Comparison of two online ACT-based interventions for adults with insulin-treated diabetes: a pilot RCT

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Table of contents

III. Comparison of two online ACT-based interventions for adults with insulin-treated diabetes: a pilot RCT

IV. Integration, impact and dissemination

V. References

VI. Appendices

List of tables

List of figures

I. Executive summary

Diabetes is a chronic physical health condition characterised by abnormally high blood glucose levels. Careful self-management is an important part of treatment, with all individuals with type 1 diabetes (T1D) and some individuals with poorly controlled type 2 diabetes (T2D) requiring insulin therapy. Individuals not only experience the daily challenge of balancing their blood glucose levels to reduce the risk of developing physical complications, but also can face significant psychosocial challenges. These difficulties can be barriers to achieving treatment goals, increasing the risk of complications and subsequently the economic burden of diabetes.

Systematic review

It is vital people with diabetes have access to effective interventions that target well-being and self-management. However, the evidence base for existing psychosocial interventions is mixed. Given that individuals can have internal experiences that accurately reflect the possibility of realistic consequences, challenging these can have limited effectiveness. Acceptance and Commitment Therapy (ACT) may be a solution as it moves away from attempts to reduce distress directly or to alter beliefs, and instead attempts to reduce the influence of difficult internal experiences on individuals' behaviour. Interest in ACT has risen as a promising approach for supporting people with diabetes.

The systematic review aimed to investigate the characteristics of ACT interventions for people with diabetes, and to what extent ACT improves the psychological, behavioural and physical outcomes of people with T1D and T2D. Database searches (PubMed, Web of Science and PsycINFO) were conducted on 15th

September 2019 using search terms related to diabetes and ACT, alongside searches of the grey literature and reference lists. Two reviewers independently completed title, abstract and full-text screens. Studies were included if they: used a quantitative experimental or quasi-experimental design; recruited participants with T1D and/or T2D; investigated ACT-based intervention(s) which included components of acceptance and committed action; and measured diabetes-related outcomes using standardised tools. A quality assessment was completed using the Effective Public Health Practice Project Quality Assessment Tool, followed by a narrative synthesis.

Overall, 87 unique records were identified, of which 70 studies were excluded due to not fulfilling criteria and 17 studies were eligible for review. The studies employed a range of research designs and included 14 peer-reviewed journal articles, two unpublished theses and one report. A control/comparison condition was used in 13 studies. All studies used pre- and post-intervention measurements, and six studies included a follow-up. Twenty different general and diabetes-specific psychological outcomes had been investigated. Behavioural outcomes mainly focused on diabetes self-management, whilst physical outcomes were primarily based on glycated haemoglobin levels (HbA_{1c}), a measure of glycaemic control over the last three months. Seven studies investigated ACT process outcomes.

A total sample size of 827 was included, belonging to a range of ethnicities although at least half were likely Iranian. Fourteen studies targeted adults and three studies targeted children. Thirteen studies recruited individuals with T2D, one study recruited individuals with T1D, and three studies recruited people with either diagnosis. The studies generally aimed to develop a feasible ACT-based intervention, to investigate the effectiveness of ACT, and/or to investigate mechanisms of change.

Although a range of formats had been utilised, group interventions ($n = 13$) were most commonly investigated. The number of sessions varied from 1 to 15, and the total intervention length varied between 1 and 90 days. All ACT components were captured by the studies. Information on delivery providers ($n = 8$) and treatment fidelity ($n = 2$) was provided by few studies. Most studies obtained an overall quality rating of "weak" ($n = 13$), followed by "moderate" ($n = 3$) and "strong" ($n = 1$).

The T2D studies revealed post-intervention improvements of small to large effect sizes for outcomes such as diabetes self-care, physical activity, diabetes-related distress, self-efficacy, perceived stress, general mental health, worry and quality of life. Inconsistent results were identified for depression, anxiety, ACT-related processes and HbA_{1c}. The only study into T1D identified a small to medium improvement in diabetes acceptance but no significant changes in HbA_{1c} and psychological outcomes. The studies investigating combined populations identified post-intervention improvements in diabetes self-management and a range of psychological outcomes including depression, resilience and well-being.

Strengths of the review included using a second reviewer and applying corrections to intervention effect sizes for small sample bias. However, the heterogeneity of the studies, combined with the limited literature, made drawing firm conclusions difficult. The review raised concerns regarding the lack of clarity around treatment content and fidelity, therapist training, and power calculations. Further, weaknesses were identified in the robustness of employed research designs, the use of generic outcome measures and reduced control over potential confounding factors, which may have contributed towards inconsistent results.

Although not substantive, the results were promising and demonstrated the acceptability and feasibility of delivering ACT to the diabetes population. The findings suggest that ACT may have the potential to address a future direction in diabetes care delivery, but high-quality research is needed first. Recommendations for future research include further investigating the impact of ACT in T1D populations, examining clinically significant impact, using robust study designs, reaching a consensus on standardised diabetes-related measures, and increasing transparency.

Empirical study

Due to the lack of psychology funding, many patients with diabetes do not have access to appropriate and effective psychological therapies, such as ACT in diabetes services. The use of brief online, modular interventions may be a solution to address this issue as they may target specific coping strategies and diabetes-related outcomes. Karekla and colleagues' (2018) theoretical mapping of ACT components onto the Common Sense Model of illness self-regulation provided a framework for the pilot study. The study aimed to investigate the impact of two online four-week, self-help interventions based on ACT components (a values-plus-goals intervention [VGI] and a mindfulness-based intervention [MBI]) on the well-being, diabetes self-management and glycaemic control of insulin-treated adults with suboptimal glycaemic control and to determine whether improvements in these outcomes were associated with changes in diabetes acceptance and valued living.

A randomised controlled mixed design was used. Fifty-six insulin-treated individuals, recruited through diabetes clinics at an NHS trust and diabetes organisations, were randomly assigned to the VGI or the MBI group. Following attrition, the final sample size was 29 (MBI: $n = 12$; VGI: $n = 17$). The sample were

predominantly middle-aged English-speaking adults with T1D (76%), male (55%) and from a White ethnic background (97%), with an average diabetes duration of 21.9 years. In the VGI, participants were asked to complete a values-clarification card-sort task and to connect with their top value. Participants then set a diabetes-related SMART goal to achieve in one month. In the MBI, participants were introduced to mindfulness and asked to complete a 10-minute practice adapted for diabetes. Participants were asked to complete the practice three to four times a week for one month.

Sociodemographic characteristics were collected at baseline. The following standardised questionnaires were completed pre-intervention, post-intervention and at follow-up: Well-being Questionnaire; Diabetes Self-Management Questionnaire; Diabetes Acceptance Scale; and Valued Living Questionnaire. HbA$_{1c}$ level was obtained at baseline and follow-up. Participants also completed a post-intervention feedback questionnaire. Data was analysed using Huyhn-Feldt corrected repeated measures analysis of variance and multiple linear regression. Reliable Changes Indices and clinically significant changes were also examined.

Attrition rates did not significantly differ between the treatment groups ($p = .289$). However, individuals with more hypoglycaemic episodes ($p = .033$), higher diabetes acceptance ($p = .028$) and higher well-being ($p = .019$) were more likely to complete the study. Participants in the MBI and VGI groups took on average 46.4 and 53.5 days respectively to complete the intervention. The MBI group completed 12 mindfulness practices on average during the programme. Twelve participants in the VGI group moved towards their value-based goal and five could not due to external factors. Both interventions were experienced as somewhat helpful, relevant and easy

to use. Ten participants in the MBI group and nine participants in the VGI group would recommend the programmes.

In the MBI condition, participants experienced non-significant improvements in their well-being and diabetes acceptance over time. Two participants experienced clinically significant improvements in their well-being. Participants' post-intervention well-being was significantly associated with changes in diabetes acceptance, controlling for their baseline well-being. However, this association was not significant at follow-up.

In the VGI condition, participants showed a non-significant positive trend in their diabetes self-management ($p = .061$, $\eta_p^2 = .270$) with post-hoc t-tests revealing a significant increase between pre-intervention and post-intervention ($p = .009$, $d = .504$), which was maintained at follow-up ($p = .020$, $d = .46$). Subscale analyses revealed that only the dietary control component of self-management significantly improved over time ($p = .01$, $\eta_p^2 = .411$), with post-hoc t-tests identifying significant improvements from pre-intervention to post-intervention ($p = .005$, $d = .478$) and follow-up ($p = .020$, $d = .46$). Clinically significant improvements were noted in three participants for dietary control and in two participants for level of physical activity. A non-significant improvement in valued living was found over the course of the study. No significant associations were found between changes in valued living and diabetes self-management at post-intervention and follow-up, controlling for baseline diabetes self-management. Follow-up HbA_{1c} values were obtained for five participants, precluding statistical analysis. Of these, four participants experienced clinically meaningful reductions at follow-up.

Overall, the hypotheses that the MBI would significantly improve well-being and diabetes acceptance were not supported, although they were significantly associated. The hypothesis that the VGI would increase diabetes self-management was partially supported, although this was found to be specific to dietary control. However, valued living did not improve and was not associated with changes in diabetes self-management as hypothesised. Promising improvements were identified for glycaemic control for a small number of participants.

Several study limitations were noted including shortfalls in the interventions, methodological drawbacks such as the use of self-report and lack of personalised feedback, and confounding factors such as diabetes duration, motivation level and external factors. An overarching issue was the small samples obtained, which led to an underpowered study and precluded cross-comparisons of the interventions.

The results in relation to diabetes self-management, dietary control and glycaemic control, combined with participant feedback on the feasibility, accessibility and relevance of the interventions, were indicative of the interventions' potential in expanding access to psychological input. This in turn may reduce complications and the economic burden of diabetes. However, further research is necessary to gain more insight into the clinical benefits of these interventions for individuals with diabetes using more rigorous studies with larger sample sizes and longer follow-ups.

Integration, impact and dissemination

The pilot study aimed to extend previous ACT for diabetes literature in a pragmatic way, with a view to facilitating real-life application and informing future trials. The systematic review confirmed the novel aspects of the empirical study, such

as contributing to the ACT for T1D literature, and being the first study to have examined ACT components in the diabetes field. Further, it incorporated an active control group and was transparent about intervention details. Delays in obtaining ethics approval, combined with limited resources, resulted in barriers such as reduced assistance with recruitment. Moreover, using a flexible approach to recruitment difficulties introduced confounding factors. Piloting the study and increasing collaboration with the diabetes team would have been beneficial to gain a better insight into these challenges. Pragmatic trials may also increase understanding of the feasibility of online ACT-based interventions in this population. Service user feedback helped to assess the relevance of the project and adapt research materials.

The interventions showed promise as a feasible and acceptable way of improving self-management and potentially HbA_{1c}. The interventions could have broader benefits for clinicians, the National Health Service and diabetes organisations. They could reduce the economic burden of diabetes and save time, money and resources. The study has raised awareness of the importance of considering well-being, mindfulness and value-based living – aspects which are often missed in routine care. This may encourage services to address local needs, which may translate into policy-driving work in the future. However, as the study was a pilot, more robust randomised controlled trials are needed to establish the effectiveness of ACT component-based interventions for the diabetes population. The systematic review provides researchers with a foundation to build on with recommendations, whilst the pilot study has highlighted implementation challenges to inform future research.

Several dissemination routes are proposed to maximise the impact of the project. These include: providing participants, local Diabetes UK groups and key

diabetes organisations with a plain English summary of the findings; providing a formal summary to the collaborating diabetes team with a service user, highlighting the recommendations that are most pertinent to clinical practice; submitting the systematic review and empirical study to a peer-reviewed diabetes journal; and presenting the empirical study at the UK & Ireland Association for Contextual Behavioural Science 2020 conference.

I. The impact of Acceptance and Commitment Therapy (ACT) on the psychological, behavioural and physical outcomes of people with diabetes: a systematic review

Abstract

Acceptance and Commitment Therapy (ACT) has been researched as a promising approach to address the psychosocial impact of diabetes. However, a systematic review of the evidence base for ACT for diabetes has not been conducted to date. The present review aimed to explore the characteristics of ACT interventions for diabetes and to examine whether ACT improves diabetes-related outcomes in people with type 1 diabetes (T1D) and type 2 diabetes (T2D). A systematic literature search was undertaken of three databases (PubMed, Web of Science and PsycINFO) and the grey literature in September 2019 to identify any quantitative studies that have investigated the impact of ACT on diabetes-related psychological, behavioural and/or physical outcomes. Following title, abstract and full-text paper screens, 17 studies were included in the review for quality appraisal and narrative synthesis. The interventions employed in these studies varied in their delivery format, duration and components. Thirteen studies found that ACT led to improvements of small to large effect sizes for several outcomes, such as diabetes-related distress and diabetes self-management, in the T2D population. The heterogeneity of psychological outcomes hindered cross-study comparisons. Inconsistent results were identified for depression, anxiety, ACT-related processes and HbA_{1c}. One study investigated ACT in adolescents with T1D, precluding generalisation. Three studies examined combined populations, finding post-ACT improvements in a range of outcomes, although diabetes type may have been a confounding factor. The review raised concerns regarding reporting bias and methodological issues, which may have contributed towards inconsistent results. Overall, the findings suggest that ACT may have the potential to address a future direction in diabetes care delivery, but high-quality research is needed to draw firmer

conclusions about its effectiveness. Recommendations for future research include using

robust study designs, reaching a consensus on standardised diabetes-related measures,

and increasing transparency about ACT interventions.

Introduction

Diabetes mellitus refers to a chronic physical health condition characterised by abnormally high blood glucose levels. Common symptoms include increased fatigue, excessive thirst, frequent urination and unintentional weight loss (Diabetes UK, 2019). There are various types of diabetes, such as type 1 diabetes (T1D), type 2 diabetes (T2D), cystic fibrosis-related diabetes, latent autoimmune diabetes in adults (LADA), monogenetic diabetes and diabetes caused by rare genetic syndromes (Royal College of Nursing [RCN], 2019). The prevalence of diabetes is rapidly growing with 3.8 million people in the United Kingdom (UK) with a diagnosis, out of whom approximately 8% have T1D and 90% have T2D – the two main types of diabetes (Diabetes UK, 2019). The National Health Service (NHS) spends approximately 10% of its yearly budget on diabetes care, primarily due to the cost of treating diabetes-related complications, indicating that diabetes has a significant economic burden (Diabetes UK, 2017).

T1D and T2D have different pathophysiological mechanisms distinguished by their relationship to insulin, a pancreatic hormone responsible for allowing cells to use glucose for energy and for lowering blood glucose levels (Diabetes UK, 2019). T1D is considered to be an autoimmune disease where insulin-secreting beta-cells in the pancreas (islets of Langerhans) have been destroyed by the immune system, resulting in no or minimal insulin being produced and high blood glucose levels. It is thought to be caused by both genetic and environmental factors, although the exact causes are unknown (RCN, 2019). The onset of T1D is typically before the age of 40. It used to be referred to as "juvenile diabetes" as it often develops during childhood or

adolescence, but it is now known that more than half of those newly diagnosed with T1D are over 18 years of age (Juvenile Diabetes Research Foundation [JDRF], n.d.).

T2D is generally more prevalent in adults (Diabetes UK, 2019). In T2D, pancreatic beta-cells can produce insulin, but cells have developed insulin resistance. Although the pancreas attempts to overcome the resistance through increased insulin production, the cells become impaired and unable to do so over time, leading to insufficient insulin secretion and inadequate control over blood glucose levels (RCN, 2019). Genes, environmental factors and physical health factors such as obesity and lack of exercise have been identified as risk factors towards the development of T2D, although the exact causal mechanisms remain unknown (RCN, 2019).

Physical complications of diabetes

Individuals with poorly controlled blood glucose levels have an increased risk of developing acute physical complications, such as hypoglycaemia (dangerously low blood glucose) and diabetic ketoacidosis (build-up of ketones in the body). Extreme hyperglycaemia (high blood glucose levels) can lead to hyperglycaemic hyperosmolar nonketotic syndrome, a life-threatening condition (Mayo Clinic, 2018). Hypoglycaemia, if not treated, can be dangerous, leading to loss of consciousness and, rarely, seizures, coma and death. Over time, with frequent episodes of hypoglycaemia, some individuals can develop hypoglycaemia unawareness where blood glucose levels drop to dangerous levels, but they do not get any of their usual warning symptoms.

Controlling blood glucose levels well is important if individuals are to avoid the risk of developing physical complications. Diabetes increases the risk of

developing macrovascular complications, such as heart disease, peripheral vascular disease and stroke, and microvascular complications such as diabetic nephropathy, neuropathy and retinopathy (Fowler, 2008). These complications can be disabling and life-threatening, contributing to most of the morbidity and mortality in both T1D and T2D (George et al., 2014).

Diabetes management

There are similarities between the management of T1D and T2D alongside some key differences (Diabetes UK, 2019). Self-management is an important aspect of both T1D and T2D management: individuals are advised to take responsibility in administering their medication, and in making and maintaining substantial lifestyle changes (George et al., 2014). Individuals with T1D control their blood glucose levels by injecting insulin, using an insulin inhaler or through continuous subcutaneous insulin infusion. There are three categories of insulin therapy with differing time-action profiles: short-acting, intermediate-acting and long-acting. The time-action profiles can vary significantly between individuals, which adds to the complexity of diabetes management (National Institute for Health and Care Excellence [NICE], 2015). Alongside insulin therapy, individuals must learn to calculate the amount of carbohydrates they are consuming and regularly monitor their blood glucose levels to ensure that they are in their target range (Bonora & DeFronzo, 2018; George et al., 2014). Individuals with T2D typically take oral antidiabetic medications to manage their blood glucose levels, although insulin therapy is also used in more severe cases (DeWitt & Hirsch, 2003; George et al., 2014). They must make and maintain lifestyle changes such as healthy eating and regular exercise, as well as engage in regular blood glucose monitoring (Bonora & DeFronzo, 2018).

Whilst the aforementioned physical complications are possible outcomes in both T1D and T2D, individuals on insulin treatment face a continuous challenge of balancing their blood glucose levels throughout their day to avoid hypoglycaemia and hyperglycaemia. They must monitor their blood glucose levels more frequently and adjust their insulin doses accordingly; sometimes a continuous glucose monitor (CGM) is used to facilitate this process (Bonora & DeFronzo, 2018). Further, blood glucose levels can change unpredictably even with careful management due to additional factors such as illness and physical activity (Mayo Clinic, 2018). Data from the National Diabetes Audit in 2016-17 indicated that only 40.8% of adults with T2D and 18.9% of adults with T1D achieved target glycaemic control, blood pressure and cholesterol results (Health and Social Care Information Centre, 2017). The significant health challenge posed by diabetes is also compounded by its psychosocial impact on individuals.

Psychosocial impact of diabetes

Individuals with diabetes can face significant psychosocial challenges as a result of the demands of diabetes care and the difficulties of integrating it into daily life (Nash, 2014). Nicolucci and colleagues examined psychosocial outcomes of people with diabetes across 17 countries in 2013, finding that 20% of people felt that their diabetes care was impacting on their relationships with family and friends, and 40% felt that it interfered with their day-to-day functioning. According to recent statistics in the UK, approximately 40% of people with diabetes experience psychological difficulties and up to 65% can experience low mood related to their condition (Diabetes UK, 2019). Accepting the diagnosis can be a struggle, with the process being likened to the stages of grief for some individuals (Kubler-Ross, 1997).

Furthermore, learning and maintaining diabetes self-management behaviours, particularly during periods of life transitions, disease progression and/or onset of complications, can lead to people feeling overwhelmed and defeated (Young-Hyman et al., 2016). Approximately 45% of people experience diabetes-related psychological distress – sometimes called "diabetes burnout" – which can include feelings of anger, frustration and guilt specific to diabetes care, anxiety around having hypoglycaemia/hyperglycaemia and worrying about the risk of developing diabetes complications (Barnard et al., 2012; Nicolucci et al., 2013; Rane et al., 2011). The fact that diabetes can lead to complications despite good treatment adherence can not only be difficult to accept at times, but also bring up feelings about the futility of good self-management (McCracken et al., 2010). Psychological difficulties have been linked to poorer diabetes self-management, impaired blood glucose control, reduced well-being, poorer quality of life and mortality (Eiser et al., 2001; Lustman & Clouse, 2005; Rane et al., 2011). Depression alongside diabetes can have an additive effect on quality of life and has been linked with an increased risk of complications and disease burden (Moussavi et al., 2007). Increased feelings of burden can result in some individuals using unhelpful coping strategies, such as avoidance of self-management behaviours (Sturt et al., 2015). Having a frightening experience such as hypoglycaemia may also result in anxiety that increases self-management difficulties, as individuals may try to keep their blood glucose levels above their target range (Nash, 2014). This is important as poor psychological well-being may act as a barrier to reaching treatment goals, such as achieving optimal blood glucose levels and reducing the risk of complications (Sturt et al., 2015). Furthermore, these difficulties have a high economic impact as individuals with diabetes seeking physical treatment,

who experience mental health difficulties, can cost the NHS up to 50% more than those without mental health difficulties (Diabetes UK, 2019).

Psychosocial interventions in diabetes

With the increasing prevalence of diabetes and its associated public health burden, improving health outcomes for people with diabetes and implementing a holistic approach to diabetes care have been stressed as national priorities (NHS England, 2018). It is vital that people with diabetes have access to effective interventions that target psychological well-being and self-management in order to improve overall health outcomes and quality of life.

A range of psychosocial interventions for adults with diabetes are used clinically to promote well-being, adaptive health beliefs as well as behavioural and lifestyle changes. These include education-based approaches, problem-solving approaches, support groups and more specific psychological interventions such as cognitive behavioural therapy (CBT), counselling, motivational interviewing and psychodynamic therapy (Harvey, 2015). A recently published meta-analysis found that diabetes-tailored psychological interventions significantly reduced diabetes-related distress and HbA_{1c} levels, a key measure of long-term glycaemic control, in both adults with T1D and T2D (Schmidt et al., 2018). However, other systematic reviews and meta-analyses in the field have identified a mixed evidence base with some studies suggesting that psychological interventions lead to improvements in HbA_{1c} levels, diabetes self-care, depressive symptoms and quality of life in adults with T1D and T2D, whilst others partially or completely contradict these results (Chew et al., 2017; Pascoe et al., 2017; Steed et al., 2003; Thorpe et al., 2012; Winkley et al., 2020a; Winkley et al., 2020b). These inconsistent findings have been

suggested to be the result of various factors such as theoretical differences between psychological interventions, difficulty targeting multiple outcome factors (e.g. mental health and physical health), and inadequate focus on maintenance of self-management (Chew et al., 2018; Harkness et al., 2010).

CBT is a widely used psychological approach which aims to alleviate distress by targeting maladaptive cognitions and behaviours through challenging cognitions and conducting behavioural experiments (Beck, 2011). It has been shown to effectively improve depression, anxiety, stress, self-efficacy, self-care behaviour, quality of life and fasting glucose levels in both adults with T1D and T2D, with mixed results for improving diabetes-related distress and blood glucose control (Harvey, 2015; Li et al., 2017). Due to the accurate nature of thoughts and distress related to health conditions at certain times and situations, challenging these inner experiences can have limited effectiveness for some individuals as they are often linked to the possibility of realistic consequences (e.g. fear of having hypoglycaemia). In line with this dilemma, CBT has evolved over the last few decades and a "third wave" of CBT interventions emerged, which aims to target individuals' relationships with their internal experiences rather than the content of these experiences (Hayes & Hofmann, 2017).

Acceptance and Commitment Therapy

Acceptance and Commitment Therapy (ACT; Hayes et al., 1999) is one of the therapeutic approaches falling within "third wave" CBT that is increasingly being used clinically to support individuals with health conditions. In contrast to traditional CBT, ACT views distress as a normal human experience and moves away from attempts to reduce distress directly or to challenge or alter beliefs. Instead, it attempts

to reduce the influence of difficult internal experiences (thoughts, memories, feelings, etc.) on the individual's behaviour. The main aim is to enable the individual to take meaningful action alongside difficult internal experiences (i.e., "I could lose a limb"). Experiential avoidance (attempts to avoid painful internal experiences and subsequent avoidant actions) and cognitive fusion (perceiving thoughts as absolute truths) are thought to be key unhelpful processes in ACT (Hayes et al., 1999). For example, cognitive fusion may lead individuals to view beliefs about their diabetes care as absolute truths, which may subsequently impact on their behaviour. Experiential avoidance may manifest as poor diabetes self-management when individuals avoid negative inner experiences about their diabetes, even when doing so causes harm.

The aim of ACT is to enable individuals to cultivate an open, mindful, and accepting stance towards difficult internal experiences, and move towards engaging in value-based living. It achieves this through promoting psychological flexibility using a range of experiential methods, such as mindfulness exercises, exercises to connect with personal values, and thought defusion exercises (Hayes et al., 1999). The core components of psychological flexibility are illustrated in the "Hexaflex" model (Figure 1), which is made up of six interrelated processes: acceptance; cognitive defusion (i.e. the ability to separate ourselves from our thoughts and not get "fused" with them); contact with the present moment (i.e. being mindful); using the self as context; connecting to our values; and taking committed value-based action (Harris, 2009; Hayes et al., 1999).

Figure 1

ACT "Hexaflex"

CONTACT WITH THE
PRESENT MOMENT
Be Here Now

ACCEPTANCE
Open Up

VALUES
Know What Matters

PSYCHOLOGICAL
FLEXIBILITY
*Be present, open up,
and do what matters*

DEFUSION
Watch Your Thinking

COMMITTED
ACTION
Do What It Takes

SELF-AS-CONTEXT
Pure Awareness
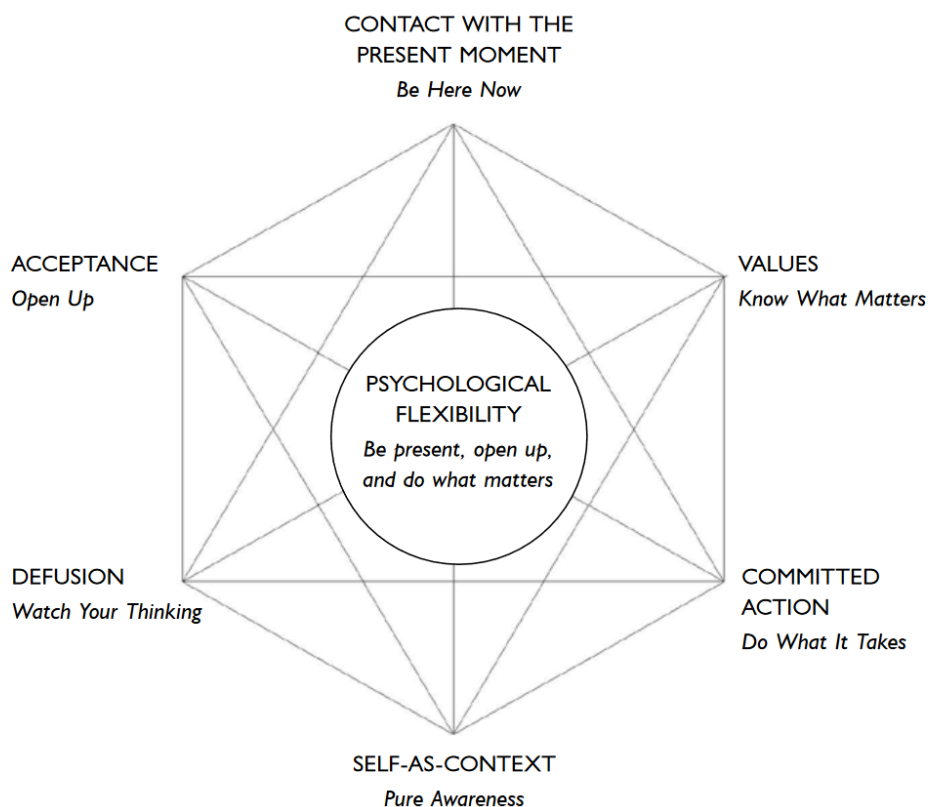
Note. Reprinted from "*ACT made simple: An easy-to-read primer on acceptance and commitment therapy*", by Harris, R., 2009, p. 10, Oakland, CA: New Harbinger Publications, Inc. Copyright 2009 by New Harbinger Publications, Inc.

Interest in ACT has risen over the years with an increasing number of randomised controlled trials and meta-analyses being conducted to establish its evidence base, given its popularity in clinical practice (Öst, 2014). For example, A-Tjak and colleagues (2015) conducted a meta-analysis of 39 studies, observing that ACT was more beneficial than treatment-as-usual and control interventions, and as favourable as established psychological interventions, such as CBT, for conditions such as depression, anxiety disorders and substance misuse. ACT's focus on acceptance and on living a meaningful life has particularly attracted attention in the

context of treating long-term conditions, with an emerging evidence base in chronic pain, tinnitus, cancer, epilepsy, cardiac disease, multiple sclerosis and diabetes (Graham et al., 2016; Hughes et al., 2017; Öst, 2014).

Current review

Due to the relative ease of applying ACT concepts to physical health conditions, ACT has been seen as a promising approach for improving the health outcomes for people with diabetes. It is increasingly being used in clinical practice following the publication of a randomised controlled trial (RCT) conducted by Gregg and colleagues (2007) which aimed to improve the diabetes self-management of adults with T2D and led to the publication of a diabetes-specific ACT treatment manual. This study generated interest into the use of ACT with the diabetes population internationally, with some of the emerging literature (six studies) captured by recently conducted systematic reviews into ACT for health conditions (Graham et al., 2016) and well-being interventions for individuals with diabetes (Massey et al., 2019).

However, a focussed systematic review of the evidence base of ACT in diabetes has not been conducted to date. Given the rapidly growing number of studies in this field, the review aimed to systematically describe the characteristics of ACT interventions for people with diabetes, and to examine whether ACT improves diabetes-related outcomes in both T1D and T2D, in order to increase current understanding of the evidence for the efficacy of ACT interventions and inform future research in this area. The research questions were:

1) What are the characteristics of ACT interventions for people with diabetes?

2) To what extent does ACT improve (i) psychological, (ii) behavioural and (iii) physical outcomes in people with T1D?

3) To what extent does ACT improve (i) psychological, (ii) behavioural and (iii) physical outcomes in people with T2D?

Method

Search strategy

A systematic review protocol and search strategy were developed, guided by Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA; Moher et al., 2009) and guidance for undertaking reviews in healthcare published by the Centre for Reviews and Dissemination (CRD; 2009). The PICOS tool (CRD, 2009) was used to develop research questions through identifying the specific components and concepts of interest. The review was registered on PROSPERO in advance (registration number: CRD42019150001).

Search terms were developed using Boolean operators to capture the concepts of diabetes and ACT in line with the research questions. As initial scoping searches indicated that there was a small number of studies for review, a decision was made to exclude more specific search terms related to outcomes to reduce the number of search restrictions. The search term "ACT" was excluded due to retrieving an excessive number of citations ($\approx$9400). The selected search terms were '(diabete* OR diabetic) AND ("acceptance and commitment therapy" OR "acceptance commitment therapy" OR "acceptance and commitment training")' based on search terms used by past relevant systematic reviews on diabetes and ACT, and verified by a librarian with

expertise in conducting systematic reviews at Royal Holloway, University of London (RHUL).

Inclusion and exclusion criteria

Studies were included in the review if they: (a) used a quantitative experimental or quasi-experimental research design; (b) recruited participants with T1D and/or T2D; (c) investigated any form of ACT-based intervention(s) (individual, group or online), which incorporated both components of acceptance and committed action to capture key processes within the model that increase psychological flexibility (Hayes et al., 1999); and (d) measured psychological, behavioural or physical diabetes-related outcome(s) using standardised tools (see Appendix A for full eligibility criteria).

Study selection

Three databases were searched on 15th September 2019 via the RHUL library: PubMed, Web of Science Core Collection (1970-present) and PsycINFO (interface: EBSCOhost Research Databases). The "Advanced Search" option was used in all searches with no restrictions on language and publication date. PubMed and Web of Science Core Collection were searched "in all fields", and PsycINFO was searched "in all text". All search results were exported to the reference management software, Zotero, and duplicates of studies were removed.

To minimise publication bias, hand-searches were conducted in the following locations to identify further eligible studies for the review: research registers such as ClinicalTrials.gov and World Health Organisation International Clinical Trials Registry Platform; databases of unpublished dissertations, theses and reports, such as

OpenGrey, ProQuest Dissertations & Thesis Global, Health Sciences Online Libraries, WHO Global Health Library, NICE Evidence, World Wide Science, PsycEXTRA, York Health Economics Consortium, Cochrane Library and Google Scholar; the publications list on the Association of Contextual Behavioural Science website (contextualScience.org); and Dr. Steven C. Hayes' (a leading researcher and developer of ACT) publications list (www.stevenchayes.com/literature/publications). Experts in the field, Dr. Steven C. Hayes and Dr. Jennifer A. Gregg (a researcher and developer of the ACT for diabetes self-management manual), were contacted via e-mail to establish whether they were aware of any further relevant studies; no additional studies were identified from their responses.

Two reviewers independently completed a title and abstract screen, which excluded any records that did not fulfil the inclusion criteria. Full-text papers of eligible studies were then screened independently by both reviewers against the inclusion and exclusion criteria. Any disagreements over eligibility were resolved through discussion. A reference list search of all eligible articles was completed to identify any final eligible studies to include in the review.

Assessment of risk of bias

The Effective Public Health Practice Project (EPHPP; 1998) Quality Assessment Tool for Quantitative Studies was used to assess the quality of the eligible studies. The EPHPP was chosen because it was specifically developed to evaluate public health interventions and has demonstrated good validity and reliability properties (Thomas et al., 2004). The following study components were rated using a three-point scale ("weak", "moderate" and "strong"): selection bias; study design; confounders; blinding; data collection methods; withdrawals or drop-outs;

intervention integrity; and analysis. A global quality rating was calculated based on the overall number of study components that were assessed as "weak". A quality assessment of each eligible study was independently carried out by the primary reviewer and 20% of the studies were assessed by a second reviewer to check for consistency (percentage agreement = 87.5%, κ = .80). Disagreements over quality ratings were resolved through discussion. The quality appraisal was not used to exclude any studies, but to inform the narrative synthesis in line with standard practice (CRD, 2009).

Data extraction

Data from each study was independently extracted by the primary researcher and 10% of the data extraction was checked by a second reviewer for consistency. Where data were missing or unclear, authors were contacted via e-mail for further information, after which any remaining missing or unclear data was marked as such.

The extracted information included: (a) publication details, including first author, year of publication, journal or source, publication status, country of study; (b) study characteristics, including study design, study methodology, study setting, aims and/or research questions, inclusion and exclusion criteria, number of trial arms, type of comparator(s), study duration, recruitment details, total number of participants randomised, number allocated to each trial arm, number in each trial arm at follow-up, and study completion rates; (c) participant characteristics, including sample size, age (mean and range), gender (% female), study population and clinical diagnosis; (d) intervention and comparator and/or control characteristics, including descriptions of intervention, format, duration and intensity of delivery, delivery provider (e.g. detail of individual, discipline, level of training in delivering ACT), total intervention

duration, control condition, and details of ACT processes and techniques; (e)

effectiveness of intervention, including details of primary outcome measure and

secondary outcome measures, measurement method, time points for data collection,

effect sizes at post-intervention and follow-up and author's conclusions; and (f) risk

of bias, indicated by the quality assessment outcome.

Data synthesis

A narrative synthesis of quantitative study findings was completed based on

guidance from the CRD (2009) and reported in accordance with the PRISMA

checklist. Differences in mean values, intervention effect sizes and statistical

significance for all psychological, behavioural and physical diabetes-related outcomes

were examined, where reported. To facilitate comparison between studies, effect sizes

were computed based on available information. For studies using a single-group

design, effect sizes were calculated by dividing the difference between pre- and post-

test means by the pre-test standard deviation (Hojat & Xu, 2004). For studies using

experimental and control groups, effect sizes were calculated by dividing the

difference between pre- and post-test mean changes of both groups by the pooled pre-

test standard deviation (Morris, 2008). All effect sizes were adjusted using a small

sample size bias correction to obtain g (Hedges, 1981).

Figure 2

PRISMA Flowchart of the Systematic Review

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┌─────────────────────────────┐   ┌─────────────────────────────┐
│ Records identified through  │   │ Additional records identified│
│ database searching          │   │ through other sources        │
│ (n = 117)                   │   │ (n = 7)                      │
└─────────────────────────────┘   └─────────────────────────────┘
                                              ┌─────────────────────────┐
                                              │ Duplicates removed        │
                                              │ (n = 37)                  │
                                              └─────────────────────────┘
┌─────────────────────────────┐
│ Titles and abstracts screened│
│ (n = 87)                     │
└─────────────────────────────┘
                                              ┌─────────────────────────┐
                                              │ Records excluded          │
                                              │ (n = 65)                  │
                                              └─────────────────────────┘
┌─────────────────────────────┐
│ Full-text articles assessed  │
│ for eligibility              │
│ (n = 22)                     │
└─────────────────────────────┘
                        ┌─────────────────────────────────────┐
                        │ Full-text articles excluded:          │
                        │ - Qualitative design (n = 1)          │
                        │ - Non-ACT-based                       │
                        │   intervention (n = 2)                │
                        │ - Duplication of same                 │
                        │   material in different               │
                        │   publications (n = 2)                │
                        │ - No access to results (n = 1)        │
                        └─────────────────────────────────────┘
┌─────────────────────────────┐
│ Studies assessed as eligible │
│ for narrative synthesis      │
│ (n = 16)                     │
└─────────────────────────────┘
                                              ┌─────────────────────────┐
                                              │ Additional articles       │
                                              │ identified through        │
                                              │ reference lists           │
                                              │ (n = 1)                   │
                                              └─────────────────────────┘
┌─────────────────────────────┐
│ Studies included in narrative│
│ synthesis                    │
│ (n = 17)                     │
└─────────────────────────────┘
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Results

Description of studies

The study selection process is depicted in Figure 2. Overall, 117 citations were retrieved from PubMed ($n = 48$), PsycINFO ($n = 38$) and Web of Science ($n = 31$). The grey literature search identified seven additional records. Following the removal of 37 duplicates of studies, a title and abstract screen of 87 records was completed, out of which 65 records were excluded from the review (percentage agreement = 100%; $\kappa = 1$) due to either not fulfilling criteria related to research design ($n = 37$), participant characteristics ($n = 36$) and/or intervention type ($n = 28$). Twenty-two full-text papers of eligible studies were screened (percentage agreement = 89.5%; $\kappa = 1$). Reasons for excluding studies included: incorrect research design ($n = 1$); incorrect intervention type ($n = 2$); and no access to results ($n = 1$). Two articles were also excluded as they were duplicates of the same studies in different publications. Two disagreements over eligibility were resolved through discussion. Sixteen articles were assessed as eligible for the review, and one additional article was found following reference list searches of all eligible articles, resulting in a total of 17 studies included for narrative synthesis. Table 1 summarises the characteristics of the studies, categorised by clinical diagnosis (T1D, T2D, and combined diabetes types).

Table 1

Study Characteristics

First author, year Country	Sample characteristics	Study design	Intervention details	Study completion rate
Type 1 diabetes				
Lehikoinen, 2018 Finland	N = 32 [a] 68.8% Female Age: M = 13.7, SD = 1.38, range = 12-16 Adolescents with T1D whose HbA_{1c} > 7.5%, recruited from paediatric outpatient clinic with parents	Pre-test, post-test experimental design Experimental group: ACT and treatment-as-usual (n = 16) Control group: Treatment-as-usual (n = 16)	Format: ACT-based group programme including discussion, exercises and voluntary homework between sessions. Components: behavioural analysis; values clarification; value-based actions; setting realistic goals; mindfulness; cognitive defusion; acceptance; using self-as-context Duration: five sessions lasting 1.5 hours each, held fortnightly (10 weeks in total) Delivery provider: a psychologist and psychology students	25/32; [a] 78.1%
Type 2 diabetes				
Ahmadsaraei, 2017 Iran	N = 40 [a] 67.5% Female Age (experimental group): M = 44.1, SD = 6.77, range = NR Age (control group): M = 43.0, SD = 4.05, range = NR	Pre-test, post-test, follow-up quasi-experimental design Experimental group: ACT (n = 20) Control group: Pre-test-post-test only (n = 20)	Format: ACT-based group programme Components: creative hopelessness; values clarification and connection; cognitive defusion; mindfulness; committed action; review Duration: eight sessions lasting 1.5 hours (length NR; 3-month follow-up) Delivery provider: NR	NR

36

First author, year Country	Sample characteristics	Study design	Intervention details	Study completion rate
	Adults diagnosed with T2D for ≥5 years with a BDI score of 29-63, referred by a local diabetes association			
Amirfakhraei, 2016 Iran	$N = 80$ 50% Female Age: M = NR, SD = NR, range = 29-52 Married adults with T2D, recruited from counselling centres and other related institutes in Bandar Abbas	Solomon four-group quasi-experimental design Experimental group: Pre-test-post-test ACT ($n = 20$) Post-test only ACT ($n = 20$) Control group: Pre-test-post-test only ($n = 20$) Post-test only ($n = 20$)	Format: ACT-based group couples therapy workshop Components: creative hopelessness; acceptance; contact with present moment; cognitive defusion; values clarification; setting goals Duration: eight sessions lasting 1.5 hours each, held weekly (eight weeks in total) Delivery provider: NR	NR
Fayazbakhsh, 2019 Iran	$N = 24$ [a] 20.8% Female Age (experimental group): M = 50.4, SD = 10.3, range = NR Age (control group): M = 42.4, SD = 10.0, range = NR	Pre-test, post-test quasi-experimental design Experimental group: ACT ($n = 12$) Control group: Pre-test-post-test only ($n = 12$)	Format: NR Components: NR Duration: eight sessions lasting 1.5 hours each (length NR) Delivery provider: NR	NR

First author, year Country	Sample characteristics	Study design	Intervention details	Study completion rate
	Patients with T2D, recruited through convenience sampling from the Iranian Diabetes Society			
Ghasemlou, 2018 Iran	$N = 30$ 100% Female Age: M = NR, SD = NR, range = 35-45 Women aged 20-45 with T2D, recruited through convenience sampling from a specialist medical diagnostic laboratory	Pre-test, post-test quasi-experimental design Experimental group: ACT ($n = 12$) Control group: Pre-test-post-test only ($n = 13$)	Format: ACT-based group counselling using group exercises based on protocol by Eifert & Forsyth (2005) Components: identifying experiential avoidance; creative hopelessness; cognitive defusion; using self-as-context; mindfulness; contact with the present moment; values clarification; valued action; distinguishing values from goals; addressing barriers; feedback Duration: 15 sessions lasting 1.5 hours each (length NR) Delivery provider: NR	NR; [a] 83.3%
Gregg, 2007 USA	$N = 81$ 46.9% Female Age (experimental group): M = 51.9, SD = NR, range = NR Age (control group): M = 49.8, SD = NR, range = NR Adults with T2D, receiving medical care at a low-income primary healthcare clinic and referred by their primary care provider	RCT with pre-test and follow-up Experimental group: ACT and education ($n = 43$) Control group: Education only ($n = 38$)	Format: Education and ACT-based group workshop including mindfulness and acceptance training [b] Components: psychoeducation; behavioural analysis; mindfulness; acceptance; values exploration and clarification; value-based action; setting goals; addressing barriers; cognitive defusion; acceptance Duration: One session lasting seven hours (one day in total with 3-month follow-up) Delivery provider: First author, [b] a clinical psychology doctoral student trained and experienced in delivering ACT	73/81; [a] 90.1%

First author, year Country	Sample characteristics	Study design	Intervention details	Study completion rate
Hor, 2014 Iran	*N* = 30 % Female NR Age (experimental group): *M* = 49, *SD* = NR, range = NR Age (control group): *M* = 47.5, *SD* = NR, *range* = NR Adults diagnosed with T2D by an "internist" and depression by the researcher using DSM-IV-TR and a BDI score cut-off of >16, recruited from a diabetes charity institution	Pre-test, post-test, follow-up quasi-experimental design Experimental group: ACT (*n* = 15) Control group: Waitlist control (*n* = 15)	Format: ACT-based group therapy using exercises and metaphors Components: creative hopelessness; cognitive defusion; using self-as-context; observer self; mindfulness; values exploration and valued actions Duration: eight sessions lasting two hours each (length NR; follow-up length NR) Delivery provider: NR	100%
Kaboudi, 2017 Iran	*N* = 26 100% Female Age: *M* = NR, *SD* = NR, range = 25-65 Women with T2D, referred to a specialist clinic and recruited through convenience sampling	Pre-test, post-test quasi-experimental design Experimental group: ACT (*n* = 13) Control group: Pre-test-post-test only (*n* = 13)	Format: ACT-based training sessions Components: creative hopelessness; values clarification; cognitive defusion; mindfulness; committed valued action; using self-as-context; review; plan forward Duration: eight sessions lasting 1.5 hours each (length NR) Delivery provider: NR	NR
Khashouei, 2016 Iran	*N* = 32 100% Female	Pre-test, post-test, follow-up quasi-experimental design	Format: NR Components: NR	NR

First author, year Country	Sample characteristics	Study design	Intervention details	Study completion rate
	Age (experimental group): $M =$ 47.2, $SD = 8.84$, range = NR Age (experimental group): $M =$ 49.6, $SD = 9.02$, range = NR Women aged 30-50 with T2D, recruited through convenience sampling of those referred to an endocrine and metabolism research centre	Experimental group: ACT ($n = 16$) Control group: Pre-test-post-test only ($n = 16$); Four ACT sessions offered after study completion - not analysed	Duration: eight sessions lasting 1.5 hours each, held weekly (eight weeks; three-month follow-up) Delivery provider: NR	
Nes, 2012 Norway	$N = 15$ [a] 33.3% Female Age: $M = 59.6$, $SD = $ NR, range = 46-71 Adults with T2D, recruited through two general practices and the social networks of researchers	Pre-test, post-test single-group design Experimental group: ACT ($n = 11$)	Format: Online via smartphone with feedback, stimulation of reflections Components: values clarification and connection; encouraging value-based behaviour; differences between values and goals; setting goals; addressing barriers; psychoeducation; awareness; acceptance and willingness Duration: three daily online diary entries (three months in total) Delivery provider: A nurse trained in ACT	11/15; [a] 73%
NHS Grampian, 2015 Scotland	$N = 35$ [a] 43% Female Age: $M = 63.7$, $SD = 9.8$, range = NR	Pre-test, post-test, follow-up single-group design Experimental group: ACT ($n = 27$)	Format: ACT-based, guided self-help programme with individual face-to-face appointments and web-based modules Components: psychoeducation; behavioural analysis; values clarification; value-based actions; addressing barriers; relapse management; plan forward	77.1%

First author, year Country	Sample characteristics	Study design	Intervention details	Study completion rate
	Adults with T2D, whose glycaemic control was among the poorest 40% in Grampian area (≥ 61 mmol/mol), recruited through self-referral from five general practices and a secondary care diabetes clinic		Duration: five to eight sessions (length NR; 3-month follow-up) Delivery provider: a trainee health psychologist and a psychological well-being practitioner	
Shayeghian, 2016 Iran	N = 106 60% Female Age: M = 55.4, SD = 8.44, range = NR Adults aged between 40-60 with T2D diagnosed within last 1±10 years, recruited through convenience sampling using referrals from an endocrinologist	RCT with follow-up Experimental group: ACT and education (n = 53) Control group: One-day education workshop (n = 53)	Format: Education and group-based ACT workshop with exposure-based and experiential exercises and mindfulness training Components: NR; based on Gregg's (2004) ACT protocol Duration: 10 weekly sessions (10 weeks in total; 3-month follow-up) Delivery provider: NR	100/106; [a] 94.4%
Welch, 2014 USA	N = 31 70% Female Age: M = 43.0, SD = 9.09, range = 32-53 Adults with T2D diagnosed for ≤2 years, displaying distress identified by a score of >3 in regimen distress and/or emotional	Pre-test, post-test single-group design Experimental group: ACT (n = 20)	Format: ACT-based group workshop split into four modules, with published ACT and mindfulness exercises followed by discussion points Components: contact with present moment; mindfulness; values clarification and connection; behaviour analysis; identifying barriers; cognitive defusion; commitment to action; creative hopelessness; acceptance; review and relapse management	20/31; [a] 64.5%

First author, year Country	Sample characteristics	Study design	Intervention details	Study completion rate
	burden subscales of DDS17, recruited from online diabetes associations and online public domains through convenience sampling		Duration: eight hours (one day in total; post-test measures obtained two weeks after workshop completion) Delivery provider: First author	
Whitehead, 2017 New Zealand	N = 157 [a] 46.6% Female Age (ACT and education group): M = 56.1, SD = 6.91, range = NR Age (Education group): M = 53.8, SD = 8.68, range = NR Age (Control group): M = 56.4, SD = 6.97, range = NR Adults with T2D with suboptimal glycaemic control (HbA$_{1c}$>7% or >53mmol/mol) for ≥1 year, recruited using adverts on radio, community newsletters and newspapers as well as letters sent to eligible patients by medical centres in one city	RCT with follow-up Experimental groups: ACT and education (n = 39) Education (n = 26) Control group: Routine care (n = 41)	Format: Group workshop incorporating ACT and psychoeducation, supplemented with workbook and slide presentation Components: mindfulness; acceptance; values clarification; value-based actions (material drawn from Gregg et al., 2007) Duration: 6.5 hours (one day in total; six-month follow-up) Delivery provider: Mental health nurse with expertise in ACT and supervised by a clinical psychologist	106/157; [a] 75.1%

Type 1 and 2 diabetes

Moazzezi, 2015 Iran	N = 40 [a] 30.6% Female	Pre-test, post-test controlled clinical trial	Format: ACT-based group therapy including exercises Components: functional analysis; creative hopelessness; values clarification; building commitment; acceptance;	36/40; [a] 90%

First author, year Country	Sample characteristics	Study design	Intervention details	Study completion rate
	Age (Experimental group): $M =$ 11.4, $SD = 2.59$, range = NR Age (Control group): $M = 9.72$, $SD = 2.37$, range = NR Children aged 7-15 with T1D or T2D for ≤1 year, recruited through convenience sampling of people referred to a local diabetes association	Experimental group: ACT ($n = 18$) Control group: Pre-test-post-test only ($n = 18$)	cognitive defusion; using self-as-context; addressing barriers; relapse prevention Duration: 10 sessions lasting 1.5 hours, held weekly (10 weeks in total) Delivery provider: NR	
Moghanloo, 2015 Iran	$N = 40$ [a] 50% Female Age (Experimental group): $M =$ 10.4, $SD = 2.91$, range = NR Age (Control group): $M = 10.6$, $SD = 3.16$, range = NR Children aged 7-15 with T1D ($n =$ 19) or T2D ($n = 15$) for ≤1 year, recruited through convenience sampling of people referred to a local diabetes association	Pre-test, post-test controlled clinical trial Experimental group: ACT ($n = 17$) Control group: Pre-test-post-test only ($n = 17$)	Format: ACT-based group therapy including exercises Components: functional analysis; creative hopelessness; values clarification; building commitment; acceptance; cognitive defusion; using self-as-context; addressing barriers; relapse prevention Duration: 10 sessions lasting 1.5 hours, held weekly (10 weeks in total) Delivery provider: A psychologist (different psychologist obtained outcome measures)	34/40; [a] 85%
Ryan, 2019 Australia	$N = 28$ 70% Female Age: $M = 54.0$, $SD = 12.8$, range = 24-74	Pre-test, post-test single-group design Experimental group: ACT ($n = 20$)	Format: "READY" an ACT-based group programme with 10 modules, including a workbook, exercises, reflections, review of key learning points and between-session personalised tasks	[a] 71.4%

First author, year Country	Sample characteristics	Study design	Intervention details	Study completion rate
	Adults with self-reported T1D (30%) or T2D (70%), recruited via Diabetes Australia and university staff e-newsletters, a radio interview, and flyers distributed through General Practitioners, pharmacies and a diabetes clinic		Components: psychoeducation; focus on resilience; mindfulness; experiential avoidance; acceptance; cognitive defusion; addressing barriers / troubleshooting; self-as-context; physical activity planning; values clarification and connection; setting realistic goals; relaxation; social connectedness; review and future planning Duration: 10 sessions (eight 2-hour sessions and two 1-hour sessions) (10 weeks in total) Delivery provider: a postgraduate clinical psychology student with formal ACT training, supervised fortnightly	

Note. [a] Calculated based on information in full-text paper; [b] Information supplemented using Gregg's (2004) dissertation

Key. ACT = Acceptance and Commitment Therapy; BDI = Beck Depression Inventory; DDS17 = Diabetes Distress Scale; DSM-IV-TR = Diagnostic and Statistical Manual of Mental Disorders – 4th Edition – Text Revision; HbA$_{1c}$ = glycated haemoglobin; NR = not reported; RCT = randomised controlled trial; T1D = type 1 diabetes; T2D = type 2 diabetes.

Study characteristics

The year of publication of the studies ranged between 2007 and 2019. In total, 14 peer-reviewed journal articles, two unpublished theses and one report were included in the review. The studies were based in a variety of countries including Iran (10 studies), USA (two studies), Finland (one study), Norway (one study), Scotland (one study), Australia (one study) and New Zealand (one study). The employed study designs included: RCTs (three studies); pre-test-post-test experimental design (three studies); Solomon four-group quasi-experimental design (one study); pre-test-post-test quasi-experimental design (six studies); and pre-test-post-test single group design (four studies). All studies included pre- and post-intervention outcome measures, and six studies included follow-up measurements, which were either three months (four studies), six months (one study) or not reported (one study). Four studies used an intervention condition only. A control/comparison condition was used in 13 studies, of which eight studies used a pre-test-post-test measurements only control condition, two studies used routine care or treatment-as-usual, one study used a waitlist control condition, and two studies used an active control condition based on education. The study completion rate was not reported by five studies. Of the 12 studies that reported figures, the completion rate ranged from 64.5% to 100%, with a mean rate of 81.8%.

The studies investigated a range of psychological, behavioural and physical health outcomes. Six studies measured physical outcomes such as glycated haemoglobin (HbA_{1c}), fasting blood glucose and cholesterol levels using blood tests. Six studies examined behavioural outcomes, which included diabetes self-management and level of physical activity. These were primarily measured using self-report questionnaires with the exception of outcomes such as weekly step count, which were measured using smart devices. All studies examined at least one psychological outcome and at least 20 different psychological outcomes were measured across all studies using self-report questionnaires. General

45

psychological outcomes included depression, anxiety, stress, quality of life, coping, self-efficacy, resilience, psychological well-being, guilt, marital satisfaction and positive emotions. Diabetes-specific psychological outcomes included diabetes-related distress, understanding of diabetes and diabetes self-management, and diabetes-related quality of life. A variety of ACT process outcomes were also measured by seven studies using self-report questionnaires, such as diabetes acceptance, psychological flexibility, experiential and emotional avoidance, frequency of automatic negative thoughts, negative thought suppression, mindfulness and valued living.

Participant characteristics

The total number of participants from all included studies was 827, with sample sizes ranging between 15 and 157. Fourteen studies investigated adult populations with ages ranging between 18 and 65, and three studies investigated paediatric populations with ages ranging between seven and 15. One study did not report participants' gender; across the remaining 16 studies, 59.8% cases were female, with two studies investigating women only. A range of ethnicities was captured by the studies, although at least half of the cases were likely Iranian. Thirteen studies solely recruited adults diagnosed with T2D and one study solely recruited people with T1D. Three studies focused on people with either diagnosis, from which one study did not report the diagnosis ratio and two studies reported that 70% and 44.1% of the participants had T2D. The criteria for meeting the diagnosis of diabetes was not reported in 13 studies, other than the participants were recruited from specialist diabetes clinics and organisations. Diagnosis of diabetes was determined by self-report in one study and confirmed by a physician or via clinical examination in three studies. Only six studies reported on mean duration of diabetes and three studies reported mean HbA_{1c} values, precluding the calculation of mean values for these factors.

With regards to sampling method, 12 studies used convenience sampling relying on self-referrals from participants, two studies selected participants based on their HbA_{1c} cut-off criteria ($>7.5\%$ and ≥ 61mmol/mol), two studies selected participants based on their Beck Depression Inventory score cut-off criteria (>16 in one study, and between 29 and 63 in the other) and one study recruited participants based on referrals from their care provider. In terms of recruitment criteria, three studies specifically targeted people with poor glycaemic control, two studies targeted people experiencing depression, one study targeted people displaying distress, one study specifically selected married people and one study selected people from a low-income primary healthcare clinic.

Characteristics of ACT interventions

All interventions were ACT-based as their primary theoretical framework. The studies had a variety of aims such as: to develop a feasible ACT-based intervention for the target diabetes population, to investigate the effectiveness of ACT in improving outcome(s) of interest, and/or to examine the role of potential moderators and mediators.

Of the 17 interventions examined, 13 interventions were described as group programmes or workshops, one study used an online programme, one study combined individual face-to-face work with an online module, and two studies did not report on intervention format. The number of sessions varied from one to 15 sessions, with the majority of the interventions lasting between eight and 10 sessions (10 studies). Three studies included a one-off day-long intervention. Sessions ran weekly in six studies and fortnightly in one study. One study required participants to take part in an online intervention three times daily, and five studies did not report the frequency of sessions. The length of the sessions varied between 1.5 hours (most common) and eight hours (in the case of one-off workshops). The

total intervention length varied from one day to three months, with six studies not reporting this figure.

Commonly reported components were the use of behavioural or functional analysis, ACT-specific psychoeducation (e.g. on creative hopelessness and experiential avoidance), mindfulness, contact with the present moment, cognitive defusion, acceptance, self-as-context, values clarification and connection, setting and making a commitment to work towards value-based goals, addressing barriers, review and future planning, in line with the core components of psychological flexibility. Some interventions also had additional components such as promoting diabetes education, resilience, relaxation, and social connectedness.

Only eight out of 17 studies reported information on the intervention delivery providers. Delivery providers included a psychologist (one study), a psychologist and their students (one study), a postgraduate/doctoral student with ACT training (two studies), a nurse trained in ACT (one study), a trainee health psychologist and psychological well-being practitioner (one study) and a doctoral student (one study). Only two studies provided information on assessing treatment fidelity, which included reviewing treatment adherence against the protocol, manual and/or study-specific coding system.

Risk of bias within studies

Quality ratings of each study are summarised in Table 2. The overall quality of the studies was poor, with 13 studies obtaining a "weak" quality rating, three studies obtaining a "moderate" quality rating and one study obtaining a "strong" rating. Areas of strength were identified in study designs (13 studies), control of confounders (13 studies) and data collection methods (17 studies). Common weaknesses were: not providing information on blinding procedures (14 studies); using convenience sampling and not providing information

on percentage of participants agreeing to participate, increasing the likelihood of selection

bias (13 studies); and not reporting withdrawals and dropouts (six studies).

Table 2

Quality Ratings of Included Studies

First Author, Year	Selection bias	Study design	Confounders	Blinding	Data collection method	Withdrawals and dropouts	Overall quality rating
Type 1 diabetes							
Lehikoinen, 2018	Moderate	Strong	Weak	Weak	Strong	Moderate	Weak
Type 2 diabetes							
Ahmadsaraei, 2017	Moderate	Strong	Strong	Weak	Strong	Weak	Weak
Amirfakhraei, 2016	Weak	Strong	Strong	Weak	Strong	Weak	Weak
Fayazbakhsh, 2019	Weak	Strong	Strong	Weak	Strong	Weak	Weak
Ghasemlou, 2018	Weak	Strong	Strong	Weak	Strong	Weak	Weak
Gregg, 2007	Moderate	Strong	Strong	Moderate	Strong	Strong	Strong
Hor, 2014	Weak	Strong	Weak	Weak	Strong	Strong	Weak
Kaboudi, 2017	Weak	Strong	Weak	Weak	Strong	Weak	Weak
Khashouei, 2016	Weak	Strong	Strong	Weak	Strong	Weak	Weak
Nes, 2012	Weak	Moderate	Strong	Weak	Strong	Moderate	Weak
NHS Grampian, 2015	Moderate	Moderate	Strong	Weak	Strong	Moderate	Moderate
Shayeghian, 2016	Weak	Strong	Strong	Weak	Strong	Strong	Weak
Welch, 2014	Weak	Moderate	Strong	Weak	Strong	Strong	Weak
Whitehead, 2017	Weak	Strong	Strong	Moderate	Strong	Moderate	Moderate
Type 1 and 2 diabetes							
Moazzezi, 2015	Weak	Strong	Weak	Weak	Strong	Strong	Weak
Moghanloo, 2015	Weak	Strong	Strong	Moderate	Strong	Strong	Moderate
Ryan, 2019	Weak	Moderate	Strong	Weak	Strong	Moderate	Weak

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

Table 3

Main Results of Included Studies: The Impact of ACT on Psychological, Behavioural, Physical and Process Outcome Measures

First Author, Year	Outcomes (Measures)	Main intervention findings (reported p and ES, and calculated g)
Type 1 diabetes		
Lehikoinen, 2018	Psychological: ▪ Depressive and anxiety symptoms (RBDI) Physical: ▪ Glycaemic control (HbA$_{1c}$) Process: ▪ General level of psychological flexibility and mindfulness (CAMM) ▪ Diabetes-specific psychological flexibility and ability to manage diabetes (DAAS)	Significant treatment effect compared to control for DAAS between pre- and post-treatment ($p < .05$; $r = .54$; [b] $g = .41$) No significant treatment effect ($p > .05$) relative to controls for anxiety ($r = .23$; [b] $g = .36$), depression ($r = .24$; [b] $g = .21$), CAMM ($r = .08$; [b] $g = .10$) and HbA$_{1c}$ ($r = .38$; [b] $g = .79$) between pre- and post-treatment
Type 2 diabetes		
Ahmadsaraei, 2017	Psychological: ▪ Depression (BDI)	Significant treatment effect over time relative to controls for depression ($p < .001$, $d = .22$) with a significant difference found between pre- and post-treatment ($p < .001$; [b] $g = 1.04$) and no significant differences between post-treatment and follow-up ($p = .51$)
Amirfakhraei, 2016	Psychological: ▪ Marital satisfaction and dysfunctional communicative attitude (RBQ)	Overall significant treatment effect found relative to controls for marital satisfaction and dysfunctional communicative attitude ($p < .01$, $\eta^2 = .502$) with significant treatment effects identified in those who completed pre-tests ($p < .01$, ES = .90; [b] $g = 7.14$) as well as those who did not ($p < .01$, ES = .96)

First Author, Year	Outcomes (Measures)	Main intervention findings (reported p and ES, and calculated g)
Fayazbakhsh, 2019	Psychological: ▪ Symptoms of Generalised Anxiety Disorder (GAD-7) ▪ Worry (PSWQ) ▪ Intolerance of uncertainty (IUS) Process: ▪ Experiential avoidance (AAQ-II)	Significant treatment effects found relative to controls for symptoms of GAD ($p < .001$, $\eta^2 = .73$; [b] $g = 1.16$), worry ($p < .001$, $\eta^2 = .67$; [b] $g = 1.36$), intolerance of uncertainty ($p < .001$, $\eta^2 = .60$; [b] $g = 1.52$) and experiential avoidance ($p < .001$, $\eta^2 = .69$; [b] $g = 1.06$) between pre- and post-treatment
Ghasemlou, 2018	Psychological: ▪ Anxiety symptoms (DASS) ▪ Quality of life (SF-36)	Significant treatment effects relative to controls with improvements observed in between pre- and post-test anxiety symptoms ($p < .05$, $\eta^2 = .17$; [b] $g = .79$) and quality of life ($p < .05$, $\eta^2 = .51$; [b] $g = .83$)
Gregg, 2007	Psychological: ▪ Understanding of diabetes (subscale of DCP) ▪ [a] Coping – emotional expression and processing (EACS) ▪ [a] Mental health-related quality of life (SF-36) Behavioural: ▪ Self-management (questionnaire devised for study) Physical: ▪ Glycaemic control (HbA$_{1c}$ and number of people with diabetic control) Process: ▪ Acceptance of diabetes-related thoughts and feelings (AADQ) ▪ [a] Frequency of automatic negative thoughts about self (ATQ) ▪ [a] Negative thought suppression (WBSI) ▪ [a] Emotional avoidance (AAQ)	Significant treatment effect compared to controls at follow-up for diabetes-specific acceptance ($p < .05$, $\eta_p^2 = .12$), self-management ($p < .05$, $\eta_p^2 = .07$; [b] $g = .59$; [a] when pre-test scores are controlled) and diabetic control status ($p < .01$, $\eta_p^2 = .08$; [a] $p < .05$) No significant pre-post differences found in understanding of diabetes at follow-up ($p = .16$, $\eta_p^2 = .03$; [a] $p = .252$) Non-significant positive trend found for HbA$_{1c}$ compared to controls at follow-up ($p = .081$, $\eta_p^2 = .04$; [b] $g = .66$) [a] No significant differences in thought suppression, emotional avoidance, coping, frequency and believability of automatic negative thoughts compared to controls at follow-up ($p > .05$)

First Author, Year	Outcomes (Measures)	Main intervention findings (reported p and ES, and calculated g)
Hor, 2014	Psychological: ▪ Depression (BDI-II)	Significant improvements compared to controls were found between pre-test and post-test depression scores ($p <.001$, ES = .432; [b] $g = 1.25$) and between pre-test and follow-up depression scores ($p <.001$, ES = .677; [b] $g = 1.57$)
Kaboudi, 2017	Psychological: ▪ Mental health (GHQ-28)	Significant treatment effect relative to controls for mental health at post-test ($p = .001$, $\eta^2 = .91$; [b] $g = 3.26$)
Khashouei, 2016	Psychological: ▪ Self-efficacy (SES) ▪ Perceived stress (PSS) ▪ Resiliency (CDRS)	Significant treatment effects ($p < .05$) observed relative to controls for self-efficacy at post-test ($\eta^2 = .43$; [b] $g = .76$) and at a 3-month follow-up ($\eta^2 = .14$; [b] $g = .13$), and for perceived stress at post-test ($\eta^2 = .17$; [b] $g = 1.37$) and at follow-up ($\eta^2 = .23$; [b] $g = 2.81$). No significant difference in resilience relative to controls at post-test ($p > .05$), but significant improvement observed at follow-up ($p < .05$; $\eta^2 = .39$; [b] $g = 1.95$)
Nes, 2012	Psychological: ▪ Diabetes-related quality of life (ADDQoL-19) ▪ Diabetes-related distress (PAID) Physical: ▪ HbA_{1c} ▪ Fasting blood glucose ▪ HDL cholesterol, LDL cholesterol and triglycerides	Positive lifestyle changes reported by participants with a positive trend in HbA_{1c} indicated by descriptive statistics (mean decrease by 0.49%), suggesting pre-post improvement in glycaemic control Remaining data available but not analysed by authors as it was a feasibility study with a small sample size ($n = 11$)
NHS Grampian, 2015	Psychological: ▪ Depression and anxiety (HADS) ▪ Diabetes-related distress (PAID) Behavioural: ▪ Fitbit weekly step count ▪ Physical activity (Scot-PASQ)	Significant pre-post improvements were found in steps walked ($p < .001$; $d = .45$), physical activity ($p = .003$; $d = .64$) anxiety level ($p = .004$; $d = .53$), depression level ($p = .003$; $d = .53$) and diabetes-related distress ($p < .001$; $d = .56$) A non-significant positive trend was observed in pre-post HbA_{1c} ($p = .055$, $d = .24$)

First Author, Year	Outcomes (Measures)	Main intervention findings (reported p and ES, and calculated g)
	Physical: ▪ Diabetes control (HbA$_{1c}$)	
Shayeghian, 2016	Psychological: ▪ Coping style strategies (Brief COPE) Behavioural: ▪ Diabetes self-management (SDSCA) Physical: ▪ Glycaemic haemoglobin (HbA$_{1c}$) Process: ▪ Acceptance of diabetes-related thoughts and feelings (AADQ)	Significant pre-post treatment effects relative to controls found for HbA$_{1c}$ ($p < .001$; $\eta_p^2 = .25$; [b] $g = .26$), self-care activities ($p < .001$; $\eta_p^2 = .22$; [b] $g = .33$) and acceptance ($p < .001$; $\eta_p^2 = .44$; [b] $g = .59$), which were maintained at follow-up Significant moderation effect of coping style found for self-care activities ($p < .01$; $\eta_p^2 = .07$), but non-significant for acceptance ($p = .06$; $\eta_p^2 = .05$) and HbA$_{1c}$ ($p < .58$; $\eta_p^2 = .01$)
Welch, 2014	Psychological: ▪ Diabetes-related distress (DDS) ▪ Depression, anxiety and stress (DASS) Behavioural: ▪ Diabetes self-care activities (SDSCA) Process: ▪ Thought Suppression (WBSI) ▪ Acceptance of diabetes-related thoughts and feelings (AADQ)	Significant pre-post improvement of self-care was found in areas of exercise ($p < .01$; [b] $g = 1.48$) and foot care ($p < .01$; [b] $g = .58$); no significant treatment effect found in general diet ($p = .09$), specific diet ($p = .06$), blood glucose testing ($p = .38$) and smoking status ($p = .11$) Levels of acceptance and thought suppression significantly increased post-treatment ($p < .05$; [b] $g = 1.69$) Significant pre-post improvement in total diabetes-related distress ($p < .001$; [b] $g = 1.36$), emotional burden ($p < .001$; [b] $g = 1.78$), regimen-related distress ($p < .001$; [b] $g = 1.69$), interpersonal distress ($p < .001$; [b] $g = .83$), depression ($p < .001$; [b] $g = .53$) and stress ($p < .001$; [b] $g = .64$) No significant treatment effect on physician-related distress ($p = .04$) and anxiety ($p = .06$)

First Author, Year	Outcomes (Measures)	Main intervention findings (reported p and ES, and calculated g)
Whitehead, 2017	Psychological: • Anxiety and depression (HADS) • Understanding of diabetes management (subscale of DCP) Behavioural: • Diabetes self-care activities (SDSCA) Physical: • Glycaemic control (HbA$_{1c}$) Process: • Acceptance of diabetes-related thoughts and feelings (AADQ)	Compared to TAU, no treatment effect was found for HbA$_{1c}$ at six months ($p = .08$) whereas the education only group significantly improved HbA$_{1c}$ ($p = .01$) No significant pre-post treatment effect relative to TAU were found for acceptance of diabetes ($p < .95$), anxiety ($p < .98$), depression ($p < .21$), and understanding of diabetes management ($p < .53$) A non-significant positive trend ($p < .07$) was identified for diabetes self-care activities, which improved compared to TAU ($^b g = .30$) and the education only group ($^b g = .47$)
Type 1 and 2 diabetes		
Moazzezi, 2015	Psychological: • Health self-efficacy (SHSES) • Perceived stress (PSS)	Significant treatment effects found compared to controls with a pre-post increase in health self-efficacy ($p < .001$; $^b g = 1.90$) and positive perceived stress ($p < .001$; $^b g = 3.50$), and a pre-post decrease in total perceived stress ($p < .01$; $^b g = .79$) and negative perceived stress ($p < .001$; $^b g = 4.10$)
Moghanloo, 2015	Psychological: • Depressive symptoms (RCDS) • Feelings of guilt (EFGS) • Psychological well-being (SWLS)	Significant treatment effects found compared to controls with a pre-post increase in psychological well-being ($p < .001$; $^b g = 4.33$) and a pre-post decrease in depressive symptoms ($p < .001$; $^b g = 3.76$) and feelings of guilt ($p < .001$; $^b g = 3.54$), after controlling for pre-test scores
Ryan, 2019	Psychological: • Resilience (RS) • Diabetes-related distress (PAID) • Depression, anxiety and stress (DASS) • Positive emotions (subscale of PANAS)	Significant pre-post improvement (all $p < .01$) in resilience ($r = .67$; $^b g = .55$), depression ($r = .36$; $^b g = .58$), stress ($r = .39$; $^b g = .63$), positive affect ($r = .39$; $^b g = .60$), psychological flexibility ($r = .49$; $^b g = .70$), valued living ($r = .39$; $^b g = .51$), step-count ($r = .51$; $^b g = 1.41$) and sitting time ($r = .52$; $^b g = .55$)

First Author, Year	Outcomes (Measures)	Main intervention findings (reported *p* and ES, and calculated *g*)
	Behavioural: ▪ Time spent in physical activity per week (AAS) ▪ Mean step-count per day (pedometer) ▪ Sitting time per day (STQ)	Pre-post improvements in diabetes-related distress ($r = .38$; [b] $g = .43$), anxiety ($r = .36$; [b] $g = .29$) and mindfulness ($r = .37$; [b] $g = .52$) approached significance ($p < .05$) due to the use of a more stringent significance level ($p < .01$)
	Process: ▪ Psychological flexibility (AAQ-II) ▪ Mindfulness (MAAS) ▪ Valued living (VLQ)	A non-significant positive trend was observed in pre-post time spent in physical activity ($p > .05$, $r = .17$; [b] $g = .16$)

Note. ES = effect size; TAU = treatment-as-usual; [a] Information supplemented using Gregg's (2004) dissertation; [b] Calculated effect size with small sample bias correction

Key. AADQ = Acceptance and Action Diabetes Questionnaire; ADDQoL-19 = Audit of Diabetes Dependence Quality of Life; AAQ-II = Acceptance and Action Questionnaire II; AAS = The Active Australia Survey; ATQ = Automatic Thoughts Questionnaire; BDI = Beck Depression Inventory; CAMM = Children and Adolescents Mindfulness Measure; CDRS = Connor-Davidson Resilience Scale; DAAS = Diabetes Acceptance and Action Scale for Children and Adolescents; DASS = Depression Anxiety Stress Scale; DCP = Diabetes Care Profile; DDS = Diabetes Distress Scale; EACS = Emotional Approach Coping Scale; EFGS = Eysenck Feeling of Guilt Scale; GAD-7 = Generalized Anxiety Disorder Scale-7; GHQ-28 = General Health Questionnaire; HADS = Hospital Anxiety and Depression Scale; IUS = Intolerance of Uncertainty Scale; MAAS = Mindful Attention Awareness Scale; PAID = Problem Areas in Diabetes Scale; PANAS = Positive and Negative Affect Schedule; PSS = Perceived Stress Scale; PSWQ = Penn State Worry Questionnaire; RBDI = Revised Beck Depression Inventory; RBQ = Relationships Beliefs Questionnaire; RCDS = Reynolds' Child Depression Scale; RS = Resilience Scale; Scot-PASQ = Scottish Physical Activity Screening Question; SDSCA = Summary of Diabetes Self-Care Activities; SF-36 = Short Form Health Survey; SES = Self-Efficacy Scale; SHSES = Special Health Self-Efficacy Scale; STQ = Sitting Time Questionnaire; SWLS = Satisfaction with Life Scale; VLQ = Valued Living Questionnaire; WBSI = White Bear Suppression Inventory

Study results

The main findings of the studies are presented in Table 3 with reported effect sizes and calculated effect sizes when means and standard deviations were reported. Three studies investigating outcomes of people with either diagnosis were considered independently as the available data in the full-text papers did not facilitate calculation of statistics separated by diagnosis.

T1D-specific outcomes

Only one study exclusively investigated the impact of ACT on people with T1D, focusing on psychological, physical and process outcomes only. Lehikoinen and Honkanen (2018) found that their 10-week ACT-based group programme did not significantly improve adolescents' depression, anxiety and HbA$_{1c}$ post-treatment compared to those assigned to treatment-as-usual, despite finding a significant post-intervention improvement in participants' diabetes-specific psychological flexibility and ability to manage diabetes (small to medium effect size).

T2D-specific outcomes

Psychological outcomes. Overall, mixed results were found for some of the psychological outcomes. Depression was investigated by five studies, out of which two quasi-experimental studies found significant pre-post large effect sizes (Ahmadsaraei et al., 2017; Hor et al., 2014), two single-group design studies found significant pre-post medium effect sizes (NHS Grampian, 2015; Welch, 2004), and one RCT found no pre-post significant difference (Whitehead et al., 2017). These differences in outcomes could be related to differences in study design.

Two studies identified significant pre-post improvements with medium effect sizes on anxiety level (NHS Grampian, 2015; Ghasemlou & Nezhadmohamadnameghi, 2018), whilst two other studies found no pre-post significant differences (Welch, 2014; Whitehead et al., 2017). Fayazbakhsh and Mansouri (2019) investigated more specific anxiety symptoms, finding significant pre-post improvements with large effect sizes for general anxiety disorder symptoms, worry and intolerance of uncertainty.

Diabetes-related stress was investigated by three studies, although only two analysed their findings which showed pre-post improvements with medium to large effect sizes (NHS Grampian, 2015; Welch, 2014). Welch (2014) also identified significant pre-post improvement in stress levels with a medium effect size. Quality of life was investigated by two studies, but only one study analysed the findings, identifying a significant pre-post improvement in quality of life with a large effect size (Ghasemlou & Nezhadmohamadnameghi, 2018). No significant pre-post improvements in understanding of diabetes management were found by two studies (Gregg et al., 2007; Whitehead et al., 2017).

Psychological outcomes were largely heterogeneous with some outcomes only being investigated by one study. Khashouei and colleagues (2016) found significant post-treatment improvements with a medium to large effect size in self-efficacy and perceived stress, which were maintained at follow-up. They also examined participants' resilience, only finding significant improvement at follow-up with a large effect size. Significant post-treatment improvements with a large effect size were found for marital satisfaction, dysfunctional communicative attitude and general mental health (Amirfakhraei et al., 2016; Kaboudi et al., 2017). Shayeghian and

colleagues (2016) investigated coping style as a potential psychological moderator, identifying that it was only significant for self-care activities accounting for 7% of the variance.

Behavioural outcomes. Five studies investigated the behavioural outcomes of ACT-based interventions in people with T2D. Two RCTs found significant improvements in diabetes self-management and self-care of small to medium effect size at follow-up (Gregg et al., 2007; Shayeghian et al., 2016) and one RCT found a non-significant pre-post positive trend in comparison to treatment-as-usual and an active education only control group (Whitehead et al., 2017). In line with this, Nes and colleagues (2012) noted positive lifestyle changes reported by participants following their online intervention, although they did not formally analyse their results due to their small sample size. Examining self-care more closely, Welch (2004) found significant post-treatment improvement with a medium to large effect size in areas of self-care pertaining to exercise and foot care, but no significant improvements in general diet, specific diet, blood glucose testing and smoking status were identified. Only one study did not use self-report questionnaires to measure behavioural outcomes; NHS Grampian (2015) investigated steps walked by participants and time spent in physical activity following their guided self-help programme, identifying significant improvements of small to medium effect size.

Physical outcomes. Of the five studies that investigated glycaemic control, one RCT found a significant improvement in HbA_{1c} of small effect size at follow-up (Shayeghian et al., 2016). The remaining four studies identified non-significant positive trends in HbA_{1c} at follow-up (Gregg et al., 2007; Nes et al., 2012; NHS Grampian, 2015; Whitehead et al., 2017). Thus, it may be that ACT interventions'

impact in reducing HbA$_{1c}$ levels may be too negligible to be considered statistically or clinically significant. However, Gregg and colleagues (2007) reported a significant improvement in the number of participants within target diabetes control status following their group workshop. Nes and colleagues (2012) identified a post-treatment positive trend in fasting blood glucose and cholesterol but did not formally analyse this due to their small sample size.

Process outcomes. Diabetes-specific acceptance was measured by four studies using the same measure (AADQ) with varying results and effect sizes. One RCT found no pre-post significant improvement in diabetes acceptance (Whitehead et al., 2017), whereas two other trials found significant improvements at follow-up with a less than small effect size (Gregg et al., 2007) or medium effect size (Shayeghian et al., 2016). A large pre-post effect size was found by a single-group design study (Welch, 2014). A significant post-treatment reduction in experiential avoidance with a large effect size was noted by Fayazbakhsh and Mansouri (2019). Welch (2014) found significant pre-post improvement in thought suppression. However, Gregg (2004) also investigated a range of other process variables (e.g. thought suppression and emotional avoidance) which did not change significantly post-intervention compared to an active control condition.

Outcomes of studies combining T1D and T2D

Psychological outcomes. The psychological outcomes investigated by studies combining people with T1D and T2D were largely heterogeneous, with only depression as a common measure in two studies which identified significant post-treatment improvements of medium to large effect size (Moghanloo et al., 2015; Ryan et al., 2019). Ryan and colleagues (2019) found a significant pre-post improvement in

adults' resilience, depression, stress and positive affect with medium effect sizes, but no significant difference in diabetes-related distress and anxiety. Moghanloo and colleagues (2015) also identified significant post-treatment improvements of feelings of guilt and psychological well-being in children with large effect sizes. Moazzezi and colleagues (2015), who appeared to be utilising the same intervention as Moghanloo (2015), found a large effect size pre-post improvement in the health self-efficacy and perceived stress of children.

Behavioural outcomes. Only one study combining T1D and T2D examined behavioural outcomes. Ryan and colleagues (2019) identified a non-significant post-treatment positive trend in time spent in physical activity, a significant increase in step-count (large effect size) and a significant reduction in sitting time (medium effect size).

Process outcomes. Only one study combining T1D and T2D investigated process outcomes. Ryan and colleagues (2019) found that psychological flexibility and valued living significantly improved following their intervention (medium effect size) but there were no significant changes in mindfulness.

Physical outcomes. None of the studies combining T1D and T2D investigated physical outcomes.

Discussion

In light of the increasing clinical interest in the use of ACT interventions to support the diabetes population, the present review aimed to systematically describe the characteristics of existing ACT interventions for people with diabetes and to investigate the extent to which ACT improves diabetes-related outcomes.

Summary of evidence

Reviewing the characteristics of ACT interventions for diabetes revealed that they have been investigated in a variety of formats, although group interventions were considerably more prevalent. Although the interventions varied in content and length, the relatively good completion rates demonstrate the acceptability and feasibility of ACT in this population. Key features of ACT, including the core components of psychological flexibility, appeared to be conveyed through the use of metaphors, exercises and discussions. However, a general lack of clarity regarding the content of treatment manual, therapist training and treatment fidelity was identified in the majority of reviewed studies.

Most of the reviewed studies targeted adults with T2D with ACT-based group interventions. Examining these studies revealed that the interventions were associated with small to large improvements in a range of behavioural and psychological outcomes such as diabetes self-care, physical activity, diabetes-related distress, self-efficacy, worry and quality of life. Mixed findings were found in relation to the impact of ACT on depression, anxiety and resilience. Whilst glycaemic control appeared to improve following ACT, only one study reported a significant reduction in HbA_{1c} levels. Inconsistent findings became apparent when reviewing changes in ACT-related processes, particularly in relation to diabetes acceptance and thought suppression.

Only one study investigated the impact of ACT in supporting the T1D population, identifying a small to medium significant improvement in diabetes acceptance following a group-based intervention for adolescents, but no significant changes in other psychological outcomes. Two studies that combined T1D and T2D

populations targeted children, demonstrating improvements in a range of psychological outcomes, such as health self-efficacy, perceived stress, well-being, depressive symptoms and feelings of guilt. Another study investigated adults with either diagnosis, although the majority had T2D, and detected small to large improvements in a range of psychological, behavioural and ACT-based process outcomes, similar to the T2D study results, although changes in diabetes-related distress, mindfulness and anxiety were not significant.

Strengths and limitations of the review

The present review had several strengths. Given the paucity of the literature in this topic area, the research questions and search strategy were deliberately broad to enable a comprehensive review of the existing ACT for diabetes literature, although a drawback was the exclusion of non-English studies. Searching the grey literature minimised the risk of publication bias and increased the likelihood that the review is representative of the existing literature. Further, the inclusion of the grey literature enabled the identification of the only T1D study included in the review (Lehikoinen & Honkanen, 2018) as well as a higher quality study (NHS Grampian, 2015). It also broadened the number and type of diabetes-related outcomes captured by the review. However, this methodology may have introduced lower quality studies as the studies may have not been peer-reviewed, in addition to introducing a subjective element, which deviates from the systematic nature of the review. Relevant qualitative studies were identified but excluded as analysing these was beyond the scope of the review. However, a future systematic review exploring qualitative research studies of ACT among people with diabetes is recommended to gain a better understanding of individual experiences of ACT interventions targeting diabetes-related outcomes.

The use of a second reviewer minimised the risk of researcher bias and methodological errors. Furthermore, using small sample bias-corrected estimates of treatment effects enabled a fairer comparison of individual findings. However, the heterogeneous nature of the studies, combined with the limited literature, made it difficult to draw firm conclusions about which outcome measures ACT has a reliably beneficial impact on, for whom specifically and in what circumstances. For example, the inclusion of one study into the impact of ACT on adolescents with T1D precludes the generalisation of the findings to the wider T1D population. As a large proportion of the studies were conducted with people with T2D in Iran, it remains unclear how applicable these findings might be to other T2D populations.

A drawback of the review was that a meta-analysis was not conducted as it could have provided a more systematic framework for synthesising study findings, which would have led to greater confidence in the conclusions drawn. Although the studies used different standardised questionnaires to measure similar diabetes-related outcomes, a meta-analysis could have been conducted to examine more commonly investigated outcomes such as depression, anxiety, diabetes-related distress, HbA_{1c} and diabetes self-management in the type 2 diabetes population, by employing a random-effects method to allow for a more conservative approach for reporting effect sizes (Borenstein et al., 2010). The calculated effect sizes and confidence intervals could have helped to inform future trials into the use of ACT with people with diabetes, in terms of the number of participants necessary to achieve sufficient statistical power. Given the considerable heterogeneity of the studies, the I^2 statistic could have been used to assess heterogeneity quantitatively (Higgins et al., 2019). As some of the included studies were assessed as having a high risk of bias, sensitivity

analyses could have been conducted to identify and acknowledge the influence of these biases on the findings (Higgins et al., 2019).

Strengths and limitations of the included studies

Whilst the ACT for diabetes literature has advanced, the review has highlighted the lack of high-quality studies in the field in addition to some inconsistencies between findings. Following the quality assessment, no notable differences in the results were observed by overall quality rating, although this was not objectively measured. However, as the majority of the studies obtained an overall quality rating of 'weak', the results should be interpreted within the context of the studies' limitations. The quality assessment identified strengths in the studies' research design, control of confounders and data collection methods. However, shortcomings in these areas were also observed. Only a few studies included an active control group, increasing the possibility that some discrepancies between findings may be linked to the robustness of the research designs employed. For example, significant improvements in thought suppression were found in a single-group design study but not in an RCT (Gregg et al., 2007; Welch, 2014). The use of interventions incorporating additional components without active control conditions and the minimal amount of follow-up data make it difficult to discern the precise impact of ACT in the long-term. The inclusion of studies that combined T1D and T2D samples enabled the comparison between separated and combined diabetes populations in the review, but it introduced ambiguity with regards to whether improvements were associated more with one population over the other.

The use of generic outcomes measures over validated diabetes-specific ones in some studies may have also resulted in a reduced sensitivity to detecting change.

Power calculations were not reported in most studies, and with the sample sizes varying from 11 to 157, it is unclear whether studies had enough statistical power to detect differences in outcomes. Moreover, it might be more clinically meaningful to measure whether participants reach their target glycaemic control, as measured by Gregg and colleagues (2007) in their RCT. Other study weaknesses included the overall lack of information on blinding procedures, number of participant withdrawals and dropouts, treatment adherence and therapist training as well as the use of convenience sampling. These increase the risk of reporting bias and selection bias. Whilst appropriate ACT-based exercises were named in some intervention descriptions, it remains unclear how appropriately these exercises were explained and interwoven into the interventions.

Discrepancies in results may also be due to other potential confounding factors. For example, the impact of ACT on diabetes acceptance was found to vary from no effect to a significantly large positive effect (Gregg et al., 2007; Shayeghian et al., 2016; Welch, 2014; Whitehead et al., 2017). Examining the methodologies employed by these studies revealed a substantial difference in the participants' average diabetes duration (from three months to 10 years), which may suggest that participants who had been diagnosed more recently experienced a greater increase in their diabetes acceptance after ACT compared to those who have had diabetes for many years. Overall, these study limitations and the results of the quality assessment indicate that caution is needed when drawing conclusions about the extent to which ACT is effective in improving diabetes-related outcomes.

Findings in context of existing evidence and theory

To the author's knowledge, this is the first review to focus solely on the impact of ACT on the diabetes population. Preliminary evidence to support the use of ACT in the diabetes field was highlighted by two previous systematic reviews which included six studies examined in the review (Graham et al., 2016; Massey et al., 2019). In line with Massey and colleagues' findings (2019), our review suggests that ACT has a beneficial impact on diabetes self-management and may improve various aspects of psychological health. The significant improvement in diabetes-related distress for people with T2D was in keeping with findings of a recent meta-analysis on the impact of diabetes-tailored psychological interventions (Schmidt et al., 2018). The impact of ACT on psychological factors such as depression and anxiety appears promising despite a few inconsistent results, as these variations in findings have also been found in systematic reviews of other psychological interventions (Pascoe et al., 2017; Steed et al., 2003). ACT appeared to have an overall positive effect on psychological health for people with T1D and T2D, although firm conclusions cannot be drawn due to the paucity of the literature.

The review challenges previous literature stating that ACT may be effective in improving glycaemic control, although the poor quality of studies questions the validity of this finding (Massey et al., 2019). The lack of treatment effect on HbA_{1c} levels has also been demonstrated in people with T1D and T2D following broader psychological interventions (Winkley et al., 2020a; Winkley et al., 2020b). An explanation might be that ACT may have a comparable minimal impact on glycaemic control. Additionally, HbA_{1c} levels may have been measured too early to detect change, or changes may be too negligible to detect. However, a recent meta-analysis

found that psychological interventions that were tailored specifically to diabetes significantly reduced HbA$_{1c}$ levels in adults with diabetes (Schmidt et al., 2018). The differences in these findings may be due to factors such as the difficulty of targeting multiple outcome measures simultaneously and an insufficient emphasis on addressing diabetes-specific issues to enable improvements in glycaemic control (Chew et al., 2018; Schmidt et al., 2018).

ACT's focus on acceptance and on living a meaningful life is likely to be attractive to clinicians when considering how best to support people with long-term health conditions such as diabetes (Graham et al., 2016). However, it was difficult to ascertain which components of psychological flexibility reliably change following ACT and how they contribute towards subsequent changes in diabetes-related outcomes, particularly as people's understanding of diabetes did not seem to change. Further exploration of the underlying mechanisms of ACT in this context is necessary.

Practice and research implications

The growing interest in ACT in the diabetes field is reflected by the high number of studies published in the past five years. The research indicates that this is a promising area for clinical practice given the range of intervention modalities, which showed significant improvements or at least changes in a positive direction in the aforementioned psychological and behavioural outcomes. Group-based ACT interventions for adults with T2D were investigated by the majority of studies, suggesting that ACT is not only feasible to implement, but is also relevant and applicable to T2D, though an outstanding question is whether the benefits of ACT are clinically significant. Promising results were observed in the studies that included

people with T1D; however, more research is required to ascertain the specific impact of ACT in T1D. Emerging high-quality studies into T1D (e.g. Amsberg et al., 2018) were not included in the review as the data is not yet available. As the literature expands, a meta-analysis employing a random-effects method is recommended as a more objective way of synthesising the evidence, including calculation of the I^2 statistic to measure heterogeneity and conducting sensitivity analyses to examine the impact of biases on the findings.

The impact of the poor research quality in increasing the risk of bias in the literature, combined with the heterogeneous nature of the studies in terms of their methodology, outcomes of interest and target population, made it difficult to generate firm conclusions about the effectiveness of ACT. The quality assessment highlighted areas for future studies to improve. Future research should use high-quality research designs such as RCTs with active control conditions and longitudinal follow-ups to elucidate the precise impact of ACT over time. Furthermore, larger sample sizes based on power calculations and rigorous participant selection methods are advised to minimise sampling bias and error. There is also a need for consensus on the main outcomes of interest and the use of diabetes-specific measures over general measures to enable valid and reliable measurements of change over time and to enable comparisons between different study findings.

Finally, whilst it is acknowledged that journal word count limits must be abided by, to minimise reporting bias, there is a need for publications in this research area to provide key information such as details of blinding procedures and numbers of participant withdrawals and dropouts. Information about treatment adherence and therapist training should also be reported to examine the validity of ACT

interventions. More transparency about the interventions through publishing treatment manuals will enable future research to investigate the underlying mechanisms of ACT by examining process measures such as the different components of psychological flexibility. Future research should also explore individual differences such as the role of diabetes duration as it may have clinical implications for targeting people with diabetes at an earlier stage.

Overall, the systematic review has provided evidence that ACT interventions may have a beneficial impact on the diabetes self-management and diabetes-related psychological outcomes of people with T2D, but their impact on physical health remains inconclusive. More research is necessary to evaluate the impact of ACT on the diabetes-related outcomes of people with T1D. ACT may have the potential to address a future direction for diabetes care delivery, although high-quality research is needed to enable valid and reliable conclusions to be drawn about its precise impact.

III. Comparison of two online ACT-based interventions for adults with insulin-treated diabetes: a pilot RCT

Abstract

The aims of the pilot study were: to investigate the impact of two online four-week, self-help interventions based on Acceptance and Commitment Therapy components (a values-plus-goals intervention [VGI] and a mindfulness-based intervention [MBI]) on well-being, diabetes self-management and glycaemic control of adults with insulin-treated diabetes; and to determine whether improvements in these outcomes were associated with changes in diabetes acceptance and valued living. A randomised controlled mixed design was employed. The final sample consisted of 29 insulin-treated adults with type 1 or 2 diabetes in the VGI ($n = 17$) and the MBI ($n = 12$) conditions. Participants completed the Well-being Questionnaire, Diabetes Self-Management Questionnaire, Diabetes Acceptance Scale, and Valued Living Questionnaire pre- and post-intervention, and at a one-month follow-up. HbA$_{1c}$ levels were collected at baseline and follow-up. Participants in the MBI condition experienced non-significant improvements in their well-being and diabetes acceptance over time; these changes were significantly associated post-intervention, but not at follow-up. Participants in the VGI condition experienced a non-significant pre-post improvement in their diabetes self-management, which was maintained at follow-up. Subscale analyses revealed that only the dietary control component of diabetes self-management significantly improved over time. Improvements in valued living did not reach statistical significance and no significant associations were found between changes in valued living and diabetes self-management over time. Follow-up HbA$_{1c}$ values were obtained for five participants, of whom four experienced clinically meaningful reductions. Study limitations included low statistical power, methodological weaknesses, and lack of control over potential confounding factors. The results, combined with participant feedback, suggest that brief

online interventions may have potential in expanding access to psychological input for people with diabetes. However, further research is recommended to gain insight into their clinical benefit using more robust studies with a larger sample size and longer follow-up.

Introduction

The challenges of diabetes

Diabetes mellitus is a chronic physical health condition affecting approximately 3.8 million people in the UK (Diabetes UK, 2019). Type 1 diabetes (T1D) and type 2 diabetes (T2D) distinguish between those who cannot produce insulin and those who no longer respond to insulin, respectively. Typically, insulin therapy is used to control blood glucose levels in T1D, whilst oral antidiabetic medication is used in T2D; however, insulin therapy is recommended in more poorly managed cases of T2D as well (DeWitt & Hirsch, 2003). As described on p. 20-21, diabetes poses a significant health challenge through increasing the risk of developing acute and chronic complications. Daily self-management is required to reduce this risk, which can be complex and difficult (George et al., 2014).

The "Too Often Missing" report highlighted that people with diabetes also face significant psychosocial challenges that can act as barriers to maintaining good diabetes self-care (Askew & Solomons, 2019). As discussed on p. 22-24, people with diabetes can experience disruptions to daily life alongside a variety of psychological difficulties ranging from low mood to diabetes-specific distress (Barnard et al., 2012; Nicolucci et al., 2013; Rane et al., 2011). Some individuals may use unhelpful coping strategies which prevent them from achieving optimal blood glucose levels (Sturt et al., 2015). These difficulties have been linked to a greater risk of complications and mortality, increasing the economic burden on healthcare services by up to double the expected cost (Diabetes UK, 2019; Lustman & Clouse, 2005; Eiser et al., 2001; Moussavi et al., 2007).

Psychosocial interventions for people with diabetes

With the growing incidence of diabetes, the importance of improving the outcomes for people with diabetes has been stressed as a national priority and there is an increasing recognition of the need to meet the psychological needs of people with diabetes (NHS England, 2018). A range of psychosocial interventions have been used to target the well-being and health outcomes of individuals with diabetes, including counselling, psychodynamic therapy and CBT; however, systematic reviews and meta-analyses in the field have found that there is mixed evidence regarding their effectiveness (Chew et al., 2017; Pascoe et al., 2017; Steed et al., 2003; Winkley et al., 2020a; Winkley et al., 2020b). These approaches often target negative diabetes-related thoughts, emotions and behaviour, as well as unhelpful coping strategies such as avoidance (e.g. not monitoring blood glucose levels) which has been associated with poor diabetes self-management (Weijman et al., 2005). Approaches that focus on challenging thoughts such as CBT may be limited in their impact, as individuals' thoughts related to chronic health conditions are often linked to the possibility of realistic consequences (Hofmann et al., 2010).

Acceptance and Commitment Therapy (ACT; Hayes et al., 1999) is an alternative therapeutic approach falling within the "third wave" CBT interventions, which has shown promise in the field of long-term health conditions (Graham et al., 2016). ACT moves away from attempts to alter internal experiences and promotes psychological flexibility in relation to individuals' relationship with their thoughts, feelings and behaviour. Psychological flexibility consists of six interrelated processes captured by the "Hexaflex" (see Figure 1, p. 27). These processes lend themselves to improving the well-being and health of people with diabetes by enabling individuals

to be mindful of and accept their internal experiences as they are, and to strive to live a meaningful life based on their personal values (Hadlandsmyth et al., 2013).

The evidence base for ACT in diabetes

Given the relative ease of applying ACT concepts to difficulties linked to chronic health conditions, there is a growing interest in ACT internationally as it is seen as a promising approach for improving diabetes-related outcomes, with an emerging evidence base. One of the first published studies in this area was conducted by Gregg and colleagues in 2007. They randomly assigned 81 patients with T2D to either an education-alone control group focused on diabetes self-management or a combined education and ACT workshop, which included learning and applying acceptance and mindfulness skills to diabetes-related thoughts based on an "ACT and diabetes self-management" manual which they later published. Their findings suggested that the participants who took part in the ACT workshop experienced greater improvements in their coping styles, diabetes self-management and glycaemic control compared to the education-only group.

Other trials of ACT interventions (see Table 3) have since been published which have shown improvements in a range of diabetes-related outcomes such as self-care, physical activity, depression, distress, worry, quality of life and stress, although some findings were inconsistent (Ahmadsaraei et al., 2017; Fayazbakhsh & Mansouri, 2019; Ghasemlou & NezhadmohamadNameghi, 2018; Khashouei et al., 2016; Moghanloo et al., 2015). Shayeghian et al. (2016) conducted a study based on Gregg's manual (2007), randomly assigning 100 adults with T2D to either a group-based 10-session ACT intervention combined with education or an education-alone group focused on diabetes self-management. They found that participants in the ACT

group had more effective coping strategies, higher acceptance, better diabetes self-care, and optimum HbA$_{1C}$ levels in the target range (a measure of average blood glucose level over three months), which remained stable at a 3-month follow-up. Similarly, Lehikoinen and Honkanen (2018) found that adolescents with T1D who took part in an ACT group, experienced significantly greater psychological flexibility than those who received treatment-as-usual. Thus, ACT interventions have been shown to be promising in diabetes populations.

The current challenge

Whilst ACT may be theoretically and practically suited to address the psychological needs of the diabetes population, it is difficult to deliver in the current NHS. There is a national lack of psychology funding in diabetes services with only 15% of services having access to diabetes-specific psychological support (Diabetes UK, 2008). The "Too Often Missing" report highlighted that 75% of people with diabetes requiring specialist psychological support felt that they could not access the support they needed (Askew & Solomons, 2019). Thus, there is a need for financially feasible and accessible interventions to support the well-being of patients with diabetes.

Web-based interventions

One way this has been addressed is through the use of web-based mental health interventions, which have increasingly become popular over the past three decades (Barak & Grohol, 2011). ACT has been delivered online successfully in the diabetes population through the use of smartphones and web-based modules. For example, as part of a quality improvement project to deliver an unmet need in the

NHS Grampian Trust (2015), a trial of a brief guided self-help ACT programme

"ACT Now!" was conducted with 27 adults with T2D who had difficulty managing

their condition (indicated by their glycaemic control, which was in the poorest 40% of

the Grampian T2D population). This involved 5-8 face-to-face meetings and web-

based modules, focusing on diabetes self-management, health-related behaviours,

anxiety, depression and diet. Overall, their qualitative interviews showed that the

programme was acceptable, feasible to deliver and helpful. The participants

experienced significant improvements in their ability to walk greater distances and

reduced levels of anxiety, depression and diabetes-related distress. Similarly, Nes and

colleagues (2012) conducted a feasibility pilot of a web-based 12-week ACT

intervention via smartphone aimed at adults with T2D, which included mindfulness

and identifying individuals' values, with the aim of supporting their self-management.

They found that it was feasible and resulted in positive lifestyle changes. Nes and

colleagues (2018) examined treatment fidelity and concluded that the different

processes within ACT can be delivered on the web in a written format. Therefore,

web-based ACT interventions may be an effective and financially feasible way of

addressing the psychological needs of people with diabetes.

Modular interventions

ACT is also a transdiagnostic approach that can be delivered in individual

modules by targeting the specific processes that encompass psychological flexibility

(Hayes et al., 1999). Thus, another solution could be the development of interventions

that target specific ACT components. For example, Villatte and colleagues (2016)

investigated two ACT component-based interventions (acceptance and values) in a

transdiagnostic adult sample, recommending that ACT components should be implemented as modular psychological interventions.

Karekla and colleagues (2018) proposed links between ACT and the Common Sense Model (CSM; Leventhal et al., 1992), a widely-used health and illness self-regulation model that outlines how individuals emotionally and behaviourally adapt to their health condition (see Figure 3). The CSM proposes that individuals with a health condition or illness all experience emotions and have beliefs related to the cause, consequences, identity (meaning assigned to symptoms), curability/controllability and timeline of the illness. This leads individuals to adopt coping strategies which can be adaptive (e.g. acceptance, problem-focused coping, seeking social support) or maladaptive (e.g. avoidance, substance misuse), which have an impact on their emotional state and health outcomes (e.g. physical functioning, well-being, illness state). The CSM posits that through a feedback loop, individuals undergo a dynamic and continuous process of appraisal and adjustment of their coping strategies by comparing their experience against their desired outcome (Leventhal et al., 1992).

Figure 3

The Common Sense Model of Health and Illness Self-regulation
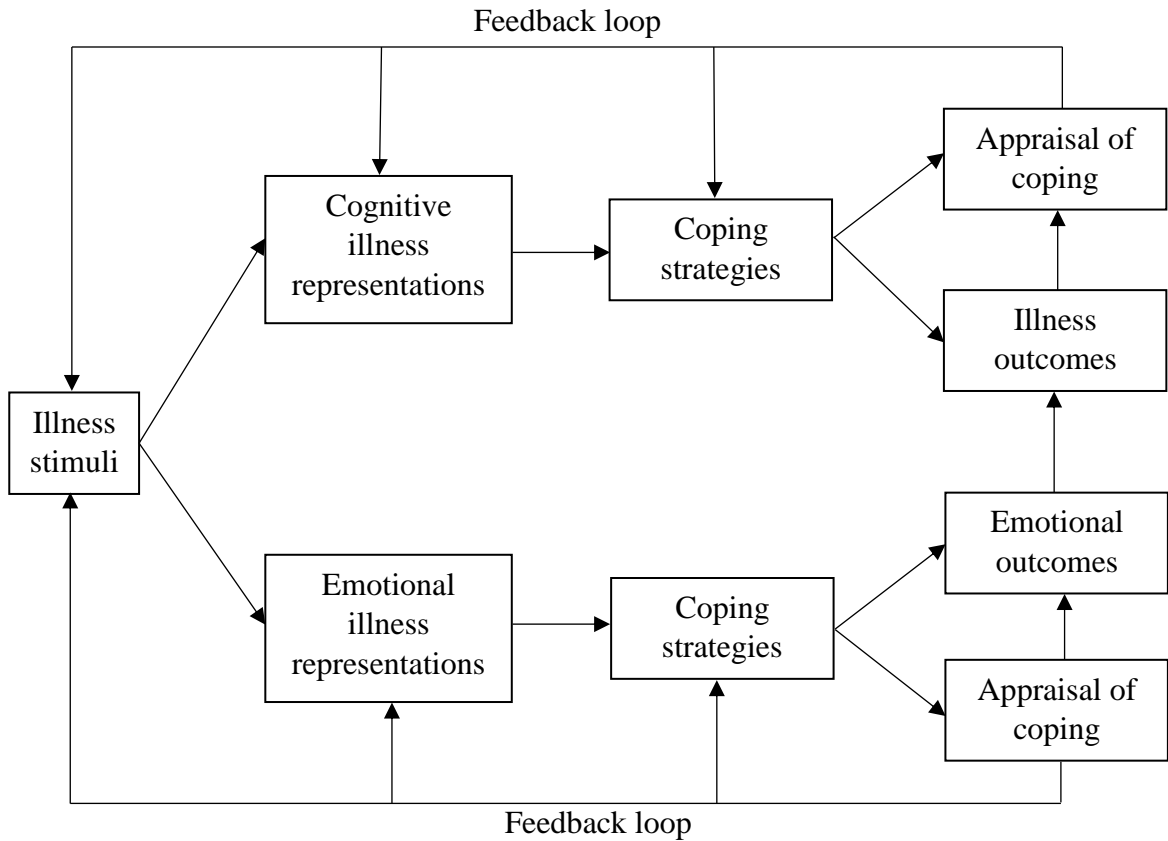
Karekla and colleagues (2018) proposed that the components of the ACT

hexaflex can be used to target and facilitate the dynamic process of adaptation to

illness and behaviour change posited in the CSM. The CSM theorises that individuals

have habitual mechanisms that are involved in illness self-regulation. When

individuals perceive illness representations as the only valid truth (also known as

cognitive fusion in ACT), this can lead to rigid and problematic ways of coping, such

as emotional avoidance–a maladaptive form of emotion-focused coping. Through

applying the mindfulness, acceptance and cognitive defusion components of the ACT

hexaflex, individuals can learn a different way of coping through disengaging from

these habitual mechanisms, and recognising and facing experiences as they are, giving them more choice for their subsequent behaviour (Karekla et al., 2018).

The CSM also emphasises the importance of having specific goals and actions to support self-regulation and how these are shaped within the context of individuals' self-system, that is, in according with their personal attitudes, identities and goals (Leventhal et al., 1992). The self-as-context, values and committed action components of the ACT hexaflex have been proposed to complement the CSM in this respect by aiming to clarify individuals' values and find meaning as to why behaviour change is personally important to them, which could facilitate better adaptation to illness by encouraging value-based actions (Karekla et al., 2018).

Mapping ACT components on the CSM can increase our theoretical understanding of how different components of ACT can be helpfully applied to the difficulties experienced by people with diabetes. Based on Karekla and colleagues' suggested intervention strategies combining the two models, it is proposed that an intervention based on the ACT components of values and committed action may promote more active, problem-focused coping styles through incorporating awareness of personal values, setting goals and encouraging committed action, as value-congruent behaviours could help to motivate individuals to act in line with their self-management plan, a vital part of adaptation to diabetes (Chew et al., 2018; Oftedal et al., 2010). An intervention based on the mindfulness and acceptance components of ACT may promote positive emotion-focused coping through helping individuals to mindfully acknowledge and live alongside difficult internal experiences, including any negative cognitive and emotional illness representations they may have (Hayes et al., 1999). Therefore, learning these ACT skills may result in improvements in coping

strategies and diabetes-related outcomes. Further, having a better understanding of the effectiveness of different components of ACT would allow services to provide a brief and more financially-feasible targeted intervention that is tailored to individuals with diabetes. However, no research examining different components of ACT with people with diabetes has been published to date.

Aims

The present pilot study aimed to extend previous research on using ACT to support the diabetes population by taking a modular approach and examining the impact of two four-week online ACT component-based interventions (a values-plus-goals intervention [VGI] and a mindfulness-based intervention [MBI]) in improving the well-being, diabetes self-management and glycaemic control of a sample of insulin-treated adults with T1D or T2D, who had suboptimal glycaemic control (HbA$_{1c}$ ≥64mmol/mol). Individuals with either T1D or insulin-treated T2D were targeted as they have similar treatment demands and impact, enabling the intervention to be accessible to anyone on insulin therapy. The study aimed to determine whether these interventions resulted in improvements in these diabetes-related outcomes post-intervention and at a one-month follow-up, and whether improvements were associated with changes in diabetes acceptance and valued living. The hypotheses were as follows:

(1) In the MBI group, self-reported well-being will be significantly greater at post-intervention and follow-up than at pre-intervention. In the VGI group, self-reported diabetes self-management activities will have significantly improved at post-intervention and follow-up compared to pre-intervention. Glycaemic control

will have significantly improved at follow-up compared to pre-intervention in the VGI group.

(2) The MBI will be associated with increased diabetes acceptance at post-intervention and follow-up, whilst the VGI will be associated with increased valued living at post-intervention and follow-up.

(3) In the MBI group, improvement in self-reported well-being at post-intervention and follow-up will be associated with an increase in diabetes acceptance. In the VGI group, improvement in self-reported diabetes self-management activities and glycaemic control at post-intervention and follow-up will be associated with an increase in valued living.

Method

Research approval

Ethical approval was obtained from the London – Surrey Research Ethics Committee (REC reference: 19/LO/1096; Appendix B), the Health Research Authority (Appendix C) and the Research Ethics Committee at Royal Holloway, University of London (Appendix D). Local research approval was granted by the Research and Development Department at Ashford and St Peter's Hospitals (ASPH) NHS Foundation Trust (Appendix E).

Participants

Power analysis

Given that no previous study to date has compared ACT component-based interventions in the diabetes field, the effect sizes of the interventions were unknown. An apriori analysis on G*Power, a statistical analysis software, was completed to

calculate the number of participants required to test the primary research hypothesis, considering diabetes self-management as the primary outcome of the present study (Erdfelder et al., 1996). An estimated effect size of $d = .65$ was used based on previous studies investigating the impact of ACT interventions in improving diabetes self-management (Gregg et al., 2007; Shayeghian et al., 2016). To conduct repeated measures analysis of variance with three measurements and with an effect size of $d = .65$, $\alpha = .05$ and power $= .80$, a sample size of 20 per group was required to detect significant changes related to the study hypotheses. Based on previous diabetes research, it was anticipated that the response rate would be approximately 58% (between 32-83%; Ramadas et al., 2011) and that the attrition rate would be 10% (Pal et al., 2013). Thus, the target sample size was a minimum of 20 participants in each group, with the understanding that 80 participants could be required to achieve this.

Sample description

Between October 2019 and April 2020, a total of 63 people with diabetes treated with insulin were recruited. Seven participants (11.1%) dropped out before completing the sociodemographic questionnaire and pre-intervention measures, resulting in a sample of 56 participants who were randomly allocated to take part in either the MBI or the VGI. The final sample size, based on those who completed pre- and post-intervention outcome measures, was 29 (MBI: $n = 12$; VGI: $n = 17$).

Of the 12 participants in the MBI condition, all reported belonging to White ethnic groups, seven were men and nine had a diagnosis of T1D. The sample had a mean age of 51.3 years ($SD = 12.5$), mean BMI of 27.1 ($SD = 4.03$), mean duration of diabetes of 22.3 years ($SD = 13.1$) and mean insulin treatment duration of 18.1 years

(SD = 15.5). Approximately half the sample reported having either long-term diabetes complications (n = 1), other comorbid health conditions (n = 2) or both (n = 4).

Of the 17 participants in the VGI condition, 16 reported belonging to White ethnic groups, nine were men and 13 had a diagnosis of T1D. The sample had a mean age of 45.7 years (SD = 18.1), mean BMI of 29.5 (SD = 6.38), mean duration of diabetes of 21.6 years (SD = 16.5) and mean insulin treatment duration of 18.9 years (SD = 17.5). Over two-thirds of the sample reported having either long-term diabetes complications (n = 3), other comorbid health conditions (n = 6) or both (n = 3). Further sociodemographic characteristics of the samples are presented in Appendix F, Table F1.

Recruitment

The majority of potential participants were recruited through diabetes clinics at ASPH NHS Foundation Trust (n = 259) during an 18-week period between October 2019 and March 2020. Flyers and posters (Appendix G) were displayed in the diabetes clinic waiting area and consultation rooms, encouraging interested participants to check their eligibility to take part with the diabetes team and to obtain a paper copy of the participant information sheet (PIS; Appendix H) and consent form (Appendix I). Clinicians and nurses were asked to raise awareness of the study to eligible patients at the end of their consultations, where possible, and to share the contact details of the researcher by providing a PIS. Eligible patients attending the diabetes clinics were also approached by the researcher to raise awareness of the study with their verbal consent. In the absence of the researcher at the clinics, a short recruitment video of the researcher explaining the study was produced for staff to share with eligible patients (https://vimeo.com/374373327).

To supplement recruitment between January 2020 and March 2020, seven diabetes charity organisations in the UK identified through the Diabetes Charity Directory on Diabetes.co.uk (a global diabetes community website) were contacted via e-mail to promote the study on their website and social media accounts and to circulate the study flyer to their members. Of these, three leading diabetes organisations agreed: Diabetes UK; JDRF – the type 1 diabetes charity; and the InDependent Diabetes Trust (IDDT). All three organisations advertised the study on their websites and social media accounts (e.g. Facebook, Twitter and LinkedIn). Individual Diabetes UK local groups, identified through the Diabetes UK website, were also contacted via e-mail. Of the 127 groups e-mailed, 19 agreed to circulate the study to their members, three responded that they no longer meet, five responded that they were groups aimed at children with diabetes only, one responded that the group members were involved in research already, and 99 did not respond. The researcher attended two local group meetings in person to present the study and hand out flyers and PISs to interested group members. A total of 38 potential participants were recruited through diabetes charity organisations.

The recruitment process including the number and reason for drop-outs are presented in Figure 4. In total, 297 patients were contacted regarding the study between October 2019 and April 2020, out of whom 63 (21.2%) were excluded based on an initial check against the eligibility criteria and 77 (25.9%) declined to participate as they were either not interested in the study or unable to commit to the study requirements. Of the 157 patients who showed an initial interest in the study and agreed to be contacted by the researcher, 28 (17.8%) did not respond to contact, 40 (25.5%) withdrew their interest or were no longer able to commit to the study time

requirements, and 26 (16.6%) were excluded following a second study eligibility check. Overall, 63 people were recruited.

Eligibility criteria

All participants met the inclusion criteria of being aged 18 or over, being fluent in English, having a diagnosis of T1D or T2D that is treated with insulin, and having access to the Internet. All participants had a latest HbA$_{1c}$ level of ≥64mmol/mol (indicative of suboptimal glycaemic control), which was either confirmed by the diabetes clinics for NHS participants or based on self-report for non-NHS participants.

Individuals were excluded from the study if they did not meet the inclusion criteria. Further exclusion criteria included: diagnosis of severe or enduring psychiatric disorder; diagnosis of another serious and/or life-threatening physical condition, significant cognitive and/or visual impairment; or, accessing psychological therapy at the time of commencing the study to minimise confounding variables.

Figure 4

CONSORT Diagram of Participant Flow through the Study

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┌────────────────────────────────┐   ┌────────────────────────────────┐
│ Patients screened for          │   │ Individuals from diabetes       │
│ eligibility at diabetes        │   │ charities screened for          │
│ clinics (n = 259)              │   │ eligibility (n = 38)            │
└────────────────────────────────┘   └────────────────────────────────┘
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Not interested or too busy (n = 77)
Excluded (n = 63):
- HbA$_{1c}$ <64 (n = 13)
- Not on insulin (n = 12)
- Not fluent in English (n = 4)
- Difficulty accessing or using Internet (n = 19)
- Diagnosis of severe or enduring mental health disorder (n = 3)
- Additional serious physical health condition (n = 2)
- Visual impairment (n = 2)
- Cognitive impairment (n = 1)
- Moving out of area (n = 2)
- Unable to contact (n = 5)

Contact details obtained to send online consent form (n = 157)

No response to contact (n = 28)
Not interested or too busy (n = 40)
Excluded (n = 26):
- HbA$_{1c}$ <64 (n = 15)
- Not on insulin (n = 1)
- Difficulty accessing or using Internet (n = 2)
- Diagnosis of severe or enduring mental health disorder (n = 3)
- Additional serious physical health condition (n = 1)
- Moved country (n = 1)
- Currently receiving psychological therapy (n = 3)

Obtained informed consent (n = 63)

Completed pre-intervention questionnaires T1 (n = 56)
Did not complete (n = 7)

Random Allocation

Allocated to MBI group (n = 27)

Completed (n = 12)
Did not start (n = 2)
Did not complete (n = 13)
- Disengaged in Week 1 (n = 7)
- Disengaged in Week 2 (n = 2)
- Disengaged in Week 3 (n = 2)
- Disengaged in Week 4 (n = 0)
- Ongoing participation (n = 2)

Completed post-intervention questionnaires T2 (n = 12)

Completed follow-up questionnaires T3 (n = 8)
Lost to follow-up (n = 4)

Obtained latest HbA$_{1c}$ level post-intervention from clinic (n = 3)

Questionnaires analysed (n = 12)
HbA$_{1c}$ analysed (n = 3)

Allocated to VGI group (n = 29)

Completed (n = 17)
Did not start (n = 4)
Did not complete (n = 8)
- Disengaged in Week 1 (n = 5)
- Disengaged in Week 2 (n = 0)
- Disengaged in Week 3 (n = 1)
- Disengaged in Week 4 (n = 0)
- Ongoing participation (n = 2)

Completed post-intervention questionnaires T2 (n = 17)

Completed follow-up questionnaires T3 (n = 11)
Lost to follow-up (n = 6)

Obtained latest HbA$_{1c}$ level post-intervention from clinic (n = 5)

Questionnaires analysed (n = 17)
HbA$_{1c}$ analysed (n = 5)

88

Design

The pilot study was developed in line with guidance on developing and evaluating complex interventions from the Medical Research Council (MRC; Craig et al., 2008). A randomised controlled mixed design was employed with between-subjects randomisation to intervention (MBI or VGI) and within-subjects measurement of outcome measures at three time-points: pre-intervention (T1), post-intervention (T2) and one-month follow-up (T3).

Measures

Sociodemographic information

A sociodemographic questionnaire (Appendix J) was used to assess the baseline characteristics of the two groups and to examine whether there were any baseline group differences.

Well-being Questionnaire (W-BQ28; Speight et al., 2000)

The W-BQ28 is a 28-item measure of generic psychological well-being and diabetes-specific well-being (Appendix K). Items are scored on a four-point Likert scale where respondents indicate how much each item applies to them in the past few weeks from "not at all" (score of 0) to "all the time" (score of 3). The measure includes four general subscales (Negative Well-being, Energy, Positive Well-being and Generic Stress) and three diabetes-specific subscales (Diabetes-specific Negative Well-being, Diabetes-specific Positive Well-being and Diabetes-specific Stress). A diabetes-specific well-being score out of 36 can be calculated, whereby greater scores suggest greater diabetes-specific well-being. The scale has been shown to be a valid and reliable tool in evaluating new interventions with good construct validity,

excellent internal consistency for each subscale (α = .80-.87) and test-retest reliability over a year ($r = \geq.79$) for all combined scales (Bradley & Lewis, 1990; Speight & Bradley, 2002).

Diabetes Self-Management Questionnaire (DSMQ; Schmitt et al., 2013)

The DSMQ is a 16-item measure of self-management activities associated with glycaemic control for people with T1D and T2D (Appendix L). Each item is scored on a 4-point Likert scale from "applies to me very much" (score of 3) to "does not apply to me" (score of 0). The measure is composed of four subscales (Glucose Management, Dietary Control, Physical Activity and Health-care Use), from which a transformed total scale score out of 10 can be calculated, where higher scores indicate more effective self-management. The DSMQ has been shown to have good overall internal consistency (α = .84), acceptable internal consistency between subscales (α = .60-.77) and significant convergent correlations (r = .52-.58) with parallel scales of self-management (Schmitt et al., 2013).

Diabetes Acceptance Scale (DAS; Schmitt et al., 2018)

The DAS is a 20-item global measure of diabetes acceptance (Appendix M). Each item is scored on a 4-point Likert scale from "always true for me" (score of 3) to "never true for me" (score of 0). It is composed of two subscales (Psychological Acceptance/Integration and Diabetes-related Motivation), which can be summed to form a total score out of 60. Higher total scores indicate fewer problems related to diabetes acceptance. Schmitt et al. (2018) demonstrated high factorial and criterion validity, as well as excellent internal reliability for the total scale (α = .95-.97) and for each subscale (α = .87-.94) for both T1D and T2D. The DAS has shown significant

convergent correlations (r = .42-.69) with parallel scales of acceptance, depressive symptoms, glucose monitoring, self-management, medication adherence and diabetes distress (Schmitt et al., 2018).

Valued Living Questionnaire (VLQ; Wilson & DuFrene, 2009)

The VLQ is a 20-item measure of value-based living in the past week across 10 life domains: Family, Relationships, Parenting, Friendship, Work, Education, Recreation, Spirituality, Citizenship, and Physical Self-care (Appendix N). Each domain is rated on a ten-point Likert scale of importance and consistency, from "not at all important/consistent" (score of 1) to "extremely important/consistent" (score of 10). These scores are combined to calculate a mean valued living composite score out of 100; greater scores indicate that the person is living life more in line with their values. Wilson et al. (2010) have shown satisfactory internal consistency and test-retest reliability for the valued living composite (α = .64-.74; r = .75), and for the individual life domains (α = .79-.83; r = .57-.79).

Glycaemic control

The most common way of measuring glycaemic control is through a blood test that assesses glycated haemoglobin level (HbA_{1c}). This provides a measure of haemoglobin molecules that have formed a bond with glucose that remains in the blood stream for approximately three months, indicative of an individuals' average glycaemic control over the last three months. Greater HbA_{1c} levels are indicative of poorer glycaemic control. Participants' latest HbA_{1c} level were either obtained from medical records or through self-report for those recruited from diabetes charity organisations at baseline and again at follow-up.

Acceptability and deliverability of interventions

To measure the acceptability and deliverability of the interventions, the number of patients who participated, the response rate and the attrition rate were examined. At the end of the intervention, participants were asked to complete a brief feedback questionnaire developed for the purposes of this study to gain a better understanding of their views on the effectiveness, user-friendliness and relevance of the intervention they took part in, including whether they would recommend the programme to others and space to describe any difficulties they experienced during the programme (Appendix O).

Interventions

Both four-week interventions used a self-help web-based format and were hosted on Qualtrics, a secure online platform for conducting research. Service user feedback was sought from three individuals with insulin-treated T2D, four individuals with T1D and one carer. Overall, the feedback was that both interventions were simple, easy to navigate and relevant to people with diabetes. Adjustments were made to the examples used in the VGI and to the debriefing process.

Values-plus-Goals Intervention (VGI)

The VGI (Appendix P) was adapted from an existing online value-affirmation and goals intervention (Kingston & Ellett, 2014; Evans et al., 2019) and an existing programme handbook developed by Ashcroft (2014), "Living Well with Physical Health Conditions". Participants were first introduced to the concept of values as understood in Acceptance and Commitment Therapy (ACT; Hayes et al., 1999), followed by a description of the relevance of values for managing diabetes. The

participants were then asked to complete a values-clarification card-sort task adapted

from Harris (2008), which involved organising 10 life domain cards ("Family",

"Marriage/Couples/Intimate Relationships", "Parenting", "Friendships/Social Life",

"Career/Employment", "Education/Training/Personal Growth and Development",

"Leisure/Recreation/Fun", "Spirituality", "Citizenship/Environment/Community

Life", and "Health/Self-care") according to their perceived level of importance into

one of three categories: "very important to me", "quite important to me" and "not

important to me". Participants subsequently chose one value that was the most

important and meaningful to them from the "very important to me" pile, and to

connect with this value, they wrote about their chosen value in a text box for up to 10

minutes, thinking about why it was meaningful to them and describing a time when it

made them feel good about themselves (based on Sherman et al., 2000). As a

manipulation check, participants were asked to rate four statements on a scale of 1

(strongly disagree) to 6 (strongly agree) to assess whether they wrote about a

personally important value that is relevant to their diabetes (Evans et al., 2019).

Following this, participants were given information and examples on using

values to set diabetes-related goals. They were given instructions on how to set a goal

that is "SMART" (specific, meaningful, adaptive, realistic and time-framed) based on

their chosen value and asked to set one for themselves to focus on over the next

month. A second manipulation check was completed by asking participant to confirm

that their chosen goal followed "SMART" principles, and they were asked to consider

solutions to overcome potential barriers to achieving their goal. Thereafter,

participants were sent a reminder e-mail every week over the four weeks, asking them

to reconnect with their chosen value, review their progress towards their goal and to reflect on the process of moving towards their goal (see example in Appendix P).

Mindfulness-based Intervention (MBI)

In the MBI, participants were introduced to the concept of mindfulness and acceptance as understood in ACT (Hayes et al., 1999), followed by a description of how these skills can be applied as a way of coping with challenging thoughts, feelings and physical sensations related to diabetes (Appendix Q). The participants were then presented with a recording of a ten-minute health-focused guided mindfulness meditation exercise read by a female clinician. The script focused on cultivating mindful awareness of internal experiences, particularly in relation to diabetes, and practising making room for any difficult internal experiences, based on scripts developed by Harris (2009). This exercise was followed by four prompting questions to promote reflections related to their diabetes following the exercise. The participants were asked to practise this exercise three to four times a week over a four-week period. As a manipulation check, participants were sent a reminder e-mail every week over the four weeks and asked to record how many times they practised the exercise over the past week on Qualtrics and to make note of their reflections on their experience each week (see example in Appendix Q).

Procedure

Figure 4 depicts the study procedure. Interested patients were asked to share their contact details with the researcher so they could be contacted via telephone and/or e-mail regarding the study and to have their questions answered. Qualtrics was used to host all stages of the study. Patients who confirmed their interest were sent a

Qualtrics link via e-mail to access the electronic version of the PIS and to complete

the consent form to proceed with the study. Three reminders were sent to potential

participants to complete the consent form; non-responses were interpreted as

withdrawal of interest in the study.

After providing informed consent, each participant was assigned a unique

identification number to access the questionnaires and intervention on Qualtrics and

to anonymise their responses. Participants then completed the sociodemographic

information questionnaire, followed by the four pre-intervention questionnaires (W-

BQ28; DSMQ; DAS; VLQ) which were presented in a random order using Qualtrics'

randomiser function to minimise any order effects. Upon completion, they were

automatically randomly allocated to take part in the VGI or the MBI by Qualtrics.

During the four-week interventions, participants were sent four mid-week

reminders to continue with their meditation practice or with pursuing their goal. They

were also sent reminders at the end of each week to complete the weekly progress

review. When participants did not complete their weekly review, they were sent

further reminders by the researcher encouraging them to complete the review at their

earliest convenience. If participants did not respond to reminders sent during this

period, it was assumed that they had disengaged from the study. After completion of

the fourth week progress review, participants were automatically redirected to

complete the same set of questionnaires and asked to provide feedback on the

intervention that they took part in. One month after intervention completion,

participants were automatically contacted through Qualtrics to complete a final set of

follow-up questionnaires. Participants' latest HbA_{1c} level was obtained from the

diabetes clinic or through self-report at the beginning of the study and two months after the end of the intervention.

At the end of the study, participants were debriefed and given the opportunity to take part in the alternative intervention without further involvement from the researcher.

Data analysis

Participants were included in the analysis using a per-protocol principle, defined as completion of their allocated intervention and completion of outcome measures for at least two time-points. Given that the study was a pilot project, using intention-to-treat principle was not deemed appropriate; thus, participants who only completed pre-intervention measures and did not complete the intervention were excluded. Descriptive statistics were utilised to examine attrition and intervention adherence in each condition, and to explore the pattern of the data using means, standard deviations, ranges, frequencies and percentages. This was followed by statistical testing to identify whether any differences were statistically significant. Data were visually inspected for missing data. Exploratory data analysis was completed on all outcome and process variables to assess whether assumptions for parametric analysis were met. Boxplots were visually inspected to identify outliers. Extreme scores were identified as falling more than three standard deviations above or below the sample mean separated for each group and for each time-point. Extreme scores were retained if they reflected meaningful variation in the data and did not appear to have a significant impact on other data points. Histograms were visually inspected to examine whether outcome measures were normally distributed in each group condition, and cross-checked by examining skewness and kurtosis through

96

calculation of z-scores. Where skewed distributions were identified ($z > 3.29$, $p <$ .001), transformations were used to obtain a normal distribution.

Groups were examined for baseline equivalence in sociodemographic information, pre-intervention outcome measures and process measures using independent samples t-tests for continuous variables and chi-square tests for categorical variables. If the data met parametric assumptions of normality and sphericity, repeated measures analysis of variances (ANOVAs) with Huynh-Feldt correction for the degrees of freedom were used for hypothesis testing. Parametric analyses were conducted despite the small sample sizes based on the findings of Oberfeld and Franke (2012), who demonstrated that applying the Huynh-Feldt correction controlled the Type I error rate for small samples as long as the data is normally distributed.

The first and second research questions related to investigating the impact of the interventions on outcome measures and process measures across the three time-points, respectively. Hypotheses were tested using repeated measures ANOVA with Huynh–Feldt correction. If the ANOVA result was significant, then this result was decomposed using post-hoc paired-samples t-tests. Whilst Bonferonni corrections were considered to control the family-wise error rate, they were not applied as the corrected p-value was deemed to be too stringent, which increases the likelihood of Type II errors (Field, 2009). Given the small sample sizes, equivalent non-parametric tests were run for all above hypothesis-testing analyses to check their impact on the results. As follow-up HbA_{1c} values were only obtained for a small number of participants, statistical testing was not deemed appropriate.

Given the small sample sizes, a post-hoc decision was made to examine whether the interventions had a clinically significant impact on well-being, diabetes self-management and HbA_{1c}. Reliable Change Indices (RCI) were calculated for each participant by dividing the difference between the scores from two time-points by the standard error of the difference between the two scores using an Excel calculator made available online (Zahra, 2010). This was completed for total well-being scores and diabetes self-management scores across all the three time-points (T1-T2, T2-T3 and T1-T3). If the RCI was greater than 1.96, the difference was considered reliable ($p < .05$) as a change of that magnitude would not be expected from measurement error alone.

Where changes were identified as reliable, they were further examined to check whether they were clinically significant changes using an online calculator (www.psyctc.org/stats/rcsc.htm). For the W-BQ28, a change in score of 3.0 was considered to be clinically significant (Speight et al., 2012). For the DSMQ, raw subscale scores were inspected against cut-off criteria which suggest poor or inadequate levels of specific aspects of diabetes self-management (Schmitt et al., 2013). A change of 5.5 mmol/mol (0.5%) in HbA_{1c} was interpreted as clinically significant, as typically considered by diabetes clinicians (Lenters-Westra et al., 2014).

For the final set of hypotheses, related to investigating associations between changes in process outcomes and changes in outcome measures across the three time-points, standard multiple linear regression were carried out, controlling for pre-intervention scores and using unstandardised residual change scores for process

outcomes. All data analysis was completed using the IBM SPSS Statistics for Windows, Version 21.0.

<div align="center">

Results

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Exploratory data analysis

Attrition

Overall, 15 participants (55.5%) did not complete the MBI and 12 participants (41.4%) did not complete the VGI. Attrition rates did not significantly differ between the two groups, $\chi^2_{(1)} = 1.13$, $p = .289$. In terms of sociodemographic characteristics, no significant differences were found between participants who completed and those who did not complete with regard to age ($t_{(54)} = 1.17$, $p = .247$), gender ($\chi^2_{(1)} = 2.70$, $p = .100$), ethnicity ($\chi^2_{(2)} = 1.57$, $p = .456$), BMI ($t_{(52)} = .319$, $p = .751$), diabetes type ($\chi^2_{(1)} = .626$, $p = .609$), diabetes duration ($t_{(54)} = 1.34$, $p = .187$), insulin treatment duration ($t_{(54)} = .916$, $p = .364$), number of diabetes complications ($\chi^2_{(1)} = .111$, $p = .740$) and additional health problems ($\chi^2_{(1)} = .721$, $p = .396$). However, individuals who experienced a greater number of hypoglycaemic episodes in the past two months ($M = 6.48$, $SD = 1.33$) were more likely to complete the study than those who experienced fewer episodes ($M = 5.48$, $SD = 1.99$), $t_{(44.9)} = 2.20$, $p = .033$.

With respect to outcome and process measures at baseline, no significant differences were found between participants who completed and those who did not complete with regard to valued living ($t_{(49.7)} = -.168$, $p = .867$), diabetes self-management ($t_{(54)} = 1.63$, $p = .109$) and HbA$_{1c}$ values ($t_{(52)} = -.665$, $p = .509$). However, individuals with higher levels of diabetes acceptance ($M = 42.8$, $SD = 12.6$) and well-being ($M = 20.7$, $SD = 10.2$) were more likely to complete the study than

those with lower levels of diabetes acceptance ($M = 34.9$, $SD = 13.6$) and well-being ($M = 14.6$, $SD = 8.39$), $t_{(54)} = 2.26$, $p = .028$ and $t_{(54)} = 2.42$, $p = .019$, respectively.[1]

Missing data

In the sociodemographic questionnaire, one participant did not report their weight and two participants did not report how frequently they take their insulin. No missing data were identified in any of the measures, as participants were alerted if they missed any items on the questionnaires by Qualtrics. Follow-up HbA$_{1c}$ values were only collected for eight out of 29 participants (MBI: $n = 3$; VGI: $n = 5$) as the study relied on data from routine blood tests, and the remainder of the sample had not had their routine blood test at the time of data analysis.

Outliers

No participants were identified as outliers in terms of age, BMI, diabetes duration, insulin treatment duration and number of hypoglycaemic episodes in the past two months. Visual inspection of boxplots revealed that four participants had one score each that was identified as an outlier on the following questionnaires, completed at follow-up: DSMQ ($n = 2$); DAS ($n = 1$); and VLQ ($n = 1$). As the outliers were within three standard deviations away from the mean, they were not considered extreme. They were retained in the dataset as they were deemed to be reflective of meaningful variation in the data and they did not impact on other data. One participant had a pre-intervention HbA$_{1c}$ value that was identified as an outlier and almost an extreme score by a difference of 1 mmol/mol. This HbA$_{1c}$ value was

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[1] These statistical results were crosschecked using Mann-Whitney U tests, which yielded the same results.

excluded from subsequent analysis as it appeared to skew the distribution of the data, as described in the next subsection.

Assumption of normality

All outcome and process measures, with the exception of one measure, were normally distributed. A positive skew was identified in the distribution of pre-intervention HbA$_{1c}$ ($z = 4.01$, $p < .001$). Applying transformations such as Box-Cox and Log10 did not lead to a normal distribution. Visual inspection of the histogram indicated that the extreme HbA$_{1c}$ value may be skewing the distribution. Removal of the extreme score led to a normal distribution ($z = .51$, $p > .01$).

Intervention adherence

MBI. The mean time taken to complete the MBI was 46.4 days ($SD = 19.0$, range = 30-84). Participants in the MBI condition practised the 10-minute meditation practice 2.94 days ($SD = 1.09$, range = 1-5) per week on average, completing a mean total of 11.8 practices ($SD = 4.35$, range = 4-20) over the course of the programme.

VGI. The mean time taken to complete the VGI was 53.5 days ($SD = 19.5$, range = 29-89). Participants in the VGI conditions chose the following values as their top value that is most meaningful and important to them: parenting ($n = 3$); marriage, couples or intimate relationships ($n = 4$); family – other than marriage or parenting ($n = 6$); community life ($n = 1$); leisure ($n = 1$); health and self-care ($n = 1$). One participant chose to focus on three values (family, intimate relationships and health); as they were able to set a single one-month goal that spanned all three life domains, their data was retained in the analysis. On a scale of 1 to 6 ("strongly disagree" to "strongly agree"), participants rated their chosen value in terms of relevance to them

(M = 5.18, SD = 0.88), importance in their life (M = 5.24, SD = 0.83), how much they try to live up to the value (M = 5.18, SD = 0.95) and how much the care about it (M = 5.47, SD = 0.94). All participants set a goal that they considered specific and achievable in the next month and relevant to their diabetes self-management. All participants, except four, reported that their goal was consistent with their chosen value. At the end of the programme, 12 participants reported that they had been able to move towards their goal, one participant reported that their goal was no longer applicable at present due to the impact of COVID-19, and four participants were not able to move towards their goal due to the impact of COVID-19 (n =2), Christmas (n = 1) and external circumstances outside of their control (n = 1).

Intervention feedback

MBI. On a scale of 1 to 10, on average participants rated the MBI programme as somewhat helpful (M = 6.33, SD = 2.90), relevant to them (M = 5.92, SD = 2.84) and easy to use (M = 5.92, SD = 2.84). They rated the length of the programme as satisfactory (M = 7.92, SD = 1.44) and 10 out of 12 participants stated that they would recommend the programme to a friend with diabetes.

VGI. On a scale of 1 to 10, on average participants rated the VGI programme as somewhat helpful (M = 6.41, SD = 2.60), relevant to them (M = 6.53, SD = 3.04) and very easy to use (M = 9.00, SD = 1.22). They rated the length of the programme as satisfactory (M = 7.88, SD = 1.76) and nine out of 17 participants stated that they would recommend the programme to a friend with diabetes.

Baseline equivalence between groups

No significant differences in sociodemographic characteristics (see Appendix F, Table F1), and pre-intervention outcome and process measures (see Appendix F, Table F2) were found between the two conditions using independent samples t-tests and chi-square tests.[2]

Hypothesis testing

The means and standard deviations of scores across the three time-points for outcome and process measures, alongside the Huyhn-Feldt corrected results of the repeated measures ANOVAs, are presented in Table 4.[3]

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[2] These statistical results were repeated using Mann-Whitney U tests, which obtained the same results.

[3] All repeated ANOVAs and paired sample t-tests were crosschecked using Friedman tests and Wilcoxon Signed-Rank tests, which yielded the same results.

Table 4

Means and Standard Deviations of Study Variables across Time and Results of Repeated Measures ANOVAs

Study Variable / Time – M (SD)	MBI ($n = 12$)			VGI ($n = 17$)			Full Sample ($N = 29$)			Test Statistic
	T1	T2	T3	T1	T2	T3	T1	T2	T3	
Diabetes self-management	6.79 (1.46)	7.08 (1.56)	7.47 (1.60)	6.40 (1.46)	7.10 (1.25)	7.44 (1.36)	6.56 (1.45)	7.09 (1.36)	7.46 (1.42)	VGI: $F(1.47, 14.7) = 3.69$, $p = .061$, $\eta_p^2 = .270$ MBI: $F(1.90, 13.3) = .749$, $p = .485$, $\eta_p^2 = .097$
Well-being	22.8 (9.94)	24.3 (8.23)	26.1 (9.30)	19.2 (10.4)	20.9 (7.86)	23.1 (9.05)	20.7 (10.2)	22.3 (8.04)	24.4 (9.03)	VGI: $F(1.62, 16.2) = .933$, $p = .395$, $\eta_p^2 = .085$ MBI: $F(1.63, 11.4) = .667$, $p = .503$, $\eta_p^2 = .087$
HbA$_{1c}$[a]	75.6 (7.62)[b]	N/A	67.0 (8.41)	77.9 (10.5)	N/A	64.0 (7.18)	77.0 (9.39)	N/A	64.4 (10.8)	VGI: N/A MBI: N/A
Valued living	51.1 (20.8)	55.8 (16.8)	49.1 (14.9)	43.3 (22.4)	47.8 (22.7)	54.6 (19.2)	46.5 (21.7)	51.1 (20.5)	52.3 (17.3)	VGI: $F(2, 20) = 1.82$, $p = .188$, $\eta_p^2 = .154$ MBI: $F(2, 14) = 2.13$, $p = .155$, $\eta_p^2 = .234$
Diabetes acceptance	46.1 (10.2)	47.0 (10.3)	50.5 (8.78)	40.4 (13.9)	43.1 (10.3)	46.2 (11.7)	42.8 (12.6)	44.7 (10.3)	48.0 (10.5)	VGI: $F(2, 19.9) = .724$, $p = .497$, $\eta_p^2 = .068$ MBI: $F(1.53, 10.7) = .347$, $p = .659$, $\eta_p^2 = .047$

Note. [a] Follow-up HbA$_{1c}$ values were obtained for $n = 2$ in the MBI group and $n = 5$ in the VGI group. Due to the small sample sizes, statistical tests were not conducted for HbA$_{1c}$; [b] Based on $n = 11$ following removal of outlier

Research Question 1 – Impact of interventions on outcome measures

Hypothesis: Well-being will be significantly greater at post-intervention and follow-up than at pre-intervention in the MBI condition. The means indicated an increase in well-being scores from pre-intervention to post-intervention, and from pre-intervention to follow-up in the MBI condition. However, a repeated measure ANOVA revealed no statistical significant differences in well-being scores over time (see Table 4).

Reliable Change Indices and Clinically Significant Changes. Two participants (16.7%) in the MBI condition were identified as having shown a reliable pre-post improvement in their well-being scores, obtaining RCI values of 2.09 and 2.47 ($p < .05$). Both changes in scores (+11 and +13 respectively) were greater than 3.0, indicating that they were clinically significant. Follow-up data was not obtained for one of these participants; the other participants did not show a reliable improvement in their well-being score between pre-intervention and follow-up ($p > .05$), suggesting that the reliable pre-post improvement was not maintained at follow-up. Reliable improvements in well-being were not identified in the remainder of participants in the MBI condition (see Table R1, Appendix R).

Hypothesis: Self-reported diabetes self-management activities will have significantly improved at post-intervention and follow-up compared to pre-intervention in the VGI condition. A repeated measures ANOVA identified a non-significant positive trend in the diabetes self-management scores across the three time-points, $F(1.47, 14.7) = 3.69$, $p = .061$, $\eta_p^2 = .270$. As the *p*-value indicated that the intervention effect was close to being statistically significant, post-hoc analyses were run using paired samples *t*-tests to decompose the effect. These revealed a

significant pre-post increase in diabetes self-management, $t_{(16)} = -2.96$, $p = .009$, $d = .504$. No significant differences in diabetes self-management were identified between pre-intervention and follow-up ($t_{(10)} = -1.96$, $p = .079$, $d = .474$), and post-intervention and follow-up ($t_{(10)} = -.113$, $p = .912$, $d = .013$). The calculated d-statistics would be considered medium effect sizes for pre-intervention to post-intervention, and for post-intervention to follow-up (Cohen, 1988). However, these results should be interpreted with caution due to the small sample and given that the overall finding did not reach statistical significance.

Post-hoc analyses of DSMQ subscales were run to explore the impact of the interventions on different aspects of diabetes self-management over time in the VGI condition. Repeated measures ANOVAs indicated no significant differences in glucose management ($F(1.54, 15.4) = .966$, $p = .381$, $\eta_p^2 = .088$), physical activity ($F(2, 20) = .907$, $p = .420$, $\eta_p^2 = .083$) and physician contact ($F(1.64, 16.4) = .56$, $p = .549$, $\eta_p^2 = .053$) across the three time-points. However, the a significant effect of time on dietary control was identified ($F(1.59, 15.9) = 6.98$, $p = .01$, $\eta_p^2 = .411$), with post-hoc t-tests revealing a significant improvement in dietary control between pre-intervention ($M = 4.71$, $SD = 2.58$) and post-intervention ($M = 5.88$, $SD = 2.14$) ($t_{(16)} = -3.23$, $p = .005$, $d = .478$), and between pre-intervention and follow-up ($M = 6.74$, $SD = 2.70$) ($t_{(10)} = -2.75$, $p = .020$, $d = .46$). No significant differences were found between post-intervention and follow-up dietary control ($t_{(10)} = -.762$, $p = .464$, $d = .081$). Overall, these results suggest that participants in the VGI condition experienced a significant pre-post improvement in their dietary control, which was maintained at follow-up.

Reliable Change Indices and Clinically Significant Changes. Four

participants (23.5%) were identified as having shown a reliable pre-post improvement

in their diabetes self-management scores, obtaining RCI ranging from 2.02 and 3.03

($p < .05$). Follow-up data was not obtained for two of these participants. One

participant showed a reliable improvement in their diabetes self-management score

between pre-intervention and follow-up (RCI = 2.27, $p < .05$), suggesting that the

reliable pre-post improvement was maintained at follow-up. One participant did not

show a reliable improvement in their diabetes self-management score between pre-

intervention and follow-up ($p > .05$), suggesting that the reliable pre-post

improvement was not maintained at follow-up. One additional participant did not

show a reliable pre-post improvement, but showed a reliable improvement from pre-

intervention to follow-up (RCI = 3.28, $p < .05$). Reliable improvements in diabetes

self-management were not identified in the remainder of participants in the VGI

condition (see Table R2, Appendix R).

Inspection of the DSMQ subscale scores revealed that participants in the VGI

condition did not obtain scores that indicated poor glucose management (raw score

below 5) or poor adherence to diabetes-related physician contact (raw score below 3)

at pre-intervention, and their scores remained above the clinical cut-off criteria at

post-intervention and follow-up for these two subscales. With regard to dietary

control, four participants in the VGI condition were identified as having poor dietary

control (raw score below 4) at pre-intervention. Three of those participants showed

clinically significant improvements in their dietary control at post-intervention; their

follow-up data was not obtained. One participant's scores indicated that they

experienced no clinically significant improvement in their dietary control over the course of the study.

Six participants were found to have poor levels of physical activity (raw score below 3) at pre-intervention, out of whom one participant showed a clinically significant improvement at follow-up and four participants did not show clinically significant improvement over time. Four additional participants at post-intervention and two participants at follow-up indicated that they had dropped to a suboptimal level of physical activity. One of these participants showed a clinically significant improvement from post-intervention to follow-up. However, follow-up data was not available for four participants.

Hypothesis: Glycaemic control will have significantly improved at follow-up compared to pre-intervention in the VGI condition. Due to the small sample size, a paired samples *t*-test was deemed inappropriate for assessing change in HbA_{1c}. Four out of five participants in the VGI condition showed clinically significant improvements in their HbA_{1c} between pre-intervention and follow-up, with reductions in HbA_{1c} ranging from 8 to 28mmol/mol (see Table R3, Appendix R).

Research Question 2 – Impact of interventions on process measures

Hypothesis: The MBI will be associated with increased diabetes acceptance at post-intervention and follow-up, whilst the VGI will be associated with increased valued living at post-intervention and follow-up. As shown in Table 4, the mean scores for diabetes acceptance indicated an improvement from pre-intervention to post-intervention, and from post-intervention to follow-up in the MBI condition. However, a repeated measures ANOVA identified no significant difference

in diabetes acceptance scores over time. In the VGI condition, the mean scores for valued living showed an improvement from pre-intervention to post-intervention, and from post-intervention to follow-up, although a repeated measures ANOVA did not identify a significant difference in valued living scores over time.

Research Question 3 – Associations between changes in outcome measures and process measures

Hypothesis: In the MBI group, improvement in self-reported well-being at post-intervention and follow-up will be associated with an increase in diabetes acceptance. Separate standard multiple linear regressions were performed with post-intervention and follow-up well-being as the dependent variables, and pre-intervention well-being and the pre-post change in diabetes acceptance as independent variables, in the MBI group. These two variables accounted for a significant amount of variance in post-intervention well-being (R^2 = .826, adjusted R^2 = .788; $F(2,9)$ = 21.4, $p < .001$) and in follow-up well-being (R^2 = .957, adjusted R^2 = .939; $F(2,5)$ = 55.3, $p < .001$). However, given the small sample size, the high R^2 values may indicate an overfit regression model. The partial regression coefficients showed that pre-intervention well-being was independently associated with post-intervention well-being (B = .700, β = .846, $t_{(9)}$ = 6.09, $p < .001$) and follow-up well-being (B = .832, β = .966, $t_{(5)}$ = 10.1, $p < .001$). The pre-post change in diabetes acceptance was independently associated with post-intervention well-being, after controlling for pre-intervention well-being, B = .413, β = .341, $t_{(9)}$ = 2.45, $p = .037$. The changes in diabetes acceptance between pre-intervention and follow-up was not independently associated with follow-up well-being, after controlling for pre-intervention well-being, B = .114, β = .047, $t_{(5)}$ = .491, $p = .644$.

Hypothesis: In the VGI group, improvement in self-reported diabetes self-management activities and glycaemic control at post-intervention and follow-up will be associated with an increase in valued living. The small sample size available for HbA_{1c} precluded the use of multiple regression to assess associations between changes in HbA_{1c} and changes in valued living. Separate standard multiple regressions were performed with post-intervention and follow-up diabetes self-management as the dependent variables, and pre-intervention diabetes self-management and the pre-post change in valued living as independent variables, in the VGI group. These two variables accounted for a significant amount of variance in post-intervention diabetes self-management ($R^2 = .567$, adjusted $R^2 = .505$; $F(2,14) = 9.16$, $p = .003$) and follow-up diabetes self-management ($R^2 = .523$, adjusted $R^2 = .404$; $F(2,8) = 4.38$, $p = .052$). This result may have been due to overfitting of the regression model. The partial regression coefficients showed that pre-intervention diabetes self-management was independently associated with post-intervention diabetes self-management (B = .647, β = -.005, $t_{(14)} = 4.24$, $p = .001$) and with follow-up diabetes self-management (B = .708, β = .702, $t_{(8)} = 2.86$, $p = .021$). However, post-intervention valued living was not independently associated with either post-intervention diabetes self-management or follow-up diabetes self-management, after controlling for pre-intervention diabetes self-management, $t_{(14)} = -.029$, $p = .977$, and $t_{(8)} = 1.04$, $p = .330$ respectively.

Discussion

The present study has contributed to the literature by exploring the impact of two four-week online interventions based on ACT components (mindfulness and acceptance, and values and committed action) as potential ways of addressing the

need for accessible and financially feasible psychological interventions to support individuals with insulin-treated diabetes and suboptimal glycaemic control. Differential intervention effects were hypothesised based on the proposed theoretical mapping of ACT processes on the CSM for understanding illness self-regulation (Karekla et al., 2018).

Key findings

Mindfulness-based Intervention

Karekla and colleagues (2018) suggested that ACT concepts of mindfulness, cognitive defusion and acceptance could help individuals to recognise inner experiences as they are and provide ways to deal with difficult thoughts. The present study hypothesised that diabetes acceptance could be considered a form of emotion-focused coping style that could influence emotional outcomes.

The hypothesis that individuals in the MBI group would report greater well-being and diabetes acceptance at post-intervention and follow-up, was not supported. Participants experienced non-significant improvements in their well-being and diabetes acceptance over time, with only two out of 12 participants experiencing clinically significant improvements in their well-being. As hypothesised, participants' post-intervention well-being was significantly associated with changes in diabetes acceptance, after controlling for baseline well-being. However, well-being at follow-up was only linked with participants' baseline well-being, suggesting that the impact of the MBI was not substantial enough to make a difference in the long-term.

One reason behind the non-significant association between the MBI and well-being might have been because diabetes acceptance did not significantly improve over

time. This finding contrasted with previous findings that ACT-based interventions led to improvements in diabetes acceptance (e.g. Gregg et al., 2007; Shayeghian et al., 2016; Welch, 2014; Whitehead et al., 2017). Differences in measurement may explain this discrepancy as previous studies utilised the Acceptance and Action Diabetes Questionnaire (AADQ; Gregg et al., 2007), whereas the DAS was used in the present study due its superiority as a theory-driven questionnaire (Schmitt et al., 2014). Further, a recent systematic review conducted by Medina and colleagues (2017) indicated that the impact of mindfulness-based interventions on diabetes acceptance has not yet been established and requires more controlled studies.

Another explanation for the non-significant finding in diabetes acceptance could equally have been due to the potential shortfalls in the format, content and length of the MBI. Participants reported that on average they completed less mindfulness practices than recommended, which may have reduced the impact of the intervention. Home practice can be influenced by factors such as motivation, perceived difficulty, understanding of the rationale and perceived benefits versus effort (Dunn et al., 2002). However, even brief mindfulness-based interventions have been shown to yield significant positive effects on health outcomes (Lloyd et al., 2018). A confounding factor could have been the quality of the mindfulness practices. Individuals' level of engagement with the practice could have been influenced by several factors which were not measured, including participants' prior experience of and expectations from mindfulness and factors such as levels of discipline, fatigue, stress and distractions in the environment.

Furthermore, Schmitt et al. (2018) found that the longer an individual's diabetes duration, the greater their diabetes acceptance. Given that the average

112

diabetes duration of the sample was 21.9 years, it may be that diabetes acceptance was not the appropriate target for improving well-being in this sample. In line with this, none of the participants obtained scores indicative of low diabetes acceptance and some provided feedback that they had felt that they would have benefited more from the MBI at the point of diagnosis.

Moreover, the relationships between mindfulness, diabetes acceptance and well-being are not clear cut. Some individuals with low diabetes acceptance may be less emotionally impacted by their diabetes due to the short-term relief associated with experiential avoidance (Schmitt et al., 2014). It was expected that diabetes acceptance would increase through reducing experiential avoidance, which could then improve well-being. On the contrary, facing one's experience of diabetes can result in being reminded of the possibility of complications despite good treatment adherence, which may increase awareness of difficult internal experiences around the futility of adhering to treatment and self-management strategies (McCracken et al., 2010). However, experiential avoidance was not measured so it is difficult to identify its relationship with acceptance and well-being.

It is possible that well-being did not improve because of its associations with factors other than diabetes acceptance, as it is a broad and complex construct that incorporates concepts such as positive affect, self-efficacy and gratitude (Ryan & Deci, 2001). Thus, the lack of significant findings could relate to the MBI's shortfalls in targeting individual barriers to well-being by people with diabetes. It could also have been a reflection of confounding variables that may have hindered well-being such as the impact of external factors such as the impact of COVID-19 and significant

life events that were not controlled for, as emotional and psychological needs can be greater during these periods (Diabetes UK, 2010).

Values-plus-Goals Intervention

Karekla and colleagues (2018) proposed that the ACT components of clarifying personal values, setting goals consistent with values and committing to take action enable behaviour change through empowering individuals and reinforcing why the behaviour change is important to them. It was hypothesised that individuals who took part in the VGI would report improvements in their diabetes self-management, glycaemic control and valued living following the intervention and at a four-week follow-up.

The hypotheses were partially supported. Participants showed a non-significant positive trend in their diabetes self-management, reporting improvements of medium effect size in their diabetes self-management post-intervention, which was maintained at follow-up. Interestingly, only the dietary control component of self-management significantly improved over time with three participants reporting clinically significant improvements. No significant changes were noted in participants' glucose management, physical activity or physician contact. Contrary to the hypotheses, the improvement in valued living over time was non-significant, and changes in valued living and diabetes self-management over time were not significantly associated when baseline diabetes self-management was controlled for.

Although the HbA_{1c} data was not analysed due to the small sample, four participants had reduced HbA_{1c} levels at follow-up, which was consistent with existing literature. Positive trends in glycaemic control have been identified following

114

ACT interventions, including Gregg and colleagues (2007) who found an improvement in individuals' diabetes control status. Further, the individual improvements observed appeared greater than the mean improvement observed by Winkley and colleagues (2020b) in their meta-analysis of CBT-based interventions; thus, this finding requires replication in a larger sample.

It is likely that the marginal, but non-significant improvement in diabetes self-management was due to the study being underpowered. The finding was broadly consistent with previous research which has shown improvements of small to medium effect size or a positive trend in individuals' diabetes self-management following ACT-based interventions (Gregg et al., 2007; Shayeghian et al., 2016; Welch, 2014; Whitehead et al., 2017). However, post-hoc analyses revealed that the VGI significantly improved diet alone. On the contrary, Welch (2014) found that their ACT intervention significantly increased exercise and foot care but had no impact of diet and blood glucose testing. These differences could be explained by clinical differences between the samples though, as Welch's sample had a shorter average diabetes duration of two years.

It is possible that ceiling effects prevented participants' glucose management and physician contact from improving if they were not problematic at baseline. It is also possible that improvements in diet were observed because this is an area of diabetes self-management that individuals have more control over. Examining participants' qualitative feedback in the weekly progress reviews revealed that some participants were not able to improve their physical activity due to external circumstances such as the impact of COVID-19, holiday seasons, deterioration in health and an increase in stress related to changes in life circumstances, in line with

literature on common barriers to diabetes self-management (e.g. Ahola & Groop, 2012; Vijan et al., 2004). Chew and colleagues (2018) identified three types of problems that can impact on disease control: problems with values, cognitions and emotions and/or motivation. Whilst the VGI attempted to increase valued living, it is possible that the other factors were stronger barriers in this sample; perhaps future studies need to focus more on overcoming these.

The impact of VGI needs to be investigated more robustly before causal inferences can be made due to the small sample size and confounding factors that were not controlled, such as treatment regime and motivation level. Adu and colleagues (2019) found that individuals' will to prevent diabetes complications enabled good diabetes self-management. In the present study, participants who experienced more hypoglycaemic episodes were more likely to complete the study. It may be that the potential to reduce the incidence of hypoglycaemia through improved self-management and glycaemic control was a motivating factor.

Contrary to expectations, valued living did not significantly improve over time, and there was no association between changes in diabetes self-management and valued living. This contrasted with the findings of Ryan and colleagues (2019) who reported an increase in valued living following a 10-week ACT intervention. It may be that a longer, more intensive intervention is needed for improving valued living in this population. Some participants did not spend 10 minutes connecting with their value as requested so it is possible that the task did not support participants to clarify and connect with their chosen value. Alternatively, given that participants were asked to focus on one top value and valued living was measured across 10 life domains, this may have resulted in reduced sensitivity to detect change. Focusing on valued life

domains (e.g. health, relationships) instead of valued personal characteristics (e.g. self-development, responsibility) might have influenced the results as they have shown to have differential impact (Stapel & van der Linde, 2011). The variance in individuals' SMART goals may have contributed towards the non-significant results (Schreurs et al., 2003); for example, one participant set a goal to reduce their HbA_{1c} in one month, which did not fulfil all criteria of "SMART" goals.

Strengths and limitations

The strengths of the study included successful randomisation of participants, using validated and standardised measures and inclusion of a one-month follow-up, although the long-term impact of the interventions remain unclear. As participants completed baseline questionnaires before random allocation to a condition, temporal causality could be examined, albeit with caution. The study also had several limitations. An overarching issue was the small sample sizes obtained as the observed power of the study was between .089 and .514, indicating that the study was underpowered to detect differences in outcomes over time. The increased risk of type II errors is likely to have contributed to the statistical non-significance of the findings and limits the conclusions that can be drawn from the study. The power analysis also underestimated the sample size required as the effect sizes observed in the study were smaller than predicted. Caution must be taken when interpreting the obtained effect sizes given the small sample size. The multiple linear regressions may have been affected by the problem of overfitting due to attempts to estimate multiple parameters with small samples of observations. This can lead to biased results in the form of inflated R^2 values, regression coefficients and p-values which may be misleading and specific to the analysed data set, reducing its generalisability beyond the present study

(Babyak, 2004). Further, conducting subgroup analysis and multiple analyses with small sample sizes have statistical limitations. Bonferroni corrections were not applied as the *p*-value would have been too stringent, increasing the risk of rejecting meaningful differences. However, this has implications when interpreting the findings due to the increased likelihood of type I errors (Perneger, 1998).

Besides the impact of small samples, the generalisability of the results is limited by the characteristics of the sample. The sample consisted of primarily adults with T1D (76%) fluent in spoken English, who were primarily from White ethnic backgrounds and were computer literate. Thus, it is unlikely to be representative of the T2D population and generally the wider and more diverse diabetes population. Further, the results indicated that individuals with higher levels of diabetes acceptance and well-being, and those who experience more hypoglycaemic episodes, were more likely to take part in the interventions, raising the possibility of bias, as it is possible that individuals who may be more affected by and/or motivated to improve their diabetes-related outcomes may have been captured in the study.

With regard to outcome measures, the use of self-report had limitations by increasing the risk of imprecision (e.g. for self-reported HbA_{1c} values and progress checks) and bias, which may bring the validity of the findings into question. Whilst using web-based interventions had advantages such as ease of access and reducing the need for therapist input, it also meant that factors such as participants' level of engagement, intervention compliance and attrition rates were not controlled, which may have influenced the results. The high attrition rate of 48.2% may been due to several factors based on qualitative feedback from participants, such as experiencing technical issues, feeling demotivated due to preconceived notions about the

effectiveness of an intervention incorporating mindfulness, perceiving the intervention as too intensive and no longer being able to commit to completing the intervention. Further potential confounding variables include sociodemographic characteristics, fatigue or loss of interest over time, the impact of individuals' treatment regimes, and the impact of COVID-19 in the last two months of data collection. As the interventions were designed as standalone self-help programmes, participants only received feedback via automated standardised messages built into the programmes. The lack of personalised feedback and contact with a therapist may have had an impact on participants' level of engagement and the attrition rate.

The pilot study broadly followed the MRC guidance on developing and evaluating interventions through using a theoretical basis to develop the interventions, providing clear descriptions of interventions and methodology to enable study replication and using a range of outcome measures, including process measures (Craig et al., 2008). Accessibility and acceptability of the interventions and study procedure were verified in consultation with service users. However, smaller-scale piloting to test and refine the interventions and study procedure were not conducted due to time restraints. A process evaluation was also omitted which could have helped to gain a better understanding of the impact of the interventions and contextual factors that may have influenced intervention delivery, mechanisms and outcomes (Craig et al., 2008). A process evaluation would have been helpful due to the unforeseen implementation challenges such as recruitment barriers and high attrition rates, which resulted in the assumptions about rates of recruitment and retention not being met. It would have also helped to more accurately estimate important parameters such as effect sizes, which were unknown due to the novelty of the interventions (Craig et al., 2008).

Implications and recommendations for future research

To our knowledge, this is the first pilot study to investigate the impact of interventions based on key components of the ACT model in improving the diabetes-related outcomes of individuals with insulin-treated diabetes. Despite the study limitations, the findings have contributed to the literature on implementing web-based, ACT component-based interventions generally, a relatively under-researched field. Understanding the impact of individual components can also build a better understanding of the underlying mechanisms in ACT.

Although there is a long way to go in addressing the psychosocial needs of individuals with diabetes, the pilot study indicated promising results in relation to diabetes self-management, dietary control and glycaemic control. Feedback from participants suggested that overall they found the interventions feasible, accessible and relevant. Further research is needed to determine whether the interventions have potential to reliably improve diabetes-related outcomes, which could subsequently be used to support individuals with diabetes with their health and well-being, in addition to existing treatment regimens.

The study has highlighted important avenues for future research. Firstly, it is recommended that the study is replicated with a greater sample size with a longer follow-up period to obtain the appropriate statistical power and to determine the long-term benefit of the interventions. It is important that future studies control for potential confounding variables to allow comparison of the precise impact of each intervention component on specific diabetes-related outcomes. The timing of the intervention is pertinent due to the impact of external factors such as holiday seasons, and should be considered. Further, incorporating ways of monitoring treatment

adherence such as the quality of mindfulness-based practice are recommended using standardised tools such as the Practice Quality-Mindfulness (Del Re et al., 2013) and Mindfulness Home-Practice Monitoring Form (Lloyd et al., 2018). Finally, mechanisms of change should be formally investigated to gain a better understanding of how the interventions work.

Participants' level of engagement and intervention adherence is likely to have been affected by the lack of therapist contact, feedback and support in the interventions. Goal-setting theory emphasises the role of feedback in tracking progress (Locke & Latham, 1990). Thus, personalised checks through telephone contact may enhance engagement with and adherence to the content of the intervention, as well as support reflection. However, Cavanagh and colleagues (2014) suggested that self-help programmes can be effective in their own right. Peyrot and Rubin (2007) reinforced the need for incorporating a relapse prevention plan, given that even if an intervention is brief, diabetes remains a chronic condition.

The study has highlighted the importance of considering the relevance and benefit of interventions for individuals. It is not only important to consider whom the interventions are appropriate for, but also to gain a better understanding of barriers to well-being and diabetes self-management. Targeting these may enhance the clinical benefit of the interventions. To reduce attrition, the drop-out rates highlight the importance of assessing individuals' readiness to take part in a self-help intervention by exploring and targeting potential barriers to change. This could be achieved through individuals having face-to-face conversations with a diabetes clinician as a primer, before offering a self-help intervention such as the VGI or MBI. Motivational interviewing techniques could be used to help resolve individuals' ambivalence and to

explore and address any preconceived notions about the helpfulness of psychological interventions (Rollnick et al., 2008). Furthermore, the reduced participant rates in individuals with lower hypoglycaemic episodes, lower well-being and lower diabetes acceptance suggest that these factors could be screened by clinicians using questionnaires to identify individuals who may benefit from additional support to maintain their engagement with the interventions. Individuals who experience more hypoglycaemic episodes may require more practical advice from the diabetes clinics in the first instance to improve their diabetes regime. Some researchers argue that illness perceptions can influence adjustment to diabetes, which may subsequently influence diabetes acceptance (Schmitt et al., 2014; Weinman et al., 1996). Thus, targeting illness perceptions may be a place to start for those with low levels of diabetes acceptance. However, engagement is harder to build via online platforms, so perhaps this could be something that diabetes teams offer within routine appointments.

Tailoring the interventions would increase their relevance. Karekla and colleagues (2018) suggested ways in which ACT can target all aspects of the Common Sense Model such as the role of the self-system, outlining that it was important for interventions to assess patients' cognitive and emotional representations about their condition with an emphasis on which behaviours they typically use to regulate these representations, and to support patients to understand the connections between these inner experiences, their behaviour and their adaptation to the condition. These steps were not included in either intervention due to the lack of therapist contact to support this process but could be investigated in future studies.

The implementation of web-based programmes has the potential to expand access to psychological input and to potentially improve diabetes self-management, which in turn may reduce complications and result in cost-savings for the NHS. This research could be of value to commissioners who aim to provide services that meet the psychological needs of people with diabetes.

Conclusion

Overall, the study did not support the hypothesis that the MBI would increase the well-being of individuals with insulin-treated diabetes and partially supported the hypothesis that the VGI leads to increases in diabetes self-management, although this was found to be specific to dietary control. Promising improvements were identified for glycaemic control although statistical analysis was not completed. Changes in diabetes acceptance were associated with changes in well-being in the MBI, but changes in valued living were not associated with changes in diabetes self-management in the VGI. Given the drawbacks of the interventions and study methodology, further research is necessary to gain more insight into the clinical benefits of these interventions.

IV. Integration, impact and dissemination

Integration

My interest in investigating ACT-based interventions for supporting people with diabetes stemmed from my desire to gain a better understanding of the differential impact of ACT components and the processes involved in conducting an RCT. Whilst there is a theoretical basis for supporting people with long-term conditions such as diabetes using ACT, it became apparent that this is often not available to patients due to a lack of funding and access to diabetes-specific psychological support (Askew & Solomons, 2019). The empirical study aimed to address the need for a cost-effective and feasible psychological intervention for this population by incorporating technology and the use of modular interventions to deliver ACT (e.g. Nes et al., 2012; Villatte et al., 2015).

To ensure that our adapted interventions had a theoretical basis, our hypotheses were informed by the proposed links between the ACT model and the CSM (Karekla et al., 2018). Given the lack of data on effect sizes for the chosen interventions, a pilot study was used to explore the impact of the interventions, understand potential mediating factors and establish the number of participants needed for a full RCT. Whilst pilot studies typically investigate the acceptability and feasibility of novel interventions, they can also be used to advance knowledge on the underlying mechanisms of interventions and to inform future RCTs for further effectiveness testing (Leon et al., 2011; National Institute of Mental Health, 2009).

Due to the doctoral course timetable, a focussed literature search was conducted to inform the empirical study, prior to the systematic review. On reflection, completing the systematic review earlier would have ensured that the study could address more of the issues identified. The review topic was chosen after discovering

that most of the articles in the ACT for diabetes field were similar, often employing quasi-experimental designs comparing ACT against a control condition. As no systematic review had been completed, the aim was to summarise existing literature by exploring the characteristics of ACT interventions for diabetes and examining whether ACT improves diabetes-related outcomes.

The systematic review revealed a lack of quantitative research into ACT interventions for people with T1D. This was surprising given the significant psychological burden in this population. In hindsight, I wonder if it would have been more appropriate to investigate the effectiveness of ACT in the T1D population before investigating the impact of ACT components. Nevertheless, this thesis has contributed to the ACT for T1D literature and is the first to have examined ACT components.

A challenging aspect of the systematic review was the substantial heterogeneity associated with the psychological outcomes. This made cross-study comparisons difficult and led me to conduct a narrative synthesis, which had the disadvantage of vote-counting, therefore weakening my conclusions (Siddaway et al., 2019). Promisingly, there was evidence of a beneficial effect of ACT on diabetes self-management and a mixture of psychological outcomes, particularly in T2D. This supported my choice to investigate key diabetes outcomes such as diabetes self-management, well-being and HbA_{1c}. Interestingly, the HbA_{1c} results were mixed in the systematic review. However, I noticed that the more robust studies did not find significant changes in HbA_{1c}. On reflection, the clinically significant reductions in HbA_{1c} observed in the empirical study may have been due to the methodological

issues, reinforcing the need for robust studies to ascertain the impact of ACT on HbA_{1c}.

A common theme identified in this area of research was reporting bias. To address this, I laid out the attrition and intervention details in my study transparently. The systematic review highlighted a need for high-quality RCTs with active controls that are powered to detect significant changes. As a result, I aimed to use an active control and attempted to reach an appropriate sample size. However, I underestimated levels of attrition due to lack of information in previous studies. This led to a smaller sample size than intended and an underpowered study.

The study findings suggest that modular ACT interventions may be able to improve diabetes self-management and dietary control. However, it appears that they may not be able to influence well-being, which raises the question of how we can improve this. Furthermore, diabetes acceptance and valued living did not increase significantly, suggesting that these processes may not be driving the changes observed. As the review examined ACT interventions and not ACT components, it is difficult to put the results into the context of the prevailing literature. Overall, the systematic review confirmed the novel aspects of the empirical study, which were: investigating specific ACT components, including both T1D and T2D populations, and including an active control group. These changes aimed to improve on previous studies and extend the literature with a view to facilitating real-life application.

Reflections on recruitment

Delays in receiving NHS ethics approval and time restraints of the project meant I was not able to conduct a pilot of the study procedure. Thus, I went through a

process of trial-and-error, adjusting my expectations of the project accordingly. Piloting the study would have been beneficial to gain a better understanding of recruitment challenges and to identify ways to overcome these.

There were several barriers to recruitment. One of these factors was a lack of platform to present the study to the consultants who could facilitate recruitment. In response to this, I tried to speak to them at their clinics and created a brief information pack to support recruitment. Short appointment times and high patient turnover in clinics meant that staff were limited in their ability to assist with recruitment. To enable a rapid recruitment phase, I communicated with and updated the team regularly. If funding was available, it would have been ideal to have hired a research nurse to assist in the identification of eligible participants. Furthermore, I had hoped that posters created to drive recruitment would be more effective. It is not known exactly how many people came across the empirical study via the posters.

In my original plan, I had hoped that staff would be able to facilitate recruitment in my absence; however, it became clear that my presence was required to drive recruitment. This was not always feasible due to placement commitments, and ultimately meant I was not able to attend most of the clinics in one recruitment site. As the diabetes team were not familiar with the research, they would often defer to me to introduce the project. I alleviated these issues by creating a video and PowerPoint slide that they could show to potential participants. On reflection, it would have been helpful to have collaborated with the diabetes team more to expand the sense of ownership over the project. Embedding the research into the service would increase its feasibility and help address recruitment issues, but it would also be important to consider organisational readiness and capacity for implementing research initiatives. I

hope to learn from this by involving more service users and clinicians in the development of future recruitment strategies.

My recruitment target was based on a power calculation and I found this to be feasible based on a previous study which recruited in the same diabetes clinics (Taylor, 2012). I chose to recruit people with insulin-treated diabetes as they are more commonly seen in these clinics. However, this is a small population with significant disease burden. I found that they were more likely to miss their appointments or be less open to discussions around diabetes. Due to the stringent HbA$_{1c}$ criteria, there were potential participants who were excluded despite showing an interest. In future studies, it would be beneficial to broaden inclusion criteria as feedback from participants suggested that high HbA$_{1c}$ is not necessarily representative of how an individual is coping psychologically with their diabetes.

I was aware of the need to over-recruit participants to meet the target sample size. However, delays in receiving NHS ethics approval and the reduction in clinics over the winter holidays slowed recruitment. To increase my recruitment rate, I expanded the target sample to include individuals from diabetes charity organisations. Expanding recruitment to other NHS trusts was considered but was not feasible given time restraints. Despite my best efforts, I did not achieve my target sample size. This issue is not uncommon as the target sample size for recruitment is met in 56% of RCTs (Walters et al., 2017). Through the project, I have gained a better understanding of realistic recruitment figures and gained an insight into some of the research barriers faced by people with diabetes.

Reflections on study methodology

Due to the small sample size, I was not able to statistically compare the two interventions. Furthermore, as the study was underpowered, the conclusions were based on theoretical inferences. This limits the extent to which the study findings can be interpreted. Furthermore, whilst I planned to carry out an RCT, the final design is more akin to a quasi-experimental design. To achieve the target sample size, I took a more flexible approach to the controls than planned, such as the intervention completion time, but this introduced confounding factors. Additionally, it was not easy to obtain HbA_{1c} values at follow-up as I had to rely on routine blood tests which occur every three to 12 months. In the future I hope to learn from this by altering my study design rather than reducing control, such as using pragmatic trials as an alternative to RCTs to identify implementation challenges (MacPherson, 2004).

Upon discussing my exclusion criteria with the diabetes team, it became clear that through excluding non-English speaking individuals and those without Internet access, I was losing a large proportion of the diabetes population. However, this felt necessary due to the pilot stage of research and a lack of funding to produce multi-language versions. I felt that these reasons justified the exclusion criteria, but in future research it is important to consider how to make the interventions accessible to a broader population.

To ensure that the intervention was adapted appropriately for the population, I attempted to target my intervention design to create a user-friendly experience. I ensured that participants could engage with mindfulness practice by easing them into practices that built in complexity. Nevertheless, I could have made some

improvements, such as incorporating a motivational amplifier into the VGI as it can be beneficial for individuals to imagine achieving a goal (Renner et al., 2019).

As eluded to in the prior sections, this study had a high attrition rate of 48.2% with an acceptable attrition rate in RCTs being considered <20% (Amico, 2009). This can be explained by potential barriers such as navigating the online format of the study. Participants were occasionally met with technical issues which may have increased dropout rates. In hindsight, it would have been valuable to track this data to better understand the feasibility of online ACT-based interventions. Furthermore, feedback from participants who withdrew from the study made me aware of some issues with the intervention. People saw the intervention as too much of a commitment and therefore it required additional input to keep them engaged. Interestingly, some participants appeared demotivated during the study following the introduction to mindfulness as they had preconceived notions on its effectiveness for supporting their diabetes, which could have impacted outcomes (Harvey & Lawson, 2009).

Reflections on service user involvement

The ladder of participation framework was used to evaluate the level of service user involvement (Arnstein, 1969). Due to time and resource constraints, service users were not involved in the development and completion of the systematic review; they were informed of the review when consulted about the empirical project. Whilst informing service users is considered the first step of participation, it falls within the "tokenism" category of the ladder as service users are not given the opportunity to share their views. Rutter and colleagues (2011) emphasised the need for active service user involvement in conducting systematic reviews, not only to

inform the selection of a review topic that is meaningful and relevant but also to ensure service user knowledge is considered in interpreting the findings.

The level of service user involvement in the empirical study would fall under the "consultation" category of the ladder. Attempts were made to identify service users to consult within the services where recruitment took place; however, a dedicated diabetes service user group was not available. Consequently, facilitators and members of local Diabetes UK groups were consulted regarding the relevance and acceptability of the study. As most members were older adults, I sought feedback from two young adults with T1D to ensure that the views obtained represented the age diversity of the population. Feedback was sought on draft versions of study documents, interventions and outcome measures. This resulted in improvements to the recruitment poster, adaptations to one of the interventions, and refinement of the research design.

Overall, due to course timetabling, service users had limited influence on the overall direction that the project took as this had been approved in advance. In hindsight, approaching service users prior to the development of the project proposal would have enabled more participatory involvement as captured by the "partnership" section of the ladder and encouraged co-production of the project. Further, access to funding and training would have enabled service user involvement in all stages of the research cycle as advised by the NIHR (2018). With regards to dissemination, it is planned to invite a service user involved from the earlier consultations to co-present the study findings to the diabetes team in ASPH NHS Foundation Trust at one of their internal seminars.

Impact

Clinical impact

There is a clear need for psychological interventions to support people with diabetes (Askew & Solomons, 2019). Whilst we discovered some interesting findings, the results were mostly inconclusive. However, a key area where we can comment is in the area of diabetes self-management. This aspect showed an improvement, potentially supporting future implementation of an ACT component-based intervention for diabetes self-management. As this would be a cost-effective and easy to administer intervention, this could potentially help people with diabetes to reduce their disease burden as demonstrated by a clinically significant reduction in HbA$_{1c}$ in a small number of patients. The key focus of the diabetes clinic was on individuals' physical health. The intervention may have improved individuals' awareness of their well-being as this was an area of focus for my research. Furthermore, engaging with this population helped to increase awareness of various concepts such as mindfulness and value-based living.

Improving diabetes self-management would have broader benefits for the NHS and clinicians working with this population. Self-management can ultimately reduce the economic burden of diabetes, which would mean more available resources for the NHS (Diabetes UK, 2019). Furthermore, there is a high turnover and patient load in diabetes clinics, which could be eased with the use of online interventions. Diabetes organisations may also benefit from using online interventions. As these are easier to disseminate, individuals could be directed to online interventions for their specific needs which could help to improve their outcomes. Furthermore, these

organisations run groups where individuals could come together to discuss and share any online interventions they use.

As this was a pilot study, it is unlikely that the results will influence policy makers or development of 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. Furthermore, a simple local implementation may be to introduce a screening questionnaire to identify individuals in need of psychological support regarding their diabetes. A key barrier to acting on the burden of psychological need is funding, which may be easier to address once further research is carried out.

Academic impact

The systematic review brought together the ACT for diabetes literature. As no previous review had done this, it provides future researchers with a good foundation to build on and recommendations for future research. Additionally, it will provide a reference for future work and help guide researchers when conducting studies in the T1D population.

The empirical study may draw the attention of researchers interested in diabetes as well as ACT. This is due to the relatively novel ACT component-based approach that the interventions used. Individuals interested in ACT may find valuable information on adapting ACT components for their own area of research, such as in chronic pain management where ACT is already established (Hughes et al., 2017). Furthermore, the use of online ACT-based interventions contributes to the growing

literature on technology-based interventions. By carrying out a pilot study that aimed to be robust and transparent, I have highlighted many implementation challenges and given a clear attrition rate to inform future study designs. Further robust RCTs are required to establish the effectiveness of these interventions.

Dissemination

Effective dissemination to a variety of audiences is an important pathway to maximise impact (National Institute for Health Research, 2019). Firstly, all participants will be provided with a plain English summary of the findings if they opted to receive this, as it is best practice to feedback the research outcomes towards which participants have contributed (HRA, 2018). This summary will also be provided to the local Diabetes UK groups that were consulted, through their newsletters to members. I will consult group facilitators for any suggestions about how and with whom the findings should be disseminated. The same summary will be shared with Diabetes UK, JDRF and IDDT, encouraging them to share the findings via their website and/or social media pages, such as Facebook, Twitter and LinkedIn. This is an important step as they are reputable organisations that connect with many people with diabetes, which increases the reach and potential impact of the study findings. A formal summary of the findings will be provided to the diabetes team at ASPH NHS Foundation Trust and presented at one of their internal seminars with a service user. To maximise the impact of disseminating the study findings to the diabetes team, I will ensure that I put the findings into context and highlight the recommendations that are most pertinent to their clinical practice.

The empirical study findings were disseminated via a recorded presentation to trainee clinical psychologists and staff members in the Department of Clinical

Psychology at Royal Holloway, University of London. To maximise the reach of the systematic review and the empirical study, they will be submitted to a high-quality peer-reviewed diabetes journal such as Diabetes Care or Diabetes Research and Clinical Practice for publication. Both are leading high impact journals in the diabetes field and encourage dissemination of psychosocial research. Peer-reviewed health psychology journals such as the British Journal of Health Psychology could also be considered. Alongside this, I have planned to present my empirical study as part of a symposium submission on ACT components at the UK & Ireland Association for Contextual Behavioural Science 2020 conference as this would be a good opportunity to target researchers and clinicians with an interest in ACT. A submission had been made to present the empirical study at the British Association for Behavioural and Cognitive Psychotherapies annual conference in July 2020. As the conference has been cancelled, I plan to re-submit the project once the conference is rescheduled. Through making the research widely available, it is hoped that clinicians and researchers will be encouraged to expand the ACT for diabetes literature and to consider investigating modular and online ACT-based interventions.

To evidence that effective dissemination had taken place, it would be useful to seek feedback from participants, Diabetes UK local groups, diabetes organisations and the diabetes team about the study findings' clarity, usefulness, applicability to clinical practice and/or to real-life, through a brief, open-ended questionnaire.

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VI. Appendices

Appendix A: Eligibility Criteria

	Inclusion criteria	Exclusion criteria
Design	Quantitative experimental and quasi-experimental designs	Quantitative description and correlational designs, qualitative designs, study protocols, systematic reviews, meta-analyses
Participant Characteristics	T1D or T2D, any age group, any ethnicity	Gestational diabetes, diabetes insipidus, steroid-induced diabetes, type 3 diabetes
Setting	Any	N/A
Dates	All	N/A
Language	English	Non-English
Methodology		
- **Intervention Type**	Any form of ACT-based intervention (individual, group, online) including both acceptance and commitment components	Non-ACT-based interventions, or ACT-based interventions that only include one component
- **Measure**	Diabetes-related outcomes obtained using standardised measures	Outcomes unrelated to diabetes or use of unstandardised measures

Appendix B: London – Surrey Research Ethics Committee Letter of Ethical Approval (08/08/19)

NHS
Health Research Authority

London – Surrey Ethics Committee
Nottingham Centre
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

> **Please note:** This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

08 August 2019

Ms Sophini Logeswaran
Clinical Psychology Department
Royal Holloway, University of London
Egham, Surrey
TW20 0EX

Dear Ms Logeswaran

Study title:	A pilot study to examine the effects of mindfulness versus values-plus-goals interventions for adults with diabetes treated with insulin
REC reference:	19/LO/1096
Protocol number:	N/A
IRAS project ID:	259017

Thank you for your submission of 1 August 2019 , responding to the Committee's request for further information on the above research.

The further information has been considered on behalf of the Committee by the Vice-Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

It is a condition of the REC favourable opinion that all clinical trials are registered on a publicly accessible database. For this purpose, clinical trials are defined as the first four project categories in IRAS project filter question 2. For clinical trials of investigational medicinal products (CTIMPs), other than adult phase I trials, registration is a legal requirement.

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Copies of advertisement materials for research participants [Recruitment poster and flyer]	2	11 June 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Professional Indemnity Certificate]	1	28 May 2019
GP/consultant information sheets or letters [GP letter]	1	28 May 2019
IRAS Application Form [IRAS_Form_29072019]		29 July 2019
IRAS Application Form XML file [IRAS_Form_29072019]		29 July 2019
IRAS Checklist XML [Checklist_01082019]		01 August 2019
Non-validated questionnaire [Programme Feedback Questionnaire]	1	28 May 2019
Non-validated questionnaire [Demographics and Clinical Information Questionnaire]	2	16 July 2019

Other [Mindfulness-Based Intervention Protocol]	1	28 May 2019
Other [Values-Plus-Goals Intervention Protocol]	1	28 May 2019
Other [Sponsor approval of project]	1	21 February 2019
Other [Proof of Employment as a Trainee Clinical Psychologist]	1	15 September 2017
Participant consent form [Consent Form]	2	16 July 2019
Participant information sheet (PIS) [Participant Information Sheet]	2	16 July 2019
Research protocol or project proposal [Research Protocol]	2	16 July 2019
Summary CV for Chief Investigator (CI) [CI - Summary CV]	2	13 May 2019
Summary CV for student [Sophini Logeswaran - CV]	1	13 May 2019
Summary CV for supervisor (student research) [Dr Michelle Taylor - CV]	2	
Summary CV for supervisor (student research) [Dr Jessica Kingston - CV]	2	01 April 2019
Validated questionnaire [Well-Being Questionnaire]	1	28 May 2019
Validated questionnaire [Valued Living Questionnaire]	1	28 May 2019
Validated questionnaire [Diabetes Self-Management Questionnaire]	1	28 May 2019
Validated questionnaire [Brief COPE]	1	28 May 2019
Validated questionnaire [Diabetes Acceptance Scale]	1	28 May 2019

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

19/LO/1096	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr   John Morton Broughall
Chair

Email:

Enclosures: "After ethical review – guidance for
                       researchers" *[SL-AR2]*

Copy to: Ms Jennifer Lutley

Appendix C: Health Research Authority Letter of Ethical Approval (03/10/19)

Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales

NHS
Health Research
Authority

Ms Sophini Logeswaran
Clinical Psychology Department
Royal Holloway, University of London
Egham, Surrey
TW20 0EX

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

03 October 2019

Dear Ms Logeswaran

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

Study title:	A pilot study to examine the effects of mindfulness versus values-plus-goals interventions for adults with diabetes treated with insulin
IRAS project ID:	259017
Protocol number:	N/A
REC reference:	19/LO/1096
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.

167

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 **259017**. Please quote this on all correspondence.

Yours sincerely,

Nicole Curtis

Approvals Specialist

Email: hra.approval@nhs.net

Copy to: *Miss Jennifer Lutley*

Appendix D: Ethical Approval from Research Ethics Committee at Royal Holloway, University of London (23/10/19)

Result of your application to the Research Ethics Committee (application ID 1863)

Ethics Application System <ethics@rhul.ac.uk>
Wed 23/10/2019 16:24

To: Logeswaran, Sophini (2017) <Sophini.Logeswaran.2017@live.rhul.ac.uk>; michelle.taylor@rhul.ac.uk <michelle.taylor@rhul.ac.uk>; ethics@rhul.ac.uk <ethics@rhul.ac.uk>

PI: Dr Michelle Taylor and Dr Jessica Kingston
Project title: A pilot study to examine the effects of mindfulness versus values-plus-goals interventions for adults with diabetes treated with insulin

REC ProjectID: 1863

Your application has been approved by the Research Ethics Committee.
Please report any subsequent changes that affect the ethics of the project to the University Research Ethics Committee ethics@rhul.ac.uk

Appendix E: Letter of Access from the Research and Development Department at Ashford and St Peter's Hospitals (ASPH) NHS Foundation Trust (10/10/19)

Research & Development Department

R&D Ref: 2019SL01SP

Ms Sophini Logeswaran
Clinical Psychology Department
Royal Holloway, University of London
Egham, Surrey
TW20 0EX

St Peter's Hospital

Guildford Road
Chertsey
Surrey
KT16 0PZ
Tel: 0193-272-3534
Fax: 0193-272-2841

Date: 10th October 2019

Dear Ms Logeswaran

Letter of Confirmation of Capacity and Capability at ASPH

Study title:	A pilot study to examine the effects of mindfulness versus values-plus-goals interventions for adults with diabetes treated with insulin
IRAS project ID:	259017
Protocol number:	N/A
REC reference:	19/LO/1096
Sponsor:	Royal Holloway, University of London

Thank you very much for submitting your study for R&D review. I am writing to confirm that Ashford & St Peter's Hospitals (ASPH) NHS Foundation Trust has the capacity and capability to deliver the above referenced single-site study.
The Chief Investigator will be responsible for the research activities at the site. I can confirm that no additional arrangements and agreements are required.

The R&D office has no objection to your proceeding with this study. However, the R&D Office would highly appreciate to receive final report of your study and any dissemination (s) from this work.

If you wish to discuss further, please do not hesitate to contact me.

Yours sincerely,

Freda Gomes
R&D Manager
E-Mail: Freda.Gomes@nhs.net

Cc: Dr Isaac John, Deputy Director of R&D, ASPH

Appendix F: Participants' Sociodemographic Characteristics and Pre-Intervention Scores by Group Condition

Table F1

Participants' Sociodemographic Characteristics by Group Condition

Sociodemographic Characteristics – M (SD)		MBI ($n = 12$)	VGI ($n = 17$)	Total ($n = 29$)	Test Statistic
Age		51.3 (12.5)	45.7 (18.1)	48.0 (16.0)	$t_{(24.9)} = .99$, $p = .35$[b]
Gender – n (%)	– Female	5 (41.7%)	8 (52.9%)	13 (44.8%)	$\chi^2_{(1)} = .083$, $p = .77$
	– Male	7 (58.3%)	9 (47.1%)	16 (55.2%)	
Ethnicity – n (%)	– White	12 (100%)	16 (94.1%)	28 (96.6%)	
	– Asian	0 (0%)	1 (5.88%)	1 (3.45%)	$\chi^2_{(2)} = 1.52$, $p = .47$
	– Black	0 (0%)	0 (0%)	0 (0%)	
	– Mixed	0 (0%)	0 (0%)	0 (0%)	
	– Other	0 (0%)	0 (0%)	0 (0%)	
Marital status – n (%)	– Single	0 (0%)	6 (35.3%)	6 (20.7%)	
	– Married/ Living with partner	10 (83.3%)	8 (47.1%)	18 (62.1%)	$\chi^2_{(3)} = 6.56$, $p = .08$
	– Divorced/ Separated	2 (16.7%)	2 (11.8%)	4 (13.8%)	
	– Widowed	0 (0%)	1 (5.90%)	1 (3.40%)	
Employment status – n (%)	– Working full-time	6 (50.0%)	9 (52.9%)	15 (51.7%)	
	– Working part-time	4 (33.3%)	2 (11.8%)	6 (20.7%)	$\chi^2_{(3)} = 2.62$, $p = .46$
	– Not working	1 (8.30%)	2 (11.8%)	3 (10.3%)	
	– Retired	1 (8.30%)	4 (23.5%)	5 (17.2%)	
Age leaving education (years)		19.9 (5.30)	18.5 (3.08)[a]	19.1 (4.15)	$t_{(26)} = .89$, $p = .38$
Body mass index (kg/m^2)		27.1 (4.03)	29.5 (6.38)[a]	28.5 (5.54)	$t_{(26)} = -1.14$, $p = .27$
Diabetes type – n (%)	– Type 1	9 (75.0%)	13 (76.5%)	22 (75.9%)	$\chi^2_{(1)} = .008$, $p = 1.00$
	– Type 2	3 (25.0%)	4 (23.5%)	7 (24.1%)	

		MBI	VGI	Total	Test Statistic
Diabetes duration (years)		22.3 (13.1)	21.6 (16.5)	21.9 (15.0)	$t_{(27)} = .11$, $p = .92$
Insulin treatment duration (years)		18.1 (15.5)	18.9 (17.5)	18.6 (16.4)	$t_{(27)} = -.132$, $p = .90$
Insulin treatment regime – n (%)	– Pen	8 (66.7%)	16 (94.1%)	24 (82.8%)	$\chi^2_{(2)} = 3.92$, $p = .14$
	– Pump	3 (25.0%)	1 (5.9%)	4 (13.8%)	
	– Syringe	1 (8.30%)	0 (0%)	1 (3.40%)	
Nº of insulin injections per day		4.00 (1.73)[b]	3.88 (0.62)[a]	3.93 (1.17)	$t_{(27)} = .27$, $p = .79$
Nº of hypoglycaemic episodes in last 2 months		6.08 (1.73)	6.76 (0.90)	6.48 (1.33)	$t_{(15.3)} = -1.25$, $p = .23$[c]
Diabetes complications – n (%)		5 (41.7%)	7 (41.2%)	12 (41.4%)	$\chi^2_{(1)} = .001$, $p = .98$
Other health conditions – n (%)		6 (50.0%)	9 (52.9%)	15 (51.7%)	$\chi^2_{(1)} = .024$, $p = .88$

Note. [a] Based on $n = 16$ due to missing data; [b] Based on $n = 11$ due to missing data; [c] *t*-statistic calculated without assumption of equal variances as Levene's test was significant ($p = .012$)

Table F2

Participants' Pre-Intervention Scores on Outcome Measures and Process Measures

Pre-Intervention Scores – M (SD)	MBI (n = 12)	VGI (n = 17)	Total (n = 29)	Test Statistic
DSMQ	6.79 (1.46)	6.40 (1.46)	6.56 (1.45)	$t_{(27)} = .71$, $p = .49$
W-BQ28 – Diabetes-Specific	22.8 (9.94)	19.2 (10.4)	20.7 (10.2)	$t_{(27)} = .93$, $p = .36$
HbA$_{1c}$	75.6 (7.62)[a]	77.9 (10.5)	77 (9.39)	$t_{(26)} = -.61$, $p = .55$
VLQ	51.1 (20.8)	43.3 (22.4)	46.5 (21.7)	$t_{(27)} = .95$, $p = .35$
DAS	46.1 (10.2)	40.4 (13.9)	42.8 (12.6)	$t_{(27)} = 1.20$, $p = .24$

Note. [a] $n = 11$ due to removal of outlier; DSMQ = Diabetes Self-Management Questionnaire; W-BQ28 = Well-being Questionnaire; HbA$_{1c}$ = glycated haemoglobin; DAS = Diabetes Acceptance Scale; VLQ = Valued Living Questionnaire

Appendix G: Recruitment Poster and Leaflet

ROYAL HOLLOWAY UNIVERSITY OF LONDON

NHS
Ashford and St. Peter's Hospitals
NHS Foundation Trust

PARTICIPANTS NEEDED

Acceptance and Commitment Therapy for Adults with Insulin-Treated Diabetes

What are we doing?

We would like to know whether two **computerised psychological treatments** for adults with insulin–treated diabetes can **improve health and well-being**.

Why is it important?

- Diabetes can have a detrimental impact on a person's health and well-being, which can lead to difficulties managing diabetes, and vice versa.
- Psychological interventions for people with diabetes can **improve health and well-being**, but these interventions are not always available to patients due to lack of funding.
- Computerised psychological treatments may be a **brief and more accessible** way of delivering interventions to people who may be struggling with their diabetes management.

Who do we need?

We need people who:
- Are **18 or over**
- Have **insulin-treated diabetes**
- Speak and write **English** fluently
- Have access to the **Internet**
- Have **difficulty managing diabetes**

What would I need to do?

We will ask you to fill out some questionnaires. This will take about 40 minutes. You will be asked to **complete an online intervention lasting 4 weeks**. This will involve completing some tasks (3-4 times per week) and answering some questions. You will be asked to fill out questionnaires again after 4 weeks and at follow-up one month later.

How can I take part?

If you are interested in taking part, please speak to a member of your diabetes care team to check your eligibility. They can provide you with a **participant information sheet** which gives more details about the study.

173

Appendix H: Participant Information Sheet

ROYAL HOLLOWAY UNIVERSITY OF LONDON

NHS
Ashford and St. Peter's Hospitals
NHS Foundation Trust

Participant Information Sheet

A pilot study to examine the effects of mindfulness versus values-plus-goals interventions for adults with diabetes treated with insulin

You are being invited to take part in the above research study. Before you decide, 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 your GP if you wish. Ask us 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 a need for brief and easily accessible interventions that are effective in supporting people with insulin-treated diabetes who may be experiencing difficulties managing their diabetes. To meet this need, researchers at Royal Holloway, University of London have developed two four-week psychological interventions, delivered via Qualtrics (a secure online computer programme) based on Acceptance and Commitment Therapy (ACT). ACT is an approach that is increasingly being used with people with long-term physical health conditions, including diabetes.

The aim of the study is to explore the effectiveness of two four-week interventions in improving diabetes self-management and well-being.

Why have I been chosen?

You have been given this invitation because you have diabetes treated with insulin and have expressed an interest in the study to a member of your diabetes care team. To be able to take part, you must meet the following criteria:
- Have a diagnosis of diabetes that requires insulin treatment
- Be at least 18 years of age
- Be fluent in written and spoken English
- Have access to the Internet
- Have a recent HbA1c value of 64 mmol/mol or higher

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and you are invited to get in touch with Sophini Logeswaran using the contact details at the end of this information sheet. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive. If you decide not to take part, it will not affect your care in any way.

174

What would taking part involve?

If you decide to take part in the study you will be asked to agree to the following:
1. The collection of some personal, demographic and medical information from you
2. To complete questionnaires that ask some questions about how you manage your diabetes, your well-being, your coping strategies and your values in life at the start of the study, four weeks later, and at one month follow-up
3. To allow the researchers to have access to your most recent average blood glucose level (HbA1c) and another HbA1c measurement 3 months later
4. To complete some tasks and activities via Qualtrics (a secure computer programme) 3-4 times per week for four weeks

The study is web-based and will be accessible from home, provided that you have access to the Internet. Participants will be involved in the research for a total period of 3 months and will not need to visit the diabetes clinic more than their usual care.

After reading this information sheet, you will have the opportunity to speak to Sophini Logeswaran, the Chief Investigator of the study, to check that you are eligible to take part and to receive answers to any of your questions. 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 at least one week to consider whether to take part or not. Your contact details will not be shared with anyone outside of the research team.

If you agree to take part in the study, we will collect your most recent average blood glucose level (HbA1c) from your medical notes. Three months after the start of the study (follow-up), we will ask for another HbA1c measurement to be taken from you by nurses at the diabetes clinic.

You will be provided with a computerised link to the study. You will be asked to complete some questionnaires about your wellbeing, how you feel about, manage and cope with your diabetes, and what you value in life. You can decide not to answer any question if you prefer not to. Completion of the questionnaires usually takes between 30 and 40 minutes.

After completing the questionnaires, you will be able to start the online intervention. This will involve reading the introduction to the programme, completing some tasks and answering some questions afterwards. This will take up to 20 minutes. You will then be asked to continue to do some tasks over the next week. You will be required to access the programme once a week in the four-week period (a total of four times). You will be sent an e-mail every week as a reminder. Each time, you will be asked some questions. At the end of the four-week intervention, you will be given the same set of questionnaires to complete. At follow-up, four weeks after the end of the intervention, you will be invited to fill in the questionnaires again.

In this study, we are comparing two interventions. Therefore, participants will either have access to one intervention or the other at first. Which one you are assigned is randomly selected by a computer which has no information about you. At the end of the study, you will be given access to the other intervention if you are interested in taking part in it.

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 possible that some of the questions or activities could cause distress, however this is unlikely. 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 have any queries or concerns, please contact Dr Michelle Taylor using the contact details provided at the end of the information sheet. You can also contact the Diabetes UK helpline for support from Monday to Friday, 9am to 6pm, on 0345 123 2399. If any of your responses lead us to believe that there may be a significant risk of harm to you or someone else, we will signpost you to your primary care team and contact your GP and diabetes care team, but we will endeavour to inform you first.

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. However, this cannot be guaranteed. 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 insulin-treated diabetes can be supported.

What happens when the research study stops?

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.

What if something goes wrong?

It is very unlikely that anything will go wrong. However, if you have any concerns about any aspect of the study, you can contact Dr Michelle Taylor or Dr Jessica Kingston, who are co-investigators on this project on 01784 276532 or 01784 414105.

If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, you may contact the Patients Advice and Liaison Service (PALS) at Ashford and St. Peter's Hospitals via e-mail (asp-tr.patient.advice@nhs.net) or phone (01932 723553). More information about PALS can be found on their website: http://www.ashfordstpeters.nhs.uk/patients/support-and-facilities/pals

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 complete 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 your agreement, your consultant/GP will be informed of your participation and given an information sheet about the study, but will not have access to the responses you write in the questionnaires. Your blood glucose levels routinely collected by the diabetes clinic will be

made available to your diabetes physician.

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?

It is 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 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 Sophini Logeswaran, a Trainee Clinical Psychologist as part fulfillment of her doctorate in clinical psychology. The project has been organised in collaboration with Dr Michelle Taylor and Dr Jess Kingston from the Department of Clinical Psychology in Royal Holloway, University of London, and Dr Thang Han and Dr Helen Ward who are both doctors at the Diabetes Outpatient Department at Ashford and St. Peter's Hospitals.

The doctors 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 an NHS Research Ethics Committee 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 Sophini Logeswaran.

RHUL will collect information from you and Ashford and St Peter's Hospitals (ASPH) NHS

Foundation Trust will collect information from your medical records 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. ASPH NHS Foundation Trust will pass these details to RHUL along with the information collected from you and your medical records. 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. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

RHUL will collect information about you for this research study from ASPH NHS Foundation Trust. 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 as outlined in the participant information sheet.

Contacts for Further Information

If you require additional information, please contact Sophini Logeswaran and leave a message identifying this specific project at the beginning of the message:

Tel.: 07308151990
E-mail: act-for-diabetes@outlook.com
Address: Department of Clinical Psychology, Royal Holloway, University of London, Egham Hill, Egham, Surrey, TW20 0EX

Or, alternatively you may wish to contact:
Dr Michelle Taylor   Dr Jessica Kingston
Tel.: 01784 276532   Tel.: 01784 414105
E-mail: michelle.taylor@rhul.ac.uk   E-mail: jessica.kingston@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 01932 723533, or e-mail asp-tr.patient.advice@nhs.net.

Thank you for reading this. We hope you agree to take part in this study and get in touch with Sophini.

You will be sent an electronic copy of this information sheet and a signed consent form to keep for reference and in case you wish to contact us with any queries.

Appendix I: Consent Form

ROYAL HOLLOWAY UNIVERSITY OF LONDON

Ashford and St. Peter's Hospitals **NHS**
NHS Foundation Trust

Consent Form

Title of Project: A pilot study to examine the effects of mindfulness versus values-plus-goals interventions for adults with diabetes treated with insulin

Researchers: Ms Sophini Logeswaran, Dr Michelle Taylor, Dr Jessica Kingston, Dr Helen Ward & Dr Thang Han

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 my medical care or legal rights being affected. ☐

4. 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. ☐

5. I understand that I will be randomly assigned to one of two interventions. I understand this will involve completing brief exercises 3-4 times a week via Qualtrics (a secure computer programme), and logging into the programme every week and answering some questions, for a total period of four weeks. I agree to take part in the study. ☐

6. I understand that I will be asked to complete five questionnaires about my diabetes self-management and wellbeing at three time-points: at the start of the study, after the study and at a one-month follow-up.
I agree for my average blood glucose level (HbA1c) to be recorded at the start of the study and three months later. ☐

7. I agree to my 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: ....
.... ☐

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

FOR REFERENCE ONLY. Please get in touch with Sophini (Chief Investigator) using the contact details on page 5 to take part in the study.

Appendix J: Sociodemographic Questionnaire

Age (in years): _____

Gender:

○ Male

○ Female

○ Other

○ Prefer not to say

Ethnicity:

○ White: British

○ White: Irish

○ White: Other

○ Asian or Asian British: Indian

○ Asian or Asian British: Pakistani

○ Asian or Asian British: Bangladeshi

○ Asian or Asian British: Chinese

○ Asian or Asian British: Other

○ Black / African / Caribbean / Black British: African

○ Black / African / Caribbean / Black British: Caribbean

○ Black / African / Caribbean / Black British: Other

○ Mixed: White & Black Caribbean

○ Mixed: White & Black African

○ Mixed: White & Asian

○ Mixed: Other

○ Other

Display This Question:
If Ethnicity: = Other

If you selected 'Other', please state your ethnicity:

_____

Marital status:

- ○ Married or living with partner
- ○ Divorced or separated
- ○ Widowed
- ○ Single

Are you in full-time education?

- ○ Yes
- ○ No

If 'no', please give your age (years) at leaving full-time education:

_____

Please indicate your employment status below:

- ○ Working full-time
- ○ Working part-time: due to diabetes complications
- ○ Working part-time: due to other health problem
- ○ Working part-time: because cannot find full-time work
- ○ Working part-time: by choice
- ○ Not working: due to diabetes complications
- ○ Not working: due to other health problem
- ○ Not working: because cannot find work
- ○ Not working: by choice
- ○ Not working: due to another reason, please state: _____
- ○ Retired: early due to diabetes complications
- ○ Retired: early due to other health problem
- ○ Retired: early by choice
- ○ Retired: at the usual retirement age for my work

If applicable, please indicate your current or most recent occupation below:

_____

Please provide your height and select your unit of choice (centimetres or feet and inches) in the drop-down menu:

	centimetres	feet and inches
Height _____	○	○

Please provide your weight and select your unit of choice (kilograms or stones and pounds) in the drop-down menu:

	kilograms	stones and pounds
Weight _____	○	○

Have you ever smoked cigarettes?

○ Yes

○ No

Display This Question:
    If Have you ever smoked cigarettes? = Yes

If 'yes', how many cigarettes do you now smoke? (per day)
_____

Display This Question:
    If Have you ever smoked cigarettes? = Yes

If you have stopped, how many cigarettes did you use to smoke? (per day)
_____

Display This Question:
    If Have you ever smoked cigarettes? = Yes

If you have stopped, how long ago did you stop?

○ Years _____

○ Months _____

Do you drink alcohol?

○ Yes

○ No

Display This Question:
    If Do you drink alcohol? = Yes

If 'yes', how many units of alcohol do you drink in an average week?
(1 unit = small glass of wine / half pint of beer / single measure of spirit)
_____

How long ago was your diabetes diagnosed?

○ Years _____

○ Months _____

For how long have you been using insulin?

○ Years _____

○ Months _____

How do you take your insulin each day?

☐ Insulin syringe

☐ Insulin pump

☐ Insulin pen

☐ Other

How many times a day do you take insulin?

_____

Which insulin(s) do you take?

☐ Humalog

☐ Lantus

☐ Levemir

☐ Novorapid

☐ Actrapid

☐ Humulin

☐ Hypurin

☐ Insuman

☐ Insulatard

☐ Other

Do you have any complications of diabetes?

○ Yes

○ No

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

☐ Diabetic eye disease

☐ Kidney problems

☐ Heart problems

☐ Circulatory problems

☐ Foot problems

☐ Nerve problems

☐ Other complication(s), please state: _____

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

○ Every day (approx. 60 days)

○ Most days (50 to 59 days)

○ Often (40 to 49 days)

○ Fairly often (30 to 39 days)

○ Sometimes (20 to 29 days)

○ Occasionally (10 to 19 days)

○ Rarely (1 to 9 days)

○ Not at all (0 days)

Do you have any other health problems not previously mentioned?

○ Yes, please state: _____

○ No

Please list any medication(s) you are currently taking:
_____
_____
_____

Thank you for your responses.

Next, we would like you to fill in some questionnaires.

Appendix K: 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

186

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: Diabetes Self-Management Questionnaire (DSMQ)

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: Diabetes Acceptance Scale (DAS)

Diabetes Acceptance Scale (DAS)

The following statements describe attitudes and behaviours regarding diabetes. Please think of your personal attitudes and behaviours during the last two weeks and indicate to which extent each statement is true for you.	Never true for me	Some-times true for me	Often true for me	Always true for me
1. I have accepted having diabetes.	0	1	2	3
2. I give diabetes the necessary space in my life.	0	1	2	3
3. Diabetes is a normal part of my life.	0	1	2	3
4. Living with diabetes is part of me.	0	1	2	3
5. I ensure that my diabetes treatment works well.	0	1	2	3
6. I accept diabetes as part of my life.	0	1	2	3
7. I am motivated to treat my diabetes properly.	0	1	2	3
8. I integrate diabetes into my daily routines as well as possible.	0	1	2	3
9. I fully accept living with diabetes.	0	1	2	3
10. I take good care of my diabetes.	0	1	2	3
11. I suffer from having diabetes.	0	1	2	3
12. When I think about having to live with diabetes, I feel low/depressed.	0	1	2	3
13. I often ignore diabetes.	0	1	2	3
14. I refuse to accept diabetes as part of my life.	0	1	2	3
15. Diabetes contributes to being dissatisfied with my life.	0	1	2	3
16. I avoid dealing with topics related to diabetes.	0	1	2	3
17. I avoid things which remind me of diabetes.	0	1	2	3
18. Living with diabetes makes me sad/depressed.	0	1	2	3
19. I have difficulties to motivate myself to perform good diabetes self-care.	0	1	2	3
20. I neglect diabetes self-care because I want to avoid topics related to diabetes.	0	1	2	3

189

Appendix N: Valued Living Questionnaire (VLQ)

Valued Living Questionnaire-1

Below are areas of life that are valued by some people. We are concerned with your quality of life in each of these areas. One aspect of quality of life involves the importance one puts on different areas of living. Rate the importance of each area (by circling a number) on a scale of 1 to 10. 1 means that area is not at all important. 10 means that area is very important. Not everyone will value all of these areas, or value all areas the same. Rate each area according to your own personal sense of importance.

Area	not at all important									extremely important
1. Family (other than marriage or parenting)	1	2	3	4	5	6	7	8	9	10
2. Marriage/couples/ intimate relations	1	2	3	4	5	6	7	8	9	10
3. Parenting	1	2	3	4	5		7	8	9	10
4. Friends/social life	1	2	3	4	5	6	7	8	9	10
5. Work	1	2		4	5	6	7	8	9	10
6. Education/training	1		3	4	5	6	7	8	9	10
7. Recreation/fun	1	2	3	4	5	6	7	8	9	10
8. Spirituality	1	2	3	4	5	6	7	8	9	10
9. Citizenship, community life	1	2	3	4	5	6	7	8	9	10
10. Physical self-care (diet, exercise, sleep)	1	2	3	4	5	6	7	8	9	10

In this section, we would like you to give a rating of how consistent your actions have been with each of your values. We are not asking about your ideal in each area. We are also not asking what others think of you. Everyone does better in some areas than others. People also do better at some times than at others. We want to know how you think you have been doing during the past week. Rate each area (by circling a number) on a scale of 1 to 10. 1 means that your actions have been completely inconsistent with your value. 10 means that your actions have been completely consistent with your value.

During the past week:

Area	not at all consistent with my value							completely consistent with my value		
1. Family (other than marriage or parenting)	1	2	3	4	5	6	7	8	9	10
2. Marriage/couples/ intimate relations	1	2	3	4	5	6	7	8	9	10
3. Parenting	1	2	3	4	5	6	7	8	9	10
4. Friends/social life	1	2	3	4	5	6	7	8	9	10
5. Work	1	2	3	4	5	6	7	8	9	10
6. Education/training	1	2	3	4	5	6	7	8	9	10
7. Recreation/fun	1	2	3	4	5	6	7	8	9	10
8. Spirituality	1	2	3	4	5	6	7	8	9	10
9. Citizenship/community life	1	2	3	4	5	6	7	8	9	10
10. Physical self-care (diet, exercise, sleep)	1	2	3	4	5	6	7	8	9	10

Appendix O: Programme Feedback Questionnaire

We are interested in your experiences of the online ACT programme and would be grateful for your feedback.

How helpful did you find the programme, on a scale of 1 to 10 where 1 means 'not at all' and 10 means 'very helpful'?

   ○ 1   ○ 2   ○ 3   ○ 4   ○ 5   ○ 6   ○ 7   ○ 8   ○ 9   ○ 10

How satisfied were you with the length of the programme, on a scale of 1 to 10 where 1 means 'very dissatisfied' and 10 means 'very satisfied'?

   ○ 1   ○ 2   ○ 3   ○ 4   ○ 5   ○ 6   ○ 7   ○ 8   ○ 9   ○ 10

How relevant did you find the programme, on a scale of 1 to 10 where 1 means 'not at all relevant' and 10 means 'very relevant'?

   ○ 1   ○ 2   ○ 3   ○ 4   ○ 5   ○ 6   ○ 7   ○ 8   ○ 9   ○ 10

Would you recommend the programme to a friend with diabetes?

   ○ Yes

   ○ No

How easy did you find it to use the programme, on a scale of 1 to 10 where 1 means 'not easy at all' and 10 means 'very easy'?

   ○ 1   ○ 2   ○ 3   ○ 4   ○ 5   ○ 6   ○ 7   ○ 8   ○ 9   ○ 10

Did you experience any difficulties when using the programme?

   ○ Yes

   ○ No

Display This Question:
   If Did you experience any difficulties when using the programme? = Yes

If 'yes', please expand:
_____

Please leave any other comments below:
_____

End of Block: Programme Feedback Questionnaire

Appendix P: Values-plus-Goals Intervention Protocol

What are Values?

In this self-help package, we would like to introduce you to the idea of values.

Values are what matter to you in the big picture of your life, what you want to stand for in life, the personal qualities you want to develop. They are the things that are most important to you, deep down inside.

Values are like a compass. Compasses can guide you through journeys by giving you direction and keeping you on track when you are travelling. Values do the same for our journey through life. We use them to choose the direction in which we want to move in and to keep us on track as we go.

Values are guiding principles in life. They are unique for each person, and there are no right or wrong values.

Values and Diabetes Care

Managing your diabetes is important for your health and well-being. Identifying your values (what really matters to you in life) can help you to make choices that support diabetes self-management, which in turn can help you to lead a rich, meaningful and fulfilling life alongside diabetes.

The aim of the next section is to help you think about your values using a short exercise.

Your Values

Below are areas of life that are valued by some people. These will mean different things to different people, and that's fine, we just want you to think about what they mean to you. There may be areas you don't value much, and that's fine too.

You are going to be shown a series of cards on the computer and we would like you to sort the cards into three piles - 'very important', 'quite important' or 'not important'. You do this by clicking on, dragging and dropping the card into the relevant pile with your mouse. If you have a value that isn't shown on one of these cards, you can write it in the 'Other' option at the bottom of the cards.
As you do this card sorting task, try to think about:

· *What is important to you deep down?*
· *What do you want your life to stand for?*
· *What do you most care about?*
· *What would you like to work towards?*

As you complete this exercise, you may find some areas in which you have not been living in line with your values as much as you would like. That's very normal, people often feel this way. The aim of this exercise is to help you identify your values so you can then decide where to begin working towards your most important value.

Items

Health/Self-care (eg. diet, exercise)
development

10 / 10

VERY IMPORTANT TO ME

QUITE IMPORTANT TO ME

NOT IMPORTANT TO ME

From the list of values that you identified as 'very important', choose one value that is most important and meaningful to you. You may have several that are very important and meaningful. For the purposes of this task, we would like you to focus on just one. There are no right or wrong answers.

My top value is:

You chose '${q://QID204/ChoiceTextEntryValue}' as your top value.

Please use the space below to describe why this value is important and meaningful to you. Think about a time in your life that this was particularly important to you and made you feel good about yourself. Write as much or as little as you wish and don't worry about how well it's written. Just focus on expressing your memory of the event(s) and the feelings that you had at the time.

Please do your best to think and write about this event and your feelings about this value for the next 10 minutes. However, it's OK if you complete the task before the 10 minutes is up.

Please rate the following statements from 1 (strongly disagree) to 6 (strongly agree) by dragging the circle across the line with your mouse:

	Strongly disagree						Strongly agree
	0	1	2	3	4	5	6
This value or personal characteristic is relevant to me.	O						
In general, I try to live up to this value.	O						
This value is an important part of who I am.	O						
I care about this value.	O						

Using values to improve your diabetes self-care

Values can help us make choices in day to day life and to set ourselves goals that are deeply personal and meaningful to us. So, values are guiding principles in life and goals are specific actions or behaviours, which can be achieved.

Doing things that are important to us can be hard. Managing diabetes can be hard. People find that using their values can help them achieve thing that are difficult in life, such as looking after your health.

We would now like you to set a short-term goal. We would like this to be a goal that relates to your diabetes self-management AND that links in with the value you selected as being most important to you. This is a goal that we will ask you to focus on over the next month

Here are some examples to help you with this task:

Example 1:
A person who selected 'parenting' as a top value might decide that they want to play more with their children. Their diabetes goal might be to improve their fitness by walking each day for 20 minutes, or to do some light exercise a few times a week.

Example 2:
A person who selected 'health' as a top value might decide they want to take better care of themselves. The diabetes related goal might be to improve their diet by eating three healthy meals per day and cutting down on sugary snacks.

Example 3:
A person who selected 'education and growth' as a top value might decide they want to find new opportunities to learn and grow as a person. The diabetes-related goal may be to join a patient education group for people with diabetes, or to access online resources and books to find out more about diabetes and strategies for improving self-management.

Ideally, you want to set a **'SMART' goal**. As you think of your goal, try to think of something that is specific (e.g. what exactly you want to accomplish), measurable, realistic, with a time frame and achievable in the time frame.

196

My Self-Care Action Plan

My top value is: ${q://QID204/ChoiceTextEntryValue}

My diabetes-related goal associated to my top value is:
(What do you want to achieve? For example: 'To eat three healthy meals a day')

Please ensure that your goal is short-term and achievable over the next month.

In order to reach my goal, I will do the following activities:
(How will you achieve it? For example: 'I will plan my meals in advance', 'I will eat more whole grain food')

Is the goal specific and achievable in the next month?

○ Yes ○ No

Is the goal consistent with your identified value?

○ Yes ○ No

Is the goal relevant to your diabetes self-management? If no, please revise your goal.

○ Yes ○ No

When we set ourselves goals, it is very common for things to get in the way. This might be external barriers such as practical issues (e.g. bad weather, finances) or internal barriers (e.g. how we feel, our physical symptoms or thoughts we are having).

What barriers may get in the way of you acting on your chosen value-based goal?

What can you do to help overcome the above barriers?

Please make a note of your goal on a piece of paper or anywhere that is a personal reminder of the goal. You will also be sent a copy of your answers via e-mail.

Thank you for doing this exercise. The next four weeks of the programme will focus on monitoring your progress towards achieving your goal. We will send you a reminder to log in again next week and check your progress.

Your unique 5-digit Login ID is: ${e://Field/ExternalDataReference}

Weekly Progress Check Example in the Values-plus-Goals Intervention

WEEK 1: Progress check and reconnecting with your chosen value

Welcome back!

In Week 1, we introduced values and how they can help you make choices that support your diabetes self-care. You then set a goal for the following month to help you move towards the value that you identified as most important and meaningful to you.

Your chosen value was:

${e://Field/Value}

Why is this value important and relevant to your diabetes care?

Your chosen goal was:

${e://Field/Goal}

Have you been able to move towards your goal?

○ Yes ○ No ○ Not applicable

Please describe how you have moved towards your goal, what barriers you faced, what you have learned and what your hopes and goals are for next week to continue your progress.

Please describe what barriers you faced, what you can do to overcome them, and your hopes and goals are for next week to move towards your goal.

Please describe why this goal or task is/was not applicable. Can you think of another goal or task that is achievable in the next three weeks?

Appendix Q: Mindfulness-based Intervention Protocol

What is Mindfulness?

In this self-help package, we would like to introduce you to the idea of mindfulness.

Mindfulness means paying attention to our experiences in the present moment, in a particular way and without judgment.

It can be easy to rush through life without stopping to notice much. Some people call this being in the 'auto-pilot' mode. Mindfulness helps us become more aware of our thoughts, feelings and body sensations in the moment. This increased awareness can help us to respond to situations with increased choices and in line with what is important to us, rather than responding automatically.

There are many ways to be mindful and often we can be mindful throughout the day without realising it. By simply being aware of or noticing a sensation, you are being mindful in that moment. For example, paying attention to the sounds around you as you walk around. There are also specific exercises that aim to promote mindfulness. There is no right or wrong way to be mindful.

Mindfulness and Diabetes

Managing diabetes can be challenging for some people. Sometimes our thoughts and feelings about diabetes, or physical symptoms, can get in the way of us doing what is important to us.

Trying to get rid of or control unpleasant thoughts and feelings, or physical symptoms associated with diabetes, is very understandable. If we could just get rid of them or control them, we'd be able to get on with things. But unfortunately it doesn't usually work like that. If we try not to think about something, it usually ends up being in our thoughts more.

Mindfulness Meditation Exercise

The aim of this exercise is to increase your mindful awareness of your thoughts, feelings and body sensations, particularly in relation to your diabetes, and to practise making room for any difficult experiences that arise.

Remember one of the key features of mindfulness is that it is non-judgmental. Therefore, there are no right or wrong ways to be mindful. However, mindfulness is a skill and often people find that with regular practice, it becomes easier to be mindful over time.

Please click play ▶ to access and listen to the 10-minute mindfulness exercise now.
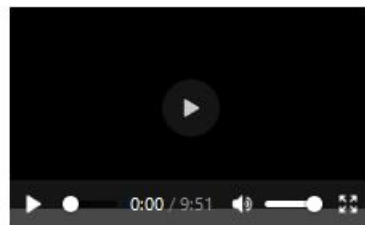
If you are having difficulty playing the clip, please e-mail Dr Michelle Taylor (michelle.taylor@rhul.ac.uk) for assistance.

Please press 'Next' once the exercise is finished.

Actively reflecting on our experiences of mindful practice is helpful in maximising the benefits of the practice. The space below gives you an opportunity to write down any reflections you had during and following this practice, with some questions to help you reflect. Please feel free to write as little or as much as you want - this is purely for your own use and we will not be analysing this as part of the study.

What was your experience like? What interested you the most?

What sensations, feelings, thoughts and symptoms were you aware of during this exercise?

What was the effect of observing them without struggling and breathing into and around 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?
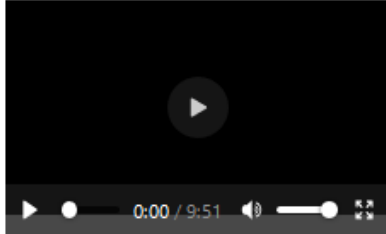
What relevance could this exercise have to your life and the way you manage your diabetes?

You will receive a link to the mindfulness practice via e-mail.

Optional:
If you would like to save the file on your device for easy access to the meditation exercise, follow the instructions below.

1. Please right-click the video below with your mouse:

2. Select the **'Save Video'** option in the menu that appears
3. **Select a location** where you would like to save the file, such as your Documents folder, Downloads folder, Music folder or Desktop, for example.
4. Select **'OK'** or **'Save'** when you are ready. Please check your chosen location to see if the file was saved.

Task for the next month

Thank you for your responses.

There is no right or wrong way to practise mindfulness. What we know is that most people find it easier and more helpful, the more they practise. We recommend that you practise this exercise 3-4 times a week over the next month. This will make it easier to use the skills when you experience unpleasant thoughts, feelings, or unpleasant symptoms.

Another link will be sent via e-mail in one week to check your progress with the mindfulness task.

Your unique 5-digit Login ID is: ${e://Field/ExternalDataReference}

'We are about to begin a 10-minute mindfulness meditation exercise. Mindfulness means paying attention, fully, to the here and now. During mindfulness we try to be open and curious about all our experiences, to welcome in experiences, even if they are difficult experiences.

It is pretty common for people to experience negative thoughts and feelings, and unpleasant physical sensations, in relation to their diabetes, such as anger, frustration, anxiety and low mood. Negative thoughts might be around not wanting to measure your blood glucose levels or of feeling that diabetes gets in the way of the things you would like to be doing, for example. Becoming mindful encourages a kind, non-judgmental attitude towards yourself, to not turn away, but to tolerate those unpleasant feelings if they arise. Mindfulness teaches you to release these thoughts and feelings, and to let them go. It teaches us to be gentler with ourselves.

The aim of this exercise is to increase your mindful awareness of your thoughts, feelings and body sensations, particularly in relation to your diabetes, but also in relation to other aspects of life that might be challenging for you right now, and to practise making room for any difficult experiences that arise.

I invite you now to sit up straight, let your shoulders drop and gently push your feet into the floor … and get a sense of the ground beneath you … and you can either fix your eyes on a spot, or close them, whichever you prefer …

And because it's so easy to get caught up with what's going on in our minds, we always begin mindfulness by bringing our attention to our bodies.

And to do this it can be helpful to bring attention to a point of contact. So bringing attention, now, to the soles of your feet. Noticing any sensations at all in this part of your body. Perhaps noticing sensations of pressure, temperature. Maybe noticing tingling sensations that move around and come and go.

Now continuing this focus in your body, bringing your attention up very deliberately through your body, up through your legs, through the pelvic area, into your tummy and back, up into your shoulders… Just noticing whatever sensations are in your body, right now.

You're not trying to make yourself relaxed, just being aware of what you're experiencing, right now, in your body. … You might find there are some parts of your body where you don't notice any sensations at all. That's fine, that's absolutely normal.

Bringing your attention up through your neck, just checking that your neck is aligned with your spine, supporting your head. And bringing awareness up into your head and jaw, face and scalp. Again, perhaps not being able to notice sensations in this part of your body. Which is fine.

And now bringing your attention to the sensations in your body as you sit here, breathing. It can help to do this by finding a place where you can most easily notice the sensations of breathing in and breathing out. Resting your attention, wherever you notice the sensations of the breath in the body. Most comfortably, most vividly. You may choose to focus on the rise and fall of your tummy or your chest, or you may prefer to focus on the air moving in and out through the tips of your nostrils.

Not trying to change or control your breathing in any way, not trying to make it slower or deeper. Mindfulness is about experiencing things just as they are … one breath just as it is.

You may find that your attention moves naturally to other things. You may notice feelings, thoughts, images, urges, or sensations arise, come into your awareness. As best you can, for these few minutes, see if you can allow them to come fully into your awareness. Whether pleasant or unpleasant, comfortable or uncomfortable, see if you can gently acknowledge them, as if nodding your head at people passing by you on the street. Gently acknowledge their presence and let them be. … Allow them to come and go as they please, and keep your attention on the breath …

From time to time, your attention will wander as you get caught up in your thoughts. Each time this happens, notice what distracted you, then bring your attention back to the breath. … No matter how often you drift off, whether a hundred times or a thousand—your aim is simply to note what distracted you and to refocus on your breath …

Again and again and again, you'll drift off into your thoughts, feelings, sensations, etc. This is absolutely fine and absolutely normal. It happens to everyone. Our minds naturally distract us from what we're doing. So each time you realize your attention has wandered, gently acknowledge it, notice what distracted you, and gently bring your attention back to the breath.

As this exercise continues, you may notice that the feelings and sensations in your body change. … There may be times when pleasant feelings showing up—you may feel relaxed, calm, peaceful… There may also be times when unpleasant ones arise, such as boredom, frustration, anxiety, or backache. See if you can allow these experiences to be exactly as they are in this moment. … Don't try to control them, just let them be as they are—regardless of whether they are pleasant or unpleasant—and keep your attention on your breathing. … Again and again, you'll drift off into your thoughts. When you notice this, as gently as you can, bring your attention back on your breath. … This is not a relaxation technique. The aim is to let your feelings be as they are, to feel whatever you feel without a struggle. … Because struggling often does not help, and might amplify feelings … So if you're noticing a difficult feeling, then silently say to yourself, 'Here's a feeling of frustration' or 'Here's a feeling of anxiety' or 'Here's a feeling of boredom'. … As you're observing a feeling, breathe into it ... Imagine your breath flowing into and around this feeling ... And as you're breathing into it, it's as if, in some magical way, all this space opens up inside you ... You open up around this feeling ... Make space for it ... Expand around it ... However you make sense of that ... Breathing into it and opening up around it ... And see if you can just allow this feeling to be there. You don't have to like it or want it ... Just allow it ... Just let it be.

And now as you come to the end of your practice, bringing your awareness back to the body, the sensations at the point of contact of your body on the chair, or wherever you are sitting. Awareness of the room around. Bringing the attention, as best you can, to bring your more open, spacious awareness to the next moments of your day.

When you feel ready open your eyes if they have been closed, and back into the room.'

Weekly Progress Check Example in the Mindfulness-based Intervention

WEEK 1: Progress check and continuing mindfulness practice

Welcome back!

In Week 1, we introduced mindfulness (paying attention to our experiences in the present moment, without judgment) and completed a mindfulness practice. We encouraged you to practise this 3-4 times over the week.

How many days did you practise the mindfulness exercise over the past week?

Did you have any reflections following this week's practice? How was your experience - the same or different from the first time you did it?

What was the effect of observing sensations, feelings, thoughts and symptoms without struggling and breathing into and around them?

What relevance could this exercise have to your life and the way you manage your diabetes?

Appendix R: Reliable Change Indices for Well-Being and Diabetes Self-Management, and Raw Differences in HbA$_{1c}$ Values

Table R1

Reliable Change Indices for Well-Being and Diabetes Self-Management in the Mindfulness-Based Intervention

	Reliable Change Indices across Time Points					
	Well-being			Diabetes self-management		
Participant	T1 - T2	T2 - T3	T1 - T3	T1 - T2	T2 - T3	T1 - T3
P1	-0.190	0.190	0.000	-1.009	-0.252	-1.261
P2	0.000	-0.190	-0.190	-0.757	1.009	0.252
P3	0.000	0.380	0.380	0.000	1.513	1.513
P4	-0.380	N/A	N/A	0.000	N/A	N/A
P5	**2.092***	N/A	N/A	-0.252	N/A	N/A
P6	**2.472***	-1.331	1.141	**2.270***	-0.757	1.513
P7	0.380	-0.761	-0.380	0.504	-0.504	0.000
P8	-0.571	0.761	0.190	-1.261	0.000	-1.261
P9	0.761	-0.380	0.380	0.504	0.757	1.261
P10	-0.571	1.331	0.761	**2.270***	-0.252	**2.018***
P11	-0.571	N/A	N/A	1.009	N/A	N/A
P12	0.000	N/A	N/A	1.009	N/A	N/A

Note. * $p < .05$

Table R2

Reliable Change Indices for Well-Being and Diabetes Self-Management in the Values-plus-Goals Intervention

	Reliable Change Indices across Time Points					
	Well-being			Diabetes self-management		
Participant	T1 – T2	T2 – T3	T1 – T3	T1 – T2	T2 – T3	T1 – T3
P13	-0.182	N/A	N/A	-1.261	N/A	N/A
P14	1.635	N/A	N/A	1.766	N/A	N/A
P15	-0.182	0.182	0.000	0.757	-0.252	0.504
P16	0.182	0.182	0.363	-0.252	0.000	-0.252
P17	-0.909	-0.363	-1.272	-1.261	-0.252	-1.513
P18	0.363	N/A	N/A	**2.018***	N/A	N/A
P19	-0.727	0.363	-0.363	0.504	-0.252	0.252
P20	**2.726***	N/A	N/A	1.009	N/A	N/A
P21	0.000	-0.909	-0.909	0.757	0.252	1.009
P22	0.545	1.272	1.817	**3.027***	-0.757	**2.270***
P23	-0.182	1.454	1.272	**2.018***	-0.504	1.513
P24	-0.182	0.182	0.000	0.757	0.252	1.009
P25	0.363	0.000	0.363	1.766	1.513	**3.279***
P26	-1.090	0.545	-0.545	-0.252	-0.252	-0.504
P27	1.635	N/A	N/A	**2.018***	N/A	N/A
P28	0.363	0.363	0.727	0.504	0.500	1.005
P29	0.909	N/A	N/A	0.504	N/A	N/A

Note. * $p < .05$

Table R3

Raw Difference in HbA$_{1c}$ Values across Both Conditions [a]

Condition – Participant	Pre-Post Change in HbA$_{1c}$ (mmol/mol)
VGI – P1	–9*
VGI – P2	–28*
VGI – P3	+1
VGI – P4	–14*
VGI – P5	–8*
MBI – P3	+5
MBI – P5	-15*

Note. [a] Data is only reported for participants whose follow-up HbA$_{1c}$ was obtained; + and – symbols indicate an increase and decrease in HbA$_{1c}$ value respectively; * Clinically significant change (>5.5 mmol/mol)