobson & Revenstorf, 1988; Jacobson & Truax, 1992) was used to calculate whether reliable change had been achieved for primary and secondary outcomes, as well as to explore whether there was reliable change in facets of trait mindfulness. Reliable Change Index (RCI) specifies the amount of change an individual must make on a psychometric measure between two measurement occasions for that change to be reliable (i.e. larger than that reasonably expected to be due to measurement error alone) (Jacobson & Truax, 1992). For each participant, a baseline score was compared with a (1) post-treatment score, and (2) follow-up score.

An Excel calculator (Zahra, 2010) was used to calculate RC for each individual. The calculation required Cronbach's alpha for each measure to compute standard error of measurement. The standard error of measurement was then used to compute standard error of difference. RCI was determined by dividing the difference between pre-treatment and post-treatment scores by the standard error of difference. Cronbach's alpha (Cronbach's α) was obtained from the wider literature for each measure (reference data in Appendix Q). For measures where there were multiple Cronbach's α, the statistic was chosen based on the sample with the most similar demographics to the current sample (Morley, 2017). A difference was considered to be reliable if the RCI value was greater than +/- 1.96 (Jacobson & Truax, 1992). Additionally, graphs for participants visually depicting RCI for the FOH measure was created using The Leeds Reliable Change Indicator (Morley & Dowzer, 2014).

Clinically significant change (CSC) was computed for participants where reliable change had been achieved on measures of FOH, well-being and diabetes self-management. CSC indicates whether the individual has made a large enough change during the intervention, that they have transitioned from a clinical to a non-clinical population. When determining the cut score to indicate whether a individual has achieved CSC, Jacobson & Truax (1992) suggests three statistical criteria. The criteria include: (a) the level of functioning after therapy should fall outside the range of the clinical population by more than 1.96 standard deviations (in the direction of a non-clinical comparison group); (b) the level of functioning should fall within 1.96 standard deviations of the mean of a non-clinical comparison group; (c) the level of functioning should fall closer to the mean of a non-clinical group than to the mean of the clinical group. The authors suggests that if norms for a non-clinical group are not

available, then criterion A should be adopted. Criterion A was used for all standardised measures as there were no non-clinical normative comparisons available in the literature. CSC was computed using an Excel calculator (Morley & Dowzer, 2014). Reference data for the calculation is included in Appendix Q.

Process Data

Data for the process measure was collected at each week of the mindfulness course. Data was computed to assess for reliable change using an Excel calculator (Zahra, 2010).

Results

This section will firstly present participants' characteristics and results on feasibility and acceptability of the web-based mindfulness course. Following this, preliminary effectiveness of the intervention will be explored using visual and statistical analyses of individual idiographic measures, and analysis of reliable change for standardised and process data.

Demographics and Diabetes Characteristics

To maintain anonymity, participants were referred to in the study by the letter "P" and a number from 1-6. Some details in Table 8 have also been changed. Four females and two males completed the study, with an average age of 39.3 years (SD= 12.19) and all were from a White background. All participants had a diagnosis of T1D, for a duration ranging from 5 to 26 years (M=19.5, SD=7.92). Half of participants self-treated using multiple insulin injections (n=3), whilst the other half used an insulin pump. Most participants measured BG using flash glucose monitoring (n=5) and one participant relied on fingerprick testing. Most participants (n=4) experienced hypoglycaemia occasionally (10 to 19 days) in the past two months. One

participant experienced this fairly often (30 to 39 days), and one experienced this often (40 to 49 days). Full participant sociodemographic and diabetes characteristics are presented in Table 8.

Table 8

Socio-demographic and Diabetes Characteristics

	P1	P2	P3	P4	P5	P6
Gender	M	F	F	M	F	F
Age	27	42	29	58	48	32
Ethnicity	Any other White background	White - English, Welsh, Scottish, Northern Irish or British	Any other White background	White - English, Welsh, Scottish, Northern Irish or British	White - Irish	White - English, Welsh, Scottish, Northern Irish or British
Marital status	Married or living with partner	Divorced or separated	Married or living with partner	Married or living with partner	Single	Married or living with partner
Employment status	Working full-time	Working full-time	Not working	Working part-time	Working full-time	Working full-time
Diagnosis duration (years)	26	16	23	25	22	5
Treatment type	Insulin pump	Multiple daily injections	Insulin pump	Multiple daily injections.	Multiple daily injections	Insulin pump
Blood glucose measurement method	Flash glucose monitoring	Self-monitoring of blood glucose (fingerprick testing)	Flash glucose monitoring	Flash glucose monitoring	Flash glucose monitoring	Flash glucose monitoring
Hypoglycaemic episodes in the previous 2 months (occasionally=10 to 19 days; fairly often=30 to 39 days; often=40 to 49 days)	Often	Occasionally	Fairly often	Occasionally	Occasionally	Occasionally

Number of times lost consciousness due to hypoglycaemia	5	0	0	0	0	1
Number of times experiencing hypoglycaemia without losing consciousness but still requiring someone's help to recover	0	2	0	0	2	0
Diabetes complications	None	Diabetic retinopathy	None	Diabetic retinopathy	None	None
Other health problems	Mild Asthma, Hay fever	None	None	Depression and Anxiety	None	None
Baseline length (weeks)	2	1	2	3	1	2

Feasibility and Acceptability

The mindfulness course was assessed for feasibility and acceptability by examining retention rates, as well as quantitative and qualitative analysis of the CSQ and additional items on the user-friendliness and appropriateness of the intervention. A summary of these findings is provided in Appendix R.

Regarding feasibility, despite meeting the recruitment target of six participants, there was high attrition, with 57% of those who completed T1 measures disengaging from the project. This indicates that retention may be low for an online MBI.

Participants rated the acceptability on the CSQ-8 between 75-100% (Appendix R, Table 1), indicating high acceptability of the mindfulness course. Overall, all participants reported that they received the kind of service they wanted and that it helped them effectively deal with their problems. Additional feedback on the appropriateness of the course indicated that all participants found the programme informative, user friendly and easy to use (Appendix R, Table 2). Despite all participants agreeing that the intervention was relevant to them, most participants rated this as 'somewhat agree' as opposed to 'strongly agree', suggesting that not all modules may have been relevant to individual needs.

Qualitative feedback (Appendix R, Table 3) highlighted that participants felt the course helped them to 'listen' to internal experiences, '[it helped with] listening to my body and the emotions'; 'the mindfulness tasks has allowed me to become more aware of my body and feelings'. The online format of the intervention was also noted as useful across participants, 'the audio instructions were really helpful', 'I could use

my phone to access the clips'. The least helpful aspects of the online format were the high number of emails received and not being able to review previous responses.

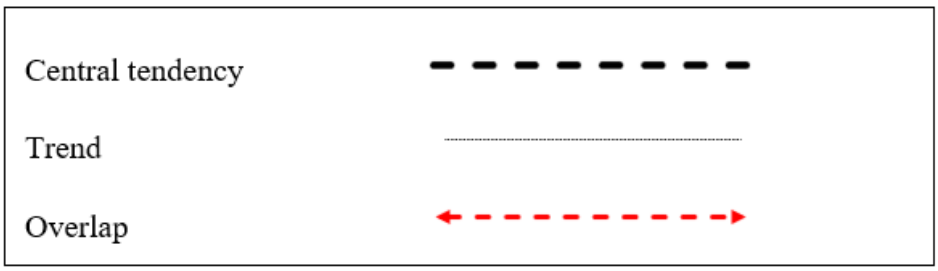
Participants also described whether the mindfulness course impacted on their experience of hypoglycaemia (Appendix R, Table 4). Feedback highlighted themes of experiencing reduced anxiety towards hypoglycaemia and increased awareness of thoughts, bodily sensations and emotions towards hypoglycaemia which encouraged objectivity.

Idiographic Results

VAS data for each phase of the study is presented in the line graphs below. Raw VAS data is shown as a blue continuous line with circle markers representing the data points. Each data point represents a score on the VAS Likert Scale (y-axis) along the point of time in the intervention (denoted as "A" for baseline, "B" for intervention", "a" for follow-up). Lines indicating central tendency, trend and overlap between phases are included (Figure 6), and phase change is marked by a black vertical line. Confounding variables are marked by a yellow line on the graphs of two participants. P2 had a death in the family at the start of the intervention phase (timepoint B9). P4 reported feeling anxious for an eye operation towards the end of follow-up (timepoint a22).

Figure 6

Indicators of Line Markers



Participants had a minimum of eight baseline data points (P6) and a maximum of thirty seven baseline data points (P4), which met the minimum requirements to demonstrate an effect (Kratochwill et al., 2010).

Results will combine interpretation from the visual graphs and from statistical (Tau-U) analysis, as organised by VAS variable. Full Tau-U data across participants are provided in Appendix S, including Tau-U for each VAS variable (Table S1) and summary of statistical change (Table S2).

Fear of Hypoglycaemia: Worry

Overall, four participants had significantly reduced self-reported FOH-worry between the baseline phase and combined intervention and follow-up phase (P1, P2, P4 and P6) (Figure 7). Three participants had significantly reduced FOH-worry between baseline and intervention, with two maintaining gains at follow-up. No significant changes were found for the remaining participants (P3 and P5).

Visual analysis showed that P1 had a reduction in central tendency and a downward trend at the point of starting the intervention and particularly at the follow-up phase. Statistical analysis confirmed this with a significant amount of data non-overlap between baseline and combined intervention and follow-up (Tau-U =-.46, p= .008) suggesting that they experienced fewer FOH-related worries after engaging in the mindfulness course.

For P2, a decrease in central tendency indicating reduced FOH-worry was observed from baseline to intervention, with a further reduction at follow-up (Tau-U= -.47, p= .011; Tau-U= -.56, p<.001). Tau-U analysis found a significant reduction in

worries between baseline and combined intervention/follow-up, indicating that there was an overall reduction after engaging in the MBI (Tau-U =-.68, p<.001)

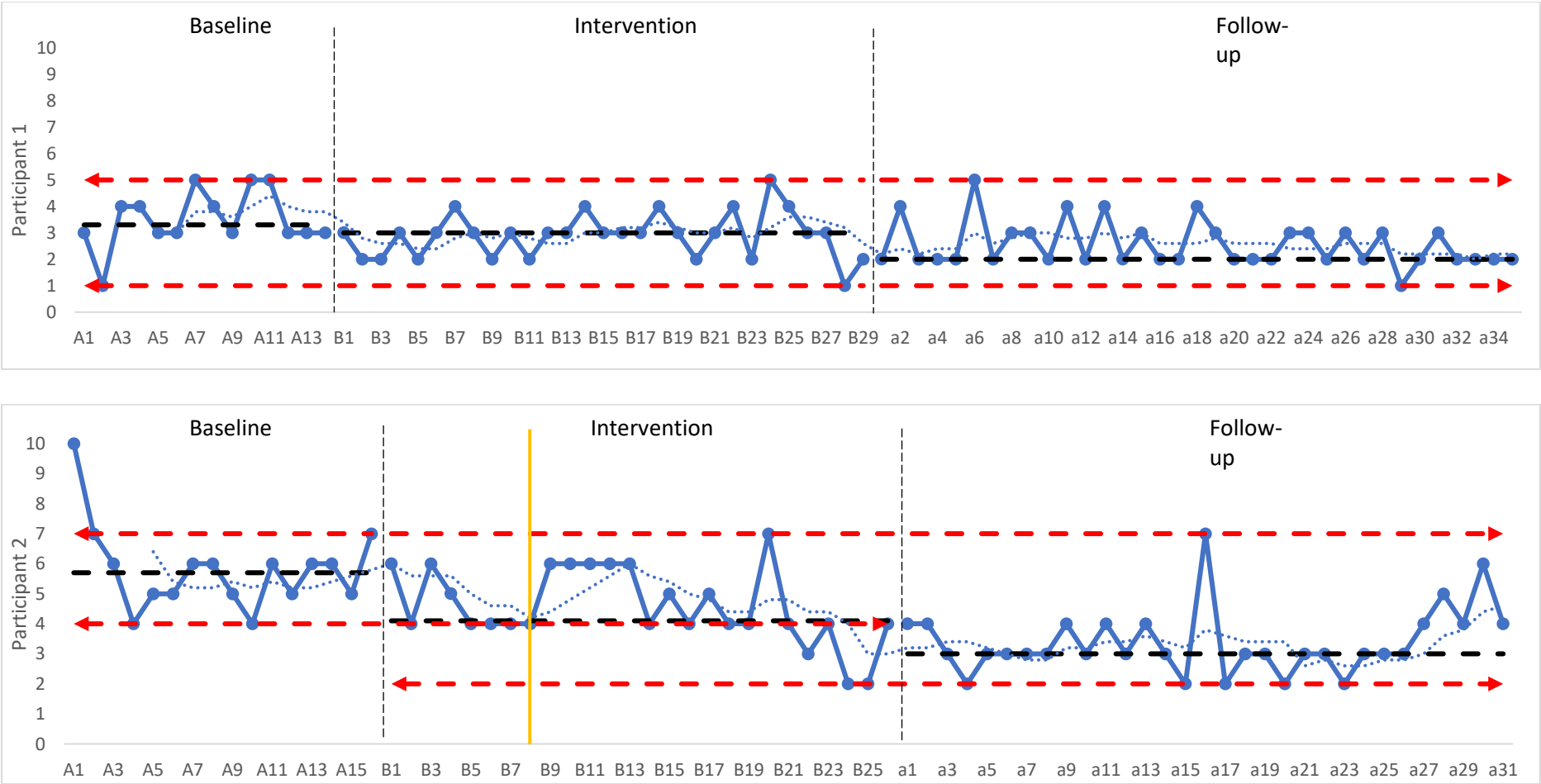
For P4, a significant baseline trend (p<.05) indicated the FOH-worries were increasing prior to the intervention, at which point, scores significantly reduced, with reductions maintained at follow-up. Tau-U analysis, controlling for baseline trend, confirmed the reduction in worries at the intervention and follow-up phases (Tau-U= -.44, p= .005; Tau-U= -.35, p= .018).

For P6, the central tendency in FOH-worry scores decreased from baseline to intervention and is corroborated by statistical analysis (Tau-U=-.50, p= .015). However, scores subsequently increased with an upward trend, which may be indicative of the participant not continuing to practice the mindfulness exercises post-intervention.

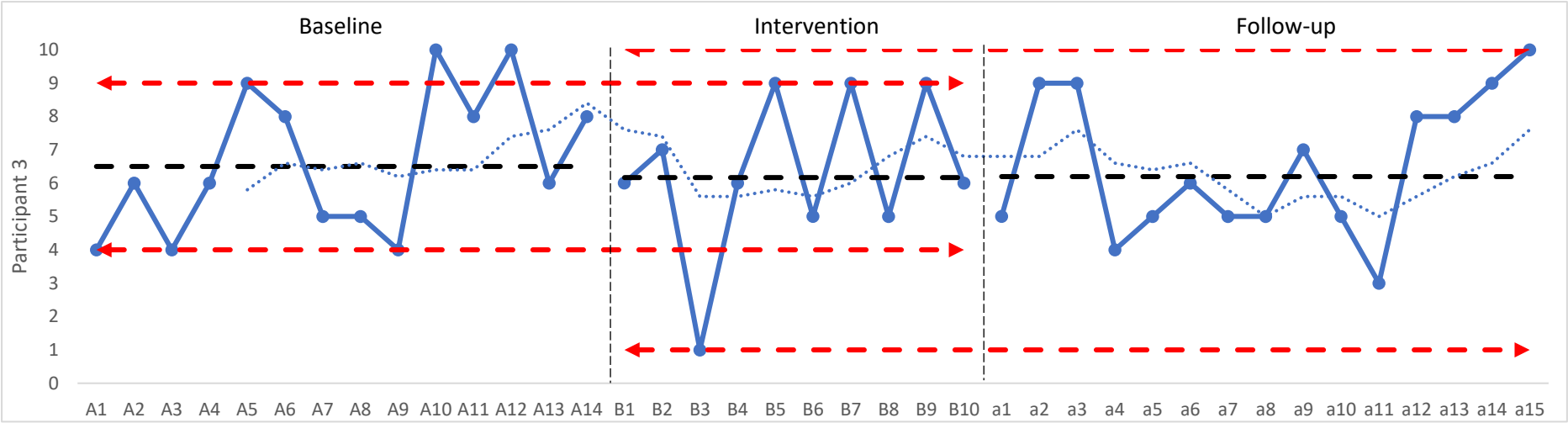
Overall, the findings revealed greater than three effect replications across participants, with self-reported FOH-worry significantly reducing between baseline and combined intervention/follow-up phases. This suggests that the mindfulness course was associated with reductions in worries about hypoglycaemia.

Figure 7

FOH-Worry VAS



Please note: yellow line indicates timepoint at which P2 disclosed there had been a death in the family.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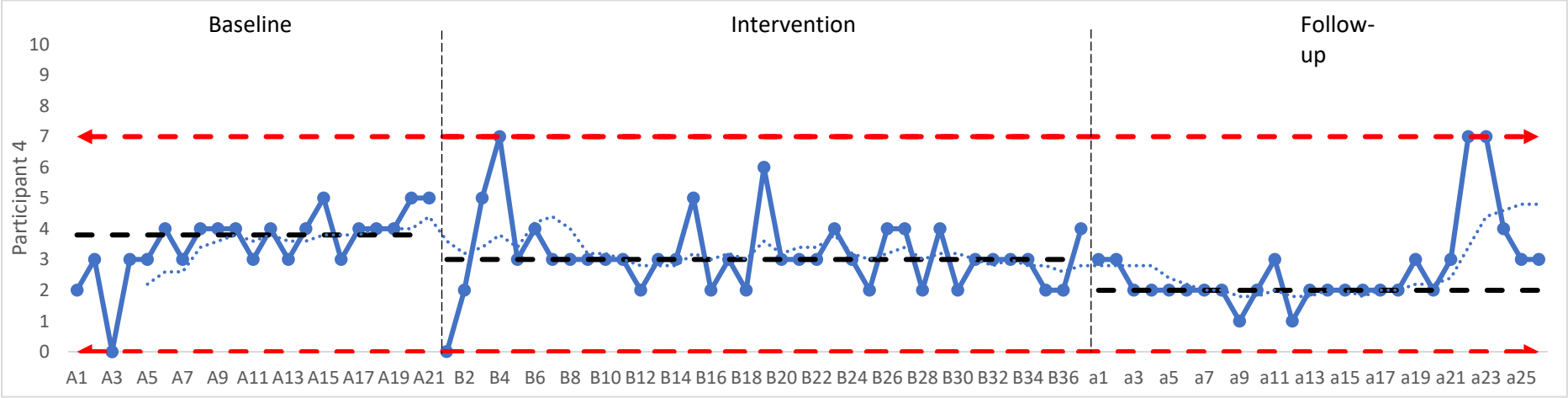
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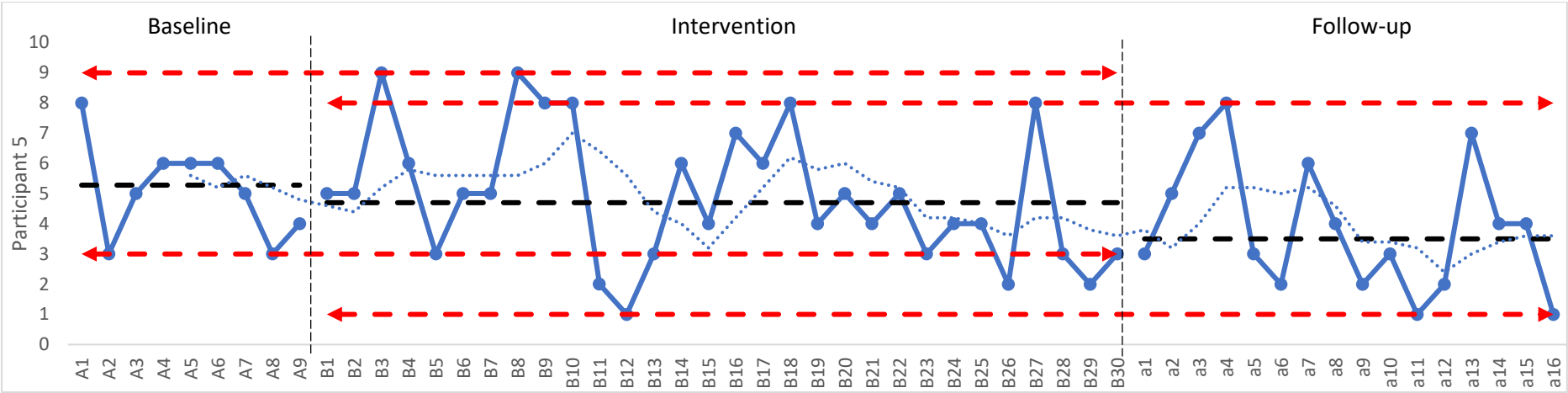
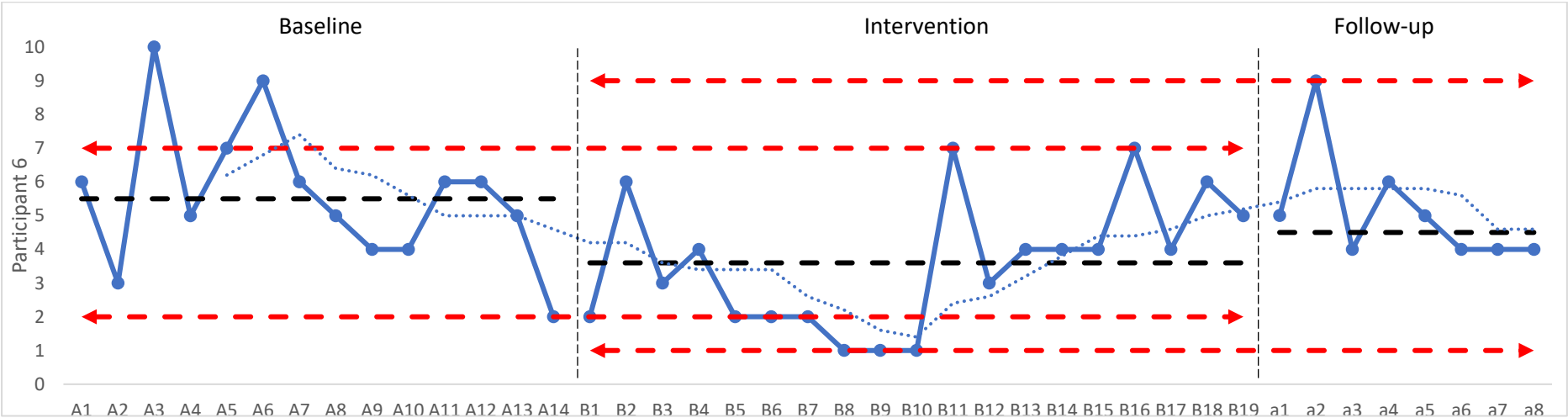




Each data point represents a self-rating on a 0-10 scale (0=Not at all, 10=Completely) of how much the person worried about hypoglycaemia over the past 24 hours.

Fear of Hypoglycaemia: Behaviour

Overall, three participants engaged in significantly fewer FOH-behaviours between baseline and combined intervention/follow-up (P1, P2 and P4) (Figure 8). Two participants engaged in significantly fewer behaviours between baseline and intervention (P1 and P4), with P4 maintaining a continued reduction at follow-up. Additionally, two participants reported significantly decreased FOH-behaviours from intervention to follow-up (P2 and P5). There were no significant changes found for P3 and P6.

P1 showed a downward change in level and a downward trend for FOH-behaviour between baseline and intervention, indicating that they engaged in fewer FOH-related behaviours after starting the mindfulness course. Scores in the follow-up phase were also less variable, when compared with baseline, suggesting that FOH-related behaviours were consistently fewer. This is further corroborated by a significant baseline and combined intervention and follow-up comparison (Tau-U= -.54, p= .001).

P2 displayed a downward trend in FOH-behaviour, particularly towards the end of the intervention which continued throughout follow-up. The change was significant between the baseline and combined intervention/follow-up phases (Tau-U=-.54, p=.001). Findings suggest that FOH-related behaviours may have reduced later in the mindfulness course once the mindfulness skills had been practiced.

Similarly, P4 displayed a decrease in central tendency and downward trend across time, indicating a reduction in FOH-related behaviours during the intervention, which was maintained at follow-up. This is supported by a significant baseline to

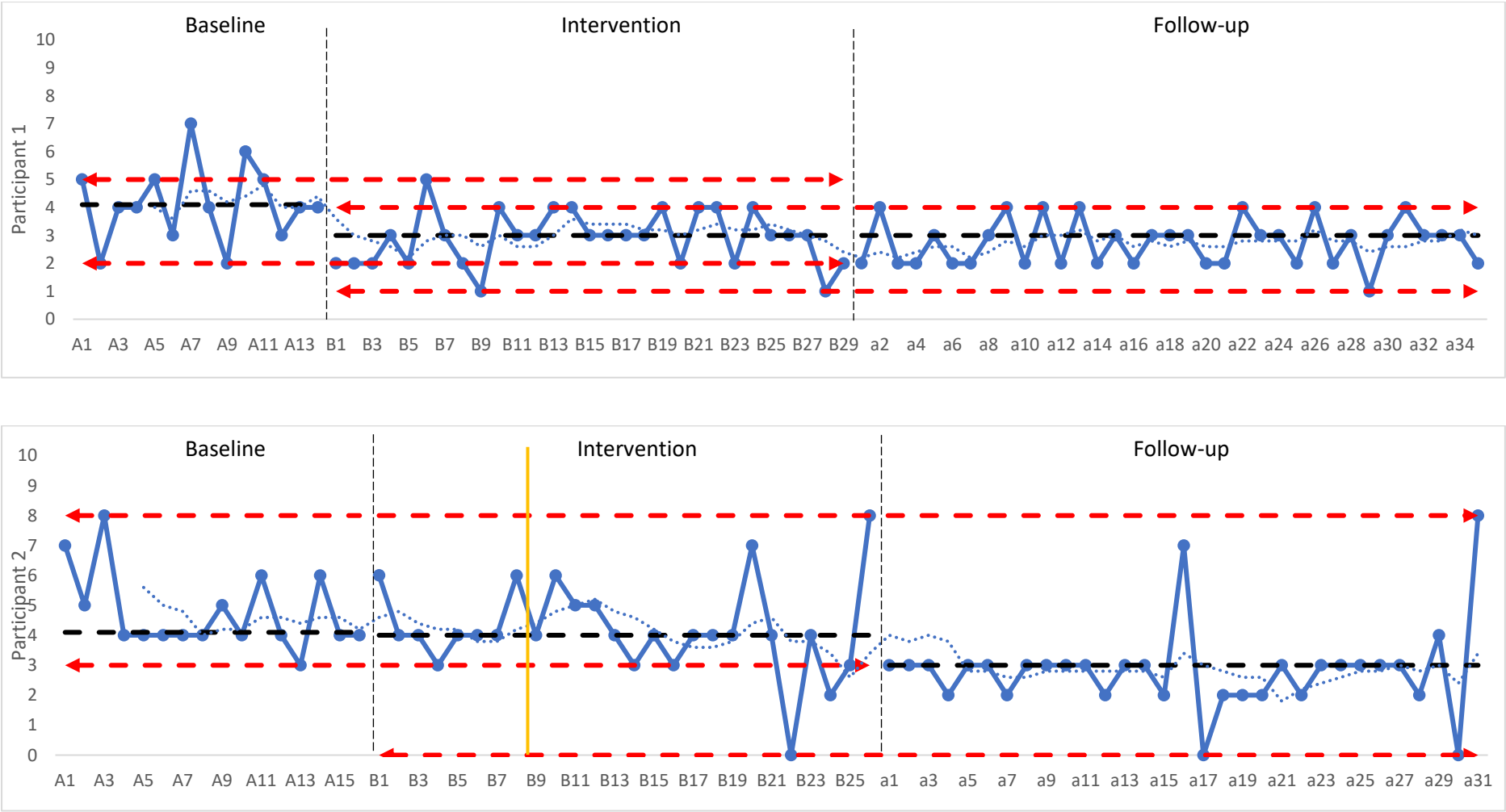
intervention comparison (Tau-U= -.36, *p*= .026) and significant baseline to combined intervention/follow-up comparison (Tau-U= -.44, *p*= .003).

P5 had a downward trend across time with a reduction in central tendency between phases. The change was significant between the intervention and follow-up phase (Tau-u= -.42, *p*= .019).

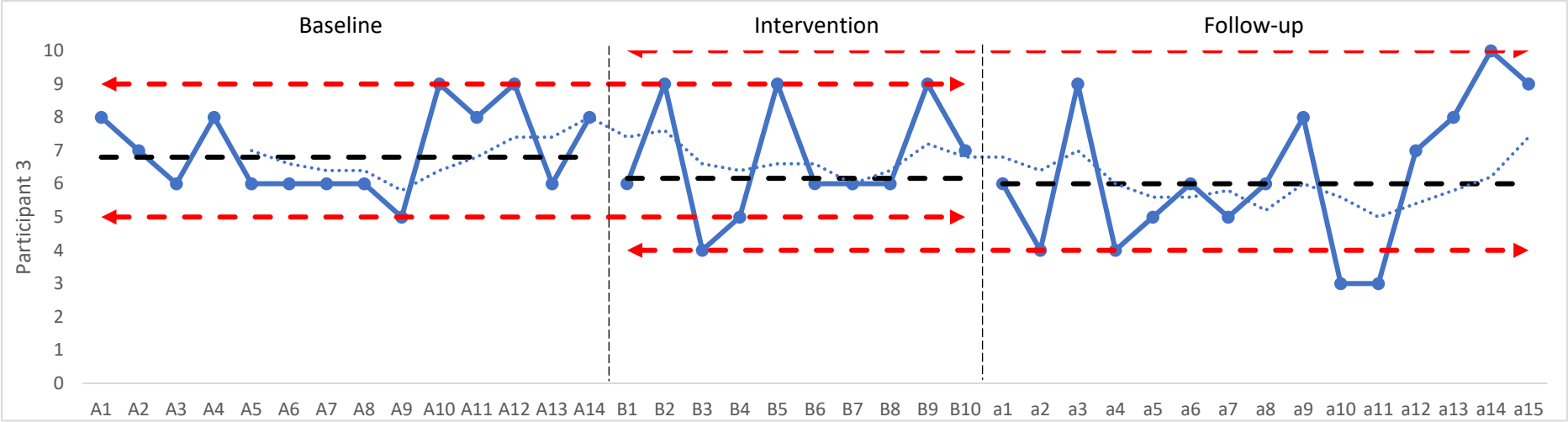
Overall, findings showed three effect replications across participants, with self-reported FOH-related behaviour significantly reducing between baseline and combined intervention/follow-up. This suggests that the mindfulness course may be associated with reductions in behaviours associated with FOH. Furthermore, for P2, P4 and P5, change was significant between the intervention and follow-up phase which may indicate that reductions continued with additional mindfulness practice.

Figure 8

FOH-Behaviour VAS



Please note: yellow line indicates timepoint at which P2 disclosed there had been a death in the family.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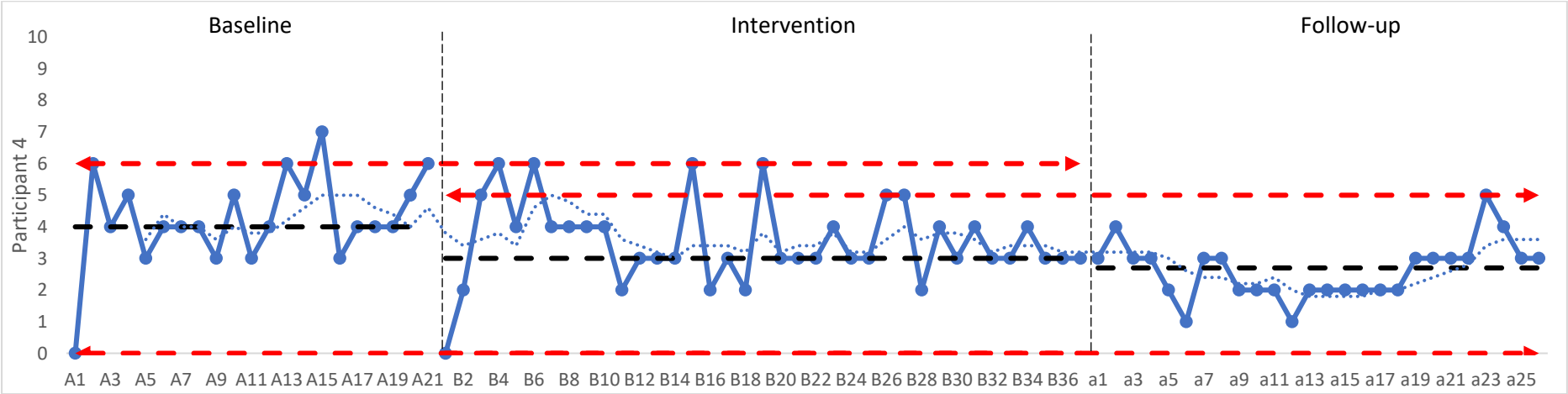
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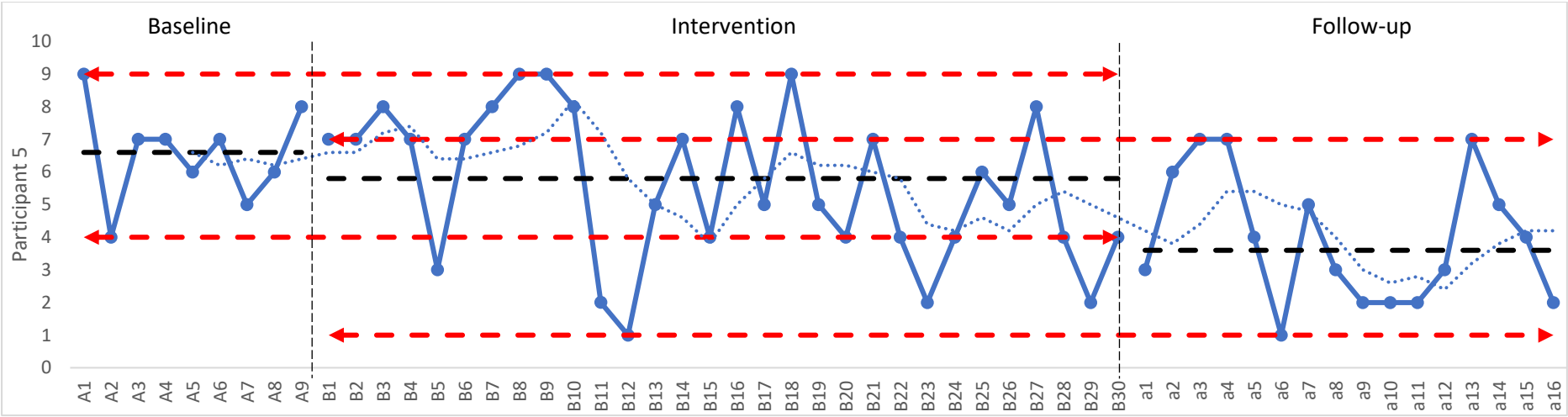
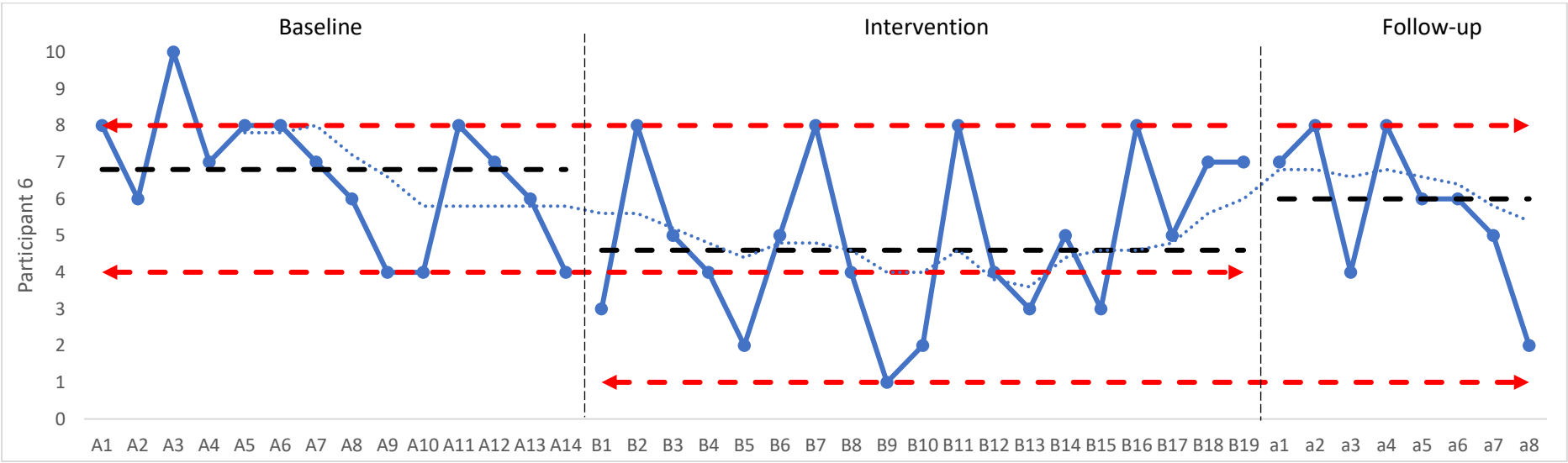




Each data point represents a self-rating on a 0-10 scale (0=Not at all, 10=Completely) of how much the person activitely took precautions to prevent hypoglycaemia in the past 24 hours.

General Low Mood and Anxiety

Visual and statistical analysis suggest that half of the participants (P2, P4 and P5) had a significant reduction in general low mood, stress and anxiety at some point during their participation (Figure 13). However, there were no repeated effects of a reduction at the same adjacent phases. For the other half of participants (P1, P3 and P6), there was no significant difference in low mood and anxiety across phases.

P2 had a downward trend and a significant decrease in central tendency between intervention and follow-up phases, which is corroborated by statistical analysis (Tau-U=-.70. $p<.001$). This indicates that they experienced less low mood and anxiety following the MBI.

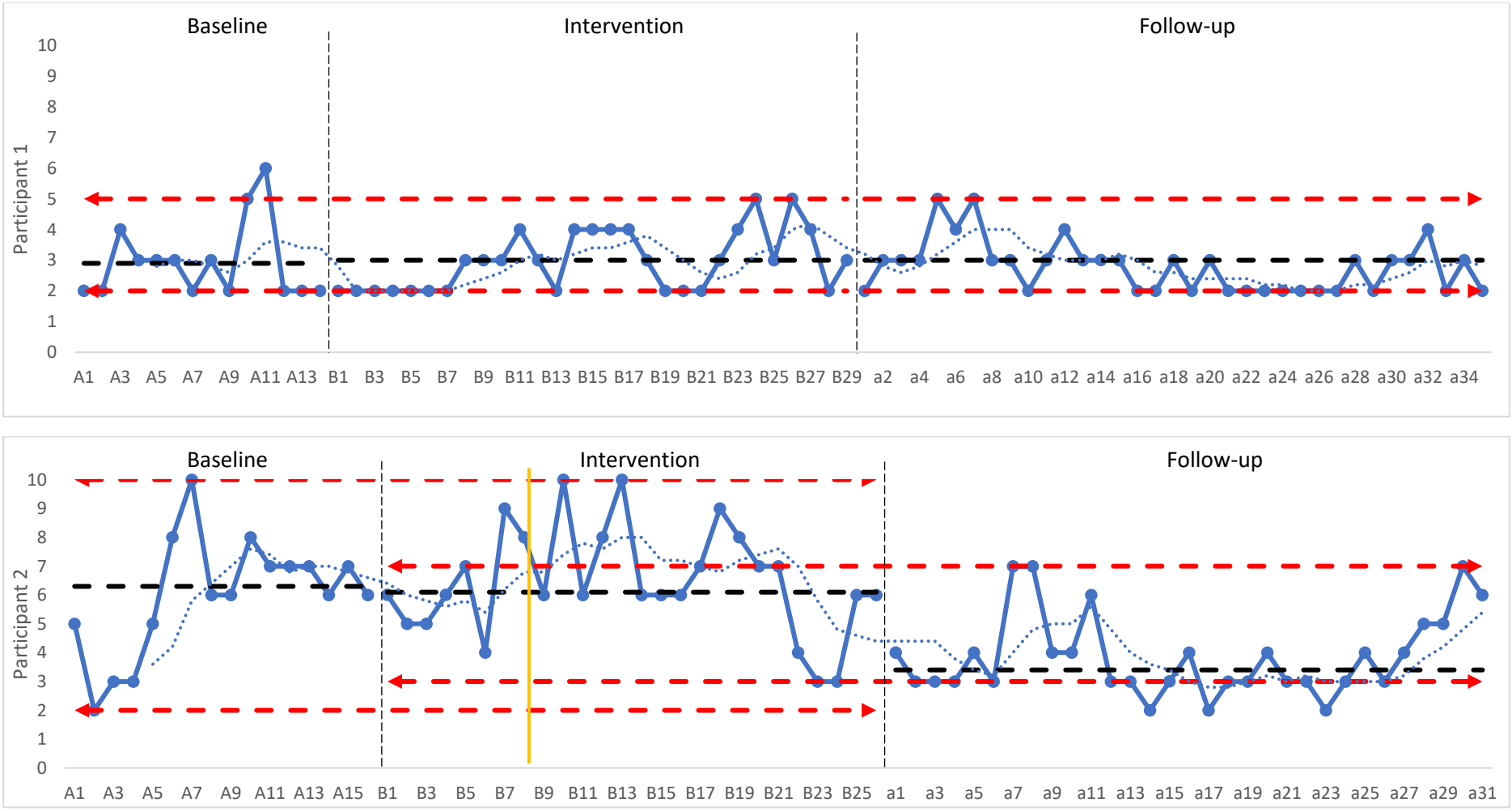
Similarly, P4 had a downward trend and decreased central tendency between baseline and intervention, which was found to be significant (Tau-U=-.33, $p=.039$). Scores also became less variable towards the end of the intervention phase, indicating that low mood and anxiety were consistently low. However, at follow-up there was an upward trend and shift to an increased central tendency which may be reflective of idiosyncratic factors (P4 commented she had an eye operation at this point which caused much anxiety).

P5 had a downward trend and consistently reduced central tendencies throughout phases, suggesting that low mood and anxiety reduced once they started the mindfulness course. Furthermore, there was a significant reduction between baseline and intervention/follow-up (Tau-u=-.49, $p=.020$).

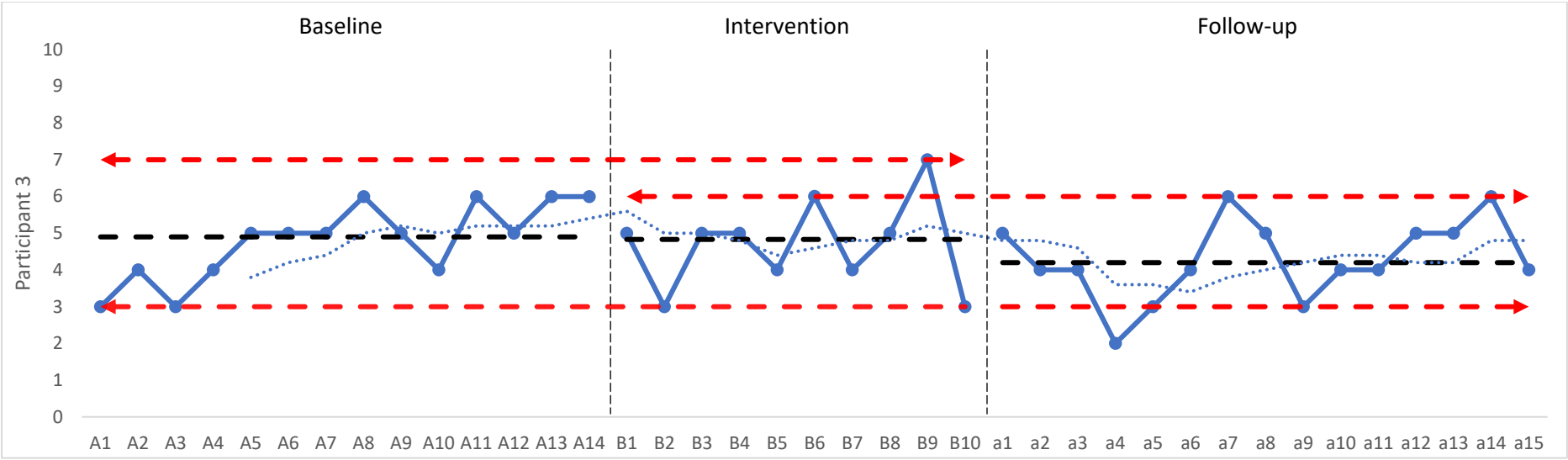
Overall, despite some significant reductions in general stress and worry for several participants, results were not consistent and so it cannot be inferred that the brief MBI reduces low mood and anxiety.

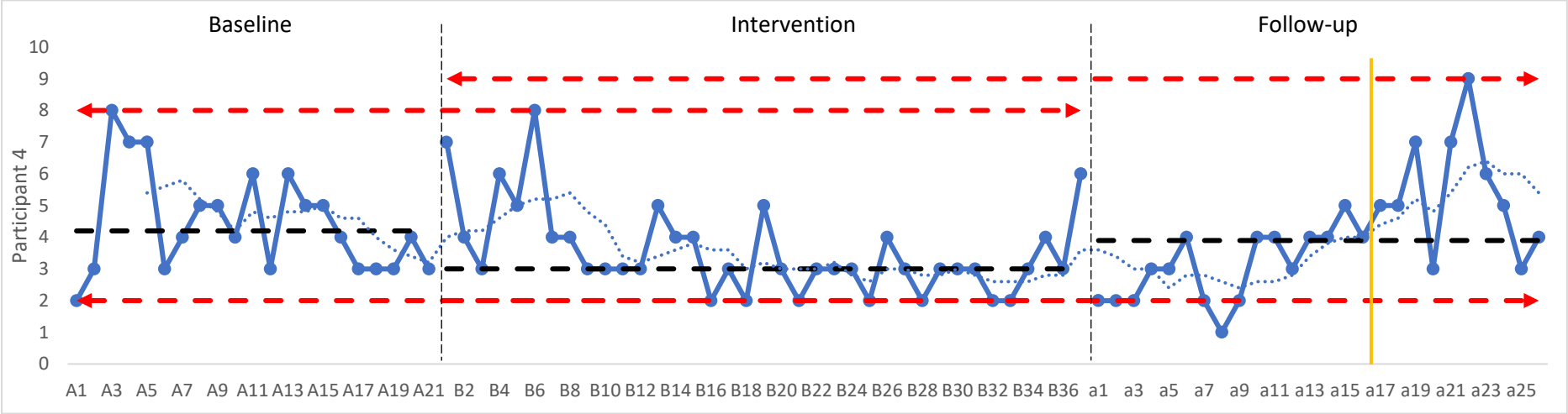
Figure 9

General Low Mood and Anxiety VAS

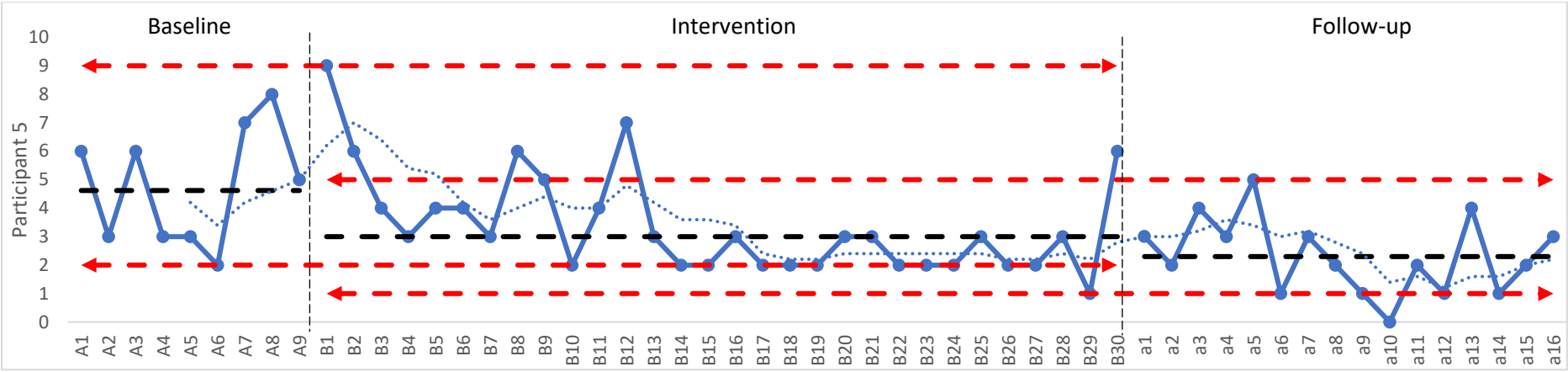


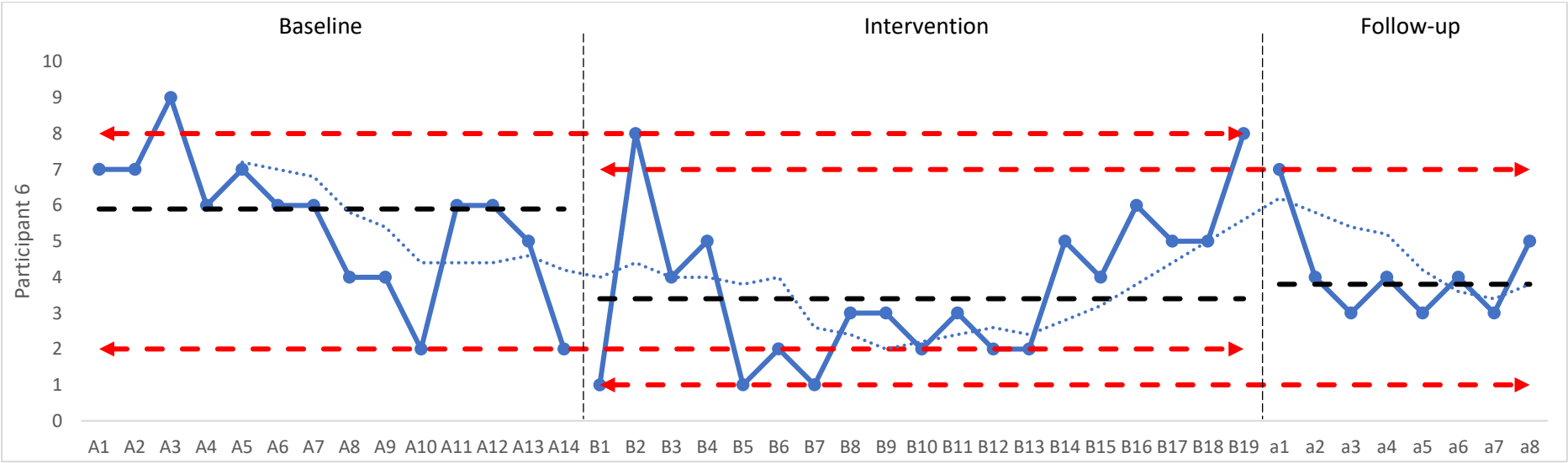
Please note: yellow line indicates timepoint at which P2 disclosed there had been a death in the family.





Please note: yellow line indicates timepoint at which P4 disclosed anxiety was increasing in anticipation of eye operation at a22.





Each data point represents a self-rating on a 0-10 scale (0=Not at all, 10=Completely) on how much the person felt low, stressed or anxious in the past 24 hours.

Dietary Adherence

Overall, P1 and P2 had significantly improved dietary adherence between baseline and intervention/follow-up phases (Figure 9). Alternatively, one participant (P3) followed their dietary regimen significantly less between the baseline and intervention/follow-up phases. P4 had improved dietary adherence between intervention and follow-up. The remaining participants (P5 and P6) showed no significant differences.

P1 had an increased central tendency and trend for dietary adherence between baseline and intervention which is corroborated by a marginally significant effect between baseline and intervention (Tau-U= .36, p=.055). This trend remained relatively stable with little variability at the follow-up phase, suggesting good compliance with diet regimen.

P2 had an upward trend in dietary adherence, however, this was in the later stages of the intervention phase into follow-up. Tau-U analysis corroborates this interpretation (intervention to follow-up: Tau-U = .62, p<.001; baseline to combined intervention/follow-up: Tau U = .34; p = .039).

By contrast, P3's dietary adherence significantly worsened over time as demonstrated by a decrease in central tendency and a downward trend across phases, as well as a significant baseline and combined intervention/follow-up comparison (Tau-U= -.64, p= .001).

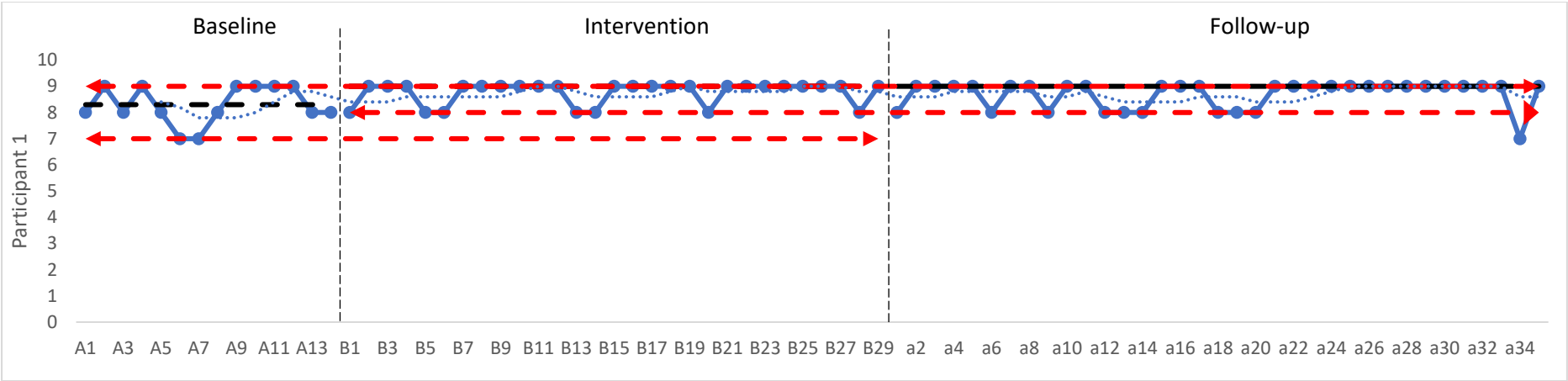
P4's dietary adherence improved between intervention and follow-up as demonstrated by an upward trend (Tau-U= .30, p= .044). The baseline phase had a

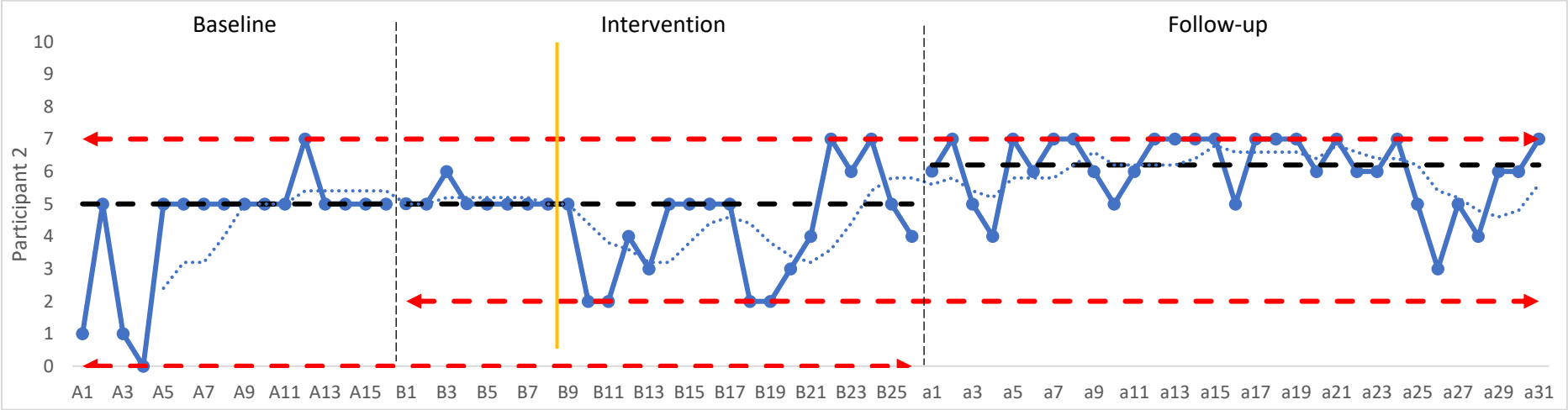
significant negative trend ($p<.05$) indicating that prior to the intervention, P4 was eating less well over time. This trend reversed during the intervention phase.

Findings indicate that dietary adherence both improved and worsened at various phases for different participants. There were no more than 2 effect replications in any phase comparison, suggesting that the mindfulness course was not significantly associated with changes in diet adherence.

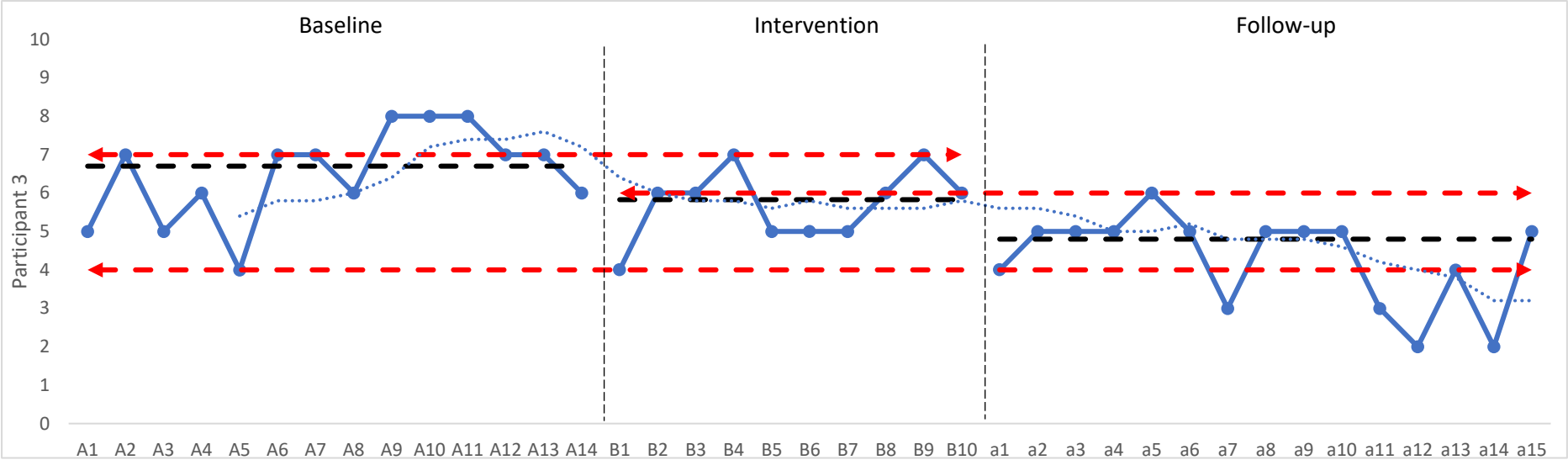
Figure 10

Dietary Adherence VAS





Please note: yellow line indicates timepoint at which P2 disclosed there had been a death in the family.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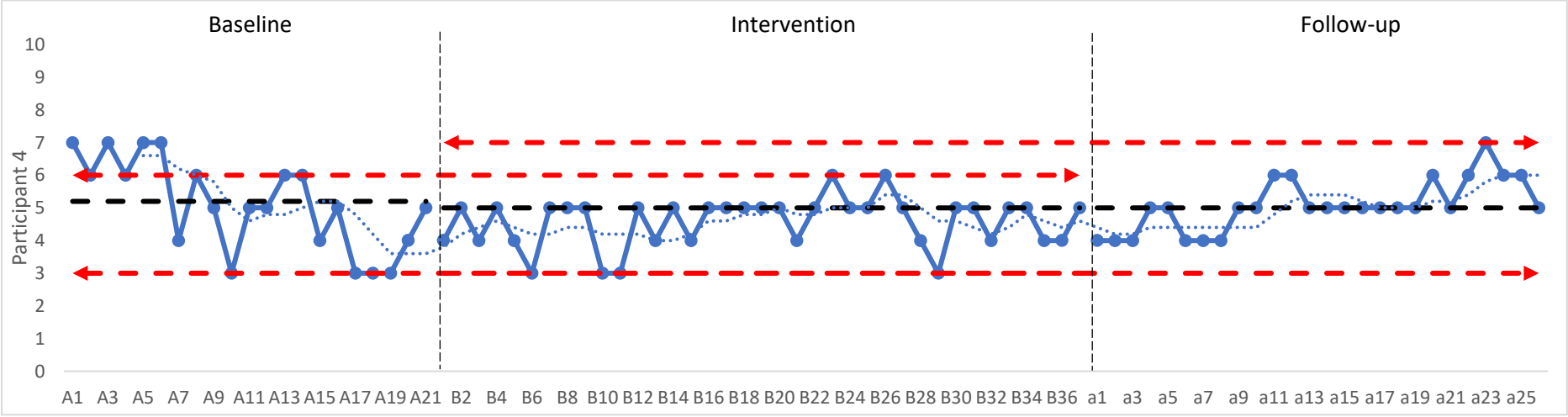
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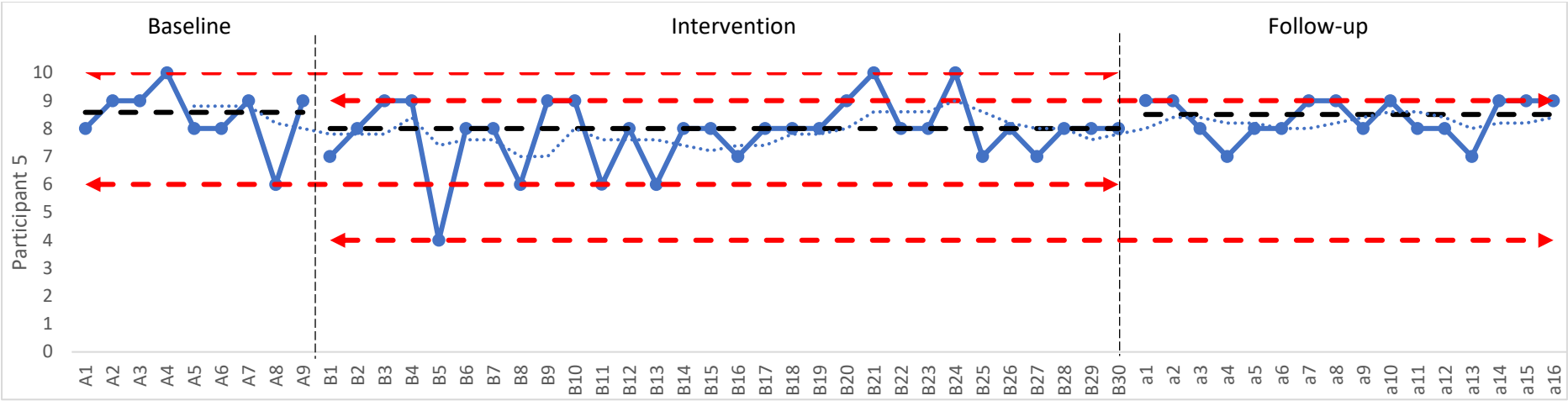
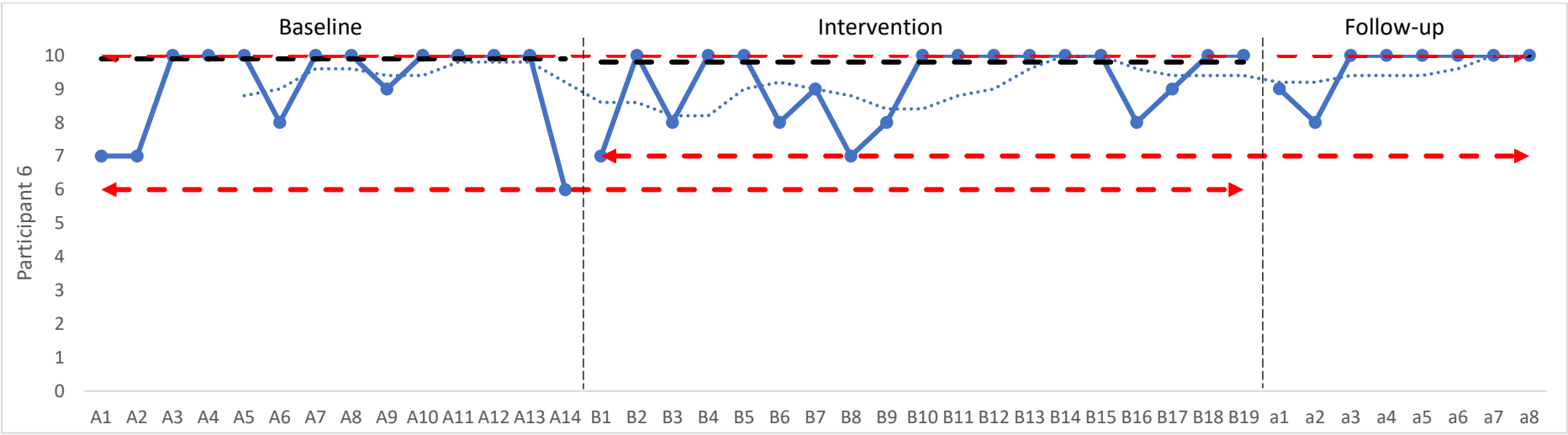




Each data point represents a self-rating on a 0-10 scale (0=Not at all, 10=Completely) on how much the person followed their diet regime in the past 24 hours.

Blood Glucose Monitoring

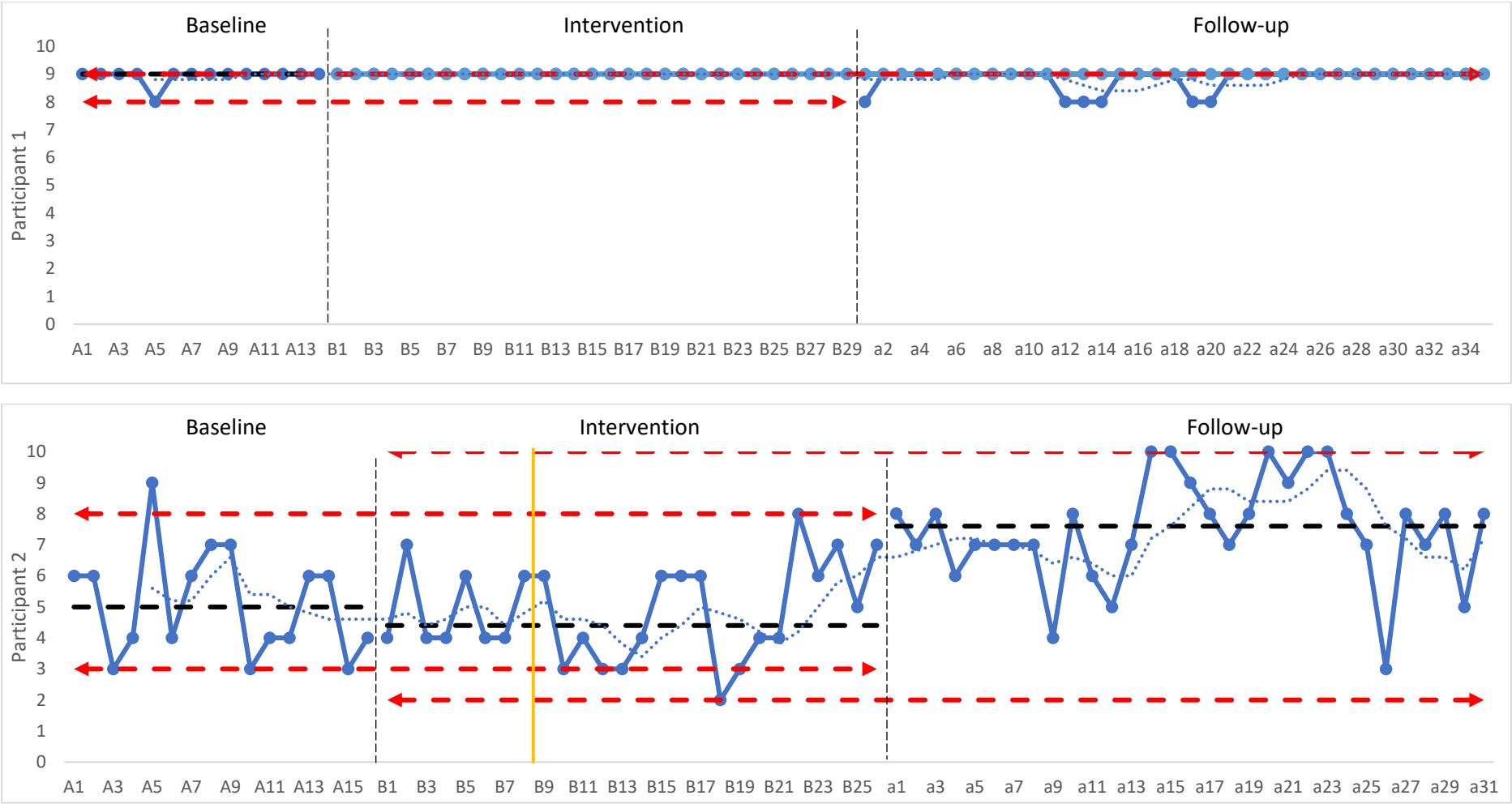
Visual analysis of adherence to BG monitoring (Figure 10), indicated that generally most participants had stable and high scores across phases, indicating good compliance with this aspect of their diabetes self-management. P2 had high variability in scores suggesting that they may have struggled with following their BG testing requirements. All participants, except P2, had no significant changes in BG monitoring between baseline, intervention and follow-up.

P2 had highly variable scores, with a trend which decreased slightly in the intervention phase and increased significantly in the follow-up phase. Central tendency also increased in the follow-up phase. These shifts suggest that P6 followed their blood testing regimen more closely during the follow-up phase. Statistical analysis corroborates this interpretation and found a significant increase in adherence between intervention and follow-up (Tau-U=.74, $p<.001$), and between baseline and combined intervention/follow-up (Tau U= .34, $p=.040$).

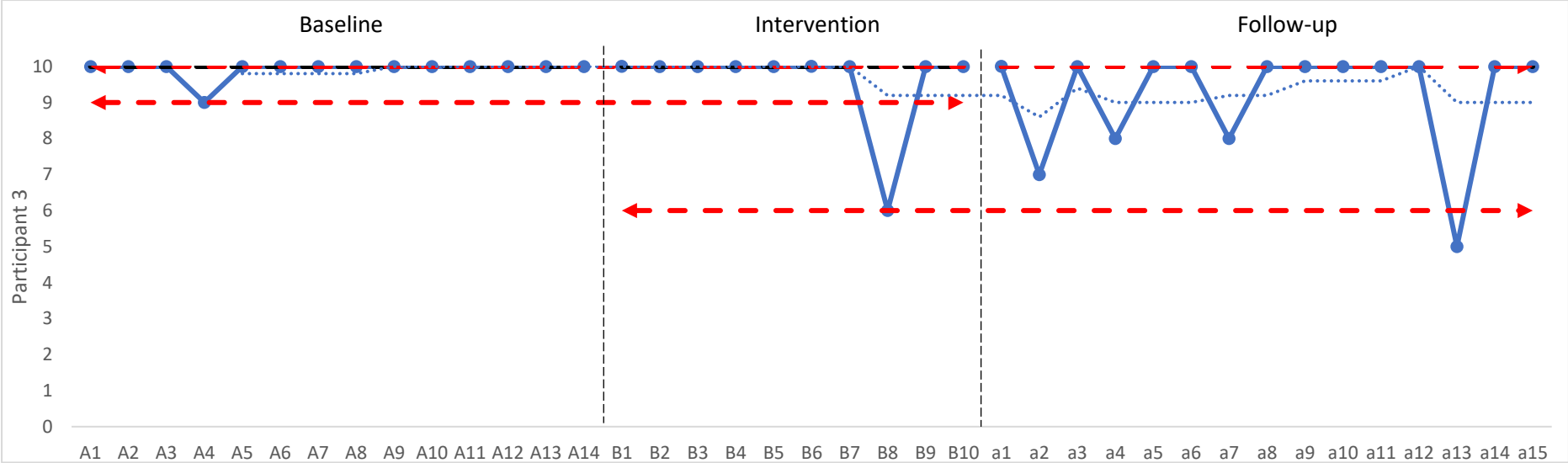
Overall, findings showed no consistent effects across participants, indicating that the mindfulness course did not significantly impact adherence to BG monitoring regimen. Although, as most participants' scores were relatively high and stable in the baseline phase there may already have been a ceiling effect.

Figure 11

Blood Glucose Management VAS



Please note: yellow line indicates timepoint at which P2 disclosed there had been a death in the family.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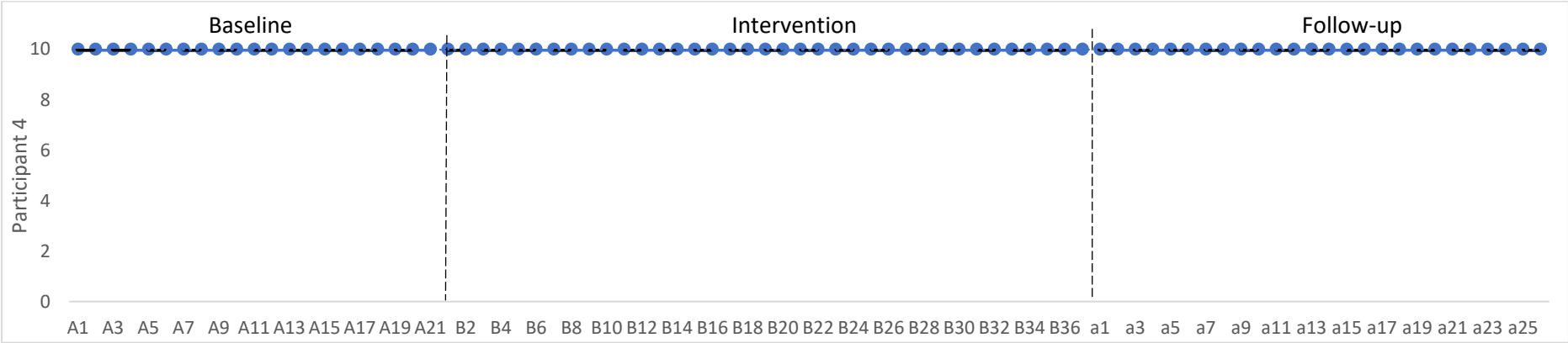
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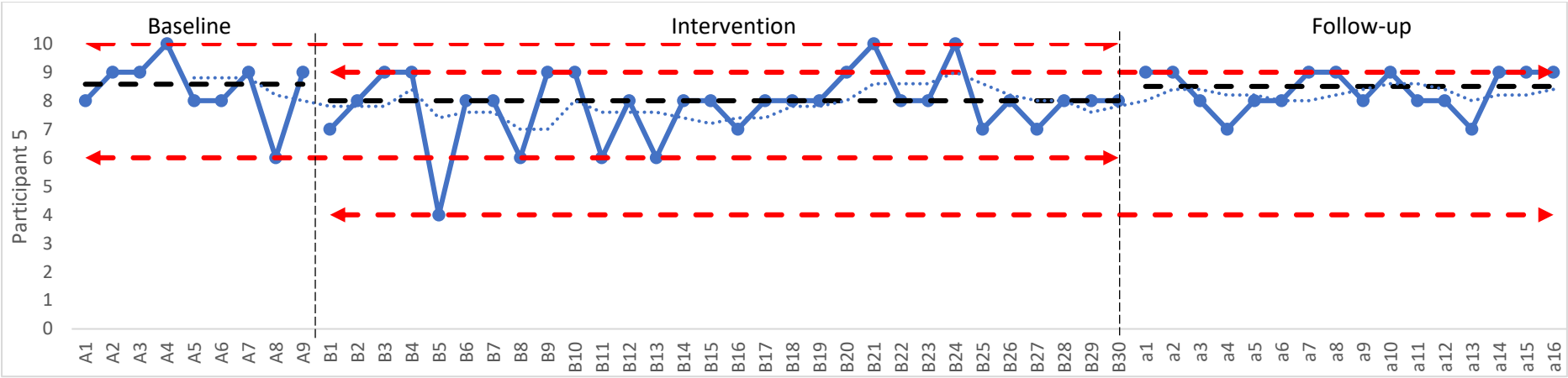
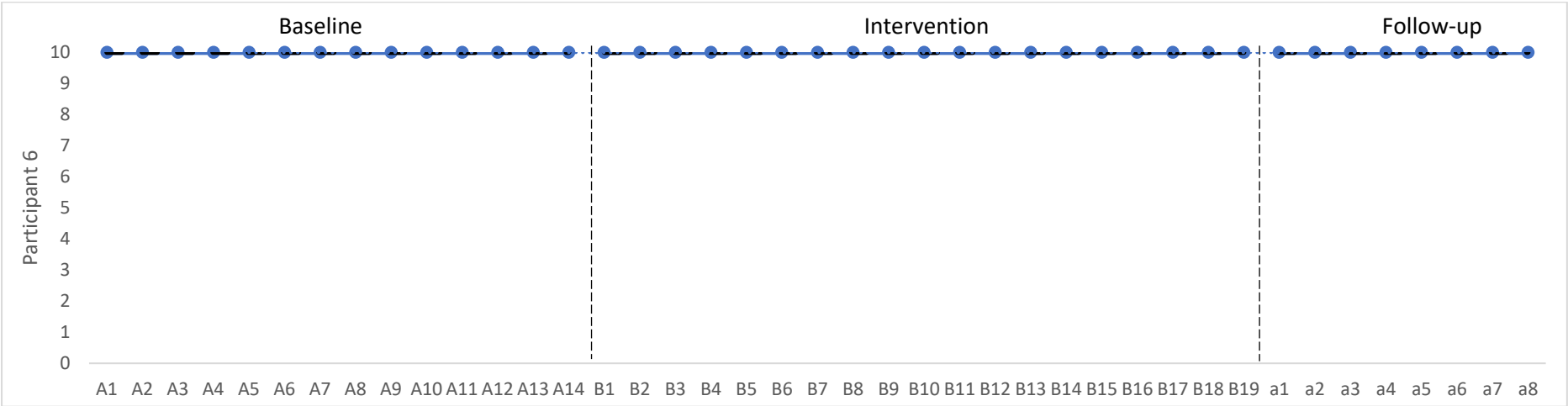




Each data point represents a self-rating on a 0-10 scale (0=Not at all, 10=Completely) on how much the person followed their BG testing requirements in the past 24 hours.

Medication Regimen Adherence

Three participants had relatively stable and high medication adherence with little variability in self-rated scores (P1, P4 and P6), indicating they complied with their medical plan. Tau-U analysis found P1, P4, P5 and P6 had no significant changes between phases (p>.05).

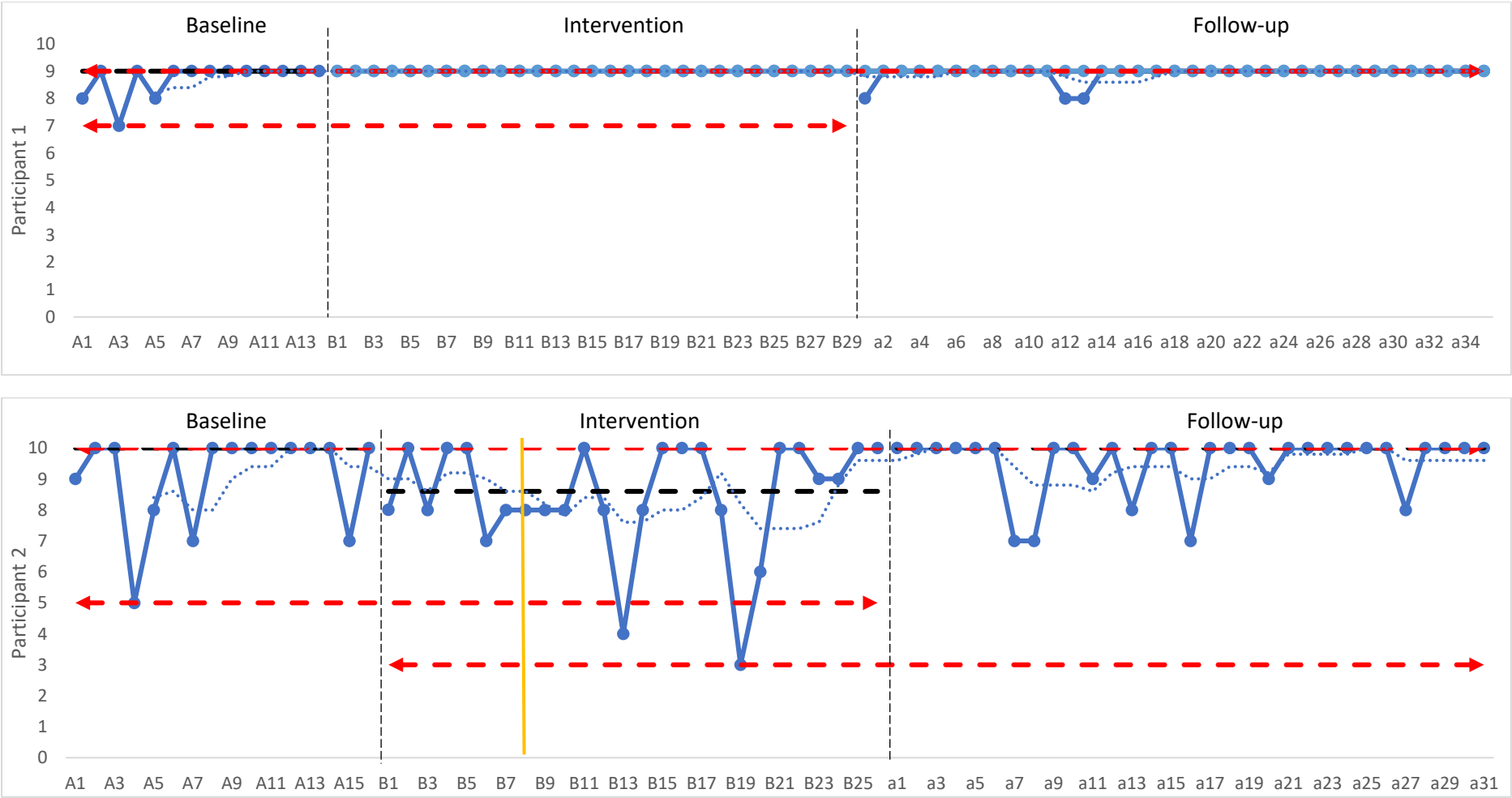
Visual analysis (Figure 11) suggests that P2 had more variable scores with a upward trend at follow-up. The central tendency reduced during the intervention as compared with baseline, and increased again in the follow-up phase (Tau-U = .36, p= 0.021). This indicates that P2 was *less* compliant with their medical regime during the intervention and then resumed a regime similar to baseline at follow-up.

P3 also had more variable scores (range between 6-10) with an upward trend across intervention and follow-up phases and an increase in central tendency between baseline and intervention/follow-up. This suggests that P3 was more compliant with their medical regime during the intervention and follow-up phases as compared to baseline. This is corroborated by statistical analyses comparing baseline and intervention/follow-up (Tau-U= .43, p= 0.027).

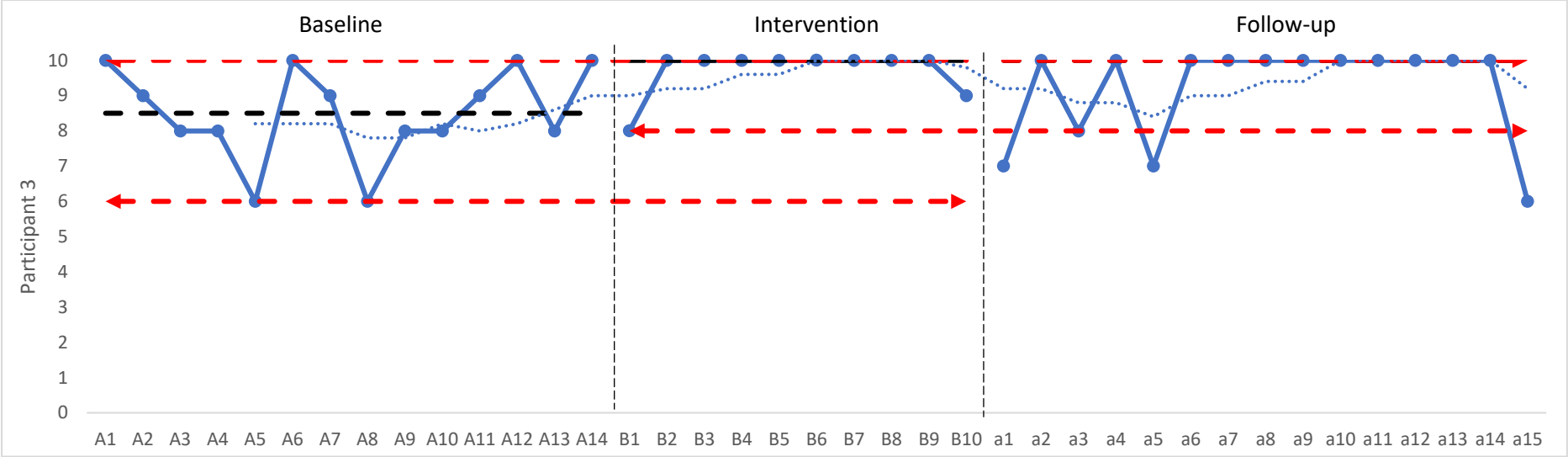
Overall, findings showed no consistent effects across participants, indicating that the mindfulness course did not significantly impact adherence to medication.

Figure 12

Medication Regimen Adherence VAS



Please note: yellow line indicates timepoint at which P2 disclosed there had been a death in the family.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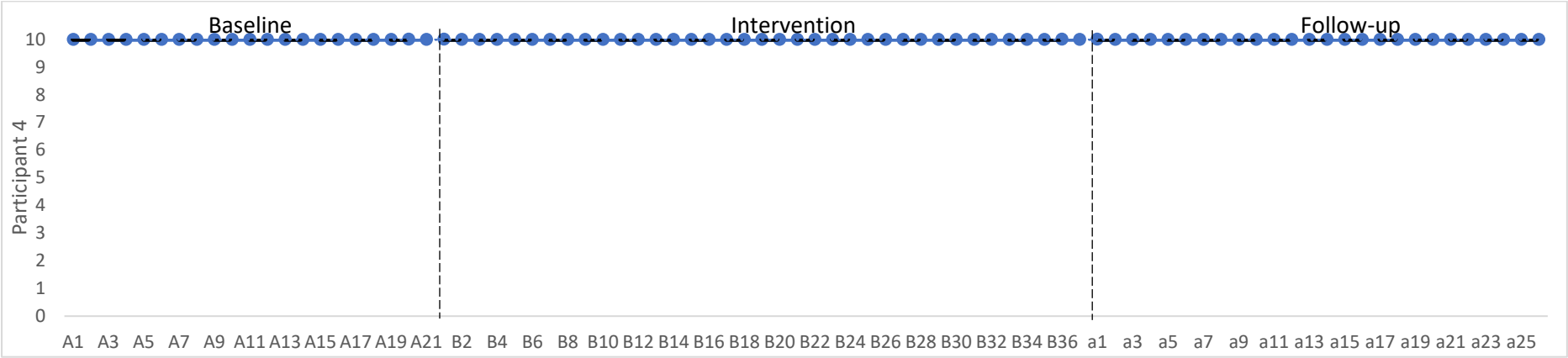
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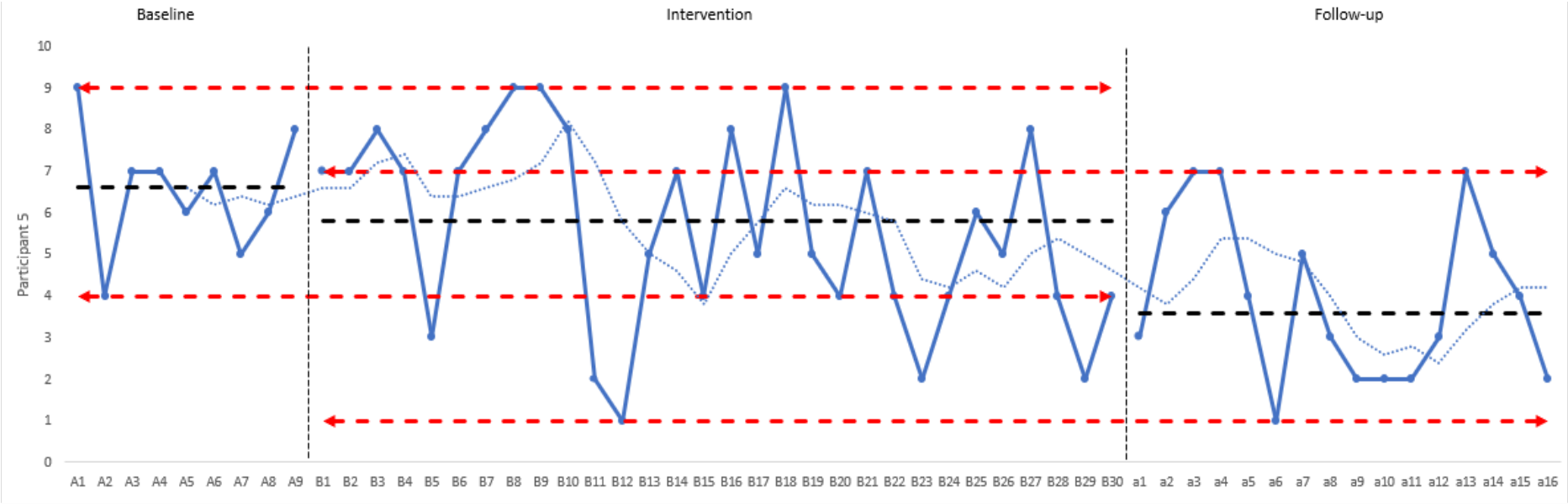
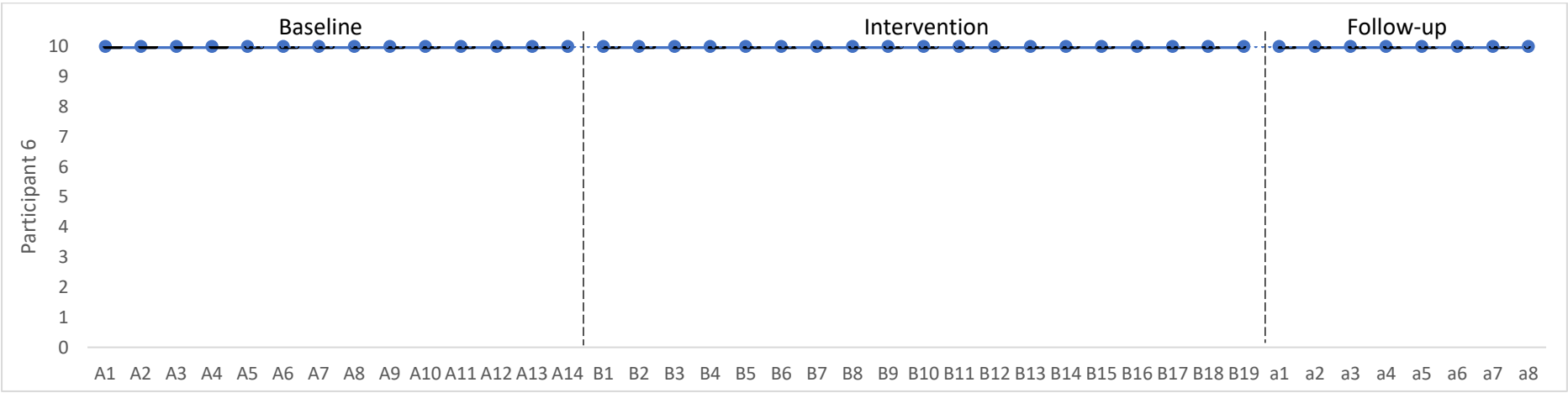




Each data point represents a self-rating on a 0-10 scale (0=Not at all, 10=Completely) on how much the person followed their medication regime in the past 24 hours.

Exercise Adherence

There were mixed findings for changes to exercise adherence across participants (Figure 12). Two participants reported decreased exercise adherence between baseline and combined intervention/follow-up (P3 and P6), and two reported increased exercise adherence (P1 and P2). P5 experienced no significant changes across phases.

P1 had an upward trend and an increase in central tendency between intervention and follow-up suggesting they increased their exercise at follow-up. This is corroborated by a significant increase between baseline and combined intervention/follow-up (Tau-U= .41, p=.016).

Similarly, P2 had an upward trend at the later stages of the intervention and follow-up, as well as an increase in central tendency at follow-up. Scores remained relatively stable at follow-up suggesting that they were following a consistent exercise routine. This is corroborated by statistical analysis which found a significant increase between these phases (Tau-U=.72, p<.001).

However, P3 had a reduction in exercise adherence with a downward trend and reduction in central tendency between baseline and intervention/follow-up phases, indicating their exercise routine worsened. This is corroborated by statistical analyses, indicating significant reductions in exercise adherence throughout time (baseline and intervention comparison: Tau-U= -.58, p= 0.018; baseline and combined intervention/follow-up comparison: Tau-U= -.59, p= 0.003).

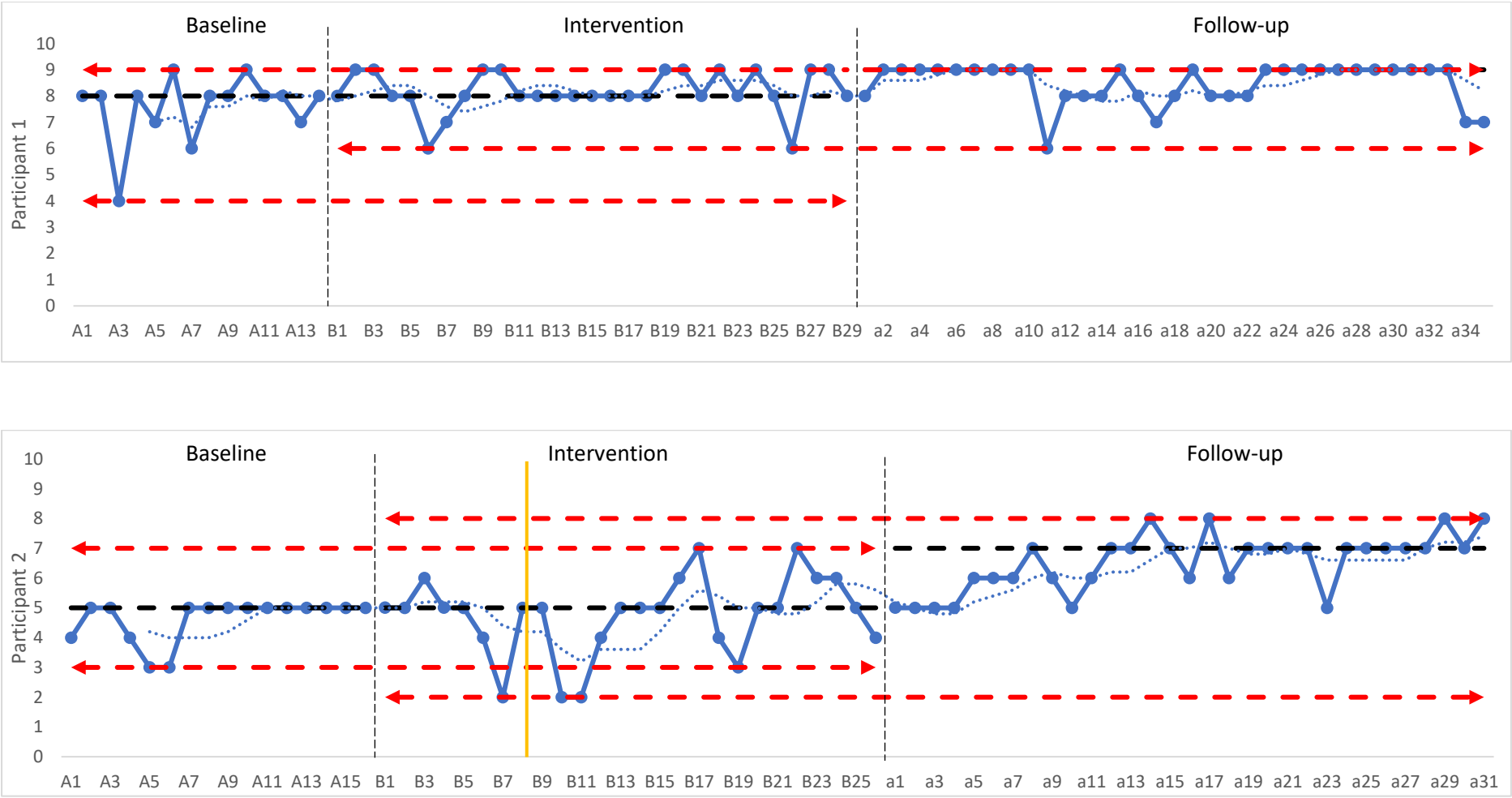
Similarly, P6 also had a reduction in exercise adherence which reduced during the intervention, and maintained low at follow-up, as shown by a downward trend and

decreased central tendency. Tau-U analysis confirmed the reduction in worries between baseline and combined intervention/follow-up (Tau-U= -.55, p= 0.004).

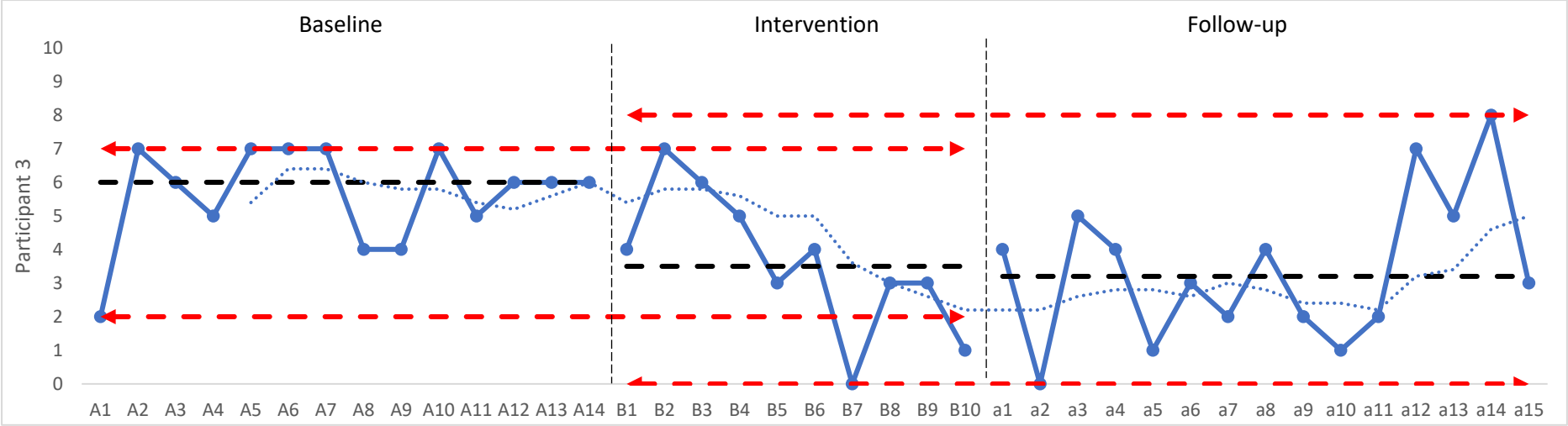
Overall, these findings indicate no consistent pattern in exercise changes in response to the mindfulness course. Several participants stuck more closely to their planned routine over time, whilst others reduced their exercising.

Figure 13

Exercise Regimen Adherence VAS



Please note: yellow line indicates timepoint at which P2 disclosed there had been a death in the family.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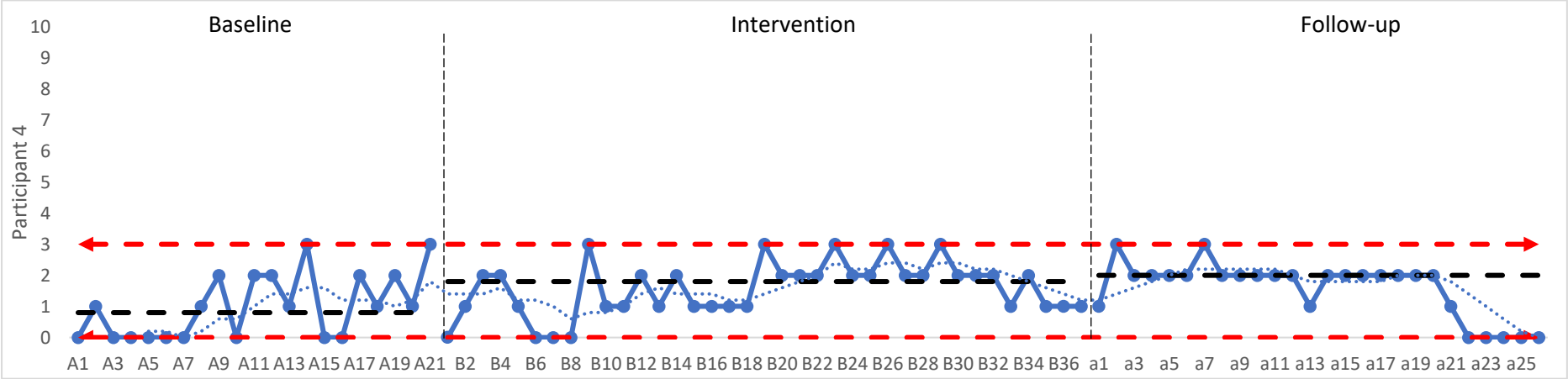
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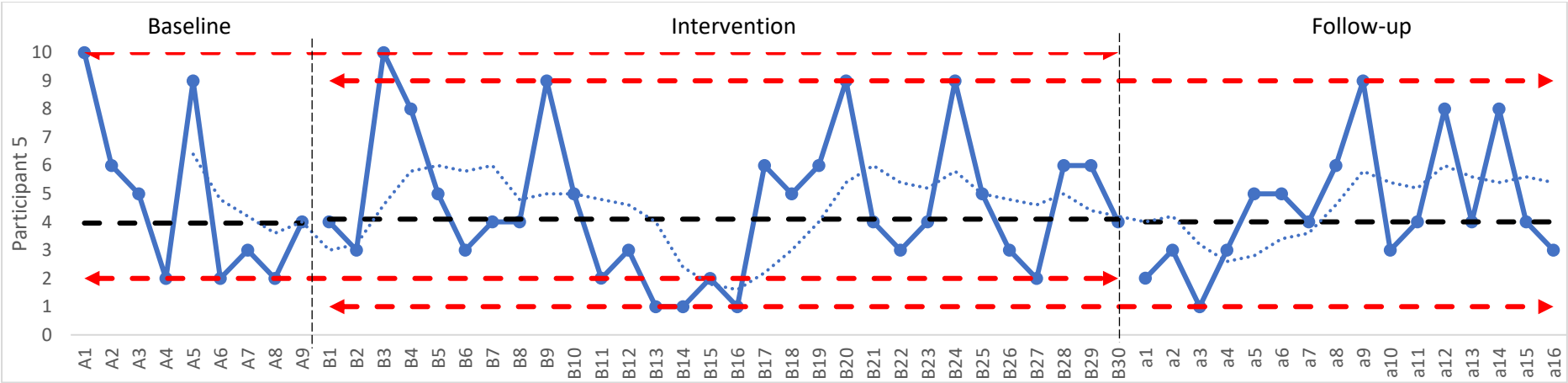
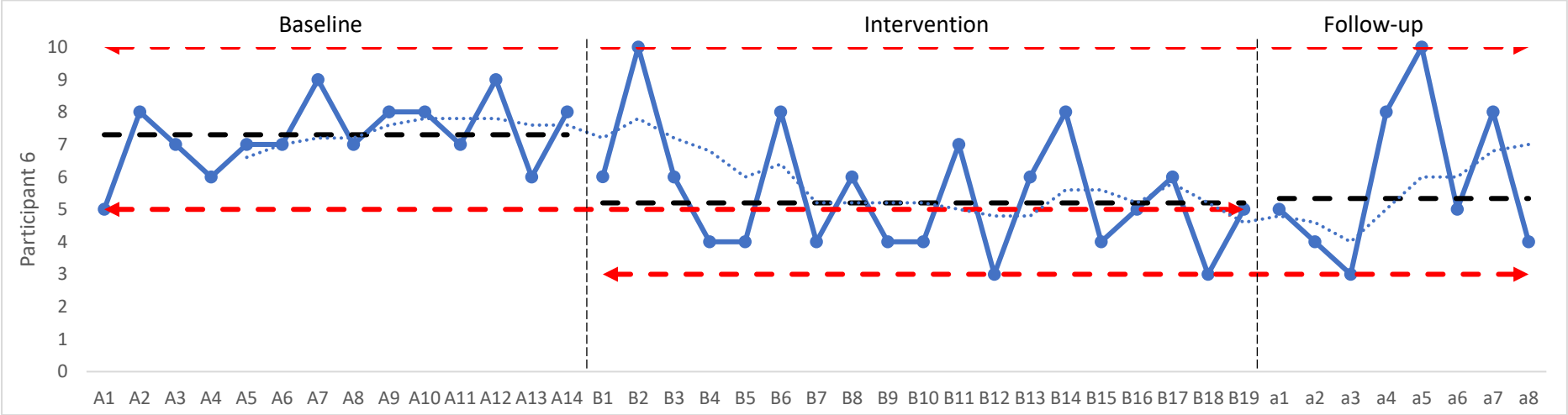




Each data point represents a self-rating on a 0-10 scale (0=Not at all, 10=Completely) on how much the person followed their exercise regime in the past 24 hours.

Omnibus Tau-U Effect Sizes

Weighted averages of data non-overlap between phases were calculated across participants for FOH-worry and FOH-behaviour (Appendix S, Table 3), as these variables had four and three effect replications between phases, suggesting an intervention effect. When combining data from intervention and follow-up relative to baseline, there were significant reductions in FOH-worry (Tau-U=-.39, $p<.001$) and behaviour (Tau-U=-.41, $p<.001$). However, causal inference from the significance of weighted averages could not be drawn due to the lack of strict control over confounding variables such as idiosyncratic events (Parker & Vannest, 2012).

Standardised Results

For standardised measures, reliable change was calculated to see whether reliable change (RC) had occurred between (1) baseline and post-intervention, and (2) baseline and one-month follow-up. Clinically significant change (CSC) was also computed where RC was achieved. The desired direction to indicate improvement for each measure is provided in Appendix Q. Raw scores for each time point and RC index (RCI) values are shown in Appendix T (Tables 1-6).

Fear of Hypoglycaemia

Most participants (n=4) achieved RC in total FOH (FOH-worry and behaviour combined) between (1) baseline and intervention; and (2) baseline and follow-up. P4 and P6 achieved RC on total FOH between baseline and directly post-intervention (RCI=-5.46; RCI=-4.13 respectively), which was maintained at follow-up (RCI=-4.66; -4.13 respectively). Furthermore, P1 (RCI=-3.33) and P5 (RCI=-2.53) also had RC between pre-intervention and follow-up which may indicate that FOH reduces once the mindfulness skill is practiced.

Regarding the worry subscale, most participants (n=4) achieved RC indicating worries reduced after engaging in the MBI. P4 (RCI=-5.51) and P6 (RCI=-5.51) had RC between baseline and post-intervention, and also between baseline and follow-up (RCI=-5.51; -5.51 respectively). P1 (RCI=-4.59) and P5 (RCI=-3.67) also had RC between pre-intervention and follow-up.

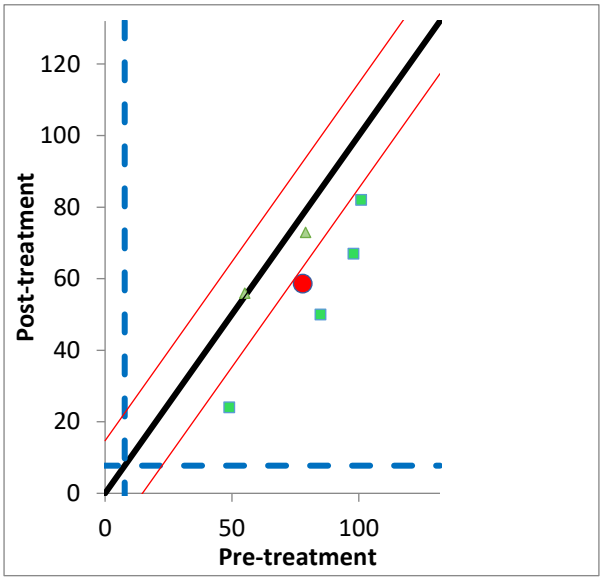
For the behavioural subscale, one participant (P4) achieved a RC between pre- and post-intervention (RCI=-2.96). No participants achieved RC between pre-intervention and follow-up. CSC was not found on either of the subscales.

These results indicate that FOH-worries reduced reliably for over half of participants, suggesting that the mindfulness course reduced feared cognitions regarding hypoglycaemia more so than altering behaviours. Figure 14 displays a graph showing RC for all participants on the HFS-II between baseline and one-month follow-up.

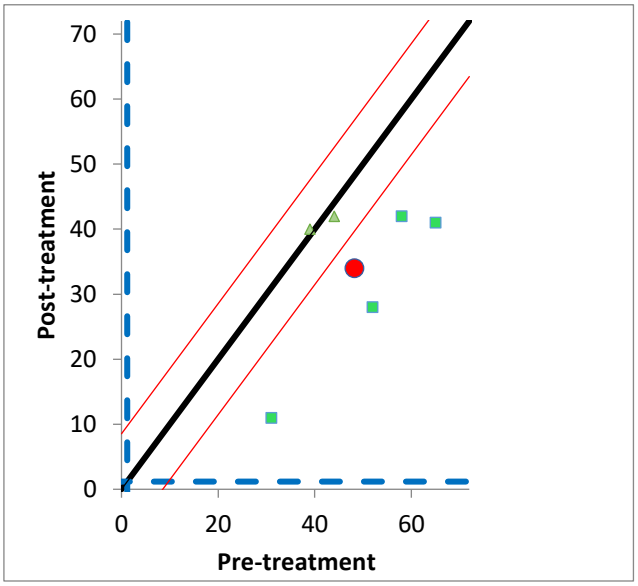
Figure 14

Reliable and Clinically Significant Change for HFS-II between Baseline and Follow-up

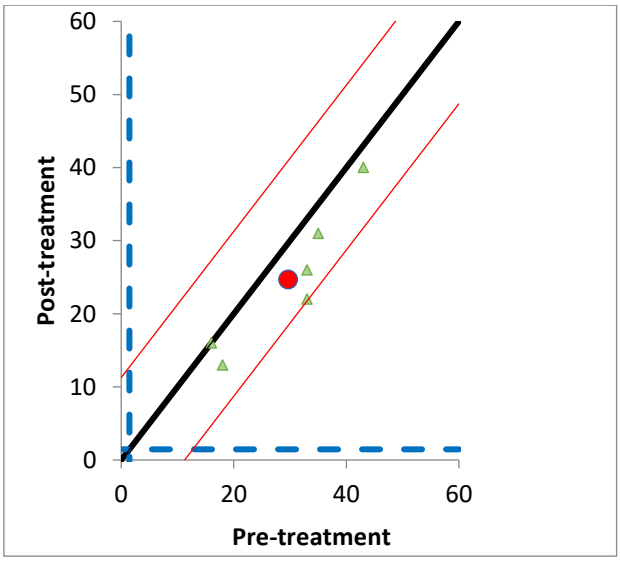
A. Fear of Hypoglycaemia Total



B. Fear of Hypoglycaemia: Worry



C. Fear of Hypoglycaemia: Behaviour



Note. Comparisons between pre-treatment and follow-up scores for HFS-II Sum score (A), HFS-II Worry Subscale (B), HFS-II Behaviour Subscale (C). Criterion A was used for CSC. =reliable change; =no change; =deterioration; =line of no change; = average clients score pre and post-intervention, cut off score=

Diabetes well-being

Most participants (n=5) achieved RC indicating a reduction in diabetes-specific negative well-being (W-BQ28). P1 (RCI=-7.05), P2 (RCI=2.35), P3 (RCI=-2.35), P4 (RCI=-7.05) and P6 (RCI=-7.05) had improved diabetes specific well-being between baseline and post-intervention, with P1, P2 and P3 maintaining changes at follow-up (RCI=-11.74, -7.05 and -2.35 respectively). Regarding diabetes-specific stress, two participants (P2 and P4) achieved improved RC (RCI=-2.84; -3.78 respectively) which was maintained at follow-up. However, P1 deteriorated from baseline to intervention (RCI=2.84) and P3 from baseline to follow-up (RCI=2.84). Two participants achieved RC and CSC in diabetes-specific positive well-being. P3 improved between baseline and intervention (RCI=5.94) and P1 improved between baseline and follow-up (8.91). Overall, results suggest that participants felt less downhearted and worried about their diabetes after engaging in the MBI.

General well-being

Findings suggest that three participants (P1, P2 and P3) experienced less generic stress and more positive well-being after starting to practice mindfulness (W-BQ28). Two participants experienced RC indicating reduced general negative well-being. P4 achieved RC at post-intervention (RCI=-2.42) and this was maintained at follow-up (RCI=-4.03). Additionally, P2 achieved RC between baseline and follow-up (RCI=-2.42). Regarding energy levels, one participant (P4) achieved RC and CSC between baseline and follow-up (RCI=2.19), indicating that they had higher energy levels one-month after course completion. There were three reliable and clinically significant improvements in generic positive general well-being, with P1 (RCI=6.7), P2 (RCI=2.68) and P4 (RCI=4.02) achieving RC at follow-up, compared with

baseline. Similarly, the same three participants achieved RC in levels of stress between pre- and post-intervention (RCI: P1=-2.08; P2= -2.08; P3=-3.47), with changes maintained at follow-up for P1 (RCI=-2.78) and P4 (RCI=-4.86). Findings indicate that the MBI was associated with improved general well-being.

Diabetes self-management

No participants reached RC on diabetes self-management (DSMQ) total score between baseline and immediately post-intervention. However, P2 reliably improved between baseline and follow-up (RCI=2.56) and demonstrated CSC by moving away from the clinical cut-off (criterion A).

Post-hoc analysis of the DSMQ subscales to explore the impact of the MBI on individual self-management behaviours showed that for BG management, RC and CSC was achieved for two participants. P3 met RC between pre- and directly post-intervention (RCI=2.04) and was maintained at follow-up (RCI=2.54). P2 also had a RC and CSC between baseline and follow-up (RCI=2.04) indicating that with continued mindfulness practice, BG management may have improved. For dietary control, one participant (P4) had RC and CSC between baseline and post-intervention (RCI=3.3) and this was maintained at follow-up (RCI=2.48). However, P3 had reliably deteriorated between pre-intervention and follow-up (RCI=-2.47). No participants had any RC in physical activity or healthcare use between pre-intervention and either follow-up point (Appendix T, Table 3). Results therefore corroborate idiographic findings and indicate that the MBI was not associated with significant improvement in diet, exercise or healthcare use.

Trait Mindfulness

Regarding trait (or dispositional) mindfulness, it was not expected that scores on each facet would change, as dispositional traits are difficult to modify. However, it is of note that of the five facets of mindfulness (acting with awareness, describing, non-judging, non-reactivity, observing), reliable change was found for 'non-judging of inner experience' for three participants. P1 (RCI=3.59), P2 (RCI=2.7) and P4 (RCI=4.94) achieved reliable improved changed on this facet between pre-intervention and follow-up. This indicates that they reduced assigning critical judgements to experienced thoughts and feelings after engaging in the mindfulness course.

Process Results

State Mindfulness Scale (SMS)

RC analysis was conducted for the SMS using The Leeds Reliable Change Indicator (Morley & Dowzer, 2014). The measure provided a sum score as well as two subscales; state mindfulness of mind and state mindfulness of body. The desired direction of change was increasing scores, which indicates increased state mindfulness. Change was assessed between week one of the module with each of the subsequent course weeks. SMS data for P4 was not available for weeks three and four owing to a technological difficulty with Qualtrics. Full data is therefore available for five participants. Raw scores and RCI scores are presented in Appendix U (Tables 1-2).

Three participants (P2, P3 and P5) achieved RC in total state mindfulness between week one and subsequent weeks, indicating that mindfulness improved with time and practice.

On the ‘Mind’ subscale (measuring ability to notice and attend to thoughts and emotions), three participants made reliable improvements throughout the course. P2 achieved RC for all weeks compared with week 1, with the largest difference in the final week (RCI=8.76), suggesting that mindfulness improved with time and practice. Similarly, P3 achieved RC in state mindfulness at week 3 which increased further by week 4 (RCI: week 3 = 4.86; week 4 = 5.84). P5 also improved reliably by week 3 with greater improvement by week 4 (RCI: week 3 = 2.92; week 4 = 3.41). Findings therefore suggest that half of participants were better able to notice and attend to thoughts and emotions throughout the course.

There are less consistent findings for the ‘Body’ subscale (measuring ability to notice and attend to physical sensations). Three participants (P2, P3, P5) improved reliably. However, improvements occurred at different timepoints. P2 improved at week 2 (RCI=4.68), with greatest improvement at week 4 (RCI=6.24), suggesting that they could better attend to physical sensations with practice. P3 achieved most reliable change in weeks 2 and 3 and reduced by week 4. This may be because weeks 2 and 3 invited participants to attend more to bodily sensations (‘The Body Scan’; ‘Mindful eating’) compared with week 4 which asked participants to attend to feelings (‘Mindfulness with difficult emotions’). P5 improved in week 2 (‘The Body Scan’) (RCI=5.46) and at no other time point. Overall, findings indicate that specific exercises may have led to greater state mindfulness of body.

Discussion

Key Findings:

- Worries about hypoglycaemia reduced significantly for the majority of participants after engaging in the online MBI.
- There is tentative support that the MBI was associated with reductions in FOH-behaviours.
- Diabetes-related well-being improved reliably for the majority of participants after engaging in the MBI.
- State mindfulness increased reliably for most participants during the MBI.
- The intervention was found to be acceptable to all participants who took part.

In the following section, findings will be summarised with reference to the wider literature. Acceptability and feasibility of the intervention will also be reviewed and strengths and limitations of the study will be discussed. Recommendations and clinical implications of the findings will be considered.

Summary of Findings

Acceptability and Feasibility

The hypothesis that the online MBI would be acceptable and feasible was partially supported. Results indicated high acceptability of the MBI and partial evidence for feasibility. Participants rated the acceptability on the CSQ-8 between 75-100%, indicating that participants felt satisfied with the amount of support they received and that it helped them effectively deal with their problems. Additional feedback on the user-friendliness and appropriateness of the online MBI indicated that all participants found the programme informative, user friendly and easy to use. Qualitative data highlighted that the online format of the mindfulness exercises was a

helpful aspect of the intervention. This corroborates research which has found online MBIs to show significant small to moderate effects on mental health outcomes (Spijkerman et al., 2016).

Regarding feasibility, despite meeting the recruitment target of six participants, there was a low retention of participants with 57% of those who completed T1 measures disengaging from the project. This may be partially reflective of common barriers to practicing mindfulness such as time constraints, motivation, and disbelief in the efficacy of the practice (Sears et al., 2011). It is worth noting that attrition may have also been due to the relatively high demands placed on participants to complete measures as part of the SCED design (e.g. daily measures), with 25% of dropping out during the baseline phase before starting the course. This is reflective of low retention in SCED designs as found in similar projects (Somaini, 2021).

Psychological Outcomes

Fear of Hypoglycaemia

Findings supported the hypothesis that the online MBI would lead to changes in FOH, with more support for worries reducing after engaging in the MBI as compared with FOH-behaviours. Overall, FOH-worry significantly reduced between baseline and combined intervention/follow-up phases for the majority of participants (n=4), as supported by visual and Tau-U analysis. Analysis of standardised measures corroborated these findings. Regarding FOH-behaviours, idiographic data showed three participants engaged in significantly fewer behaviours between baseline and combined intervention/follow-up. However, the standardised FOH measure (HFS-II) found conflicting evidence as most participants (n=5) did not achieve reliable change. This may be resultant of the VAS measure only asking one question which may have

not captured the construct as sensitively as the 15-item HFS-II Behaviour Subscale. Overall, results indicate that the brief mindfulness course may be most effective in targeting the cognitive aspects of FOH.

This finding may be explained by Monitor and Acceptance Theory (Lindsay & Creswell, 2017), whereby reducing thought suppression and cultivating non-judgement towards unwanted thoughts is associated with reduced emotional reactivity (Lindsay & Creswell, 2017). It is also in line with the argument for the suitability of third-wave CBT approaches in supporting people with long-term health conditions, where feared thoughts (e.g. experiencing hypoglycaemia) are often linked to the possibility of realistic consequences. In a systematic review of 16 studies analysing web-based MBIs for people with various physical health conditions (i.e. cancer, fibromyalgia, IBS, epilepsy, heart disease, tinnitus, acquired brain injury), findings indicated positive effects of MBIs compared with usual care on a variety of outcomes including pain acceptance, coping measures, and depressive symptoms (Toivonen et al. (2017). This may indicate how changing the way an individual relates to health-related cognitions using third-wave approaches, may be more helpful than challenging the content of cognitions (Hofmann et al., 2010).

Literature shows that current psychological and educational interventions have a limited impact on reducing FOH in adults with T1D. Psychological interventions such as CBT have predominantly non-significant effects on FOH-worries and limited but more promising findings on reducing behavioural aspects of FOH (Amsberg et al., 2009; Ismail et al., 2008; Snoek et al., 2001). Regarding educational interventions, BGAT seems the most promising in targeting FOH, but there are still inconsistent findings for it's impact on worries and behavior (Rondags et al., 2016a; Rondags et

al., 2016b; Cox et al., 2001; Schachinger, 2005). Literature investigating DAFNE courses suggest no long-term impacts of DAFNE on FOH (De Zoysa et al., 2014; George et al., 2008; Cooke et al., 2015). Overall, MBIs may present a viable alternative which can target cognitive aspects of FOH in a novel way.

One participant (P3) did not experience reduced FOH-worries or behaviours on either VAS or standard measures. This participant also described experiencing hypoglycaemia 'fairly often' (30 to 39 days out of 2 months) compared to most other participants (n=4) who reported 'occasionally' (every 10-19 days). In line with the biopsychobehavioual model of risk, P3's risk of hypoglycaemia is therefore comparatively higher. Fear for this individual may be proportionate to their level of risk. It has been proposed that there is a discrepancy between actual risk of hypoglycaemia and level of fear in people with T1D (Anderbro et al., 2015; Irvine et al., 1992). Those with high risk should first receive educational and technological interventions aimed at reducing the occurrence of hypoglycaemia (e.g. DAFNE; Choudhary et al., 2015). Alternatively, those with high fear but low risk may benefit more from interventions which aim to reduce anxiety (e.g. CBT, ACT; Vallis et al., 2014). This may explain why the MBI was less effective in reducing FOH in P3, as it was not targeting the underlying factors contributing to FOH.

Well-being

Results indicated that diabetes-specific well-being improved significantly for most participants, and there is evidence to suggest that general well-being improved. Most participants (n=5) showed reliable improvements in diabetes-specific well-being, particularly reductions in negative well-being, suggesting that they felt less downhearted and worried about their condition. Regarding general well-being, visual

analysis indicated reductions in low mood and anxiety for half of participants, although statistical analysis of idiographic data did not find three significant repeated reductions. RCI for standardised measures indicated reliable change in reduction of general stress and an increase in positive well-being for half of participants. Findings are corroborated by wider literature. A systematic review investigating fifteen MBIs delivered to people with diabetes, found that across well-being outcomes, diabetes-related distress and anxiety were more often reported as having most consistently reduced post-intervention (Massey et al., 2019).

Behavioural Outcomes

Diabetes Self-management

The hypothesis that the MBI would lead to changes in self-management behaviours was not supported. Results indicated that behaviours were not associated with engagement in the mindfulness course, with most participants not achieving reliable change on diabetes self-management total score (DSMQ) (n=5). This is corroborated by findings for each subscale when idiographic and standardised measures were analysed.

Regarding BG management, there was a discrepancy between idiographic and standardised data. VAS data showed that generally most participants (n=5) had stable and high scores across phases, and therefore did not significantly improve, which may have been resultant of a ceiling effect. For the standardised measure, which is able to sensitively capture more aspects of BG management, there was reliable and clinically significant improvement for two participants. These findings are corroborated by the wider literature which has also found mixed results on the impact of MBIs in improving glycaemic control. Some studies suggest improvements when compared

with a control (Armani Kian et al., 2018; Rosenzweig et al., 2007), and others have found no significant difference (Tovote et al., 2013, 2014; van Son et al., 2013).

There was also no consistent pattern in adherence to diet, medication or exercise regime. Several participants stuck more closely to their planned regimens during intervention and follow-up, whilst others were less compliant. This differs to the wider literature which suggests that increased mindfulness positively impacts diet. In a study on over 600 people with T1D and T2D, high state mindfulness was associated with less emotional and less environment-influenced eating patterns (Tak et al., 2015). A potential explanation for current results is that the MBI was a brief four-week course, and therefore mindfulness skills may not have yet been practiced enough to show secondary effects on behaviour.

Mindfulness

The hypothesis positing that mindfulness processes would increase during the MBI was supported. Findings indicated that of the five participants who provided process data on state mindfulness, three achieved reliable change. This suggests that for these participants the course did what was intended and increased their ability to observe internal states. More consistent improvements were shown across the mind subscale, with all three participants improving at weeks 2 or 3 compared to week 1, with further improvements at week 4. This suggests that with time and practice, ability to observe thoughts and feelings mindfully improved. There were less consistent improvements for the 'Body' subscale, indicating that specific exercises may have led to greater state mindfulness of body ('The Body Scan'; 'Mindful eating'), rather than continued practice and time.

Regarding trait mindfulness, it was not expected that scores on each facet would change, as dispositional traits are difficult to shift, with some research suggesting that brief MBIs have no significant impact on facets of trait mindfulness on the FFMQ (Manuel et al., 2017). However, there was an interesting observation as one facet, 'non-judging of inner experience', reliably improved for three participants between baseline and follow-up. This indicates that these participants reduced assigning critical judgements to internal experiences (thoughts and emotions) after engaging in the mindfulness course. Two of these participants experienced significant reductions in FOH-worry and so it can be tentatively considered that this is an underlying mechanism to reducing worry. This corroborates Monitor and Acceptance Theory which posits that cultivating non-judgement towards internal experiences is associated with reduced emotional reactivity and improvements in affect regulation (Lindsay & Creswell, 2017).

Strengths and Limitations

There were strengths and limitations in the design, sampling, measures and analysis aspects of the project. Single-case designs are beneficial in that they solve some problems which arise in group designs such as 'The Group Fallacy', whereby findings apply to the 'average' person who may not exist. Furthermore, the multiple baseline aspect of the design and randomisation of participants to baseline acted as a control against several threats to validity including reactive intervention, history and maturation (Morley, 2017). The format of the intervention was also ecologically valid as participants accessed the course online, and intervention integrity was maintained with all six participants reporting they practiced mindfulness 2-3 times per week (as recommended). However, the design was limited in that the baseline phase did not

finish for each participant once the target idiographic variable, FOH, was stable. This was due to project time constraints. It is important to have a stable pattern of data points across the baseline period so that it can be reasonably concluded that a change in level or trend at the introduction of the MBI is associated with the intervention (Kazdin, 2019; Morley, 2017). A lack of a stable baseline can reduce internal validity as there is a risk extraneous variables are causing variability in the data at the point in which the intervention begins. Further limitations include the possibility for demand characteristics as participants were aware that the course was aimed at supporting people experiencing FOH, which may have led to response bias.

Regarding the sample, there may have been a potential for selection bias. As the advert was posted on social media, it is difficult to discern the amount of people who saw it and the percentage of the target population who expressed interest. There may also have been a bias towards people who have an interest in mindfulness which may not be representative of a wider population. Furthermore, all six participants were of white background which limits generalisability. Differences have been found across geographical regions, with lower levels of FOH in Northern Europe and Canada compared with South East Asia (Khunti et al., 2017). The sample was also mostly female and research suggests gender differences in predictors of FOH (Hendrieckx et al., 2019). For example, FOH is associated with over-interpretation of hypoglycaemic symptoms in women, and frequency of hypoglycaemia in men (Anderbro et al., 2010). However, a strength was that the sample was geographically representative of the UK, with participants residing in Scotland, southern and northern England. Additionally, one participant was originally from Ireland.

Regarding strengths and limitations of the measures, the standardised measures assessing FOH, well-being and diabetes self-management have been widely used in the literature and demonstrate high validity and reliability. Additionally, VAS have been described as a sensitive measurement method as they enable the rater to make more 'fine-grained' responses without the constraints of direct quantitative terms (Sung & Wu, 2018). The process measure (SMS) has been found to have strong internal consistency ($\alpha = .90–.95$) as well as high convergent and discriminant validity (Tanay & Bernstein, 2013). However, a limitation of the SMS is that it may not capture the 'non-judgement' aspect of mindfulness as conceptualised by Monitor and Acceptance Theory, which was developed to comprise the 'mindfulness' components most commonly cited in the literature. The SMS only considers the monitoring or 'observing' element of mindfulness and therefore may lack construct validity.

Regarding data collection and analysis, use of statistical Tau-U analysis was a strength in that it removes observer bias which may occur during visual analysis (Jones et al., 1978). However, using multiple measures to assess each construct (VAS, standard), may have increased risk of a type 1 error as there were multiple opportunities for hypotheses to be tested.

Implications and Recommendations

Findings from the pilot have clinical implications for mental health and diabetes services. Many NHS diabetes services do not include access to diabetes-specific psychological support due to funding limitations (Trigwell et al., 2008). Furthermore, there are no current interventions specifically targeting FOH. Online MBIs may present a low-cost method of support which could help to fill a gap in service provision by directly supporting individuals with this presentation. MBI's may

particularly target the cognitive aspects of FOH and could also be combined with CBT or BGAT which have been found to reduce behaviours associated with FOH (see 'Systematic Review').

Findings also indicate directions for future research which could focus on testing the impact of the online MBI in a larger scale randomised controlled trial (RCT). This could involve adapting the intervention to incorporate more behavioural aspects, such as combining the mindfulness course with ACT where there is a valued living component to enhance behavioural changes. A larger scale RCT could also compare various conditions on aspects of FOH (e.g. 'mindfulness only'; 'mindfulness with valued living'; 'mindfulness with BGAT'). Trials would also benefit by expanding to a more diverse population to enhance generalisability of findings. Additionally, future research could investigate the underlying mechanisms of FOH and whether there are associations between FOH and particular facets of mindfulness.

Conclusions

Overall, the current study indicated that a brief online MBI targeting FOH, may lead to reductions in FOH and increase diabetes-specific well-being in adults with T1D. In particular, the mindfulness exercises are potentially associated with the cognitive aspect of FOH, and in reducing worries. Changes in outcomes may be resultant of an increase in state mindfulness, which involves learning to observe and cultivate a non-judgement stance towards inner states (thoughts, emotions, bodily sensations).

Online MBIs may offer a low-cost intervention which can help to meet a gap in service provision, in line with the NHS England Five Year Forward View for Mental Health (2015) which highlighted the importance of integrating mental and

physical health approaches. More specifically, MBIs offer an accessible way to support people who fear hypoglycaemia, which is not yet specifically targeted in current psychological, educational or technological interventions. The online MBI was found to have high acceptability as participants found the course informative, relevant to their needs and user friendly. Although, low retention rates may indicate that the course is not suitable for all adults with T1D. Future research could benefit from testing the online MBI in a larger scale trial to assess whether findings are substantiated.

IV. Integration, Impact and Dissemination

In this section I will integrate the systematic review (SR) and empirical study, discuss the clinical and academic impacts of the project and illustrate the plan for dissemination. Critical appraisal and reflections on different aspects of the project are included.

Integration

The primary aim of the project was to gain an understanding of the effectiveness of current interventions in reducing fear of hypoglycaemia (FOH) in adults with type 1 diabetes (T1D), and to develop a new mindfulness-based course to support people with this presentation. This is an important research avenue because it has been identified that many NHS diabetes services do not include access to diabetes-specific psychological support due to funding limitations (Trigwell et al., 2008). I chose this topic because I have an interest in the impact of long-term physical health conditions on mental health. More specifically, I am interested in the psychological impact of hypoglycaemia and how psychological theory can inform evidence-based interventions to support people with this presentation.

A natural starting point was therefore to develop an SR question which considered the current impact of psychological and educational interventions on FOH in adults with T1D. There were two previous systematic reviews which had explored prevalence and predictors of FOH and included brief summaries on efficacy of interventions (Martyn-Nemeth et al., 2016; Wild et al., 2007). The review aimed to build on these summaries and investigate research which had since been published, including trials on Dose Adjustment for Normal Eating (DAFNE) courses, which were not previously included.

There were several challenges when conducting the SR. As FOH is an under-researched construct in effectiveness trials, it was often a secondary outcome in the majority of studies. Although this re-affirmed that the review was targeting a gap in the literature, it caused a difficulty as descriptive statistics for FOH were not always reported. As most authors did not respond to requests for this information, I could not calculate effect sizes which impeded comparison between interventions at the data synthesis stage. Furthermore, many courses were adapted versions of Blood Glucose Awareness Training (BGAT), or DAFNE which had been developed for a particular service context. Descriptions of these interventions were not provided in all papers and there was heterogeneity in intervention content. This also made it difficult to assess how effective an approach was when interpreting a cluster of trials with slight differences in content. I responded by aiming to be as clear as possible in the extraction tables and referred to study protocols for further information. This process taught me the importance of clarity in describing an intervention which was incorporated into the empirical project.

The SR identified that there are few interventions targeting FOH, particularly DAFNE and third-wave CBT models such as Acceptance and Commitment Therapy (ACT) and mindfulness-based interventions (MBI). The educational and psychological interventions included in the review also showed limited effectiveness in reducing FOH. BGAT was found to be the most promising approach, with small to medium effect sizes. It was hypothesised this may be because it supports people to be more in tune with their physical sensations and therefore learn to better discriminate between symptoms of anxiety and those of hypoglycaemia. This may reduce overinterpretation of bodily sensations which has found to be associated with FOH

(Anderbro et al., 2015). It was recommended that further research was required to investigate novel interventions which focus on the mind-body link. In line with this, the empirical project aimed to explore the impact of a MBI on FOH and other diabetes-related outcomes. Results found that the MBI showed preliminary effectiveness in reducing FOH and improving well-being, and was acceptable for use in a T1D population.

Reflections on study methodology

The design of the empirical project was initially a Randomised Controlled Trial (RCT). However, this was later amended owing to the large number of participants required in order to meet statistical power. This recruitment target did not seem feasible within the timeframe of a doctoral thesis. It was also noted that a previous doctoral RCT project recruiting from the same population, encountered high attrition and was underpowered which limited the conclusions (Logeswaran, 2020). Using a Single Case Experimental Design (SCED) ensured the study was adequately powered with a small sample size, with each participant acting as their own control (Kazdin, 2019).

However, there were some challenges. An aspect of SCED designs is to collect daily idiographic data so that outcomes can be assessed over time in order to detect real-time, nuanced changes (Morley, 2017). However, this may have placed a relatively high demand on participants, contributing to low retention. A large number of participants (25%) dropped-out during the baseline phase, before accessing the mindfulness course. This was reflective of low retention in SCED designs as found in similar projects (Somaini, 2021). I tried to overcome this barrier initially by clearly describing the measurement process during the screening phone calls and assessing

motivation to engage. I also used email and telephone check-ins where barriers to questionnaire completion were problem-solved (e.g. having a set time each day, putting a reminder on the phone). This was quite challenging due to the additional planning and administrative burden which made me reflect on the challenges this may bring if adopted in services. However, I particularly valued engaging with participants and felt it was central to their engagement in the intervention. I've learnt about the importance of blended approaches with research suggesting that it can lower drop-out rates for online interventions (Erbe et al., 2017).

Furthermore, there were technological difficulties with Qualtrics (electronic platform used to deliver the MBI and collect data). I noticed that some participants were not continually accessing modules on time or were delayed in completing the standardised measures. After exploring this during check-in emails and phone calls, I became aware that Qualtrics was not consistently sending out links to modules and measures. I tried to overcome this issue by contacting the Qualtrics support team however, they could not identify the issue other than considering a system update had caused an error. I responded by continually monitoring whether emails were sent out to each participant on time and manually sending links if they hadn't. This added an administrative burden which had not been anticipated. The issue did cause frustration for some participants, and I realised that a user-friendly and accessible digital platform can be as important as the content of the course. In hindsight it would have been helpful to collect feedback from those who dropped out as it is unclear whether technological issues, demand for daily measures or lack of acceptability of the MBI were reasons for drop-out. This feedback would have also provided a more balanced understanding of the acceptability of the intervention as the final feedback analysed

were from those who completed the project and did not encounter technological issues.

Reflections on recruitment

The changing of the design led to a delay in submitting for Health Research Authority (HRA) approval which postponed recruitment via two NHS diabetes services. Approval was granted in September 2021 however, there were subsequently further delays with the Research and Development (R&D) departments at the Trusts with which we were collaborating. Due to these delays, a decision was made to broaden the recruitment pool and advertise the project through charities and diabetes support groups. In December 2021, I contacted diabetes support groups across the UK and posted the project poster on various diabetes support groups on Facebook. I noticed that despite initial high interest to my Facebook posts (n=50), individuals would often not follow-up to arrange a screening appointment. On the other hand, of those expressing interest via charity support groups, most would proceed to provide informed consent. On reflection, it is unclear whether high drop-out was due to individuals not meeting eligibility criteria, a reluctance to engage with measurement demands, or re-considering the helpfulness of an online MBI. It would be useful for future research to explore factors promoting engagement in an online MBI and what the main draws and barriers are to commitment.

Regarding recruitment via NHS services, I liaised with a clinical psychologist and consultant endocrinologist in Charing Cross hospital who identified nine potential participants presenting with FOH (according to self-report and clinician judgement). I also attended a multidisciplinary team (MDT) meeting at the service to raise awareness to the clinical team. During recruitment with Barts, I liaised with a clinical

psychologist who disseminated the project advert through a newsletter and SU mailing list. I also attended a pump support group to raise awareness to SUs. During recruitment, I noticed that patients referred from Charing Cross hospital seemed to voice that FOH was a concern more so than participants recruited through charities and social media. They also appeared to score consistently higher on the Hypoglycaemia Fear Survey (HFS-II; Gonder-Frederick et al., 2011) worry items at the screening stage. This may have been because clinicians had identified those who presented clearly with FOH which led to more appropriate referrals. Retention for those who expressed interest in NHS services was comparatively higher to those from charities and support groups. This may suggest that people are more motivated to engage with an online targeted MBI if FOH is a more significant problem. This has made me reflect on who the course may be useful for and that an MBI tool may initially be better placed in NHS diabetes services.

Reflections on service user involvement

The Ladder of Participation model (Arnstein, 2019) was used to evaluate the level of service user involvement in the project. Due to time and resource constraints, service users were not involved during the SR process. Participants in the empirical project were informed of the review findings. According to the model, this level of involvement sits under the 'informing' rung of the ladder. This is regarded as an important first step towards service user participation, however, it is limited in that it relies upon a one-way flow of information (i.e. from researchers to service users), with no channel provided for feedback. It therefore falls within the 'tokenism' category of the ladder. I found reading about the model of participation to be instructive and have reflected on the ways in which service users can be empowered

to inform different aspects of the SR process e.g. considering priority topics and questions; suggesting and appraising the literature; interpreting findings. SU views can ultimately be helpful in understanding the perceived usefulness of synthesised research evidence and in addressing barriers to the uptake of evidence into practice (Pollock et al., 2018).

For the empirical project, the level of SU-involvement sat under the 'consultation' rung of the ladder. I contacted a group of service users from a diabetes service at Barts who are interested in involvement opportunities. They were informed of the project topic and invited to provide consultation. Despite there being a group of over five people interested, only two could be recruited due to the financial and time constraints of the project. This was a shame as I felt the content of the course could have benefited from the voice of multiple experts by experience. I had developed the mindfulness scripts from two books (Nash, 2013; Teasdale & Segal, 2007) but am aware that sometimes use of psychological terminology is less accessible or 'natural' to the public. Two SUs were provided with the course scripts and were asked to provide feedback in a 1:1 online meeting. Both recommended changes to wording and provided useful examples of day-to-day stresses pertinent to people who have diabetes, which were included in the psychoeducation material. One SU had also attended a mindfulness course at her diabetes clinic and advised on the barriers to practicing mindfulness which was incorporated into the course. On reflection, I felt SU involvement increased the user-friendliness of the course and I consider it an integral aspect of project development.

Overall, due to doctoral time constraints, the involvement of SUs was still limited and remained at the 'tokenistic' level. Further access to funding could have

supported involvement at all stages of the research cycle as advised by the NIHR (2012). For example, focus groups could have been held at the levels of design (i.e. clarifying the research question) and data interpretation to consider how the findings could inform service provision.

Impact

Clinical impact

Findings from the pilot have clinical implications for NHS diabetes services. The online MBI showed preliminary effectiveness in reducing FOH and increasing well-being. It was also found to be acceptable, with participants commenting that it was user-friendly and accessible. NHS diabetes services could benefit from incorporating a digital intervention such as this into care provision. For example, clinicians could incorporate an online MBI to support with the cognitive aspect of FOH, when delivering behavioural interventions such as BGAT. Similarly, in diabetes services where there are mindfulness groups, an MBI app could be used as a tool for at-home practice. Clinicians in diabetes services (e.g. psychologists, endocrinologists) could also signpost patients to the app if they self-report FOH during medical appointments, as a form of guided self-help. It is hoped that by clearly detailing the intervention in the write-up, clinicians working in psychology settings could have an example of how an MBI can be adapted for use by people with diabetes. This could help to reduce the burden on clinicians in diabetes clinics as these settings tend to have high turnover and patient load. Benefits and effectiveness of the tool could also be evidenced by regular feedback (e.g. through an app). This would support development to ensure it is meeting SU needs (Muñoz et al., 2018).

Furthermore, reducing FOH could have long-term financial benefits for the NHS as supporting people to stop engaging in safety behaviours which keep blood glucose levels high (a physiological state known as 'hyperglycaemia'), could reduce the risk of long-term microvascular and macrovascular complications (Diabetes UK, 2020). Developing interventions which support diabetes self-management behaviours would similarly provide the same outcome.

An app version of the MBI could also be circulated on a wider scale via charity websites or through support groups. The current findings show that there was high interest in an online mindfulness course on social media. Research also indicates that receptiveness to mindfulness apps are high, although there can be barriers to maintaining retention (Militello et al., 2022). A wider scale dissemination of an MBI app could support people to learn tools to maintain well-being and prevent deterioration of FOH. This 'preventative' rather than 'reactive' approach could ease longer-term burdens on diabetes and mental health services.

As this was a pilot study, it is unlikely that the results will influence policy makers or development guidelines at this stage. However, it is possible that services at a local level may begin to address local needs and to consider carrying out further research into this area due to the potential cost-saving benefits (Diabetes UK, 2010). This may eventually translate into larger policy driving work.

Academic impact

The SR identified that there is limited research into the impact of psychological and educational interventions on FOH in adults with T1D. Current educational and psychological interventions (i.e. BGAT, DAFNE, CBT) had small-to-medium effect sizes at best, with some inconsistencies across studies. These findings

benefit researchers as it provides guidance to investigate alternative approaches targeting FOH, such as ACT and MBIs. It was also recommended that studies investigating FOH would benefit by including the behavioural subscale of the HFS-II so that different aspects of the construct are captured in effectiveness trials.

The empirical pilot found that an online MBI targeted at reducing FOH, showed preliminary effectiveness in reducing FOH and improving well-being. The study provides a foundation for a larger scale RCT and outlines a clear example of the content of the MBI which can be used as a template. It could benefit the literature to see if findings are substantiated as this would further suggest that MBIs may be used at a clinical level. Alternatively, if it were found to be ineffective then this would indicate further research into novel approaches are required, which again would progress the literature base. Recommendations are also provided to explore variations of interventions on psychological outcomes in a diabetes population (e.g. 'mindfulness only', 'mindfulness with valued living' and 'mindfulness with BGAT'). Trials would also benefit by expanding to a more diverse population to enhance generalisability of findings. As the empirical study includes omnibus effect sizes, it could be used in meta-analytic reviews.

Project findings also contribute to theory, such as Monitor and Acceptance Theory (MAT; Lindsay & Creswell, 2017). It suggests that cultivating acceptance towards negative internal experiences may be associated with reductions in anxiety where worries are related to realistic consequences (e.g. fear of having hypoglycaemia) (Hofmann et al., 2010). It was interesting to see a shift in the 'non-judging' facet of mindfulness in the Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006) although this should be interpreted tentatively as it was found in

half of participants in a small pilot study. Future research could further explore the underlying mechanisms of FOH and whether there are associations between FOH and particular facets of mindfulness. One study has already found that lower mindful parenting was related to greater FOH in parents of children with T1D (Aalders et al., 2018). Exploring these associations further could add to add to existing theory and inform evidence-based models for presentations such as FOH.

Dissemination

In order to maximise impact, the SR and empirical project will be disseminated to a variety of audiences. All study participants will receive a plain English summary of the findings, if they opted to receive this. This is in line with best practice to feedback research outcomes towards which participants have contributed (HRA, 2018). A formal summary will also be provided to NHS professionals at diabetes services in Charing Cross Hospital and Barts.

A summary of the empirical project will be circulated to group leads at the diabetes support groups involved with recruitment. They can further disseminate to their members via newsletters, website bulletins or social media. I will also share the summary on social media platforms, including the Facebook diabetes support groups involved in recruitment. It is hoped that using social media will optimise reach to people with T1D, even if FOH is not a primary concern.

The empirical study was presented to trainee clinical psychologists and staff members in the Department of Clinical Psychology at Royal Holloway, University of London. The thesis will be available on Pure, the institutional repository of Royal Holloway for student and staff access. It is hoped that future students can continue to

explore the growing literature base on supporting people with FOH and can potentially build on findings of the current project.

I plan to prepare a manuscript of the SR and empirical project for submission to a peer-reviewed diabetes journal such as *Diabetes Care, Diabetic Medicine* or *Diabetes Research and Clinical Practice* for publication. Both are leading high impact journals in the diabetes field and would support dissemination of the findings to experts in the field. A peer-reviewed health psychology journal such as the *British Journal of Health Psychology* could also be considered. I am also planning to present the project at a conference such as the annual BPS Health Psychology Conference, or at a diabetes conference such as the Diabetes UK Professional Conference.

Through making the research widely available, it is hoped that clinicians and researchers will be encouraged to expand the literature on mindfulness for people with diabetes and to consider further investigating online MBIs in supporting people with FOH.

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VI. Appendices

Appendix A: Extraction Form

First author and date	
Country	
Study design	
Aims	
General findings	
Participants	
Number	
Age (mean, SD)	
Diagnosis	
Sex (% female**)**	
Characteristics	
Referral details	
Study completion rate Post (& follow-up if available) (n and percentage)	
Intervention	
Model (CBT, DAFNE, BGAT):	
Format:	
Components:	
Duration/no of sessions:	
Delivery provider:	
Adherence if stated (% and number):	
Control description:	
Outcomes	
Outcomes (primary and secondary)	
Outcome timings (comparator)	
Results	
Analyses	
Main intervention findings	
Additional comments	
Quality Assessment with comments	
Comments	

Appendix B: Ethics Approval

Appendix B1: *Ethical Approval from Wales Rec 3 NHS Research Ethics Committee*

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Miss Kate Landowska
Trainee Clinical Psychologist
Camden and Islington NHS Foundation Trust
Clinical Psychology Department
Royal Holloway, University of London
Egham, Surrey
TW20 0EXN/A

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

Re-issued 06 October 2021

Dear Miss Landowska

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Development and pilot testing of an online mindfulness-based intervention for improving fear of hypoglycaemia, well-being and self-management in adults with Type 1 diabetes**
IRAS project ID:	**295448**
Protocol number:	**N/A**
REC reference:	**21/WA/0218**
Sponsor	**Royal Holloway, University of London**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **295448**. Please quote this on all correspondence.

Yours sincerely,
Ann Parry

Email: Wales.REC3@wales.nhs.uk

Copy to: *Ms Leisha Wickham*

Appendix B2: *Approval from Ethics Committee at Royal Holloway University of London*

Ethics Review Details

You have chosen to self certify your project.

Name:	Landowska, Kate (2019)
Email:	NHJT019@live.rhul.ac.uk
Title of research project or grant:	Development and pilot testing of an online mindfulness-based intervention for improving fear of hypoglycaemia, wellbeing and self-management in adults with Type 1 diabetes
Project type:	Royal Holloway postgraduate research project/grant
Department:	Psychology
Funding Body Category:	No external funder
Funding Body:	
Start date:	01/08/2021
End date:	01/06/2022

Declaration

By submitting this form, I declare that the questions above have been answered truthfully and to the best of my knowledge and belief, and that I take full responsibility for these responses. I undertake to observe ethical principles throughout the research project and to report any changes that affect the ethics of the project to the University Research Ethics Committee for review.

Certificate produced for user ID, NHJT019

Date:	23/09/2021 11:09
Signed by:	Landowska, Kate (2019)
Digital Signature:	Kate Landowska
Certificate dated:	23/09/2021
Files uploaded:	Full-Review-2709-2021-05-24-12-14-NHJT019.pdf 21_WA_0218 IRAS 295448 Further Information Favourable Opinion.pdf 295448_(Approval)_Letter_of_HRA_Approval .pdf KL IRAS Form_295448.doc V2 IRAS_295448_Patient Information Sheet_K.Landowska.docx V2 IRAS_295448_Consent Form_K.Landowska.docx Full-Review-2709-2021-09-17-12-04-NHJT019.pdf Full-Review-2709-2021-09-23-11-25-NHJT019.pdf

Appendix C: Recruitment Email Advert

Hello,

My name is Kate Landowska and I'm a Trainee Clinical Psychologist based at Royal Holloway. I have been developing a new mindfulness course tailored for people with type 1 diabetes who also have worries about hypoglycaemia. I am wanting to pilot this course and am looking for participants to get involved in this project.

We know that some people with type 1 diabetes can worry about experiencing hypoglycaemia and these worries can be difficult to manage. We have developed this course to explore whether it can reduce this anxiety and improve diabetes self-management.
What is involved?

- Participants will be offered a **4-week online mindfulness course** which has been tailored specifically for people with diabetes.
- The project will take between 9 and 11 weeks. We will ask you to fill in a 2-minute daily questionnaire to check on your well-being.
- There will also be a set of questionnaires to complete before, after and at one-month follow-up of the course.
- You will receive a £10 Amazon voucher on completion of the final questionnaires as a small thank you!

Who can take part?
People who are aged 18 and over, are fluent in written and spoken English, diagnosed with Type 1 diabetes for at least one year and have access to the Internet.

If you would like to find out more, please contact me either by email at k.landowska@nhs.net or call me on 07470 259 736.

Best wishes,
Kate

Kate Landowska
Trainee Clinical Psychologist

Michelle Taylor
Project supervisor and Clinical Tutor

Appendix D: Recruitment Poster

ROYAL HOLLOWAY UNIVERSITY OF LONDON

Do you struggle with fears related to hypoglycaemia?

This project may be of interest to you.

Summary of Project

We know that some people with type 1 diabetes can worry about experiencing hypoglycaemia and these worries can be difficult to manage. We have developed a new online mindfulness intervention to reduce this anxiety and improve diabetes self-management.

What is involved?

You will be offered a **4-week online mindfulness course** which has been tailored specifically for people with diabetes.
You will receive a **£10 Amazon voucher** on completion of the final questionnaires as a small thank you!
The project will take between 9 and 11 weeks. We will ask you to fill in a 2-minute daily questionnaire to check on your well-being. There will also be a set of questionnaires to complete before, after and at follow-up of the course.

Who can take part?

People who are aged 18 and over, are fluent in written and spoken English, diagnosed with Type 1 diabetes for at least one year and have access to the Internet.

If you would like to find out more, please contact Kate Landowska on kate.landowska.2019@live.rhul.ac.uk or call me on 07470 259 736.

Appendix E: Participant Information Form

Participant Information Sheet

Development and pilot testing of an online mindfulness-based intervention for improving fear of hypoglycaemia, well-being and self-management in adults with Type 1 diabetes.

You are being invited to take part in the above research study developed at Royal Holloway, University of London by Kate Landowska (Trainee Clinical Psychologist), Dr Michelle Taylor (Researcher and Clinical Psychologist) and Dr Jane Vosper (Clinical Tutor and Clinical Psychologist).

Before you decide whether you want to take part, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with friends, relatives and relevant health professionals if you wish. Get in touch with the research team using the contact details at the end of this form to ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

If you wish to know more about medical research in general, Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'. A copy may be obtained from CERES, PO Box 1365, London N16 0BW.

Thank you for reading this.

What is the purpose of the study?

Research has shown that having insulin-treated diabetes can affect a person's well-being and quality of life. There is therefore a need to develop accessible

interventions to support people with type 1 diabetes in improving their quality of life and well-being. To meet this need, researchers at Royal Holloway, University of London have developed a 4-week mindfulness-based practice, which can be delivered via Qualtrics (a secure online computer programme). Mindfulness is a technique which has been found to improve general well-being and diabetes self-management in people with type 1 and type 2 diabetes. The aim of this study is to explore whether a brief online course of mindfulness exercises is feasible and acceptable for use with people with type 1 diabetes. It also aims to explore how effective the mindfulness sessions are in reducing fear of hypoglycaemia and improving diabetes self-management and well-being.

Why have I been given this invitation?

You have been given this invitation because your Diabetes Care Team has identified that you may be eligible to take part in this course of mindfulness sessions designed to reduce fear of hypoglycaemia and improve self-management and well-being, and you have expressed interest in finding out more about the study.

To be able to take part, you must meet the following criteria:

- Have been diagnosed with type 1 diabetes for at least one year
- Be at least 18 years of age
- Be fluent in written and spoken English
- Have access to the Internet
- Experience anxiety regarding or worry about having hypoglycaemic episodes
- Have hypoglycaemia symptom awareness

Do I have to take part?

It is up to you to decide if you would like to take part in the study. You can withdraw at any time without giving a reason and this will not impact on the standard of care you receive now or in the future. The data you have supplied up to that point will be removed and won't be used in the study.

What does taking part involve?

The study will be done completely online and will be accessible from home through a link that you will be sent via email, provided that you have access to the Internet. Participants will be involved in the research from nine to eleven weeks and will not need to visit any medical centre (e.g. diabetes clinic) more than their usual care.

If you decide to take part in the study, you will be asked to agree and give consent to the following:

Prior to the start of the study	• You will complete two short screening questionnaires (5-10 minutes) to assess if you are eligible to take part.
At the start of the study	• You will be asked to complete questionnaires about your worries about hypoglycaemia and any actions taken to avoid hypoglycaemia, your well-being, how you manage your diabetes and how mindful you are. Completion of the questionnaires usually takes between 30 and 40 minutes. • We will collect some personal, demographic and medical information from you. • You will be waiting for either one, two or three weeks to start the course of mindfulness sessions.
While you wait to start the mindfulness-based intervention Duration of this phase: one to three weeks	• You will fill in brief daily questions which will measure fear of hypoglycaemia, well-being and self-management behaviours. These will take no longer than 2 minutes in total, per day.
During the Mindfulness-based intervention Duration of this phase: four weeks	• You will be asked to access the course of mindfulness sessions via Qualtrics (a secure computer programme) once per week for 4 weeks to complete each of the four modules. Completion of the modules will take approximately 20 minutes per week and will include some educational material and a mindfulness exercise. • You will also be asked to access a link to practice a short mindfulness exercise three times per week during the four-week programme. This will involve listening to a mindfulness script, lasting approximately 10-15 minutes, which will encourage you to focus on being present in the moment, without interpretation or judgement. There will be a new mindfulness exercise to practice each week. • You will continue to fill in the daily questions mentioned above (taking less than 2 minutes per day). • Once per week, at the beginning of each weekly module you will be asked how often and for how long you practiced

	mindfulness in the past week (approx.1 minute). • Once per week, at the end of each module you will complete a brief questionnaire measuring how mindful you were during the mindfulness session (approx. 3-5 minutes).
<u>At completion of Mindfulness-based intervention</u>	• You will be asked to complete the standard measures again (approx. 30-40 minutes). • You will provide feedback on how you found the intervention by completing two brief questionnaires.
<u>Follow-up (4-weeks after completion of intervention)</u>	• Throughout the 4-week follow-up period you will continue to complete the daily questions. These will take less than 2 minutes per day. • You will complete the standard measures for a final time at the end of the four week follow-up period (approx. 30-40 minutes).

Once you have completed the final set of questionnaires, we will email you a £10 electronic Amazon voucher as a thank you for your participation.

After reading this information sheet, you will have the opportunity to speak to Kate Landowska, the Chief Investigator of the study, to check that you are eligible to take part and to receive answers to your questions. If you still wish to take part, you will then be sent an electronic version of this information sheet and a consent form on Qualtrics to electronically sign using your computer mouse. You will have a minimum of 24 hours to consider whether to take part or not. Your contact details will not be shared with anyone outside of the research team.

After starting the study, you will be informed how long you have to wait before accessing the course of mindfulness sessions. Once you have started the course, you will be sent an e-mail every week as a reminder to complete the next module. You can also opt to receive reminders to complete the daily measure and between session mindfulness exercises if you wish. Kate Landowska will also be available to support you over the phone and will contact you before starting the intervention, mid-way through and at the end of the intervention. She will get in touch via e-mail to arrange a suitable time for a telephone call (maximum 10 minutes) to check how you are progressing with the intervention, discuss any challenges, and answer your questions. On the last call you will also have the chance to provide some feedback on the intervention received.

Kate and the research team will be available to answer any questions or concerns you may have throughout your participation. Please see contact details at the end of this Participant Information Sheet.

You will not be required to have additional tests or receive extra drugs or medicines.

What are the possible disadvantages and risks of taking part?

There will be no risks to your health and your usual treatment will not be affected whether or not you agree to take part in this study. It is unlikely, but possible, that some of the questions or mindfulness exercises could cause distress. In the event that the questionnaires or exercises do cause upset and you require support, we advise that you contact the medical team involved in your diabetes care and/or your GP. Likewise, if considering your physical symptoms in questionnaires raise health concerns, we advise that you contact the medical team involved in your diabetes care or your GP.

If any of your responses lead us to believe that there may be a significant risk of harm to you or someone else, disclosure of confidential data and privacy would be broken. In this event, we would signpost you to your primary care mental health team and contact your GP and diabetes care team. We will endeavour to inform you first.

If you have any queries or concerns about the research, please contact Kate Landowska, Chief Investigator, using the contact details provided at the end of the information sheet.

If you feel you need further support or just want to talk things through about diabetes, please call the Diabetes UK helpline from Monday to Friday, 9am-6pm, on 0345 123 2399.

If you feel you are struggling to cope or are at risk of harming yourself, please call Samaritans:
Telephone: 116 123 (24/7 and free helpline)
Email: jo@samaritans.org (response time is 24 hours)

What are the possible benefits of taking part?

We hope that taking part in the intervention will help you by gaining a greater insight into any difficulties you may be experiencing related to your diabetes and finding ways to cope with them. You will also have the chance to develop mindfulness skills which involves building a non-judgmental present moment awareness of experiences and accepting difficult thoughts, emotions and physical sensations. Taking part may also encourage some individuals to start conversations with their diabetes nurse and/or doctor about any difficulties they may be experiencing related to their diabetes. The information from this study is likely to help us better understand how individuals with type 1 diabetes can be supported.

As a small thank you, for participation in the study we will give all participants who complete the project a £10 Amazon voucher. Participants will receive this voucher upon completion of the study.

What happens when the research study stops?

If you complete all three phases of the study, you will receive a £10 Amazon voucher. At the end of the research your diabetes care team will continue to care for you. We will be happy to provide you with a summary of the study's main findings if you wish.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential and stored in accordance with General Data Protection for Research (GDPR) and Data Protection Act 2018. Only the researchers will have access to the questionnaires you compete and in the study you will be known only by a pseudonym. Any information about you will be stored separately from your signed consent form, and your name and address, so that you cannot be recognised from it.

With agreement, your consultant/GP will be informed of your participation and given an information sheet about the study, but will not have access to any of the information or responses you provide as part of the study.

If a participant loses capacity to consent whilst taking part in the study, no new data will be collected but the data already collected will be kept. All data will be stored until 6 months after publication of the research or 5 years, whichever is the greater.

There is a possibility that the study will be audited by independent bodies, to verify that the research has been carried out in accordance with NHS Health Research Authority protocol and in lines with the GDPR and Data Protection Act 2018. They may have access to the consent forms and data collected as part of the study.

What will happen to the results of the research study?

The results of this study will be written up as part of Kate Landowska's (Chief Investigator of the study) doctoral thesis. **It is also anticipated that the results of this study will be published in a national or international journal. All the information we collect will be anonymised and you will not be identified in the thesis or any report or publication.**

Who is organising and funding the research?

This research study is funded by Royal Holloway, University of London. The study is being carried out by Kate Landowska, a Trainee Clinical Psychologist

as part fulfilment of her doctorate in clinical psychology. The project has been organised in collaboration with Dr Michelle Taylor, a researcher at Health Psychology Research Limited, and Dr Jane Vosper, a lecturer in Clinical Psychology, Royal Holloway, University of London. Furthermore, NHS collaborators include Dr Vicky McKechnie, a Clinical Health Psychologist at Charing Cross Hospital, Dr Nick Oliver, a Consultant Endocrinologist at Charing Cross Hospital and Dr Sonya Frearson, a Clinical Psychologist at Barts.

The researchers and clinicians conducting this research will not receive any payments for including and looking after the patients in the study other than their usual salaries.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the Wales Research Ethics Committee (REC) 3 and the Ethics Committee at Royal Holloway, University of London.

How will my data be used?

Royal Holloway, University of London (RHUL) is the sponsor for this study based in the United Kingdom. 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. RHUL will keep identifiable information about you for up to 6 months after the study has finished.

Your rights to access, change or move your information are limited as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Kate Landowska or by referring to the Health Research Authority's outline on 'Patient information and health and care research' at www.hra.nhs.uk/information-about-patients

RHUL will collect information from you for this research study in accordance with our instructions.

RHUL will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals

from RHUL and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

The only people in RHUL who will have access to information that identifies you will be people who need to contact you to enable you to take part in the study or audit the data collection process. Regarding questionnaire data, it should be noted that there is a small chance the research team may be able to identify you as there are low numbers of participants in the study and demographic information will be obtained.

RHUL will collect information about you for this research study. This information will include your name and contact details, and health information, which is regarded as a special category of information. We will use this information to contact you about the research study and to obtain information about your health.

Who is involved in this study?

The principle researcher for this study is Kate Landowska (Trainee Clinical Psychologist). The research will be overseen and supervised by Dr Michelle Taylor (Researcher & Clinical Psychologist) and Dr Jane Vosper (Clinical Tutor & Clinical Psychologist), and supported by Dr Vicky McKechnie (Clinical Health Psychologist), Dr Nick Oliver (Consultant Endocrinologist) and Dr Sonya Frearson (Clinical Psychologist).

Contacts for Further Information

Please do not hesitate to contact Kate Landowska.
Tel: Tel: 01784 414012 (**Please note:** this is the Royal Holloway, University of London general phone line for queries regarding research participation. You will be asked to leave a voicemail and should state your name and which project/person you are calling for. The named person will then call back once they receive this message).
Email: kate.landowska.2019@live.rhul.ac.uk

Or, alternatively you may wish to contact:

Dr Jane Vosper
Tel: Tel: 01784 414012 (**Please note:** this is the Royal Holloway, University of London general phone line for queries regarding research participation. You will be asked to leave a voicemail and should state your name and which project/person you are calling for. The named person will then call back once they receive this message).
E-mail: jane.vosper@rhul.ac.uk

Dr Michelle Taylor
Tel: Tel: 01784 414012 (**Please note:** this is the Royal Holloway, University of

London general phone line for queries regarding research participation. You will be asked to leave a voicemail and should state your name and which project/person you are calling for. The named person will then call back once they receive this message).
E-mail: michelle.taylor@rhul.ac.uk

You can also contact a member of your treatment team if you would like to discuss the study or would like advice about whether to participate.

If you would like independent advice or information about participating in this research project you can contact the Patient Advice and Liaison Service (PALS) on 020 3313 0088, or e-mail imperial.PALS@nhs.net.

Thank you for your time. We hope you agree to take part in this study and get in touch with Kate.

Appendix F: Electronic Consent Form

Consent Form

Title of Project: Development and pilot testing of an online mindfulness-based intervention for improving fear of hypoglycaemia, well-being and self-management in adults with Type 1 diabetes.

Researchers: Miss Kate Landowska, Dr Michelle Taylor, Dr Jane Vosper

Please initial box:

1. I confirm that I have read and understand the Participant Information Sheet for the above study. ☐
2. I confirm that I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without it affecting my medical care. ☐
4. I understand that I am free to refrain from answering any questions I do not want to, and choosing not to answer will not affect the care I am receiving. ☐
5. I understand that sections of my medical notes may be looked at by responsible individuals from my diabetes care team. I understand that some information concerning my health, as outlined in the Participant Information Sheet, will be shared with the research team. I give permission for these individuals to have access to my data. ☐
6. I understand that I will be participating in a study for 9, 10 or 11 weeks and that I will have to wait 1, 2 or 3 weeks before accessing the course of mindfulness sessions. ☐
7. I understand that I will be asked to complete five questionnaires (taking approximately 30-40 minutes in total) about my well-being, diabetes self-management activities, and mindfulness at three points in time: upon signing up for the study, after completing the course of mindfulness sessions, and at 4-week follow-up. ☐

8. I understand that I will be asked to provide some basic demographic and clinical information once upon signing up to the study, and that there is a small chance the researchers will be able to identify my identity based on these answers. ☐

9. I understand that taking part in the course of mindfulness sessions will involve logging into the intervention programme at least three times every week and practicing the mindfulness exercises via recordings on Qualtrics (a secure computer programme). This will be for a total period of four weeks. ☐

10. I understand that once per week, during the course, before the mindfulness module I will be asked for how long and how often I practiced mindfulness in the past week. Once per week, at the end of each module I will also complete a brief mindfulness questionnaire (taking approximately 3-5 minutes), for the duration of the intervention (a total of 4 times). ☐

11. I agree to logging into the programme daily to complete short scales (no longer than 2 minutes in total) measuring well-being, diabetes self-management and fear of hypoglycaemia for the entire duration of the study (9-11 weeks). ☐

12. I understand that this study will include a four-week period after completing the mindfulness course. During this time, I will continue to complete the short scales daily. ☐

13. I agree to receive weekly e-mail reminders to prompt me to access the mindfulness intervention. ☐

14. I agree to receiving a £10 voucher on completion of the final set of questionnaires after the end of the four-month follow-up period. ☐

15. After having reviewed the Participant Information sheet, I agree to take part in the study. ☐

16. I agree for Kate Landowska, Chief Investigator, to contact me over the phone on three occasions: prior to the start, mid-way and at the end of the mindfulness course to provide guidance, answer any questions I may have, and ask for my feedback. ☐

17. I would like to receive feedback on the results and findings of the study via email once the research has concluded. ☐

18. I agree to my diabetes healthcare team and my GP being informed of my participation in this study. ☐

    Please provide details below to enable us to write to your GP.

    Date of Birth: ……../……/……

Your address:
……
……

GP name and address:
……
……

Please state whether you are currently involved in any other research. If you are, we may contact you to check-in that you feel comfortable to be involved in more than one project.

Yes ☐ No ☐

This Consent Form will be stored separately from the responses you provide.

An original copy of the participant information sheet and completed informed consent form will be sent to you via e-mail for your reference, in addition to the copy filed in the researcher's file.

…….	……	……
Name of Patient	Date	Signature
…….	……	..……
Researcher	Date	Signature

Appendix G: Demographic and Clinical Information Sheet

Wherever options are provided with boxes, please put a cross in any box that applies:

1) Age in years:

2) Are you: Male ☐ Female ☐ Prefer not to declare ☐

3) Marital status:

Married or living with partner ☐ Widowed ☐ Divorced or separated ☐ Single ☐

4) Please indicate your ethnic origin below?

a) White:

English, Welsh, Scottish, Northern Irish or British ☐

Irish ☐ Gypsy or Irish Traveller ☐ Roma ☐

Any other White background, please state ☐ _____

b) Mixed or Multiple Ethnic groups

White & Black Caribbean ☐ White & Black African ☐

White & Asian ☐

Any other Mixed or Multiple background ☐

please state_____

c) Asian or Asian British:

Indian ☐ Pakistani ☐ Bangladeshi ☐ Chinese ☐

Any other Asian background ☐ please state_____

d) Black, Black British, African or Caribbean:

Caribbean ☐ African background (write below) ☐

Any other Black, Black British or Caribbean background ☐

please state_____

d) Other ethnic group

Arab ☐ Any other ethnic group, please state ☐_____

5) Please indicate your current main activity:

a) Working full-time: ☐
b) Working part-time: ☐
c) Part-time education: ☐
d) Full-time education: ☐
e) Not working: ☐
f) Retired: ☐

6) When was your diabetes diagnosed? _____ (month) _____ (year)

7) Please state whether insulin is delivered by:
Insulin pump ☐

Multiple daily injections ☐

a) If it is multiple daily injections, on average, how many injections per day do you take? ☐

8) How do you monitor blood glucose levels

Real time continuous glucose monitoring (e.g. Dexcom G6) ☐

Flash glucose monitoring (e.g. Freestyle Libre) ☐

Self monitoring of blood glucose (fingerprick testing ☐

9) Is there any additional information you wish to provide regarding your diabetes or your treatment?

☐

10) Do you have any complications of diabetes? Yes ☐ No ☐

If 'yes', which of the following complications do you have?

Diabetic eye disease ☐

Renal problems ☐

Heart problems ☐

Circulatory problems ☐

Foot problems ☐

Neuropathy (nerve problems) ☐ If known: Autonomic ☐
Peripheral ☐

Other complication(s) ☐ please state _____

11) Do you have any other health problems not previously mentioned?

Yes ☐ No ☐

If 'yes', please state: _____

12) In the past two months how many times have you experienced hypoglycaemia (a 'hypo' due to low blood sugar levels)?

Everyday (approx. 60 days)	☐	Sometimes (20 to 29 days)	☐
Most days (50 to 59 days)	☐	Occasionally (10 to 19 days)	☐
Often (40 to 49 days)	☐	Rarely (1 to 9 days)	☐
Fairly often (30 to 39 days)	☐	Not at all (0 days)	☐

13) Have you ever lost consciousness due to a hypo?

Yes ☐ No ☐

If 'yes', on how many occasions? _____ times

14) Have you ever experienced a hypo without losing consciousness but still required someone's help to recover from the episode?

Yes ☐ No ☐

If 'yes', on how many occasions? _____ times

Thank you for your time in completing these questionnaires

Appendix H: The Hypoglycaemia Fear Survey II (HFS-II)

HFS-II (Adults)
© University of Virginia 1998

I. Behavior: Below is a list of things people with diabetes sometimes do in order to avoid low blood sugar and its consequences. Circle one of the numbers to the right that best describes what you have done during the last 6 months in your daily routine to AVOID low blood sugar and its consequences. **(Please do not skip any!)**.

To avoid low blood sugar and how it affects me, I ...	Never	Rarely	Sometimes	Often	Almost Always
1. Ate large snacks.	0	1	2	3	4
2. Tried to keep my blood sugar above 150.	0	1	2	3	4
3. Reduced my insulin when my blood sugar was low.	0	1	2	3	4
4. Measured my blood sugar six or more times a day.	0	1	2	3	4
5. Made sure I had someone with me when I go out.	0	1	2	3	4
6. Limited my out of town travel.	0	1	2	3	4
7. Limited my driving (car, truck or bicycle).	0	1	2	3	4
8. Avoided visiting friends.	0	1	2	3	4
9. Stayed at home more than I liked.	0	1	2	3	4
10. Limited my exercise/physical activity.	0	1	2	3	4
11. Made sure there were other people around.	0	1	2	3	4
12. Avoided sex.	0	1	2	3	4
13. Kept my blood sugar higher than usual in social situations.	0	1	2	3	4
14. Kept my blood sugar higher than usual when doing important tasks.	0	1	2	3	4
15. Had people check on me several times during the day or night.	0	1	2	3	4

II. Worry: Below is a list of concerns people with diabetes sometimes have about low blood sugar. Please read each item carefully (do not skip any). Circle one of the numbers to the right that best describes how often in the last 6 months you WORRIED about each item because of low blood sugar.

Because my blood sugar could go low, I worried about...	Never	Rarely	Sometimes	Often	Almost Always
16. Not recognizing/realizing I was having low blood sugar.	0	1	2	3	4
17. Not having food, fruit, or juice available.	0	1	2	3	4
18. Passing out in public.	0	1	2	3	4
19. Embarrassing myself or my friends in a social situation.	0	1	2	3	4
20. Having a hypoglycemic episode while alone.	0	1	2	3	4
21. Appearing stupid or drunk.	0	1	2	3	4
22. Losing control.	0	1	2	3	4
23. No one being around to help me during a hypoglycemic episode.	0	1	2	3	4
24. Having a hypoglycemic episode while driving.	0	1	2	3	4
25. Making a mistake or having an accident.	0	1	2	3	4
26. Getting a bad evaluation or being criticized.	0	1	2	3	4
27. Difficulty thinking clearly when responsible for others	0	1	2	3	4
28. Feeling lightheaded or dizzy.	0	1	2	3	4
29. Accidently injuring myself or others.	0	1	2	3	4
30. Permanent injury or damage to my health or body.	0	1	2	3	4
31. Low blood sugar interfering with important things I was doing.	0	1	2	3	4
32. Becoming hypoglycemic during sleep.	0	1	2	3	4
33. Getting emotionally upset and difficult to deal with.	0	1	2	3	4

Appendix I: Idiographic VAS Measures

Fear of Hypoglycaemia items

To what extent have you **actively taken precautions** to prevent hypoglycaemia in the past 24 hours?

Not at all Completely

0 1 2 3 4 5 6 7 8 9 10

Slide the bar to indicate

To what extent have you been **concerned** or **worried** about the possibility of having an episode of hypoglycaemia?

Not at all Completely

0 1 2 3 4 5 6 7 8 9 10

Slide the bar to indicate

Self-management items

To what extent did you follow your **diet** regime in the past 24 hours?

Not at all Completely

0 1 2 3 4 5 6 7 8 9 10

Slide the bar to indicate

To what extent did you follow your **blood glucose testing** requirements in the past 24 hours?

Not at all Completely

0 1 2 3 4 5 6 7 8 9 10

Slide the bar to indicate

To what extent did you follow your **medication** regime in the past 24 hours?

Not at all Completely

0 1 2 3 4 5 6 7 8 9 10

Slide the bar to indicate

If you are taking insulin injections, how many did you take in the past 24 hours?

To what extent did you follow your **exercise** regime in the past 24 hours?

Not at all Completely

0 1 2 3 4 5 6 7 8 9 10

Slide the bar to indicate

Well-being item

To what extent have you felt **low**, **stressed** or **anxious** in the past 24 hours?

Not at all Completely

0 1 2 3 4 5 6 7 8 9 10

Slide the bar to indicate

Appendix J: The Five Facet Mindfulness Questionnaire (FFMQ)

Five Facet Mindfulness Questionnaire (FFMQ)
Ruth A. Baer, Ph.D.
University of Kentucky

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes your own opinion of what is generally true for you.

1	2	3	4	5
never or very rarely true	rarely true	sometimes true	often true	very often or always true

_____ 1. When I'm walking, I deliberately notice the sensations of my body moving.

_____ 2. I'm good at finding words to describe my feelings.

_____ 3. I criticize myself for having irrational or inappropriate emotions.

_____ 4. I perceive my feelings and emotions without having to react to them.

_____ 5. When I do things, my mind wanders off and I'm easily distracted.

_____ 6. When I take a shower or bath, I stay alert to the sensations of water on my body.

_____ 7. I can easily put my beliefs, opinions, and expectations into words.

_____ 8. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.

_____ 9. I watch my feelings without getting lost in them.

_____ 10. I tell myself I shouldn't be feeling the way I'm feeling.

_____ 11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.

_____ 12. It's hard for me to find the words to describe what I'm thinking.

_____ 13. I am easily distracted.

_____ 14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.

_____ 15. I pay attention to sensations, such as the wind in my hair or sun on my face.

_____ 16. I have trouble thinking of the right words to express how I feel about things

_____ 17. I make judgments about whether my thoughts are good or bad.

_____ 18. I find it difficult to stay focused on what's happening in the present.

_____ 19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.

_____ 20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.

_____ 21. In difficult situations, I can pause without immediately reacting.

1	2	3	4	5
never or very rarely true	rarely true	sometimes true	often true	very often or always true

_____ 22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.

_____ 23. It seems I am "running on automatic" without much awareness of what I'm doing.

_____24. When I have distressing thoughts or images, I feel calm soon after.

_____ 25. I tell myself that I shouldn't be thinking the way I'm thinking.

_____ 26. I notice the smells and aromas of things.

_____ 27. Even when I'm feeling terribly upset, I can find a way to put it into words.

_____ 28. I rush through activities without being really attentive to them.

_____ 29. When I have distressing thoughts or images I am able just to notice them without reacting.

_____ 30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.

_____ 31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.

_____ 32. My natural tendency is to put my experiences into words.

_____ 33. When I have distressing thoughts or images, I just notice them and let them go.

_____ 34. I do jobs or tasks automatically without being aware of what I'm doing.

_____ 35. When I have distressing thoughts or images, I judge myself as good or bad, depending what the thought/image is about.

_____ 36. I pay attention to how my emotions affect my thoughts and behavior.

_____ 37. I can usually describe how I feel at the moment in considerable detail.

_____ 38. I find myself doing things without paying attention.

_____ 39. I disapprove of myself when I have irrational ideas.

Appendix K: The Well-being Questionnaire (W-BQ28)

Well-being Questionnaire (W-BQ28)

Please circle one number on each scale, from 3 (all the time) to 0 (not at all), to indicate how often you feel each statement has applied to you in the past few weeks.

	All the time	Often	Sometimes	Not at all
1. I have crying spells or feel like it	3	2	1	0
2. I feel downhearted and blue	3	2	1	0
3. I feel afraid for no reason at all	3	2	1	0
4. I get upset easily or feel panicky	3	2	1	0
5. I feel energetic, active or vigorous	3	2	1	0
6. I feel dull or sluggish	3	2	1	0
7. I feel tired, worn out, used up or exhausted	3	2	1	0
8. I have been waking up feeling fresh and rested	3	2	1	0
9. I have been happy, satisfied or pleased with my personal life	3	2	1	0
10. I have lived the kind of life I wanted to	3	2	1	0
11. I have felt eager to tackle my daily tasks or make new decisions	3	2	1	0
12. I have felt I could easily handle or cope with any serious problem or major change in my life	3	2	1	0
13. I feel that too many demands are made on me	3	2	1	0
14. I feel frustrated by obstacles which occur in my life	3	2	1	0
15. I have too many problems to cope with	3	2	1	0
16. I feel stressed	3	2	1	0

Please note that the following items are concerned with the effects of your diabetes:

		All the time	Often	Sometimes	Not at all
17.	Talking or thinking about my diabetes gets me upset or feeling downhearted	3	2	1	0
18.	Because of my diabetes I get depressed	3	2	1	0
19.	I worry about the management of my diabetes	3	2	1	0
20.	Because of my diabetes I worry about the future	3	2	1	0
21.	Managing my diabetes means I have too many things to do	3	2	1	0
22.	I feel frustrated that I have to live with diabetes	3	2	1	0
23.	I feel stressed by keeping to a schedule with my diabetes	3	2	1	0
24.	I feel irritated by my diabetes	3	2	1	0
25.	I feel well adjusted to my diabetes	3	2	1	0
26.	I feel a sense of satisfaction from managing my diabetes	3	2	1	0
27.	I feel positive about my diabetes management	3	2	1	0
28.	I feel I can cope with the challenges my diabetes might present	3	2	1	0

Please make sure that you have considered each of the 28 statements and have circled one number in response to each statement.

Appendix L: The Diabetes Self-Management Questionnaire (DSMQ)

The following statements describe self-care activities related to your diabetes. Thinking about your self-care over the **last 8 weeks**, please specify the extent to which each statement applies to you. Note: If you monitor your glucose using continuous interstitial glucose monitoring (CGM), please refer to this where 'blood sugar checking' is requested.	applies to me very much	applies to me to a consider-able degree	applies to me to some degree	does not apply to me
1. I check my blood sugar levels with care and attention. *Blood sugar measurement is not required as a part of my treatment.*	3	2	1	0
2. The food I choose to eat makes it easy to achieve optimal blood sugar levels.	3	2	1	0
3. I keep all doctors' appointments recommended for my diabetes treatment.	3	2	1	0
4. I take my diabetes medication (e. g. insulin, tablets) as prescribed. *Diabetes medication/insulin is not required as a part of my treatment.*	3	2	1	0
5. Occasionally I eat lots of sweets or other foods rich in carbohydrates.	3	2	1	0
6. I record my blood sugar levels regularly (or analyse the value chart with my blood glucose meter). *Blood sugar measurement is not required as a part of my treatment.*	3	2	1	0
7. I tend to avoid diabetes-related doctors' appointments.	3	2	1	0
8. I do regular physical activity to achieve optimal blood sugar levels.	3	2	1	0
9. I strictly follow the dietary recommendations given by my doctor or diabetes specialist.	3	2	1	0
10. I do not check my blood sugar levels frequently enough as would be required for achieving good blood glucose control. *Blood sugar measurement is not required as a part of my treatment.*	3	2	1	0
11. I avoid physical activity, although it would improve my diabetes.	3	2	1	0
12. I tend to forget to take or skip my diabetes medication (e. g. insulin, tablets). *Diabetes medication/insulin is not required as a part of my treatment.*	3	2	1	0
13. Sometimes I have real 'food binges' (not triggered by hypoglycaemia).	3	2	1	0
14. Regarding my diabetes care, I should see my medical practitioner(s) more often.	3	2	1	0
15. I tend to skip planned physical activity.	3	2	1	0
16. My diabetes self-care is poor.	3	2	1	0

Appendix M: The State Mindfulness Scale (SMS)

State Mindfulness Scale

There is a list of statements below. Please use the rating scale to indicate how well each statement describes your experiences in the past 15 minutes.

Please describe what you were doing during this 15 minute period of time? _____

_____

1	*2*	*3*	*4*	*5*
Not at all	*A little*	*Somewhat*	*Well*	*Very well*

1. ___I was aware of different emotions that arose in me
2. ___I tried to pay attention to pleasant and unpleasant sensations
3. ___I found some of my experiences interesting
4. ___I noticed many small details of my experience
5. ___I felt aware of what was happening inside of me
6. ___I noticed pleasant and unpleasant emotions
7. ___I actively explored my experience in the moment
8. ___I clearly physically felt what was going on in my body
9. ___I changed my body posture and paid attention to the physical process of moving
10. ___I felt that I was experiencing the present moment fully
11. ___I noticed pleasant and unpleasant thoughts
12. ___I noticed emotions come and go
13. ___I noticed various sensations caused by my surroundings (e.g., heat, coolness, the wind on my face)
14. ___I noticed physical sensations come and go
15. ___I had moments when I felt alert and aware
16. ___I felt closely connected to the present moment
17. ___I noticed thoughts come and go
18. ___I felt in contact with my body
19. ___I was aware of what was going on in my mind
20. ___It was interesting to see the patterns of my thinking
21. ___I noticed some pleasant and unpleasant physical sensations

Appendix N: Feedback Questionnaire

Feedback questions

Acceptability and feasibility

We would like to get your feedback on the acceptability and feasibility of the online programme you have completed.

The feedback you provide will remain anonymous.

Please rate how much you agree or disagree with the following statements:

	Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
The information on the online mindfulness programme was easy to understand	1	2	3	4	5
The information in the mindfulness programme was clear in meaning	1	2	3	4	5
The information on the online mindfulness programme was informative	1	2	3	4	5
The information on the online mindfulness intervention was relevant to me	1	2	3	4	5
The online mindfulness programme was user friendly	1	2	3	4	5
The online mindfulness programme was easy to use	1	2	3	4	5

We would like to hear about any positive experience as well as difficulty with the **online format** of our intervention.

1. What was most helpful about it?

_____

_____

_____

2. What was least helpful about it?

_____

_____

_____

We would also like to know if you have noticed any changes in your experience of hypoglycaemia since practicing the mindfulness techniques (e.g. symptoms experienced, anxiety levels)? If so, could you describe this.

Client Satisfaction Questionnaire (CSQ)

Please help us improve our program by answering some questions about the services you have received.

We are interested in your honest opinion, whether it is positive or negative.

Please answer all of the questions. We also welcome your comments and suggestions.

Thank you very much, we really appreciate your help.

1. How would you rate the quality of services you received?

4	3	2	1
Excellent	Good	Fair	Poor

2. Did you get the kind of services you wanted?

1	2	3	4
No, definitely not	No, not really	Yes, generally	Yes, definitely

3. To what extent has our program met your needs?

4	3	2	1
Almost all of my needs have been met	Most of my needs have been met	Only a few of my needs have been met	None of my needs have been met

4. If a friend were in need of similar help, would you recommend our program to him or her?

1	2	3	4
No, definitely not	No, not really	Yes, generally	Yes, definitely

5. How satisfied are you with the amount of help you have received?

1	2	3	4
Quite dissatisfied	Indifferent or mildly dissatisfied	Mostly satisfied	Very Satisfied

6. Have the services you received helped you deal more effectively with your problems?

4	3	2	1
Yes, they helped a great deal	Yes, they helped somewhat	No, they really did not help	No, they seemed to make things worse

7. In an overall, general sense, how satisfied are you with the service you have received?

4	3	2	1
Very satisfied	Mostly satisfied	Indifferent or mildly dissatisfied	Quite Dissatisfied

8. If you were to seek help again, would you come back to our program?

1	2	3	4
No, definitely not	No, not really	Yes, generally	Yes, definitely

Appendix O: Web-based Mindfulness Intervention Protocol

Module 1

Introduction to Mindfulness

Living with diabetes

Life with diabetes can be difficult as it comes with demands and stresses which can impact on day-to-day life. People with type 1 diabetes need to make adjustments to their diet, regularly monitor blood glucose levels and take insulin doses accordingly. It can be challenging to balance these demands and sometimes the stress experienced can make it harder to control blood glucose levels, which can, in turn, lead to increased levels of anxiety and poorer well-being.

The demands of managing diabetes can also interfere with social life, as well as relationship to food. Additionally, it can be easy to worry about having a hypoglycaemic episode or about developing health complications of diabetes in the future.

Some people may try to avoid difficult thoughts and feelings by distracting themselves or trying to suppress thoughts. However, the ironic thing is, by trying to avoid difficult thoughts, they can come back even stronger. This is where mindfulness can be helpful.

Please Press 'Next'

What is mindfulness?

Mindfulness is a practice which focuses on developing a non-judgmental present moment awareness of our experiences. This includes difficult inner experiences such as anxious thoughts or negative emotions like sadness or anger. The more we struggle against difficult thoughts and feelings, the more difficult it becomes to manage them. The more aware we are of our negative thoughts and feelings, and the more willing we are to experience them, the less power they have over us.

Research studies have shown that regular practice of mindfulness has helped people with type 1 and type 2 diabetes to improve their management of diabetes and also their emotional well-being.

We hope that participating in this study will help you learn more about your difficulties and how to manage your life with diabetes to the best of your abilities.

The best way to get the most out of this programme is to participate in every aspect of it.

Please Press 'Next'

Overcoming common barriers to practicing mindfulness

There are three main barriers to practicing mindfulness which can be overcome.

1. Mindfulness takes ongoing effort. When first practicing, you may find that your thoughts are chaotic or that you get distracted easily. This is normal. The important thing is to try each time to re-direct your thoughts to the present moment. Try not to judge yourself too harshly by thinking of 'should' statements e.g. "I should be getting deeply relaxed by now" or "My mind shouldn't be wandering again". These will hamper your ability to develop the mindfulness skill. The good news is

that the more you practice focusing on being fully where you are, the easier it will be to direct your attention to the present moment.

2. There may not seem to be enough time in the day. It is important to plan to set some time aside for yourself to listen to the recordings. Remember this is your time for self-care and it should be prioritised and scheduled in to your day.

3. You may also find that progress doesn't always come quickly. This is also completely normal. Like anything, mindfulness is a skill to be practiced, and with time will get easier. Even if nothing seems to be happening at first, the fact that you have made a commitment and you are steadfast in pursuing it is progress.

The practice of mindfulness during the session may not always feel as if it is making an immediate change. Remember that the small shifts in perspective and distress management will likely be felt at other times during the day.

Please Press 'Next'

Throughout this programme you will have access to a new mindfulness session each week for four weeks. Each session will have a different focus in practicing the mindfulness skill. We encourage you to listen to the recordings at least an additional two times per week.

The mindfulness skill is like a muscle and so the more you practice it, the stronger it will become. We will be checking in with how many times you have practiced each week. This is not to pressure you but to see whether more practice is associated with more positive changes.

Please Press 'Next'

Introduction to mindful breathing

We will start with an exercise on mindful breathing. This is a simple exercise which lays the foundation for the practice of mindfulness. Our breathing is with us wherever we go. No matter what we are doing, feeling or experiencing, it is always available to help us to reconnect our attention to the present moment. Because we can attend to the movements of our breath only in the moment they are arising, it provides a useful anchor line with which we can reconnect to the here and now.

Please Press 'Next'

[Downloadable link of audio/script]

The following script has been adapted from 'The Mindful Way through Depression, Freeing Yourself from Chronic Unhappiness' by Williams et al. (2007) and 'Diabetes and Well-being, Managing the Psychological and Emotional Challenges of Diabetes Types 1 and 2' by Dr Jen Nash (2013)

Exercise: Present moment focus through breathing

Find yourself a comfortable position, sitting down on a chair with your feet flat on the floor and uncrossed. Straighten your back against the backrest. If you would like to close your eyes you can, but this isn't necessary.

Bring your attention first to physical sensations you are experiencing. Notice how you can feel the pressure of where your body meets the chair. Notice the feeling of touch in your hands, arms, back, legs. Take a moment to pay attention to this.

Pause.

Now we're going to bring the focus to your breath. Focus on the movement in your stomach and chest as you inhale and exhale. Pay attention to the sensations in your nostrils as air floods in and out. Pause. You may find your mind starts to wonder. This is completely normal. If this starts to happen just gently bring your attention to noticing your breathing. Stay in touch with the mild sensations of stretching as the abdominal wall gently expands with each in-breath and on the sensations of gentle release as the abdominal wall deflates with each out-breath. Try to pay attention to these movements for the duration of one in-breath and one out-breath. Perhaps you are noticing the slight pauses between each in-breath and out-breath and between each out-breath and new in-breath. You may prefer to zone your focus in to one part of your body such as the nostrils. Focus on the experience of the sensations you experience.

There is no need to control your breathing. Simply allow the breath to be. All you are trying to do, is to observe your body with each in- and out-breath. As best as you can, also bring this attitude of allowing to the rest of your experience. There is nothing that needs to be fixed, and no particular state that needs to be achieved.

Again, your mind may occasionally wander from the focus of your breath. You may find thoughts start to pop into your head about what you need to do later, or a memory from your day may flood to the forefront of your mind. Or you may start to fall into a daydream or think about the itch in your elbow. This is completely normal and is not a sign that you are doing badly in this task. In fact, it is something to be celebrated because as soon as you have noticed your attention has gone somewhere, you are back on the path to refocus on the sensation of breathing. Be kind to yourself and simply observe, 'my mind has wandered, let me bring it back to my breathing'.

Pause.

You may find it helpful to note what your mind does when it starts to wonder. For example, noting passing thoughts as 'thought', or a worry as 'worry'. Then you can gently bring your attention back to the breath and the changing pattern of physical sensations you experience.

Continue with this practice for 5-10 minutes, or longer if you wish, perhaps reminding yourself that the focus is simply to be aware of your experience moment to moment, using the breath as an anchor to reconnect with the present.

When you are finished, congratulate yourself on completing this exercise. It's really positive you have taken the time for yourself, to practice mindfulness.

This script has been adapted from ‘The Mindful Way through Depression, Freeing Yourself from Chronic Unhappiness’ by Williams et al. (2007) and 'Diabetes and Well-being, Managing the Psychological and Emotional Challenges of Diabetes Types 1 and 2' by Dr Jen Nash (2013)

Please Press ‘Next’ at the end of the exercise

Reflecting on your experience

When we take a few moments to actively reflect on our experience of mindfulness exercises, we can maximise their benefits. Thinking about your experience of mindfulness is a practice in itself and is something that may feel difficult to do at first but with time will become easier.

Below there are some questions to guide the reflections that you might have had during and following the breathing exercise. Please feel free to write as little or as much as you want.

What was your experience like? What did you notice?

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Were you aware of any sensations, feelings, thoughts and/or symptoms during the exercise? What were they?

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What was it like to observe them without struggling against them? What do you think would happen if you noticed them the same way you did in this exercise, next time you felt them in your daily life?

_____
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Could this exercise have any relevance to your life and the way you manage your diabetes?

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_____
_____

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Please Press 'Next'

In order to live well with diabetes and reduce its negative impact on our lives it is sometimes important to change the focus of our attention.

Living with diabetes can affect how you feel emotionally which in turn can make it more difficult to manage diabetes. It is possible, however, that these multi-directional relationships between how we feel and how we manage diabetes can be used for improvement as well. Perhaps focusing on changing how we respond to our experiences will allow the greatest opportunity for improving how we live our lives with diabetes.

Please Press 'Next'

Task for next week

What we know is that mindfulness is like a muscle. The more we exercise it, the more it will grow! Your task for the week is therefore to listen to this recording at least twice more. Try to plan this beforehand into your day. It can get easy for the busyness of life to take over, and it's important to prioritise space for self-care.

The more we practice when we are not stressed, the easier it will be to do mindfulness when you are experiencing unpleasant thoughts, feelings or physical symptoms.

We also encourage you to practice being mindful in everyday life. Bring moment-to-moment awareness to routine activities such as showering, driving, brushing your teeth and so on. In these moments, attend to what you are doing. Pay attention to what you can see, smell, hear, touch or taste!

Please Press 'Next'

If things get difficult

If you have any queries or concerns, please get in touch with Kate Landowska (e-mail: k.landowska@nhs.net; phone: 07470 259 736).

In the event that the questionnaires or activities do cause upset and you require support, we advise that you contact the medical team involved in your diabetes care and/or your GP.

If you feel you need further support or just want to talk things through about diabetes, please call the Diabetes UK helpline from Monday to Friday, 9am-6pm, on 0345 123 2399.

Please press 'Submit' when you have finished

Module 2

Body Scan

Welcome back!

In Module 1 we introduced you to the idea of mindfulness which is the practice of being aware of our surroundings and our internal experiences (thoughts, feelings, physical sensations) non-judgementally. During the week you have been growing your mindfulness muscle by practicing the mindfulness exercises.

Today we will be focusing on a new mindfulness exercise, called the body scan. This will involve practicing paying attention to different parts of the body.

Living with diabetes involves being in tune with the body. It is important to be attentive to changes in bodily sensations. This can help you to notice and respond appropriately to physical symptoms which can let you know when your blood sugar levels are dropping too low or are becoming too high. However, we also know that concern about hypoglycaemia can lead to a hypervigilance to bodily changes and symptoms. That it, excessively scanning the body for an indicator that blood glucose levels are low. This can also involve misinterpreting otherwise normal bodily sensations as indicative of low blood sugar levels. Other people may avoid or ignore noticing body sensations all together to distract from feared thoughts of hypoglycaemia.

Today we are going to practice being more in tune with our body and to notice sensations *non-judgementally.* Our bodies are always experiencing sensations – these can be in response to emotions, physical needs such as hunger, illness, or tiredness and sometimes for no particular reason at all! Our job today is to be present in these experiences and to not label them with feared thoughts.

Please Press 'Next'

[Downloadable link of audio/script]

The following script has been adapted from The Mindful Way through Depression, Freeing Yourself from Chronic Unhappiness, by Williams et al., 2007.

Remember that this is not an exercise in relaxation and it is therefore ok if you do not feel relaxed afterwards. You are working a new muscle and are being asked to think about your body in a different way which will take some mental effort. With time this practice will become easier.

Exercise: Body Scan

Start by lying or sitting down. Make yourself comfortable and close your eyes gently. Start to notice all the points where your body touches the chair or bed. Consider where you feel the sensations of touch or pressure where your body makes contact with the chair or bed. On each out-breath, allow yourself to sink deeper into the furniture.

Remember that the intention in this exercise is not to change the way you are feeling or to become more relaxed. The intention is to bring awareness to the sensations in your body at the present

moment and to consider them in a non-judgemental way. Do this as we go through each part of the body in turn.

Firstly, bring your attention to your stomach. Focus on how your stomach expands with each in-breath, and starts to deflate on the out-breath. Bring awareness to how much it inflates, to the sensations of holding the breath and to the feeling of the stomach slowly deflating. Pause.

Now I would like you to shift your focus to your left leg. Start on the upper part of the leg and slowly shift your focus down to your left foot, and all the way to your toes. Focus on each toe in turn, moving from right to left. Take an interested and affectionate stance and investigate the quality of the sensations you experience. Perhaps you can notice a tingling sensation. Perhaps you can notice coldness or warmth. Perhaps you are aware of the ways in which the toes connect to one another. As one moves, maybe others do as well. Perhaps, you don't feel any sensations. This is all ok. Anything you experience is ok. It is the present moment. It is the here-and-now.

The mind will inevitably wander away from the breath and body from time to time. This is what our minds are designed to do and it is ok. Just note that your attention has drifted, and start to refocus back to the breath. You can label what your mind has done. For example, note that it was a 'thought' or a 'daydream' before refocusing your attention.

Now start to imagine when you are breathing in, that the oxygen is passing down your lungs, through your torso, through your left leg and to the toes of your left foot. As you breathe out, imagine the pull of the air as it flows back up through the toes, the foot, leg and torso and out through the nose. As best you can, continue to imagine the flow of air pass through your body this way. Down your lungs, through your torso and down your left leg to your toes and back up again.

Now direct the breath down the right leg, to the foot and then the toes. Again, on the out-breath, allow the air to shoot upwards, through your right leg, torso and lungs.

Now I would like you to shift your attention to other parts of the right foot. Focus on the sole of the foot… the in-step… the heel. Be aware of the pressure where your heel touches the bed or floor. Allow your awareness to move upwards to the lower leg… along the calf… the shin… and knee.

Continue to scan the body upwards, lingering for a time with each part of the body: the thighs… the groin… hips… the lower back and abdomen… the upper back … the chest and shoulders. Then we move to the hands, focusing on both at the same time. Draw your attention to the sensations in your fingers and thumbs… the palms and backs of both hands… the wrists…the lower arms and elbows…the upper arms and shoulders. Keep moving upwards to focus on the sensations in your neck, and face. Focus on each facial feature; the jaw… lips… nose… cheeks… ears… eyes and forehead. And then the entirety of the head.

If you notice a tension or other intense sensations in a part of the body, you can 'breathe in' to the sensation, just as you've done with other body parts. Use the in-breath to gently bring awareness right into the sensations. Welcome the sensations.

After you have scanned the whole body, bring your awareness to the body as a whole and to the breath flowing freely in and out of it.

Please Press 'Next' at the end of the exercise

Reflecting on your experience

When we take a few moments to actively reflect on our experience of mindfulness exercises, we can maximise their benefits.

Below there are some questions to guide the reflections that you might have had during and following the breathing exercise. Please feel free to write as little or as much as you want.

What was your experience like? What did you notice?

_____
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Were you aware of any sensations, feelings, thoughts and/or symptoms during the exercise? What were they?

_____
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What was it like to observe them without struggling against them? What do you think would happen if you noticed them the same way you did in this exercise, next time you felt them in your daily life?

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Could this exercise have any relevance to your life and the way you manage your diabetes?

_____
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Please Press 'Next'

Task for next week

What we know is that mindfulness is like a muscle. The more we exercise it, the more it will grow! Your task for the week is therefore to listen to this recording at least twice more. Try to plan this beforehand into your day. It can get easy for the busyness of life to take over, and it's important to prioritise space for self-care.

The more we practice , the easier it will be to do mindfulness when you are experiencing unpleasant thoughts, feelings or physical symptoms.

We also encourage you to practice being mindful in everyday life. Bring moment-to-moment awareness to your routine activities. Take a moment to choose one or two activities you can commit to being mindful with over the next week. This can be an activity such as showering, driving, brushing your teeth, walking or travelling on a train. In these moments, attend to what you are doing. Pay attention to what you can see, smell, hear, touch or taste!

Next week's task will require you to have a small piece of food (ideally a raisin). The exercise will be based on eating a raisin, however, if this isn't to your taste, you can bring along another fruit or vegetable such as a grape, apple or carrot.

Please Press 'Next'

If things get difficult

If you have any queries or concerns, please get in touch with Kate Landowska (e-mail: k.landowska@nhs.net; phone: 07470 259 736).

In the event that the questionnaires or activities do cause upset and you require support, we advise that you contact the medical team involved in your diabetes care and/or your GP.

If you feel you need further support or just want to talk things through about diabetes, please call the Diabetes UK helpline from Monday to Friday, 9am-6pm, on 0345 123 2399.

Please press 'Submit' when you have finished

Module 3

Mindful Eating

Welcome back!

Last week we focused on the body scan and learning to pay attention non-judgementally to bodily sensations in the present moment. During the week you have been growing your mindfulness muscle by practicing body scanning as well as bringing mindfulness to some of your daily activities.

This week we will be focusing on a new exercise. We will be practicing mindful eating. Mindful eating is all about slowing down and enjoying your food more mindfully. We are surrounded by external cues to eat such as TV adverts, hearing those around us discuss their dinner plans, seeing restaurant and café storefronts and smelling delicious scents when we walk through a high street or market! We also have internal cues to eat such as eating in response to a feeling. Many of us may eat too much due to boredom, sadness, loneliness or out of habit. For people who fear hypoglycaemia, there may be an internal cue to eat more sugary foods to keep blood glucose levels high and avoid hypoglycaemia at times. Eating in response to internal cues can also make us feel guilt or shame.

Mindful eating helps us to eat more purposely and to bring the appreciation back to the experience of eating, rather than eating in response to an unhelpful internal cue. By practicing this exercise, you can learn to experience eating with a different perspective.

For this session you will need a piece of food. The exercise will be based on eating a raisin however, if this isn't to your taste, you can use another fruit or vegetable such as a grape, apple or carrot.

Please Press 'Next'

[Downloadable link of audio/script]

The following script has been adapted from 'The Mindful Way through Depression, Freeing Yourself from Chronic Unhappiness' by Williams et al. (2007) and 'Diabetes and Well-being, Managing the Psychological and Emotional Challenges of Diabetes Types 1 and 2' by Dr Jen Nash (2013)

Exercise: Mindful eating

Pick up the raisin and hold it between your finger and thumb or in the palm of your hand. Notice the feeling of it pressing against your skin and the weight of it. Imagine you are a visitor to this planet and have never seen a raison before. Focus on this object with new eyes.

Keep looking at the raisin. Let your eyes wander over the ridges, curves and hollows of it. Notice the colours. Does there seem to be a uniform colour? Or can you pick up changes in hues or tones.

Now shift your focus to concentrating more on the texture of the raisin. You can start to move it in between your fingers. Focus on how it feels against your skin. Is it soft or hard? Is it spongey or rigid?

Now bring the raisin to your nose and notice any smells or fragrance you can pick up on. Pay attention to your mouth and stomach and any physical changes as you inhale the smell.

Now place the raisin on your tongue without chewing. Explore how it feels to rest there.

Take a bite into the raisin. Focus on the experience of the flavour flooding into your mouth. Notice the change in flavour moment to moment. Bite again and see if the taste changes.

When you are ready, prepare to swallow the raisin. Notice there is an intention to swallow before you actually do it.

As you swallow the raisin, notice the sensation of it moving down your throat. How is your body feeling now that you have eaten it in a mindful way?

Please Press 'Next' at the end of the exercise

Reflecting on your experience

When we take a few moments to actively reflect on our experience of mindfulness exercises, we can maximise their benefits.

Below there are some questions to guide the reflections that you might have had during and following the breathing exercise. Please feel free to write as little or as much as you want.

What was your experience like? What did you notice?

_____
_____
_____
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Were you aware of any sensations, feelings, thoughts and/or symptoms during the exercise? What were they?

_____
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What was it like to observe them without struggling against them? What do you think would happen if you noticed them the same way you did in this exercise, next time you felt them in your daily life?

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Could this exercise have any relevance to your life and the way you manage your diabetes?

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Please Press 'Next'

Task for next week

What we know is that mindfulness is like a muscle. The more we exercise it, the more it will grow! Your task for the week is therefore to listen to this recording at least twice more. Try to plan this beforehand into your day. It can get easy for the busyness of life to take over, and it's important to prioritise space for self-care.

Now that you are practicing mindfulness more with everyday tasks, apply the technique to some aspect of your diabetes regime, maybe testing your blood glucose, weighing yourself, taking your insulin. Notice what thoughts, emotions and body experiences occur for you and allow yourself to acknowledge them non-judgementally.

Indicate below which activities (no more than two), you will choose e.g. mindful eating, blood glucose testing.

1. _____

2. _____

Please Press 'Next'

If things get difficult

If you have any queries or concerns, please get in touch with Kate Landowska (e-mail: k.landowska@nhs.net; phone: 07470 259 736).

In the event that the questionnaires or activities do cause upset and you require support, we advise that you contact the medical team involved in your diabetes care and/or your GP.

If you feel you need further support or just want to talk things through about diabetes, please call the Diabetes UK helpline from Monday to Friday, 9am-6pm, on 0345 123 2399.

Please press 'Submit' when you have finished

Module 4

Mindfulness with Difficult Emotions

Introduction

Welcome back!

Last week we focused on mindful eating which involved building your awareness on the experience of eating. During the week you have been growing your mindfulness muscle by practicing mindful eating.

In this next exercise for the week, we will be working on sitting with difficult feelings related to diabetes. This could be a feeling of anxiety, sadness, frustration or shame. This may seem like an uncomfortable prospect. It is important to remember that the more we struggle against difficult feelings, the more they can appear to take over. When we stop trying to resist unpleasant feelings, and accept them for what they are, we can find that they lose their intensity.

During today's session you will be asked to think about a recent unpleasant feeling. It can be helpful to start with a less intense emotion. For example, if you choose to think about anger, you may start with thinking of a situation that caused you to feel irritated rather than rageful. With time, you can start to approach bigger feelings as you practice this skill.

Please Press 'Next'

[Downloadable link of audio/script]

The following script has been adapted from 'The Mindful Way through Depression, Freeing Yourself from Chronic Unhappiness' by Williams et al. (2007) and 'Diabetes and Well-being, Managing the Psychological and Emotional Challenges of Diabetes Types 1 and 2' by Dr Jen Nash (2013)

Exercise: Mindfulness with difficult feelings about diabetes

Bring to mind a difficult thought or situation you have in relation to your diabetes. Something you don't mind staying with for a short while. Start with one that feels easiest to bring to awareness. This could be a recent worry about needing to postpone eating due to a social pressure. Or a time you recently tried a new meal and worried about overestimating the amount of insulin required.

It doesn't need to be something important or critical, but it should be something you are aware of which is perhaps unresolved or slightly unpleasant.

Now, once you are focusing on the troubling thought or situation, direct your attention to the emotion this brings up in you. This could be a feeling of anxiety, or sadness, frustration or shame. Allow yourself to tune into this emotion. The instinct might be to not allow this feeling to come forward, but to push it away. This is completely normal. Just try your best to gently bring your attention towards it. Pause.

Now I would like you to shift your attention again to notice where in the body you experience this feeling. Feel the emotion as a sensation in the body. What does this difficult feeling evoke in your body? Where does this happen? Perhaps a tightness in your chest, or a hollowness in your stomach,

or tension in your arms or legs. Become aware of these aspects of your body and see if you are able to note and approach the sensations. Consider where the sensations are the strongest and embrace them. This gesture might include breathing into that part of the body on the in-breath and breathing out from that region on the out-breath. Pause.

Be with the emotion as you would be with a child or pet whom you love and is in distress. You may even place your hand where in the body you're physically feeling the difficulty the most, meeting this experience with kindness. Recognise that this would be difficult or painful or challenging for anyone. Hold the feeling and yourself with compassion.

Once your attention has settled on the bodily sensations, as unpleasant as they may be, you can start to practice accepting the emotion by saying to yourself 'It's OK. This feeling is here with me right now and I will be open to it'. Rather than saying, 'I am anxious' or 'I am sad or 'I am angry, say to yourself that 'I am noticing something ***in*** *me that is anxious or sad or angry'. Stay with your awareness of these emotions and your relationship to them, breathing them in, accepting them, allowing them to be. It may be helpful to repeat 'It's here right now. Whatever it is, it's already here. Let me be open to it'. Soften and open to the sensations you become aware of, letting go of any tensing and bracing. You can say to yourself 'softening' or 'opening' on each out-breath to help with this.*

It's already here. It's ok. You are not judging the feeling or saying that everything is fine or can be fixed. You are simply being aware of the sensation in the here-and-now.

When you notice that the bodily symptoms are not pulling you in as intensely, then start to shift your focus back to your breathing. If you still feel the emotions strongly then that is OK. Give yourself some more time, just allowing it to be. Continue to notice where in the body you experience the emotion, and observe these sensations without judgement. Once you feel the sensations are not pulling you in as intensely, simply shift your attention back to your breathing as we have done in our previous breathing exercise.

Long pause.

Now let us end the exercise by placing your hand on your heart and saying to yourself, may I be safe, may I be peaceful and may I live with ease. Your mind may wander to different places and this is ok. Remember to anchor yourself back with these three phrases; may I be safe, may I be peaceful and may I live with ease.

Please Press 'Next' at the end of the exercise

Reflecting on your experience

When we take a few moments to actively reflect on our experience of mindfulness exercises, we can maximise their benefits.

Below there are some questions to guide the reflections that you might have had during and following the breathing exercise. Please feel free to write as little or as much as you want.

What was your experience like? What did you notice?

_____

_____

_____
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Were you aware of any sensations, feelings, thoughts and/or symptoms during the exercise? What were they?

_____
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What was it like to observe them without struggling against them? What do you think would happen if you noticed them the same way you did in this exercise, next time you felt them in your daily life?

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Could this exercise have any relevance to your life and the way you manage your diabetes?

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Please Press 'Next'

Well done for completing this exercise. It can feel uncomfortable to allow yourself to focus on difficult emotions. What we know is that by sitting with the short-term discomfort of focusing on negative emotions non-judgementally, we are able to change our relationship with them which allows them to dissipate.

If you feel this session brought up difficult feelings which you would like support for, please use the contact details recommended at the end of this module.

Please Press 'Next'

Task for the next month

Congratulations! You have completed all four modules of the mindfulness course. We hope you have found sessions useful in starting to build your mindfulness muscle.

We encourage you to continue building this muscle over the next month by continuing to practice the mindfulness skills you have learnt in these sessions. You can playback the recordings and write any reflections you have in your phone or journal if you find this helpful. We also encourage you to continue applying mindfulness to aspects of your diabetes regime; for example testing your blood glucose, weighing yourself or taking your insulin. Notice what thoughts, emotions and body experiences occur for you and allow yourself to acknowledge them non-judgementally.

Over the next month, we also ask that you continue completing the daily questionnaires.

Please Press 'Next'

At the end of this week, we will be asking you to complete questionnaires measuring mindfulness, diabetes self-management, fear of hypoglycaemia and well-being. This should take 30-40 minutes. We would also like to hear your feedback on the course of mindfulness by completing two additional questionnaires.

Please Press 'Next'

If things get difficult

If you have any queries or concerns, please get in touch with Kate Landowska (e-mail: k.landowska@nhs.net; phone: 07470 259 736).

In the event that the questionnaires or activities do cause upset and you require support, we advise that you contact the medical team involved in your diabetes care and/or your GP.

If you feel you need further support or just want to talk things through about diabetes, please call the Diabetes UK helpline from Monday to Friday, 9am-6pm, on 0345 123 2399.

Please press 'Submit' when you have finished

Appendix P: General Practitioner Participation Letter

Kate Landowska
Trainee Clinical Psychologist
Department of Clinical Psychology
Royal Holloway, University of London
Egham Hill, Egham
Surrey
TW20 0EX
Telephone number

[GP address]

[Date]

Dear Dr [GP],

Re: [Name]

DOB:

Address:

I am writing to inform you that the above named patient of yours has consented to participate in a study entitled **'Development and pilot testing of an online mindfulness-based intervention for improving fear of hypoglycaemia, well-being and self-management in adults with type 1 diabetes'**. The study is being undertaken as part fulfilment for a doctorate qualification in clinical psychology. Ethical approval has been obtained from the [Area] NHS Research Ethics Committee.

I enclose a copy of the participant information sheet for your interest.

If you would like further information or have any queries, please contact me at the address or telephone number above.

Yours sincerely,

Kate Landowska

Trainee Clinical Psychologist and Principal Investigator

Enclosed: Participant information sheet

Appendix Q: Reference Data for Reliable Change Index and Clinically Significant Change Calculations

Measure		Range of scores	Direction of clinical gain	Cronbach's α (source)	Clinical norm (source)	CSC Criterion
HFS-II	Total Score	0-132	Decrease	α = 0.94 (Gonder-Frederick et al., 2011)	M = 58.3, SD = 25.8 (Little, 2018)	A
	Behaviour Subscale	0-60	Decrease	α = 0.85 (Gonder-Frederick et al., 2011)	M = 23.8, SD = 11.4 (Little, 2018)	A
	Worry Subscale	0 - 72	Decrease	α = 0.94 (Gonder-Frederick et al., 2011)	M =34.7, SD = 17.1 (Little, 2018)	A
Well-being Questionnaire (W-BQ28)	Generic Negative Well-being	1-12	Decrease	0.78 (Speight et al., 2012)	M = 2.21, SD = 2.2 (Speight et al., 2012)	A
	Generic Energy	1-12	Increase	0.73 (Speight et al., 2012)	M = 4.93, SD = 1.4 (Speight et al., 2012)	A
	Generic Positive Well-being	1-12	Increase	0.81 (Speight et al., 2012)	M = 7.05, SD = 2.7 (Speight et al., 2012)	A
	Generic Stress	1-12	Decrease	0.81 (Speight et al., 2012)	M = 3.96, SD = 2.8 (Speight et al., 2012)	A
	Diabetes-Specific Negative Well-being	1-12	Decrease	0.84 (Speight et al., 2012)	M = 2.63, SD = 2.6 (Speight et al., 2012)	A
	Diabetes-specific stress	1-12	Decrease	0.86 (Speight et al., 2012)	M = 2.92, SD = 3 (Speight et al., 2012)	A
	Diabetes-specific Positive Well-being	1-12	Increase	0.9 (Speight et al., 2012)	M = 7, SD = 3.3 (Speight et al., 2012)	A

DSMQ	Sum Scale	0-10	Increase	α = .84 (Schmitt et al., 2013)	M = 6.9, SD = 1.7 (Schmitt et al., 2013)	A
	Glucose Management Subscale	0-10	Increase	α = .77 (Schmitt et al., 2013)	M = 7.5, SD = 2.3 (Schmitt et al., 2013)	A
	Dietary Control Subscale	0-10	Increase	α = .77 (Schmitt et al., 2013)	M = 5.2, SD = 2.4 (Schmitt et al., 2013)	A
	Physical Activity Subscale	0-10	Increase	α = .76 (Schmitt et al., 2013)	M = 6.5, SD = 2.6 (Schmitt et al., 2013)	A
	Healthcare Use Subscale	0-10	Increase	α = .60 (Schmitt et al., 2013)	M = 8.5, SD = 1.9 (Schmitt et al., 2013)	A
FFMQ	Nonreactivity Subscale	7-35	Increase	α = .75 (Baer et al., 2006)		
	Observing Subscale	8-40	Increase	α = .83 (Baer et al., 2006)		
	Acting with Awareness Subscale	8-40	Increase	α = .87 (Baer et al., 2006)		
	Describing Subscale	8-40	Increase	α = .91 (Baer et al., 2006)		
	Nonjudging Subscale	8-40	Increase	α = .87 (Baer et al., 2006)		
State Mindfulness Scale (Process Measure)	SMS Total	21-105	Increase	α = .94 (Tanay and Bernstein, 2013)		
	SMS Mind Subscale	15-75	Increase	α = .95 (Tanay and Bernstein, 2013)		
	SMS Body Subscale	6-30	Increase	α = .89 (Tanay and Bernstein, 2013)		

Note. M = Mean; SD = Standard Deviation

Appendix R: Acceptability Data

Table R1: *CSQ-8 Raw Scores and Acceptability Conversion*

CSQ-8 total/32	Acceptability/100
32	100%
30	94%
32	100%
31	97%
29	91%
24	75%

Table R2: *Percentage of Agreement on User-friendliness and Appropriateness*

	Strongly Agree	Somewhat Agree
The information on the online mindfulness programme was easy to understand	83%	17%
The information in the mindfulness programme was clear in meaning	67%	33%
The information on the online mindfulness programme was informative	100%	
The information on the online mindfulness intervention was relevant to me	33%	66%
The online mindfulness programme was user friendly	100%	
The online mindfulness programme was easy to use	100%	

Table R3: *Qualitative Feedback on the Online Mindfulness Course*

	What was most helpful about the online format of the intervention?	**What was least helpful about the online format of the intervention?**
Feedback 1	Focussing on issues in an objective way enabled me to realise that I was having negative reactions/feelings to alarms, low or high readings, set change reminders etc. I knew this already, but it hadn't really occurred to me that this might be something I could change. It has also become clear that I deal with hypos (and the possibility of hypos) much more calmly than hypers. This may be misplaced.	The daily check in could have more automated, so I didn't have to write out my email each time. Also I was unable to see my previous responses or check if I'd remembered to respond the previous day.
Feedback 2	Ground myself and think more	No response.
Feedback 3	The modules listening to your body and the emotions module. It gave me time to concentrate on me, I was surprised at the emotions I felt.	I have never had a food or exercise plan. I did not find those questions helpful. If there are such plans I would like them please.
Feedback 4	The audio instructions were really helpful. Very easy to understand and to do.	No response.
Feedback 5	Easy questions.	Too many emails.
Feedback 6	I could use my phone to access the clips.	No response.

Table R4: *Qualitative Feedback impact of intervention on experience of hypoglycaemia*

	Have you noticed any changes in your experience of hypoglycaemia since practicing the mindfulness techniques (e.g. symptoms experienced, anxiety levels)?
Feedback 1	Since noticing some of my negative reactions I have been able to be a little more objective when I'm dealing with a low/high for example. I'm wondering if I should try to balance my feelings about lows and highs and try to avoid each in equal measure.
Feedback 2	Less anxiety
Feedback 3	I have not had a hypo since doing this course. I feel positive about going forward and I do feel my anxiety levels have come down a little.
Feedback 4	My anxiety seems to be much lower regarding hypos. And I've been using the techniques when I do have a hypo.
Feedback 5	Helping when having an hypo to control the amount of food intake and just allow myself time to feel back to normal
Feedback 6	I don’t think I feel much different as of now but I feel the mindfulness tasks has allowed me to become more aware of my body and feelings and allows me to prioritise time for myself to complete mindfulness tasks

Appendix S: Tau-U Data

Table S1: *Tau-U for Each VAS Variable*

	FOH-WORRY				
	Comparison	Tau	SD Tau	*p*-value	90% CI
P1					
	A x B	-.35	.19	.064	-.665<>-.040
	B x a	-.26	.15	.074	-.501<>-.021
	A x (B + a)	-.46	.17	.008**	-.740<>-.176
P2					
	A x B	-.47	.19	.011*	-.779<>-.168
	B x a	-.56	.15	.000***	-.813<>-.304
	A x (B + a)	-.68	.16	.000***	-.950<>-.409
P3					
	A x B	.00	.24	1	-.401<>.401
	B x a	-.03	.24	.890	-.429<>.362
	A x (B + a)	-.01	.20	.942	-.335<>.307
P4					
	A x B	-.44~	.16~	.005**~	-.704<>-.181~
	B x a	-.35	.15	.018*	-.597<>-.107
	A x (B + a)	-.50~	.15~	.001**~	-.737<>-.255~
P5					
	A x B	-.10	.22	.641	-.469<>.262
	B x a	-.28	.18	.128	-.572<>.022
	A x (B + a)	-.20	.21	.357	-.545<>.154
P6					
	A x B	-.50	.21	.015*	-.840<>-.160
	B x a	.45	.25	.071	.040<>.855
	A x (B + a)	-.41	.19	.032*	-.729<>-.096
			FOH-BEHAVIOUR		
	Comparison	Tau	SD Tau	*p*-value	90% CI
P1					
	A x B	-.52	.19	.006**	-.835<>-.210
	B x a	-.10	.15	.504	-.338<>.143
	A x (B + a)	-.56	.17	.001**	-.846<>-.282
P2					
	A x B	-.21	.19	.260	-.514<>.096
	B x a	-.64	.15	.000***	-.895<>-.385
	A x (B + a)	-.54	.16	.001**	-.813<>-.272
P3					
	A x B	-.10	.24	.682	-.501<>.301
	B x a	-.15	.24	.524	-.549<>.242
	A x (B + a)	-.18	.20	.356	-.501<>.141
P4					
	A x B	-.36	.16	.026*	-.617<>-.094
	B x a	-.44	.15	.003**	-.688<>-.198
	A x (B + a)	-.50	.15	.001**	-.744<>-.263

P5					
	A x B	-.20	.22	.368	-.566<>.166
	B x a	-.42	.18	.019*	-.720<>-.126
	A x (B + a)	-.36	.21	.086	-.714<>-.015
P6					
	A x B	-.30~	.21~	.150~	-.637<>.043~
	B x a	.24	.25	.326	-.164<>.651
	A x (B + a)	-.28~	.19~	.149~	-.594<>.039~

DIET

	Comparison	Tau	SD Tau	*p*-value	90% CI
P1					
	A x B	.36	.19	.055	.052<>.677
	B x a	-.05	.15	.726	-.292<>.189
	A x (B + a)	.33	.17	.051*	.053<>.617
P2					
	A x B	-.01	.19	.938	-.320<>.291
	B x a	.62	.15	.000***	.369<>.879
	A x (B + a)	.33	.17	.051*	.053<>.617
P3					
	A x B	-.41	.24	.095	-.808<>-.006
	B x a	-.64	.24	.008**	-1<>-.245
	A x (B + a)	-.64	.20	.001**	-.961<>-.319
P4					
	A x B	-.12~	.16~	.462~	-.379<>.145~
	B x a	.30	.15	.044*	.055<>.545
	A x (B + a)	-.08~	.15~	.563~	-.325<>.156~
P5					
	A x B	.07	.22	.764	-.299<>.432
	B x a	-.21	.18	.254	-.503<>.091
	A x (B + a)	-.01	.21	.964	-.359<>.340
P6					
	A x B	-.01	.21	.956	-.351<>.328
	B x a	.21	.25	.396	-.197<>.618
	A x (B + a)	.04	.19	.837	-.277<>.356

BLOOD GLUCOSE MANAGEMENT

	Comparison	Tau	SD Tau	*p*-value	90% CI
P1					
	A x B	.07	.19	.707	-.241<>.384
	B x a	-.17	.15	.241	-.412<>.069
	A x (B + a)	-.02	.17	.896	-.304<>.260
P2					
	A x B	-.07	.19	.717	-.373<>.238
	B x a	.74	.15	.000***	.486<>.995
	A x (B + a)	.34	.16	.040*	.067<>.608
P3					
	A x B	-.04	.24	.884	-.437<>.366
	B x a	-.15	.24	.524	-.549<>.242
	A x (B + a)	-.14	.20	.464	-.464<>.178

P4					
	A x B	.00	.16	1	-.262<>.262
	B x a	.00	.15	1	-.245<>.245
	A x (B + a)	.00	.15	1	-.241<>.241
P5					
	A x B	-.33	.22	.134	-.699<>.032
	B x a	.29	.18	.112	-.010<>.585
	A x (B + a)	-.25	.21	.237	-.601<>.098
P6					
	A x B	.00	.21	1	-.340<>.340
	B x a	.00	.25	1	-.408<>.408
	A x (B + a)	.00	.19	1	-.317<>.317

MEDICATION

	Comparison	Tau	SD Tau	*p*-value	90% CI
P1					
	A x B	.21	.19	.260	-.098<>.527
	B x a	-.09	.15	.557	-.326<>.155
	A x (B + a)	.17	.17	.319	-.111<>.453
P2					
	A x B	-.24	.19	.204	-.541<>.070
	B x a	.36	.15	.021*	.104<>.613
	A x (B + a)	-.05	.16	.759	-.321<>.220
P3					
	A x B	.56	.24	.022*	.156<>.958
	B x a	-.11	.24	.637	-.509<>.282
	A x (B + a)	.43	.20	.027*	.110<>.752
P4					
	A x B	.00	.16	1	-.262<>.262
	B x a	.00	.15	1	-.245<>.245
	A x (B + a)	.00	.15	1	-.241<>.241
P5					
	A x B	-.33	.22	.143	-.691<>.040
	B x a	-.03	.18	.872	-.326<>.268
	A x (B + a)	-.36	.21	.092	-.707<>-.008
P6					
	A x B	.00	.21	1	-.340<>.340
	B x a	.00	.25	1	-.408<>.408
	A x (B + a)	.00	.19	1	-.317<>.317

EXERCISE

	Comparison	Tau	SD Tau	*p*-value	90% CI
P1					
	A x B	.30	.19	.114	-.012<>.613
	B x a	.25	.15	.084	.012<>.493
	A x (B + a)	.41	.17	.016*	.130<>.694
P2					
	A x B	.10	.19	.587	-.204<>.406
	B x a	.72	.15	.000***	.462<>.972
	A x (B + a)	.51	.16	.002**	.240<>.782

P3					
	A x B	-.58	.24	.018*	-.980<>-.177
	B x a	-.08	.24	.739	-.475<>.315
	A x (B + a)	-.59	.20	.003**	-.907<>-.265
P4					
	A x B~	.23~	.16~	.155~	-.035<>.488~
	B x a	.04	.15	.764	-.200<>.290
	A x (B + a) ~	.27~	.15~	.069~	.025<>.507~
P5					
	A x B	.00	.22	1	-.366<>.366
	B x a	-.02	.18	.917	-.316<>.278
	A x (B + a)	.00	.21	.991	-.347<>.352
P6					
	A x B	-.62	.21	.003**	-.960<>-.281
	B x a	.07	.25	.770	-.335<>.480
	A x (B + a)	-.55	.19	.004**	-.864<>-.231

LOW MOOD AND ANXIETY

	Comparison	Tau	SD Tau	*p*-value	90% CI
P1					
	A x B	.08	.19	.669	-.231<>.394
	B x a	-.10	.15	.492	-.341<>.140
	A x (B + a)	.04	.17	.810	-.241<>.323
P2					
	A x B	.10	.19	.604	-.209<>.402
	B x a	-.70	.15	.000***	-.959<>-.450
	A x (B + a)	-.27	.16	.105	-.537<>.004
P3					
	A x B	-.45~	.24~	.065~	-.851<>-.049~
	B x a	-.19	.24	.437	-.582<>.209
	A x (B + a)	-.34~	.20~	.082~	-.661<>-.019~
P4					
	A x B	-.33	.16	.039*	-.590<>-.066
	B x a	.14	.15	.364	-.110<>.380
	A x (B + a)	-.26	.15	.073	-.503<>-.022
P5					
	A x B	-.40	.22	.069	-.769<>-.038
	B x a	-.33	.18	.067	-.628<>-.034
	A x (B + a)	-.49	.21	.020*	-.842<>-.143
P6					
	A x B	-.30~	.21~	.150~	-.637<>.043~
	B x a	.18	.25	.474	-.230<>.585
	A x (B + a)	-.34~	.19~	.076~	-.658<>-.025~

Note. P1 = participant 1; P2 = participant 2; P3 = participant 3; P4 = participant 4; P5 = participant 5; P6 = participant 6; A = Baseline; B = Intervention; a = Follow-up; SD = standard deviation; CI = confidence interval; green box = significant improvement; red box= significant deterioration; * = p <.05; ** = p <.01; *** = p <.001; ~ =baseline corrected for trend.

Table S2: *Summary of Statistical Change (Tau-U) Across Idiographic Variables*

Idiographic variable	*Phase contrast*	*Number significantly improved (P)*	*No significant change (P)*	*Significant deterioration (P)*
FOH-worry	A x B	3 (P2, P4, P6)	3 (P1, P3, P5)	0
	B x a	2 (P2, P4)	4 (P1, P3, P5, P6)	0
	A x (B + a)	4 (P1, P2, P4, P6)	2 (P3, P5	0
FOH-Behaviour	A x B	2 (P1, P4)	4 (P2, P3, P5, P6)	0
	B x a	3 (P2, P4, P5)	3 (P1, P3, P6)	0
	A x (B + a)	3 (P1, P2, P4)	3 (P3, P5, P6)	0
Diet	A x B	0	6 (all)	0
	B x a	2 (P2, P4)	3 (P1, P5, P6)	1 (P3)
	A x (B + a)	2 (P1, P2)	3 (P4, P5, P6)	1 (P3)
Blood glucose management	A x B	0	6 (all)	0
	B x a	1 (P2)	5 (all but P2)	0
	A x (B + a)	1 (P2)	5 (all but P2)	0
Medication	A x B	1 (P3)	5 (all but P3)	0
	B x a	1 (P2)	5 (all but P2)	0
	A x (B + a)	1 (P3)	5 (all but P3)	0
Exercise	A x B	0	4 (P1, P2, P5, P6)	2 (P3, P6)
	B x a	1 (P2)	5 (all but P2)	0
	A x (B + a)	2 (P1, P2)	2 (P4, P5)	2 (P3, P6)
Low mood & anxiety	A x B	1 (P4)	5 (all but P4)	0
	B x a	1 (P2)	5 (all but P2)	0
	A x (B + a)	1 (P5)	5 (all but P5)	0

Note. A = Baseline; B = Intervention; a = Follow-up; P = participant; P1 = participant 1; P2 = participant 2; P3 = participant 3; P4 = participant 4; P5 = participant 5; P6 = participant 6.

Table S3: *Weighted Averages of Data Non-overlap Between Phases for FOH-worry and FOH-Behaviour*

	Comparison	Tau-U	p-value	95% CI
FOH-Worry	A x B	-.33	.000***	-0.4942<>-0.1692
	B x a	-.23	.000***	-0.3786<>-0.0726
	A x (B + a)	-.39	.000***	-0.5400<>-0.2493
FOH-Behaviour				
	A x B	-.29	.000***	-0.4540<>-0.1290
	B x a	-.29	.000***	-0.4425<>-0.1366
	A x (B + a)	-.42	.000***	-0.5632<>-0.2724

Note. A = Baseline; B = Intervention; a = Follow-up; CI = confidence interval; *** = p <.001.

Appendix T: Standardised Measures Data

Table T1: *Raw scores for Standardised Measures*

PARTICIPANT	MEASURE	T1	T2	T3
P1	HFS-II Behaviour	18	13	13
	HFS-II Worry	31	27	11
	HFS-II Total	49	40	24
	DSMQ Glucose Management	14	15	15
	DSMQ Dietary Control	9	9	9
	DSMQ Physical Activity	9	9	9
	DSMQ Healthcare Use	8	8	8
	DSMQ Sum Scale	43	44	45
	W-BQ28 Generic Negative Well-being	2	1	1
	W-BQ28 Generic Energy	5	7	7
	W-BQ28 Generic Positive Well-being	4	5	9
	W-BQ28 Generic Stress	6	3	2
	W-BQ28 Diabetes-Specific Negative Well-being	6	3	1
	W-BQ28 Diabetes-specific stress	4	7	2
	W-BQ28 Diabetes-specific Positive Well-being	5	5	11
	FFMQ Observing	35	31	33
	FFMQ Describing	30	26	33
	FFMQ Acting with Awareness	27	29	26
	FFMQ Nonjudging of inner experience	28	30	36
	FFMQ Nonreactivity to inner experience	18	24	24
P2	HFS-II Behaviour	16	18	16
	HFS-II Worry	39	34	40
	HFS-II Total	55	52	56
	DSMQ Glucose Management	5	8	10
	DSMQ Dietary Control	7	6	7
	DSMQ Physical Activity	2	5	6
	DSMQ Healthcare Use	9	8	8
	DSMQ Sum Scale	25	28	33
	W-BQ28 Generic Negative Well-being	6	4	3
	W-BQ28 Generic Energy	3	4	5
	W-BQ28 Generic Positive Well-being	5	6	7
	W-BQ28 Generic Stress	6	3	5
	W-BQ28 Diabetes-Specific Negative Well-being	7	6	4

	W-BQ28 Diabetes-specific stress	7	4	4
	W-BQ28 Diabetes-specific Positive Well-being	2	3	2
	FFMQ Observing	31	30	33
	FFMQ Describing	30	28	30
	FFMQ Acting with Awareness	27	28	30
	FFMQ Nonjudging of inner experience	24	25	30
	FFMQ Nonreactivity to inner experience	20	20	23
P3	HFS-II Behaviour	35	35	31
	HFS-II Worry	44	45	42
	HFS-II Total	79	80	73
	DSMQ Glucose Management	6	12	13
	DSMQ Dietary Control	6	4	2
	DSMQ Physical Activity	8	6	7
	DSMQ Healthcare Use	8	8	8
	DSMQ Sum Scale	30	33	32
	W-BQ28 Generic Negative Well-being	5	5	5
	W-BQ28 Generic Energy	7	8	5
	W-BQ28 Generic Positive Well-being	6	7	6
	W-BQ28 Generic Stress		5	4
	W-BQ28 Diabetes-Specific Negative Well-being	7	6	6
	W-BQ28 Diabetes-specific stress	4	5	7
	W-BQ28 Diabetes-specific Positive Well-being	5	9	6
	FFMQ Observing	23	27	26
	FFMQ Describing	22	24	26
	FFMQ Acting with Awareness	22	15	16
	FFMQ Nonjudging of inner experience	20	18	15
	FFMQ Nonreactivity to inner experience	22	22	22
P4	HFS-II Behaviour	33	16	22
	HFS-II Worry	52	28	28
	HFS-II Total	85	44	44
	DSMQ Glucose Management	15	15	14
	DSMQ Dietary Control	4	8	7
	DSMQ Physical Activity	0	0	3
	DSMQ Healthcare Use	8	9	9
	DSMQ Sum Scale	29	34	35
	W-BQ28 Generic Negative Well-being	7	4	2
	W-BQ28 Generic Energy	2	2	5

	W-BQ28 Generic Positive Well-being	7	5	10
	W-BQ28 Generic Stress	9	4	2
	W-BQ28 Diabetes-Specific Negative Well-being	8	5	8
	W-BQ28 Diabetes-specific stress	8	4	4
	W-BQ28 Diabetes-specific Positive Well-being	3	2	4
	FFMQ Observing	25	29	28
	FFMQ Describing	20	23	25
	FFMQ Acting with Awareness	20	26	25
	FFMQ Nonjudging of inner experience	19	22	30
	FFMQ Nonreactivity to inner experience	21	22	23
P5	HFS-II Behaviour	43	37	40
	HFS-II Worry	58	56	42
	HFS-II Total	101	93	82
	DSMQ Glucose Management	11	13	10
	DSMQ Dietary Control	5	5	4
	DSMQ Physical Activity	5	5	5
	DSMQ Healthcare Use	7	8	8
	DSMQ Sum Scale	30	33	29
	W-BQ28 Generic Negative Well-being	3	3	2
	W-BQ28 Generic Energy	5	5	6
	W-BQ28 Generic Positive Well-being	7	8	7
	W-BQ28 Generic Stress	2	4	4
	W-BQ28 Diabetes-Specific Negative Well-being	6	6	6
	W-BQ28 Diabetes-specific stress	3	3	3
	W-BQ28 Diabetes-specific Positive Well-being	5	3	5
	FFMQ Observing	25	29	28
	FFMQ Describing	20	23	25
	FFMQ Acting with Awareness	20	26	25
	FFMQ Nonjudging of inner experience	19	22	30
	FFMQ Nonreactivity to inner experience	21	22	23
P6	HFS-II Behaviour	33	26	26
	HFS-II Worry	65	41	41
	HFS-II Total	98	67	67
	DSMQ Glucose Management	14	14	14
	DSMQ Dietary Control	5	7	5
	DSMQ Physical Activity	7	7	5

	DSMQ Healthcare Use	9	9	9
	DSMQ Sum Scale	38	40	35
	W-BQ28 Generic Negative Well-being	4	5	2
	W-BQ28 Generic Energy	6	6	6
	W-BQ28 Generic Positive Well-being	5	4	5
	W-BQ28 Generic Stress	4	4	4
	W-BQ28 Diabetes-Specific Negative Well-being	7	4	7
	W-BQ28 Diabetes-specific stress	4	4	4
	W-BQ28 Diabetes-specific Positive Well-being	6	4	4
	FFMQ Observing	25	29	28
	FFMQ Describing	26	23	26
	FFMQ Acting with Awareness	38	31	33
	FFMQ Nonjudging of inner experience	29	25	27
	FFMQ Nonreactivity to inner experience	13	21	21

Note. T1 = baseline; T2 = end of intervention; T3 = follow-up.

Table T2: *RCI Values for HFS-II by pair-wise comparison*

	FOH Total		FOH-Worry		FOH-Behaviour	
	T1-T2	T1-T3	T1-T2	T1-T3	T1-T2	T1-T3
P1	-1.199	-3.330	-0.918	-4.591	-0.869	-0.869
P2	-0.400	0.133	-1.148	0.230	0.348	0.000
P3	0.133	-0.799	0.230	-0.459	0.000	-0.695
P4	-5.461	-4.662	-5.509	-5.509	-2.956	-1.913
P5	-1.066	-2.531	-0.459	-3.673	-1.043	-0.522
P6	-4.129	-4.129	-5.509	-5.509	-1.217	-1.217

Note. T1 = pre-intervention; T2 = post-intervention; T3 = 1-month follow-up; green box = reliable improvement (FOH has decreased); red box= reliable deterioration (FOH has increased).

Table T3: *RCI Values for DSMQ by pair-wise comparison*

	Sum Scale		Blood Glucose Management		Dietary Control		Physical Activity		Healthcare use	
	T1-T2	T1-T3	T1-T2	T1-T3	T1-T2	T1-T3	T1-T2	T1-T3	T1-T2	T1-T3
P1	0.000	0.000	0.509	0.509	0.000	0.000	0.000	0.000	0.000	1.485
P2	1.282	2.565[a]	1.017	2.035[a]	-0.824	0.000	1.436	1.795	-1.485	-1.485
P3	1.282	1.282	2.035[a]	2.544[a]	-1.648	-2.473	-0.718	-0.359	0.000	0.000
P4	1.282	1.282	0.000	-0.509	3.297[a]	2.473[a]	0.000	1.077	1.485	1.485
P5	1.282	0.000	1.017	0.000	0.000	-0.824	0.000	0.000	1.485	1.485
P6	1.282	0.000	0.000	0.000	1.648	0.000	0.000	-0.718	0.000	0.000

Note. T1 = pre-intervention; T2 = post-intervention; T3 = 1-month follow-up; [a] = clinically significant change; green box = reliable improvement (self-management behaviour has improved); red box= reliable deterioration (self-management behaviour has deteriorated).

Table T4: *RCI Values for W-BQ28 (subscales on generic well-being) by pair-wise comparison*

	Generic Negative Well-being		Generic Energy		Generic Positive Well-being		Generic Stress	
	T1-T2	T1-T3	T1-T2	T1-T3	T1-T2	T1-T3	T1-T2	T1-T3
P1	-0.806	-0.806	1.462	1.462	1.339	6.697[a]	-2.081	-2.775
P2	-1.612	-2.417	0.731	1.462	1.339	2.679[a]	-2.081	-0.694
P3	0.000	0.000	0.731	-1.462	1.339	0.000	0.000	-0.694
P4	-2.417	-4.029	0.000	2.193[a]	-2.679	4.018[a]	-3.469	-4.857
P5	0.000	-0.806	0.000	0.731	1.339	0.000	1.388	1.388
P6	0.806	-1.612	0.000	0.000	-1.339	0.000	0.000	0.000

Note. T1 = pre-intervention; T2 = post-intervention; T3 = 1-month follow-up; [a] = clinically significant change; green box = reliable improvement (well-being has improved in this area); red box= reliable deterioration (well-being has worsened in this area).

Table T5: *RCI Values for W-BQ28 (subscales on diabetes-specific well-being) by pair-wise comparison*

	Diabetes-specific Negative Well-being		Diabetes-specific Stress		Diabetes-specific Positive Well-being	
	T1-T2	T1-T3	T1-T2	T1-T3	T1-T2	T1-T3
P1	-7.045	-11.742	2.835	-1.890	0.000	8.911[a]
P2	-2.348	-7.045	-2.835	-2.835	1.485	0.000
P3	-2.348	-2.348	0.945	2.835	5.941[a]	1.485
P4	-7.045	0.000	-3.780	-3.780	-1.485	1.485
P5	0.000	0.000	0.000	0.000	-2.970	0.000
P6	-7.045	0.000	0.000	0.000	-2.970	-2.970

Note. T1 = pre-intervention; T2 = post-intervention; T3 = 1-month follow-up; [a] = clinically significant change; green box = reliable improvement (well-being has improved in this area); red box= reliable deterioration (well-being has worsened in this area).

Table T6: *RCI Values for FFMQ by pair-wise comparison*

	Acting with Awareness		Describing		Non-judging		Non-reactivity		Observing	
	T1-T2	T1-T3	T1-T2	T1-T3	T1-T2	T1-T3	T1-T2	T1-T3	T1-T2	T1-T3
P1	0.622	-0.311	-2.033	1.525	0.898	3.593	1.836	1.836	-1.481	-0.740
P2	0.311	0.933	-1.017	0.000	0.449	2.695	0.000	0.918	-0.370	0.740
P3	-2.177	-1.866	1.017	2.033	-0.898	-2.246	0.000	0.000	1.481	1.110
P4	1.866	1.555	1.525	2.542	1.347	4.940	0.306	0.612	1.481	1.110
P5	-0.933	-0.622	-2.542	-1.525	0.449	0.449	-1.836	-1.530	1.481	1.851
P6	-2.177	-1.555	-1.525	0.000	-1.797	-0.898	2.448	2.448	1.481	1.110

Note. T1 = pre-intervention; T2 = post-intervention; T3 = 1-month follow-up; green box = reliable improvement (state mindfulness facet has improved); red box= reliable deterioration (state mindfulness facet has deteriorated).

Appendix U: Process Measure Data

Table U1: *Raw Scores for Process Measure*

SMS Total				
	T1	**T2**	**T3**	**T4**
P1	76	71	62	73
P2	64	81	70	90
P3	71	79	87	87
P4	64	65		
P5	63	74	70	70
P6	84	68	44	87
SMS Mind				
	T1	**T2**	**T3**	**T4**
P1	56	49	45	52
P2	46	57	52	64
P3	52	54	62	64
P4	43	42		
P5	47	51	53	54
P6	60	45	29	62
SMS Body				
	T1	**T2**	**T3**	**T4**
P1	20	22	17	21
P2	18	24	18	26
P3	19	25	25	23
P4	21	23		
P5	16	23	17	16
P6	24	23	15	25

Note. T1 = Intervention phase week 1; T2 = week 2; T3 = week 3; T4 = week 4

Table U2: *RCI Values for SMS by pair-wise comparison*

	SMS Total			SMS Mind			SMS Body		
	T1-T2	T1-T3	T1-T4	T1-T2	T1-T3	T1-T4	T1-T2	T1-T3	T1-T4
P1	-1.717	-4.808	-1.030	-3.405	-5.350	-1.946	1.560	-2.341	0.780
P2	5.838	2.060	8.928	5.350	2.918	8.755	4.681	0.000	6.242
P3	2.747	5.494	5.494	0.973	4.864	5.837	4.681	4.681	3.121
P4	0.343	na	na	-0.486	na	na	1.560	na	na
P5	3.777	2.404	2.404	1.946	2.918	3.405	5.462	0.780	0.000
P6	-5.494	-13.736	1.030	-7.296	-15.079	0.973	-0.780	-7.022	0.780

Note. T1 = Intervention phase week 1; T2 = week 2; T3 = week 3; T4 = week 4; green box = reliable improvement (mindfulness has increased); red box= reliable deterioration (mindfulness has reduced).