Title: Feasibility of MyHealthAvatar mobile phone application for reducing prolonged sedentary behaviour in Type 2 diabetes

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Feasibility of MyHealthAvatar mobile phone application for reducing prolonged sedentary behaviour in Type 2 diabetes

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Declaration of Authorship

I Lucie Mugridge declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

Feasibility of the MyHealthAvatar mobile phone application for reducing prolonged sedentary behaviour in Type 2 diabetes

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Abstract

Objective: Time spent in a prolonged sedentary state can have detrimental health effects in people with Type 2 diabetes mellitus (T2DM). The aim of this study was to assess the feasibility of a mobile phone app, MyHealthAvatar, for reducing prolonged sedentary behaviour in people with T2DM. **Methods:** Twelve individuals with recently diagnosed T2DM were randomised to either an intervention or control group for 8 weeks. The intervention group utilised the app for 8 weeks and the control group continued their normal behaviour. Physical activity and sitting were measured at baseline and during the last intervention week. Health measures were taken at baseline and post-intervention. Semi-structured interviews were carried out post-intervention to gain participant feedback on the usability of the app. **Results:** The intervention group decreased total sedentary time by 50.52 minutes/day and increased number of breaks from sedentary time by 4.08 breaks per day, standing time by 41.76 minutes/day and light physical activity by 5.28 minutes/day from baseline to post-intervention compared to the control group. **Conclusion:** MyHealthAvatar has the potential to reduce prolonged sedentary behaviour in individuals with T2DM. The effectiveness of this app requires investigation in a fully powered randomised controlled trial.

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Chapter 1: Introduction

There are 4 million people in the UK living with diabetes mellitus, with 90% of these cases being Type 2 diabetes mellitus (T2DM) (Diabetes UK, 2015). In the past ten years, the number of cases of T2DM has increased by 60% in the UK (Diabetes UK, 2015). Diabetes costs the NHS £9 billion each year (Diabetes UK, 2015) and has become a public health epidemic. Cardiovascular disease accounts for 52% of deaths in people with T2DM (Diabetes UK, 2015) and having this disease increases the risk of other health problems including poor mental health, cancer, kidney disease and eye disease (Taber and Dickinson, 2015). Raised levels of fasting and postprandial glucose are a significant contributor to increased risk of cardiovascular disease and mortality in people with T2DM (Cavalot et al., 2011) and thus, interventions to reduce level of glycaemia are needed in this population.

Evidence suggests that high levels of sedentary behaviour are associated with an increased risk of certain chronic diseases (e.g. T2DM and cardiovascular disease), independent of engagement in moderate-to-vigorous physical activity (Wilmot et al., 2012). The American Diabetes Association recommends that adults with T2DM should decrease the total amount of time-spent sitting and interrupt prolonged sitting with bouts of at least light-intensity activity every 30 minutes for blood glucose benefits (Colberg et al., 2016). Therefore, effective interventions to reduce total sitting time and interrupt prolonged periods of sitting in people with T2DM need to be identified to help with the management of this disease.

The increasing prevalence of T2DM justifies the need for cost-effective, self-management treatment strategies. Technology is readily available and widely used in modern society and has thus been identified as a potentially effective method to aid in self-management of T2DM (Quinn et al., 2011). Computers, internet and electrical devices could help to enhance levels of care for diabetes sufferers as well as increasing patient independence through disease management education. The use of mobile phones allows greater opportunity for incorporation of self-management strategies into an individual's daily routine, as they are portable, unlike computer-based technology (Arsand et al., 2012). Mobile phone apps have a number of functions that make them appropriate for health care, such as time management, communication (data sharing), detailed information, data storage, and feedback to the patient or health practitioner. These functions allow individuals to detail their day-to-day experiences in an easy and simplistic way that could help in the self-management of their disease (Zhao et al., 2016). Quinn et al. (2011) found that a mobile phone behaviour change intervention significantly improved glucose control in people with T2DM compared with usual care. A systematic review and meta-analysis of studies reported that mobile phone app self-management interventions for T2DM significantly improved glucose control (Hou et al., 2016). However, the majority of mobile phone apps that have been developed for self-management of T2DM are focused on providing personalised feedback on self-monitoring data (e.g. blood glucose), food intake, and physical activity (Hou et al., 2016). There is a need to develop and test mobile phone apps that include self-monitoring and behaviour change techniques in relation to sedentary behaviour that is now recognised as a distinct treatment target for people with T2DM (Colberg et al., 2016). The primary aim of this study was therefore to assess the feasibility of a mobile phone app for reducing prolonged sedentary behaviour in people with T2DM.

Chapter 2: Literature Review

2.1 Type 2 diabetes mellitus

T2DM is a multifactorial progressive metabolic disease that is attributed to insulin resistance, leading to excessive glucose production and impaired insulin secretion (Phillips, 2016). Insulin assists the body's cells in the absorption of glucose for it then to be used as a source of energy (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2009). If an individual experiences insulin resistance, the cells do not effectively absorb glucose from the blood (NIDDK, 2009). In an attempt to overcome this, the beta cells in the pancreas produce a greater amount of insulin to suppress glucose, however, if the body cannot achieve this, blood glucose levels will maintain an abnormally high level, defined as hyperglycaemia (Phillips, 2016). Persistent hyperglycaemia further increases insulin resistance and can cause beta cell dysfunction, resulting in T2DM (Kahn, 2003).

There are a number of ways in which T2DM can be diagnosed. The two main methods used are fasting plasma glucose (FPG) and the Oral Glucose Tolerance Test (OGTT) (American Diabetes Association, 2013). Diabetes is diagnosed as a FPG concentration of ≥ 7 mmol/mol or a 2 hour OGTT glucose concentration of > 11 mmol/mol (American Diabetes Association, 2013). Once diagnosed with T2DM, individuals may have HbA1c (glycated haemoglobin) measured to indicate 3 month glycaemic control (Beard et al., 2010). HbA1c is typically measured every 2-3 months and a level of ≥ 48 mmol/mol is expected for those suffering with T2DM (Diabetes UK, 2017). HbA1c levels can be affected by genetic, illness and blood related elements (Gallagher et al., 2009) suggesting that its use as a diagnostic tool could potentially be problematic. Conditions such as uremia and hemoglobinopathy can result in varying, inaccurate HbA1c results (Kahn, 2003). Additionally, HbA1c is not yet readily available worldwide and no standardisation of testing is in place (Kahn, 2003). However, it has been argued that HbA1c should be considered in the diagnosis of T2DM due to its ability to measure long-term glycaemic control and thus may be a more appropriate marker for the presence of T2DM than FPG, which does not reflect long-term glycaemic control (International Expert Committee, 2009). HbA1c measurements can be performed unfasted and at any time in the day, which can increase patient compliance with blood glucose control measures and allow more flexibility for diagnostic measurement compared to FPG. Thus, HbA1c is now recommended by the American Diabetes Association (2013) and the World Health Organisation (2011) as a diagnostic tool.

2.2 Diabetes prevalence

An estimated 422 million adults worldwide have diabetes, with a third of these currently undiagnosed (World Health Organisation, 2015). In the past ten years, the number of cases of T2DM in the UK has increased by 60% and it is predicted to follow a similar trend in the years to come (Phillips, 2016). This increasing prevalence of T2DM is placing major burdens on individual health and the economy. In the UK, an average of 700 people are diagnosed with T2DM each day (Phillips, 2016) and there are an estimated 4.5 million people living with diabetes in the UK (Diabetes UK, 2015). The UK's total expenditure for diabetes alone is greater than £9 billion a year, making up 10% of the NHS total annual budget (Diabetes UK, 2015).

2.3 Risk factors for Type 2 diabetes

The current research remains unclear as to the true cause of diabetes, but it is likely a combination of environmental, lifestyle and hereditary factors (Ali, 2013). Scheen (2017) reported that the causes may be multifactorial and specific to each individual and their personal circumstances. The risk factors for T2DM can be categorised into genetic (family history, ethnicity) and non-genetic factors (obesity, lack of physical activity, poor diet) (Taber and Dickinson, 2015).

Components of lifestyle such as diet, time spent in a sedentary state and physical activity levels can all increase the risk of T2DM (Ali, 2013). Individuals with a family history of T2DM are six times more likely to suffer with the disease in comparison to those with no family history (Meigs et al., 2000). An individual could have experienced a healthy childhood but still be at high risk of T2DM due to their lifestyle behaviours in their adult years (Klein et al., 2004). Therefore, the risk of developing T2DM is a combination of both an individual's genetic predisposition and lifestyle factors such as inactivity and poor diet (Klein et al., 2004). The prevalence of T2DM is rising in correlation with an increase in rates of obesity (Inzucchi et al., 2015; Phillips et al., 2016). Although not all individuals with T2DM are obese, there is a significant proportion of those that are, with body mass index (BMI) and waist circumference (WC) levels positively associated with T2DM (Yaturu, 2011). Many individuals suffering with obesity have elevated levels of free fatty acids (FFAs), which can cause muscular insulin resistance and in the long term result in T2DM (Yaturu, 2011).

2.4 Health risks of Type 2 diabetes mellitus

As well as the primary implications of T2DM, such as fatigue, blurred vision and excessive thirst, there are a number of additional health complications that can arise as a result of long-term poor management of glucose levels. This includes an increased risk of poor mental health, obesity, cancer, cardiovascular disease (CVD), liver disease and foot ulcers (Taber and Dickinson, 2015). T2DM is a heterogeneous syndrome that causes abnormalities in the metabolism of fat and carbohydrate (Scheen, 2003). This can result in high levels of fat being stored in the body leading to excessive weight gain (Scheen, 2003). Excessive weight gain is associated with abnormalities in insulin discretions and glucose metabolism, further inhibiting an individual's ability to self-manage their T2DM (Scheen, 2017). A moderate weight loss of just 5% has been reported to lower fasted blood glucose levels, improve insulin action and decrease reliance and need for medication (Klein et al., 2004). Poor self-management of T2DM results in many individuals requiring additional treatments and medication in an attempt to achieve glycaemic control (Taber and Dickinson, 2015).

The effects of hyperglycaemia are separated into two sub categories: (1) microvascular, which includes retinopathy and neuropathy, and (2) macrovascular, which includes stroke, atherosclerosis and coronary heart disease (Fowler, 2008).

2.4.1 Microvascular

An individual's risk of developing a microvascular complication is comparable to the duration and intensity of time spent in a hyperglycaemic state (Fowler, 2008). Retinopathy is the most prevalent microvascular complication associated with diabetes and has resulted in over 10,000 cases of blindness a year reported in America alone (Fowler, 2008). A major complication with retinopathy is that in a significant number of cases it starts to develop well before T2DM is medically diagnosed causing additional health issues (Fong et al., 2004). Similar to retinopathy, 7% of individuals with T2DM will already be showing signs of microalbuminuria (kidneys leaking albumin into the urine; a marker of kidney disease), which could lead to renal failure (Gross et al., 2005). The leading cause of renal failure is diabetic nephropathy, which is kidney damage caused by the onset of T2DM (Fowler, 2008). As with most microvascular complications, nephropathy is a result of prolonged hyperglycaemia and therefore, a significant reduction in glucose levels would help to prevent or manage this condition (Gross et al., 2005).

2.4.2 Macrovascular

Individuals with T2DM have an increased risk of developing CVD (Fowler, 2008). Coronary heart disease, myocardial infarction (MI), hypertension, stroke and premature death are all of extended risk to someone diagnosed with T2DM (Almdal et al., 2004). Numerous studies report that T2DM increases the risk of CVD independent of other factors such as family history and genetics (Fowler, 2008; Almdal et al., 2004). Observed over a 20 year period, a quarter of participants with T2DM had at some point experienced CVD (Almdal et al., 2004). This increased risk was positively correlated with greater levels of HbA1c (Stratton et al., 2000).

2.4.3 Mortality rates

It was reported that T2DM was responsible for 4.6 million deaths worldwide in 2011 and this figure is expected to rise (Arsand et al., 2012). Meigs et al. (2000) conducted a study on a variety of families and the heritability of T2DM and observed a significant variance in the prevalence of diabetes from one generation to the next, with the risk of onset ranging from 20-80%. This suggests that certain individuals are predisposed to the onset of T2DM and others have an increased risk due to environmental factors that can be self-managed.

Individuals with T2DM generally die 4-6 years earlier, suffer from disabilities 6-7 years earlier, and spend 1-2 years longer in a dependant-disabled state, compared to non-diabetic counterparts (Bardenheier et al., 2016). Similarly, mortality rates were compared between a T2DM and non-diabetic population and found to be 2-6 years earlier in the diabetic group, with the majority of cases attributed to uraemia, defined as raised levels of urea and other waste products within the blood (Deckert et al., 1978). If untreated, uraemia can result in unconsciousness and ultimately death. This increased risk of mortality is associated directly with T2DM and the additional complications and health risks that become apparent due to a poorly managed disease state and on-going complications. Even a minor reduction in glycaemia is associated with the prevention of early mortality and other complications associated with T2DM (Stratton et al., 2000). A 1% reduction in HbA1c levels was associated with a 21% lower risk of diabetes related deaths (Stratton et al., 2000) further stressing the importance of effective glucose control and disease management for long-term health and wellbeing.

2.5 Sedentary behaviour

Sedentary behaviour is defined as "any waking behaviour characterized by energy expenditure ≤1.5 metabolic equivalents (METs), while in a sitting, reclining or lying posture" (Tremblay et al., 2017). Sedentary behaviour is associated with a number of health issues such as obesity, cancer and CVD (Chomisteck et al., 2013). In addition to the physical complications, increased levels of sedentary behaviour were also associated with a greater risk of depression and poor wellbeing (Zhai et al., 2015). Sedentary behaviour is further associated with an increased risk of developing T2DM (Falconer et al., 2015). Research suggests that large amounts of sedentary behaviour are associated with a 112% increased risk of this disease (Wilmot et al., 2012). Furthermore, every hour spent in a sedentary position increases the risk of developing T2DM by 22% (Van der Berg et al., 2016). When compared to individuals with an impaired or normal glucose metabolism, T2DM individuals spend a longer duration in a sedentary state (over 9 hours per day) (Van der Berg et al., 2016). However, all of these studies utilised questionnaires to measure sedentary behaviour, which is a major limitation due to the validity issues associated with self-reported sedentary behaviour and therefore may not be a true representation of the participant's actual sedentary behaviour levels.

Individual's with T2DM accumulate 65% of the day in a sedentary state and 46% of this time is accumulated in prolonged bouts of >30 minutes at a time (Falconer et al., 2015). However, Falconer et al., (2015) utilised a waist worn accelerometer, which brings into question the validity of the data as such accelerometers are unable to distinguish between standing and sitting time. Due to their location, worn around the waist, this type of activity monitor cannot accurately measure breaks from sitting, as it cannot use inclinometry, unlike the ActivPAL.

Prolonged sedentary bouts may therefore have been overestimated. A study comparing different sedentary behaviour durations found that those who spent the greatest amount of time in a sedentary state were associated with a three times greater likelihood of an individual experiencing depression than those in the least sedentary group (Vallance et al., 2011).

It is suggested that prolonged sedentary behaviour is not only associated with a number of health complications, such as obesity, CVD, atherosclerosis, mental health and T2DM (Hamer et al., 2014), but also results in a greater risk of all-cause mortality, independent of physical activity levels (Van der Ploeg et al.,2012). During a single day, adults can regularly sit for more than 10 hours, much of which is accumulated in prolonged bouts (Dempsey et al., 2014). Prolonged bouts of sedentary behaviour were reported to be of greater detriment to wellbeing in overweight and obese individuals, which is common in those with T2DM (Vallance et al., 2011).

An increased number of light-intensity physical activity breaks in sedentary time, such as walking, are associated with a reduction in WC, BMI (Cooper et al., 2012), and 2- hour glucose levels (Healy et al., 2008). Both of these studies (Cooper et al., 2012 & Healy et al., 2008) used observational evidence alone to conclude their studies. Additionally, both studies utilised waist worn accelerometers to measure activity levels. This limits the validity of the data collected due to the inability of the accelerometer to accurately distinguish between sitting, walking and breaks from sedentary behaviour. Reducing and/or breaking up prolonged sedentary time can also be beneficial to cardio metabolic health (Dempsey et al., 2016). Interrupting prolonged sedentary time every 20 minutes with 2 minutes of light physical activity was resulted in a reduction in postprandial glucose and insulin levels in overweight and obese individuals (Dunstan et al., 2012). Similar results were reported in individuals with T2DM when an 8-hour period of sitting was broken up every 30 minutes with 3 minutes of walking (Dempsey et al., 2016). When comparing light to moderate intensity breaks, postprandial glucose and insulin both showed similar significant reductions in response to each intensity (Dunstan et al., 2012). However, the studies by Dunstan et al., (2012) and Dempsey et al., (2016) only observed breaking up sitting time over an acute period and therefore the long-term responses to interrupting sitting cannot be inferred and should be investigated.

2.5.1 Sedentary behaviour, mood and wellbeing

Research suggests a positive correlation between sedentary behaviour (sitting time) and poor mental wellbeing in adults (Atkin et al., 2011). Sedentary behaviour can result in poor mental health and both anxiety and depression have been attributed to high levels of sedentary behaviour (Teychenne et al., 2015). A significant association was found between total sedentary time per day and an individual's risk of experiencing depression (Zhai et al., 2017). Additionally, a review article reported associations between depression and sedentary behaviour in all observational studies, suggesting a strong link between these two variables (Teychenne et al., 2010).

Research in sedentary females found an improvement in both positive mood and fasted blood glucose levels following regular short breaks from sedentary behaviour, 1-2 minute breaks every 30 minutes (Mailey et al., 2017). However, this is a relatively new area of research with a lack of evidence for individuals with T2DM, which therefore requires investigation. Individuals who completed between 8-20 minutes of MVPA reported a decrease in levels of depression in an adult population (Vallance et al., 2011). Research has also found physical activity interventions to have a positive effect on quality of life and mood states (Penedo and Dahn., 2005). However, it was highlighted that many studies failed to measure the long-term effects of a physical activity intervention on mood and wellbeing (Penedo and Dahn., 2005). Additionally, participants often relapse into bad habits, such as physical inactivity, following a period of intervention and thus if mood is associated to levels of physical activity, individuals are likely to see a decline in this also (Galper et al., 2006). There is therefore a need for investigations into whether decreasing sedentary behaviour and increasing physical activity can result in favourable changes in mood and wellbeing in individuals with T2DM.

2.6 Management of Type 2 diabetes

After diagnosis of T2DM, the first stage of treatment is usually recommended behaviour change, such as diet and physical activity with the aim of improving glucose control. If this is unsuccessful or becomes too difficult to manage, medication is prescribed to support the individual with their glucose management (Florence and Yeager, 1999). The main function of the medication is to decrease insulin resistance and suppress glucagon production leading to improved glucose control (Juang and Henry, 2000). Metformin is the most commonly used pharmaceutical for the treatment of T2DM. The on-going increase in T2DM cases requires a more cost-effective, self-management strategy to be implemented, as medicinal interventions are costly and poorly adhered to (Phillips, 2016). Over 30% of individuals with chronic illnesses, including T2DM, do not take their medication as prescribed (Horne et al., 1999), which is often due to beliefs in a lack of necessity of the medication or concerns regarding their side effects, which could be targeted through effective psycho-social education. This was further supported by Quinn et al. (2011) who reported that less than half of patients diagnosed with T2DM were receiving education on the management of their disease.

The increase in T2DM prevalence highlights the necessity for an effective self-management strategy to reduce healthcare costs and reduce patient reliance on the NHS (Phillips, 2016). In addition to minimising treatment costs, effective self-management is vital for preventing the development of associated health complications (Norris et al., 2002). A lack of basic health care skills and limited information from health care professionals underpins many cases of poorly managed diabetes (Tran et al., 2012). Phillips, (2016) concluded that with the use of self-management strategies there is great potential to minimise additional health complications of T2DM. Arsand et al. (2012) also stated that the management of glucose and leading a healthy lifestyle are both vital to decrease the risk of long-term health complications, such as cardiovascular and liver diseases. However, there is currently no recognised self-managed treatment option for T2DM and research therefore needs to evaluate potential strategies to assist with this.

2.6.1 Weight loss

Weight loss is considered an important target in T2DM management. Excess body fat is one of the many contributing factors to the onset of T2DM and weight loss management is the most influential method for reducing this risk (Hu et al., 2001). Weight loss with the addition of calorific deficit can positively influence glycaemic control in individuals with T2DM (Wing et al., 2001). Weight loss alone has positive effects on low-density lipoprotein cholesterol (LDL) and total cholesterol (Wing et al., 2001). Improved blood pressure levels and better fat distribution can also be obtained via weight loss in T2DM (Stevens et al., 2001). It seems that weight loss in the treatment of T2DM could be important for helping with glucose control and reduce the risks of secondary health complications.

2.6.3 Management through sedentary behaviour and physical activity

Structured exercise is considered a cornerstone treatment for T2DM and short and long-term improvements in fasting and postprandial glucose occur in response to exercise (Colberg et al., 2010). Physical activity is associated with a number of positive health-related markers, for example, a decrease in systolic blood pressure, depression and cardiometabolic risk markers, which can all contribute to a greater quality of life (Agboola et al., 2016). Regular exercise, especially aerobic, has shown to improve insulin sensitivity and glucose levels (Hu et al., 1999) and physical activity increases glucose tolerance and improves insulin sensitivity in individuals with T2DM (Asano et al., 2014). However, more than 60% of individuals with T2DM are not meeting the daily physical activity recommendations of at least 150 minutes of moderate to vigorous intensity physical activity per week (Connelly et al., 2013). Furthermore, of those who initially followed an NHS or similar post-diagnosis exercise programme, the dropout rate was a staggering 80% (Connelly et al., 2013). Physical activity has been reported as one of the best non-pharmacological treatments for the control of T2DM (Asano et al., 2014). However, adherence to regular physical activity in this population is poor for a variety of reasons, such as an individual's motivation, enjoyment and self-efficacy (Forkan et al., 2006). All adults, particularly those with T2DM, should not only look to increase their physical activity levels but also decrease their sedentary time (Colberg et al., 2016). It is suggested that bouts of sitting should be broken up every 30 minutes in order to gain greater glycaemic control (Colberg et al., 2016). Therefore, by utilising a mobile phone app and focusing on reducing sedentary behaviour, rather than increasing physical activity levels, adherence rates and health benefits may be greater.

2.6.4. Theory of Planned Behaviour

The Theory of Planned Behaviour (TPB) incorporates attitudes, subjective norms (SN) and perceived behavioural control (PBC), all of which contribute to the prediction of an individual's intentions and thus behaviour (Ajzen, 1985). A range of behaviours have been explained utilising the TPB, such as physical activity, healthy eating and alcohol use (Hagger et al., 2002, Povey et al., 2000 & McMillan and Conner, 2003). PBC describes the extent to which an individual feels able to enact a certain behaviour and whether or not they perceive the action to be in or out of their control (Francis et al., 2004). SN takes into consideration social pressures, acceptance of behaviours in society and one's motivation to comply (Francis et al., 2004). Attitude looks at how an individual perceives a certain behaviour (i.e. good/bad, harmful/beneficial), taking into consideration one's beliefs and consequences of the behaviour (Francis et al., 2004). PBC, SN and attitudes form together to create an intention which is hypothesised to predict an action such as decreased sedentary time. It was reported that PBC was the greatest predictor of the level of self-care in a T2DM population (Gatt and Sammut, 2008). It is therefore imperative to improve an individual's PBC in order to assist them in better management of T2DM, whilst also taking the other factors into consideration.

2.7 Technology

2.7.1 Technology for the treatment of Type 2 diabetes

Computers, internet, multimedia and mobile phones could help to enhance levels of care for diabetes sufferers as well as increasing patient's independence through self-management education (Jackson et al., 2006). Mobile phones, unlike computer based technology, allow for portability of diabetes management and treatment (Arsand et al., 2012). This allows greater incorporation of self-management strategies into an individual's daily routine (Tartara et al., 2009). Using technology to implement sustainable interventions for lifestyle factors such as sedentary behaviour may be convenient for the user and permit access to disease help and support for those individuals in remote locations with limited access to local doctor surgeries (Connelly et al., 2013).

2.7.2 Technology for reducing sedentary behaviour

Using smart phone apps has the potential to change unhealthy behaviours, such as prolonged sedentary time and physical inactivity, and result in long-term active lifestyles (Kirwan et al 2012). Mobile phones have internal sensors that track movement and location allowing for automatic tracking to occur and assist with physical activity measurements (Dennison et al., 2013). By simply giving an individual an activity-tracking device, physical activity levels can increase by 13% (Cadmus-Bertram et al., 2015).

A mobile phone app linked to an accelerometer, with an alarm going off each time 20 minutes of sedentary behaviour was recorded, successfully reduced sedentary time in over 85% of individuals with T2DM over a one-month period (Pellegrini et al., 2015). The use of a mobile phone app, with the addition of persuasive reminders to break up sitting time, was additionally successful in reducing overall sedentary time in office workers (Van Dantzig et al., 2013). A sedentary behaviour review reported that the use of either a computer or mobile phone intervention achieved a 41 minute reduction in total sedentary time (Stephenson et al., 2017). Additionally, a mobile phone intervention has the capability to not only decrease sedentary behaviour but also increase levels of physical activity (Kendzor et al., 2016). Bond et al., (2014) suggested that as a first port of call for certain individuals, those overweight or obese, frequent short duration breaks from sitting is the most beneficial strategy to implement in an attempt to reduce sedentary behaviour and increase physical activity levels. However, more longitudinal studies are required to support these findings and discover whether the changes can be maintained long-term.

It was further detailed that having a device with real-time feedback, such as a mobile phone app, increased individual's awareness of time spent in a sedentary state (Pellegrini et al., 2015). It was reported that with the ability to monitor sitting time and step count daily via a mobile phone app, participants were more inclined to do reduce their sedentary time (Kirwan et al., 2012). However, Kirwan et al. (2012) utilised a self-selected intervention group), potentially being more inclined to change their behaviour. The use of technology to promote physical activity and decrease sedentary behaviour overcomes many of the barriers associated with face-to-face interventions such as transport, facilities, cost and time (King et al., 2013). Pellegrini et al. (2015) suggested a need for mobile phone apps to incorporate built in activity monitors so that individuals would only need to remember to keep their phone with them, thus reducing loss of data and misrepresentation of activity levels. However, the issue remains if participants forget to carry their phone on them at all times and therefore, further investigation is required as to the best course of action to ensure the greatest level of compliance and accuracy of data.

Although, in the current study, the app did seem feasible, it is still important to explore different methodological approaches in order to obtain the greatest level of compliance and feasibility for individuals with T2DM.

2.7.3 Personal Health Applications

With constant technological advancements, devices such as smart phones could have the ability to improve patients' self-monitoring of disease states (Jacob et al., 2012). In recent years there has been a surge of mobile phone app developments which are being introduced into clinical settings (Zhao et al., 2016) such as orthopaedics, neurology and pharmacy (Aungst, 2013). It is important that as technology becomes a more regular aspect of day-to-day life, this is used as a form to better monitor health and disease states in a convenient and simple way for patients (Tran et al., 2012). With more than 2.7 billion people owning or having access to a mobile phone across the globe, it seems appropriate for the future of health care to include these devices for ease and simplicity (Quinn et al., 2011). A recent report stated that for android and iPhone devices alone there are over 100,000 health related apps available to members of the general public (Jahns, 2014). With the ability to communicate (with family, friends and peers) with ease and global access, it seems personal health applications (PHA) will have an important part to play in the future of disease management (Quinn et al., 2008).

Portability is a key feature that a mobile phone offers in addition to a number of functions that makes them potentially appropriate and effective for health care. Time management, detailed information and data storage allow individuals to detail their day-to-day experiences in an easy and simplistic way that is clear to them (Zhao et al., 2016). In addition, mobile phones with their ability to file share can be an effective tool for chronic diseases, such as diabetes, by assisting with self-management strategies and lifestyle alterations (Arsand et al., 2012). This is a key feature of a PHA as it allows the possibility for patients to share their data with their doctor, increasing patient to doctor communication levels and the reliability of patient information as it can be stored in real time. No studies to date have done this effectively and PHAs that facilitate such features need to be investigated in people with T2DM.

PHA's can be user-friendly, permit additional personalisation and specific feedback, which were all described as important features in an effective health app (Kirwan et al., 2013). It was also established that PHAs with real-time feedback were beneficial to participants and increased the likelihood for individual daily goals to be achieved by highlighting any adjustments that an individual could make to reach their target (Muntaner et al., 2015). Real time feedback for sedentary behaviour goals could be effective for individuals with T2DM, such as reductions in total sedentary time and increases in the number of breaks in sedentary time. With this knowledge, it is now important to assess the feasibility and effectiveness of such PHAs.

It was reported that the use of a behavioural change apps with decision support improved HbA1c levels by 1.9% over a 12-month period in individuals with T2DM compared with a group that used the app alone (Quinn et al., 2011). Furthermore, a review of ten studies found a consistent decrease of 0.5% in HbA1c levels following a self-management mobile phone app intervention in T2DM (Hou et al., 2016), suggesting that this type of intervention could be a successful self-management strategy. Furthermore, rates of engagement with a PHA or online tools had a positive correlation with health-related behaviour changes (Kirwan et al., 2012). However, previous studies have found poor compliance rates with mobile phone app usage, with only 35% of individuals regularly using such an app as part of a health promoting intervention (Hou et al., 2016). With this in mind, it is imperative to ensure that future mobile phone apps have high adherence rates to increase participant compliance.

2.8 Behavioural change techniques

A behaviour change technique (BCT) is defined as 'observable, replicable and irreducible component of an intervention designed to alter the processes that regulate behaviour' and there are currently 93 recognised in the BCT Taxonomy version 1 (Michie et al., 2013 pp. 82). BCTs can be used singularly or in conjunction with others to support effective change to health behaviours (Michie et al., 2013).

For a successful disease management strategy, it is important to specify the behaviour to be targeted before attempting to implement a BCT, yet this is regularly neglected resulting in mixed outcomes for BCT intervention programmes (Michie et al., 2007). Additionally, behaviour change interventions are more likely to be effective when underpinned by theoretical models and frameworks (Michie et al., 2009), such as the Theory of Planned Behaviour (Ajzen, 1991), the Behaviour Change Wheel and COM-B (Michie et al., 2011). This helps determine specific behaviours to target and strategies to implement to maximise the likelihood of success.

Using BCT's effectively has been positively correlated with a change in numerous behaviours, such as sedentary behaviour, physical activity and healthy eating (Michie et al., 2009). A recent review found that 'feedback on behaviour', 'information on consequences of behaviour' and 'problem solving' to be instrumental in online self-management programmes for individuals with T2DM (Van Vugt et al., 2013). However, it has been noted that certain BCT's may be effective to some individuals, but ineffective to others, dependant on factors such as personality, psychological state and general characteristics (Cradock et al., 2017). In comparison to standard diabetes care, BCT interventions produced a significant reduction in HbA1c levels in T2DM (Avery et al., 2012). However, it was suggested that, in order to encounter a clinically significant difference in HbA1c level, a minimum of 10 BCT's need to be used (Avery et al., 2012). Apps based on BCTs require further development and more vigorous, in-depth testing (Van Vugt et al., 2013).

2.8.1 Behaviour change techniques and self-regulation

An individual's motivation towards and subsequent performance of behaviour has been found to be greatly influenced by self-regulation, which comprises of self-monitoring (i.e. recording behaviour) and self-efficacy (one's belief in their ability to perform an action) (Bandura, 1991). Self-monitoring can be described as an individual's capability to recognise and understand the outcomes of their actions, in an attempt to change future behaviours (Epstein et al., 2009). Self-efficacy is related to an individuals' behaviour and can therefore influence goal setting for behaviours such as sitting time and physical activity (Bandura, 1998).

Previous research has found self-monitoring with pedometers to be an effective tool in increasing physical activity levels in individuals with diabetes (El-Gayar et al., 2013). Similarly, Kooiman et al., (2018) reported an increase in 30-minute bouts of MVPA and daily step count, in individuals with T2DM, following a self-monitoring activity tracking intervention compared to a control group who showed no difference. In addition, participants reported that they found the tracking devices to be a useful tool (Kooiman et al., 2018), suggesting that self-monitoring is feasible in individuals with T2DM. Similar was also described by overweight and obese individuals completing a smart-phone based self-monitoring intervention (which provided real time feedback), who highlighted an increase in motivation to break up sitting and increase physical activity levels following use of the app (Bond et al., 2014).

Self-monitoring of sedentary behaviour can be executed using either a postural sensor (e.g. wearable activity device or smartphone) or a pressure sensor (chair pad) which connects to a device such as a mobile phone, allowing for real-time feedback of behaviour (Sanders, 2016). Real time feedback has shown to increase the likelihood of a behavioural change and could therefore be vital for effective self-monitoring (Martin et al., 2017). An increase in breaks from sitting and a decrease in total sitting time was reported following a self-monitoring smart-phone intervention, in an adult population (Arrogi, 2017). Similarly, Bond et al (2014) reported that following a self-monitoring smartphone intervention, overweight and obese individuals significantly decreased their sedentary time and seemingly replaced it with time spent completing light and/or moderate physical activity.

A study looking at the differences in self-monitoring feedback, via a mobile phone app, reported no significant differences in behavioural changes when participants received data on their standing versus sitting time (Martin et al., 2017). However, Martin et al., (2017) reported that participants found it easier to make changes to their physical activity levels than their sitting time and reductions in sedentary behaviour were replaced with physical activity. Therefore, it questions whether monitoring of physical activity or sitting time is key to changing sedentary behaviour. Sanders (2016) described that although there has been a sharp increase in devices allowing for self-monitoring of physical activity, further research is still required on the effectiveness of self-monitoring of sitting time/sedentary behaviour.

It seems that in order to achieve self-regulation, individuals become reliant upon a 'resource' such as a Fitbit or a pedometer, which in itself is limited in terms of long-term effectiveness. Therefore, to succeed in changing a behaviour, trait self-control is required which comes from within an individual and is strongly associated with levels of self-efficacy (Baumeister, 2009). Individuals with T2DM who recorded their daily physical activity levels for a 6-week period reported enhanced levels of self-efficacy when compared to a control group (Gleeson-Kreig, 2006). However, both groups reported an increase in physical activity levels at the end of the intervention, although physical activity was self-reported and may therefore lacking validity.

In a review of physical activity and healthy eating interventions, it was found that using self-monitoring as a behaviour change technique was the most effective at changing behaviour (Michie et al., 2009). An observational study found self-monitoring of behaviour to be beneficial for individuals with T2DM in their attempt to manage blood glucose levels (Karter et al., 2006). Similarly, self-monitoring of blood glucose was shown to be effective in individuals' with T2DM utilising insulin as it allowed them to alter the dosage to be administered where applicable (Welschen et al., 2005). It is further suggested that self-monitoring of blood glucose could be beneficial to individuals with T2DM, not on insulin, allowing a greater understanding of lifestyle factors affecting the disease and the influence they have on blood glucose levels (Karter et al., 2001). However, this has not yet been supported by experimental evidence and thus suggests a correlation between the two rather than cause and effect. Furthermore, Farmer et al. (2007) highlighted that although there may be an association between self-monitoring and glucose management in individuals with T2DM, this cannot be measured independently to other lifestyle factors that may also influence glucose control, such as a change in diet or physical activity levels. Based on the evidence above, it appears that self-regulation techniques to reduce sitting time and manage blood glucose levels could be effective and should therefore be utilised in T2DM interventions.

2.8.2 Tailoring behavioural change techniques for personal health applications

The use of PHAs for health promotion and disease management are most effective when used in conjunction with BCT's (Direito et al., 2014). Interventions with the greatest number of BCT's were usually the most effective in changing physical activity behaviours, however, this is not always the case (Schoeppe et al., 2016). The use of personalisation in PHA produced greater physical activity behaviour changes in an adult population (Rabbi et al., 2014). Current mobile phone apps allow for personalisation of support received based upon disease state, gender, ethnicity and other grouping measures to ensure that each individual receives the most appropriate support for their disease state (Rodgers et al., 2005). This allows individuals to obtain individualised and appropriate support to assist with their T2DM self-management, hopefully producing the greatest benefits to the individual's health and wellbeing.

2.8.3 Motivational Interviewing

Motivational interviewing (MI) is defined as "a directive, client-centred counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence" (Rollnick and Miller, 1995 pp. 325). MI assists an individual in recognising a potential problem and supports an attempt to solve it through a change in behaviour (Rubak at el., 2005). In order to stimulate behaviour change, researchers must identify an individual's values and goals to ensure success (Rollnick and Miller, 1995. For individuals who are reluctant and hesitant to change, MI is deemed an effective method for behaviour change (Rubak at el., 2005). It is further reported that in an attempt to increase physical activity levels, MI is particularly efficient (Hardcastle et al., 2012).

The intention of MI is to improve an individual's intrinsic motivation to encourage change from within a person, rather than being reliant upon external influences (Rollnick and Miller, 2002). It was reported that MI had a significant effect on a number of anthropometrical measures, including BMI, cholesterol and blood pressure (Rubak at el., 2005). Face to face MI has been found to be effective in assisting with the management of T2DM by increasing physical activity, decreasing HbA1c levels and improving medication compliance (Do Valle Nascimento et al., 2017), however, MI is not widely used in a health care setting due to lack of knowledge and training available for practitioners.

With this in mind, utilising a mobile phone approach for MI may be promising, with the addition of overcoming a number of barriers, such as time, cost and poor adherence rates (De Greef et al., 2011). It is clear, with such common barriers, there is a need for a method that involves less face-to-face contact in order to sustain healthy behaviours (De Greef et al., 2011). Utilising a text message MI approach allows for greater facilitation in day to day life, regardless of location and other commitments (Gerber et al., 2009). A study using MI reported a significant improvement in physical activity levels following a six-month period of two weekly

MI sessions (Hardcastle et al., 2012). A study using MI via a phone call technique found positive physical activity and sedentary behaviour changes in individuals with T2DM (De Greef et al., 2011). Unlike other MI research projects, it was reported that adherence to a more active and less sedentary lifestyle was achieved for a minimum of six months, suggesting that for long term behavioural changes, a technological approach may be beneficial (Cradock et al., 2017).

2.9 Primary aim

The primary aim of this study was to evaluate the feasibility and acceptability, including measuring both recruitment and retention rates as well as number of complete data sets at the end of the study period, of the MyHealthAvatar mobile phone app for reducing prolonged sedentary behaviour in individuals with T2DM.

2.9.1 Secondary aims

The secondary aims of this study were to assess the preliminary effectiveness of the MyHealthAvatar mobile phone app for reducing prolonged sedentary behaviour, enhancing determinants of behaviour, mood, wellbeing, and a number of physiological health markers in people with T2DM.

2.9.2 Hypothesis

It was hypothesised that it would be feasible for individuals to accept and utilise the MyHealthAvatar mobile phone app for the 8-week period. It was further hypothesised that if individuals did comply, they would reduce their prolonged sedentary behaviour and report an improvement in attitude, PBC, SN, mood, wellbeing and glucose control.

Chapter 3: Methodology

3.1 Study overview

This was a feasibility study to inform a subsequent full-scale intervention. It employed an experimental design with two arms to examine the effectiveness of the MyHealthAvatar (MHA) mobile phone app in T2DM self-management. Participants were asked to attend the University of Bedfordshire Sport and Exercise Science Laboratories at baseline and at 8 weeks for a data collection session. After baseline measures, participants were randomly allocated to either the control group or intervention group (these are described below) for 8 weeks. Randomisation was completed using an online research randomiser tool (www.randomizer.org) with a block size of four. The study was reviewed and approved by the Cambridge South NHS Research Ethics Committee (approval number 17/EE/0070). Following a verbal explanation of the study and the risks involved, written consent was obtained from all participants prior to baseline measures.

3.2 Participants

Twelve (7 male and 5 female) individuals aged 18-65 (56± 6.5) years with self-reported T2DM diagnosed within the last four years were recruited. Individuals had to be in the first stage (single non-insulin blood glucose lowering therapy) or first intensification (dual treatment of metformin plus one other drug) of drug treatment or using a diet and exercise management strategy only to be included (National Institute for Health and Care Excellence, 2016). Participants also had to be able to read and speak in English, stand and walk unassisted, have previous experience using a smart phone, no additional co-morbidities related to T2DM (e.g. heart disease, damage to the retina and kidney problems) and BMI < 45 kg/m^2. Participants were excluded if they were in third stage drug treatment for T2DM or pregnant.

Recruitment of participants was through a variety of methods including posters and leaflets at the University of Bedfordshire and in local GP surgeries. In addition, participants were recruited from a local Diabetes UK support group and via social media.

3.3 Materials

3.3.1. Data collection

Data collection occurred at baseline and 8 weeks (end of the intervention period). Participants were asked to fast for a minimum of 10 hours prior to the morning of each data collection session. Participants completed an Oral Glucose Tolerance Test (OGTT) to determine their postprandial glucose levels in addition to fasting blood glucose, height (cm), weight (kg), body fat%, WC (cm) and resting blood pressure measures. These measures were taken at both data collection sessions. At the end of the baseline data collection session and in the penultimate week of the study period, participants were provided with an activity monitor to wear for the following 8 days to record sitting, standing and stepping time.

3.3.2 Measures

Fasting blood glucose: A finger prick blood sample was taken upon arrival to the laboratory while the participant was rested to measure fasting blood glucose concentrations. Approximately 30 μL of whole blood was collected for each sample into a microvette (Microvette CB300 EDTA, Sarstedt Ltd, Leicester, UK) that was then analysed using the YSI 2300 STAT plus glucose and lactate analyzer (YSI Inc., Yellow Springs, OH, USA).

Oral glucose tolerance test: following the initial finger prick blood sample, described above, participants consumed 75 g glucose (100% dextrose monohydrate powder; Thornton & Ross Ltd, UK) mixed with 300 mL water. Participants were instructed to consume this within 2 minutes. A blood sample was then taken following the above procedures 2 hours after consumption of the glucose load to determine postprandial blood glucose concentrations using the YSI 2300 STAT plus glucose and lactate analyser.

Height: this was measured to the nearest 0.1 cm using a stadiometer (Holtain Ltd., Crymych, Wales) with participants instructed to stand upright looking forwards, heels on the floor and feet together.

Body weight and body fat %: this was measured using electronic weighing scales and bio-electrical impedance analysis (BIA) with the BC-418 Segmental Body Composition Analyzer (Tanita Corp., Tokyo, Japan). This method works by sending low-level electrical currents through the body, via the feet and hand sensors, to then calculate body fat using the resistance of the flow. Participants were asked to wear light clothing and remove shoes and socks prior to measurement. This BIA device produces valid and reliable body fat estimations in adults (Hurst et al., 2016).

Body Mass Index: this was calculated as weight (kg) / height^2 (m).

Waist circumference: this was measured using an adjustable tape measure (HaB International Ltd., Southam, UK) to the nearest 0.1 cm at the level of the umbilicus at the end of gentle expiration.

Psychological measures: determinants of sedentary behaviour were measured based on the Theory of Planned Behaviour (Ajzen, 1985) using standardised wording formats (Francis et al., 2004) that included overcoming barriers (self-efficacy/perceived behavioural control), attitudes, subjective norms, intentions and action planning (See appendix 5). Below is an example question in which participants would score, as per the scale, and then results would be compared from baseline to follow-up.

I feel under social pressure to avoid long periods of sitting over the next week:

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Questionnaire scoring: the psychological measures were calculated as below.

- **Overcoming barriers:** each question was scored from 1 (very certain) to 4 (very ucertain), scores from all 5 questions were added together to get a total number out of 30. The higher the number, the more self-efficacy an individual portrayed towards overcoming barriers to physical activity.
- **Attitudes, Perceived Behavioural Control, Subjective norms and Intentions:** all of these measures were calculated using a 1-7 likert scale (1= strongly disagree 7= strongly agree), taking the average from the questions to calculate an overall score. The greater the total score, the greater the attitude/SN/PBC/intention towards a certain behaviour.
- **Plans:** this measure was calculated by an individual scoring each question on a scale of 1 (completely disagree) to 4 (completely agree) and the average being taken from the 6 questions. The greater the overall number, the more planning an individual had completed.

In addition, the participant's current mood was measured using the Positive and Negative Affect Scale (PANAS) (Watson, Clark & Tellegen, 1988) and psychological wellbeing was assessed using the Office for National Statistics (ONS) National Wellbeing Measurement (http://www.ons.gov.uk/peoplepopulationandcommunity/wellbeing/bulletins/measuringnationalwellbeing/2015-09-23) and the Warwick Edinburgh Mental Well-Being Scale (WEMWBS) (Tennant et al, 2007). Details of the scoring of these measures are below:

- **PANAS:** each variable was scored from 1-5 (1 = not at all, 5= extremely) variables were then split into positive and negative and a total for each was given, ranging from 10-50. The greater the total number the higher level of positivity/negativity.
- **Wellbeing:** the total score is obtained by summing the score for each of the 14 questions, with scores ranging from 1 – 5 (1= none of the time, 5= all of the time) giving a total score between 14-70. The higher the number, the greater level of wellbeing. The ONS questions were scored individually looking at happiness, anxiety, worthwhileness and satisfaction with life on a scale of 1-10 (10 being high).

Objectively measured sitting, standing and stepping: participants were provided with a small activity monitor (activPAL; PAL Technologies, Glasgow) that was attached to their right thigh, using an adhesive dressing, to be worn for eight consecutive days. The activPAL provides a valid and reliable measure of sitting, standing, stepping and postural transitions in adults (Lyden et al., 2012, Grant et al., 2006, Ryan et al., 2006). The following variables were calculated from this device:

1. Total daily time spent sitting (sedentary)
2. Total daily time spent standing
3. Total daily time spent stepping
4. Total daily steps
5. Total daily number of breaks in sedentary time
6. Total daily sitting time in bouts of 0-30 min, 30-60 min, 60-90 min, and >120 min in duration
7. Total daily minutes in light and moderate-to-vigorous stepping

These variables were calculated across the total waking time using the average of the included days. Included days required a minimum of 10 hours wear time and 500 steps (Winkler et al.,2016). Participants were asked to complete a daily log (appendix 6) to note the time they woke up and get out of bed, the time they went to bed, time they went to sleep, and any periods during the day when the device was removed. This information was used to overcome any potential technological errors in the data set, via manual corrections, in which non-sleep may have been mis-interpreted as sleep due to a lack of movement. Sleep was described as either ‘the longest bout per 24 hour period lasting more than two hours’, or any bouts lasting more than five hours of non-movement (Winkler et al., 2016).

The accelerometry data was extracted from the ActivPAL device (activPAL™ Professional v7.2.32; PAL Technologies Ltd., Glasgow, UK). Initially, the data was processed using an automated algorithm in STATA v14.0 (StataCorp Texas, USA). This was then used to produce heat maps using SAS 9.4 (SAS Institute Inc., Cary, USA), which were visually assessed for any missing or obscure data periods, to which manual corrections were made utilising the participant’s daily logs. Finally, the outputs were created (see above) and displayed on a variable spreadsheet for each day and the mean across all valid wear days at baseline and end of the intervention were used in the analysis.

3.5. Procedure

3.5.1. Intervention group

Participants randomised to the intervention arm were instructed on how to download the MHA app onto their smart phone device, register for an account and how to login. They then received an in-depth explanation and demonstration from the research team on how to use the app, which lasted approximately 30 min. They were then provided with a leaflet (appendix 10) that gave a simple and concise overview of MHA and how to use it on a daily basis.

Participants received two text messages, weekly, from the research team that were based upon MI and utilised the principles of the G.R.O.W; goal/reality/opportunity/will; model of Health Coaching (Whitmore, 2002). The messages were consistently sent at the start (Monday) and end (Friday) of the week (appendix 11).

3.5.2 Post-intervention interviews

All participants in the intervention group were interviewed, post-intervention, to permit qualitative analysis. This was completed using a semi-structured interview with a series of open-ended questions regarding participant experience of using the app and recommendations for any changes to improve the app to assist with better T2DM management. The interviews were audio-recorded and transcribed verbatim. Participants were given pseudonyms to ensure confidentiality at all times; see Table 5 for demographics of participants who took part in these interviews.

3.5.3 MyHealthAvatar mobile phone application

MHA is a mobile phone app system that serves as a suite for self-monitoring of health and lifestyle data. The user can enter and track health and lifestyle information related to non-communicable disease that encourages self-monitoring and self-management. There are different versions of the app available for specific diseases. The version used in this project is MyHealthAvatar-Diabetes. There are a number of features that allow the user to add personal lifestyle and health data (see Table 1). Interactive visualisation of this data is facilitated within the app.

The MHA app is currently only available to Android devices. If volunteers did not have an Android device, but were familiar with using a smartphone, the research team provided them with an Android phone to use during the study and instructed them on how to use the device.

3.5.4 Control group

Participants randomised to the control group did not receive the intervention during the study. They were asked to continue their normal behaviours throughout the study period. At the end of the study, participants in the control group were offered the opportunity to use the MHA app for a minimum of 8 weeks.

Table 1 Behavioural Change Techniques used in the MyHealthAvatar app

Behaviour Change Technique*	Use within the MyHealthAvatar app
1.1 Goal setting (behaviour)	Individuals can set personal short or long term goals relating to sedentary time, breaks in sedentary time and physical activity (step counts). These goals are monitored within the app and the patient has a visual representation of the progress they are making toward each goal in the form of tables and charts.
1.4 Action planning	The calendar allows planning of behaviour and scheduling of future activities.
1.5 Review behaviour goal(s)	Diary allows individuals to review daily/ weekly data/ behaviour/goals.
1.6 Discrepancy between current behaviour and goal	Daily sitting, breaks from sitting time and step count goals set by the participant can be tracked and progress towards goal can be viewed.
1.7 Review outcome goals(s)	Target weight, BMI, glucose levels, blood pressure, sitting, activity and mood can be reviewed and monitored.
2.2 Feedback on behaviour	Individuals can be informed of the amount of breaks from sitting time and the time spent sedentary. Data on various behaviours can be seen on the overview page giving individuals a quick view.
2.3 Self-monitoring of behaviour	Individuals can monitor their sitting, stepping and breaks from sitting time behaviours.
2.4 Self-monitoring of outcome(s) of behaviour	Daily weight, glucose, blood pressure and mood can be inputted to allow for self-monitoring of the outcome of behaviour.
2.7 Feedback on outcome(s) of behaviour	Numerous opportunities for individuals to gain feedback on the outcome of their behaviour i.e. weight, glucose and blood pressure.
3.1 Social support (unspecified)	Individuals are sent motivational text messages relating to their goals and behaviour.
5.1 Information about health consequences	The app links to external NHS news and information websites related to T2DM and the benefits of breaking up sitting time/physical activity to serve as an educational tool for the patient
5.4 Monitoring of emotional consequences	Individuals can see their mood state and relate this with the other health and lifestyle measures within the app.
7.1 Prompts/cues	A reminder get up and move around can be set to alert every 30 minutes to help encourage participants to meet their daily goals for breaking up sitting time. Participants also receives two text messages weekly prompting a decrease in sedentary behaviour.

*Behavioural change techniques based on Michie et al. (2013) Taxonomy v1

3.6. Data Analysis

3.6.1. Quantitative

Data analysis included calculating eligibility, recruitment and retention rates in order to evaluate the feasibility of the MHA study. Statistical analysis was conducted to determine whether the intervention and control groups differed in changes between baseline and follow-up in the outcome measures using Microsoft Excel macros (Microsoft Corporation, USA) to inform development of a fully powered randomised controlled trial (RCT). Within and between-group differences in the outcome variables at baseline to follow-up were calculated. Cohen's d effect sizes were calculated to describe between-group differences at baseline to follow-up; 0.2, 0.5 and 0.8 were considered to represent small, medium or large effects, respectively (Cohen, 1988).

3.6.2. Qualitative

Thematic analysis was used to analyse the post-intervention interviews. This method is an analytical approach used to identify patterns in a qualitative data set (Braun and Clarke., 2016) and permits the research team to access in-depth perceptions made by the individuals regarding the intervention (Low., 2012). The data was then collated to identify common themes within the data set (see appendix 10). This information could then be utilised to inform future developments of the app to increase compliance and adherence rates in a future study.

Chapter 4: Results

4.1 Feasibility of the trial

4.1.1 Eligibility, uptake and retention rates

Participants were recruited from January 2017 until June 2017. In this time, a total of 50 individuals showed initial interest in participating in the study. Preliminary consent was obtained from 25 individuals. However, 10 (20%) individuals were ineligible as they did not meet the study criteria and 20 (40%) declined to take part or did not respond to follow-up contact. An additional six individuals are currently completing the study. This resulted in a total of 12 participants being included in the present analysis. All participants who provided consent for this study provided complete data for all outcome variables at both time points.

4.1.2 Participant characteristics

Twelve (7 male and 5 female) participants in total were recruited to take part in this study. Participants were 57 ± 7 years with a baseline fasted blood glucose of 6.1 ± 1.4 mmol/L and a BMI of 31.2 ± 5.5 kg/m^2. Seven participants were White British and the remaining five participants were of Afro-Caribbean, Bangladeshi, West Indian, Black Caribbean and Caucasian (Scotland) ethnicities.

4.2 Sitting, standing and stepping

Table 2 displays the baseline and follow-up data for objectively measured sitting, standing and stepping time for the control and intervention groups. The intervention group decreased their total sedentary time more than the control group with a medium effect size for this difference. The intervention group increased their time spent in sedentary bouts lasting 0-30 minutes, whereas the control group decreased their time in this bout duration (large effect size). Both groups marginally decreased their time spent in sedentary bouts lasting 30-60 minutes.

Additionally, the intervention group decreased their time spent in sedentary bouts lasting 60-90 minutes, in comparison to the control group who showed an increase with a large effect size for this difference. Time spent in sedentary bouts lasting >120 minutes was decreased more in the intervention group than the controls (medium effect size). The intervention group also increased their number of breaks in sedentary time compared to a decrease in the control group (large effect size).

Total standing time increased more in the intervention group than the control (small-medium effect size). Total stepping time and total steps per day decreased more in the control than intervention group with a medium effect size for these differences. The intervention group increased their time spent in light physical activity compared to those in the control group where a decrease was seen (large effect size). Both groups decreased their time spent in moderate-to-vigorous physical activity with a trivial effect size for this difference.

4.2 Type 2 diabetes health markers

Table 3 displays baseline and follow-up health marker data for the control and intervention groups. There was no difference in fasted blood glucose (FBG) between the intervention and control groups over the intervention period (trivial effect size). The intervention group decreased their 2-hour blood glucose over the 8-week period whereas there was no change in the control group with a small effect size for this difference.

Waist circumference decreased in the intervention group and increased slightly in the control group (medium effect size). Systolic blood pressure increased more in the intervention group than the control but this difference had a trivial effect size. The intervention group's diastolic blood pressure showed no change, whereas the control group's increased slightly (small effect size). There was a large effect for the difference in heart rate with a reduction in the intervention group and an increase in the control group.

Table 2 Objectively measured sitting, standing and stepping time from baseline to follow-up. Data presented as mean (SD)

	Within-group differences							
Variable	**Control baseline (n=7)**	**Control follow-up (n=7)**	**Mean difference**	**Intervention baseline (n=5)**	**Intervention follow-up (n=5)**	**Mean difference**	**Between-group difference from baseline to follow-up**	**Effect size**
Number of sedentary bouts lasting 0-30 minutes	50.71 (20.15)	40.93 (16.42)	-9.78 (13.78)	46.03 (9.55)	50.54 (12.80)	4.51 (7.95)	14.29	1.21***
Number of sedentary bouts lasting 30-60 minutes	3.29 (1.48)	2.93 (1.77)	-0.35 (1.53)	4.00 (0.72)	3.91 (1.46)	-0.09 (1.44)	0.26	0.17*
Number of sedentary bouts lasting 60-90 minutes	1.37 (0.38)	1.86 (0.64)	0.49 (0.36)	1.86 (0.61)	1.60 (0.32)	-0.26 (0.78)	-0.75	1.32***
Number of sedentary bouts lasting >120 minutes	0.29 (0.20)	0.23 (0.17)	-0.09 (0.27)	0.35 (0.08)	0.14 (0.25)	-0.21 (0.19)	-0.12	0.50**
Total sedentary time (minutes/day)	577.54 (136.28)	576.60 (178.46)	-0.94 (83.56	682.68 (65.33)	631.56 (111.07)	-50.52 (100.29)	-51.46	0.55**
Number of breaks in sedentary time per day	55.43 (19.43	45.72 (16.12)	-9.71 (12.43)	51.77 (9.73)	55.85 (13.25)	4.08 (7.27)	13.79	1.29***
Total standing time (minutes/day)	300.09 (123.90)	312.00 (144.81)	11.91 (102.18)	209.28 (50.53)	250.44 (66.53)	41.76 (71.25)	29.25	0.32*
Total stepping time (minutes/day)	117.69 (40.65)	100.20 (35.57)	-17.49 (30.30)	99.96 (40.03)	96.72 (30.56)	-3.24 (19.13)	14.25	0.54**
Total steps per day	9072.48 (3188.38)	7657.91 (2888.76)	-1414.56 (2519.24)	8212.86 (4353.52)	7588.34 (3008.47)	-624.52 (1876.02)	790.04	0.35*
Light PA (minutes/day)	47.74 (17.85)	41.23 (15.44)	-6.51 (13.38)	32.04 (8.86)	37.32 (6.94)	5.28 (10.19)	11.79	0.97***
MVPA (minutes/day)	69.86 (24.03)	59.06 (21.54)	-10.80 (19.35)	67.92 (40.95)	59.40 (25.10)	-8.52 (19.07)	2.28	0.12
Waking wear time (hours/day)	16.58 (1.00)	16.48 (2.12)	-0.10 (1.75)	16.52 (0.35)	16.31 (1.11)	-0.21 (0.78)	-0.11	0.08

PA, physical activity; MVPA, moderate-to-vigorous physical activity

*small effect size; ** medium effects size; ***large effect size

4.3 Mood and wellbeing

Table 4 displays psychological questionnaire data at baseline and follow-up for the control and intervention groups. The wellbeing of participants in the intervention group increased, whilst the control group's wellbeing decreased (large effect size). The intervention group showed an increase in their positive mood compared to a decrease reported by the control group with a large effect size for this difference. The intervention group decreased their negative mood more than the control group (small effect size).

Subjective norms increased in the control group but decreased in the intervention with a medium effect size for this difference. PBC increased in the control group but showed a reduction in the intervention group, with a medium effect size for this difference. Individuals' beliefs in overcoming barriers to reducing their prolonged sedentary behaviour increased from baseline to follow up more in the control group than the intervention (medium effect size). Both plans, a large effect size, and intentions (trivial effect size) increased more in the intervention group than the control. Attitude also increased more in the intervention group than the control with a small effect size for this difference.

Table 3 Health markers from baseline to follow-up. Data presented as mean (SD).

	Within-group differences							
Variable	**Control baseline (7)**	**Control follow-up (7)**	**Mean difference**	**Intervention baseline (5)**	**Intervention follow-up (5)**	**Mean difference**	**Between-group difference from baseline to follow-up**	**Effect size**
Weight (kg)	88.2 (21.6)	88.3 (20.5)	0.1 (1.8)	95.5 (19.8)	97.2 (20.2)	1.7 (2.5)	1.59	0.76***
Body fat %	32.1 (8.8)	32.5 (8.7)	-1.9 (8.6)	36.6 (13.9)	37.0 (12.4)	0.4 (1.6)	2.29	0.34*
BMI	30.64 (5.06)	30.69 (4.86)	0.04 (0.72)	32.08 (7.16)	32.66 (7.43)	0.58 (1.00)	0.54	0.64**
Waist circumference (cm)	106.1 (13.1)	107.3 (12.8)	1.3 (2.9)	106.4 (17.5)	106.0 (16.0)	-0.3 (2.9)	-1.56	0.55**
Heart Rate (bpm)	67 (11)	68 (9)	0.57 (5.41)	67 (14)	62 (14)	-4.80 (8.23)	-5.37	0.80***
Systolic Blood pressure	133 (21)	136 (23)	3.00 (11.14)	129 (17)	130 (25)	1.80 (17.74)	-1.20	0.08
Diastolic blood pressure	83 (12)	84 (13)	1.43 (6.55)	81 (11)	81 (11)	0.00 (13.06)	-1.43	0.15*
Fasted blood glucose (mmol/L)	6.37 (1.74)	6.55 (2.75)	0.18 (1.46)	5.83 (0.96)	6.11 (1.07)	0.28 (0.44)	0.10	0.09
2 hour blood glucose (mmol/L)	11.19 (2.57)	11.18 (3.82)	-0.01 (1.98)	9.87 (1.58)	9.41 (1.03)	-0.46 (0.99)	-0.45	0.27*

*small effect size; ** medium effects size; ***large effect size

4.4 Post-intervention interview feedback

Following the 8-week intervention, all members of the intervention group were interviewed surrounding their experience of using MyHealthAvatar. From this data, four key themes emerged: 'prompting behaviour change', 'sense of achievement', 'environmental barriers' and 'technical complications' (see Figure 1). All four themes contributed to the usability of the app and either resulted in high levels of compliance or a lack of use, dependant on whether or not the individuals could overcome the issues reported and focus on the positive beneficial aspects of the app.

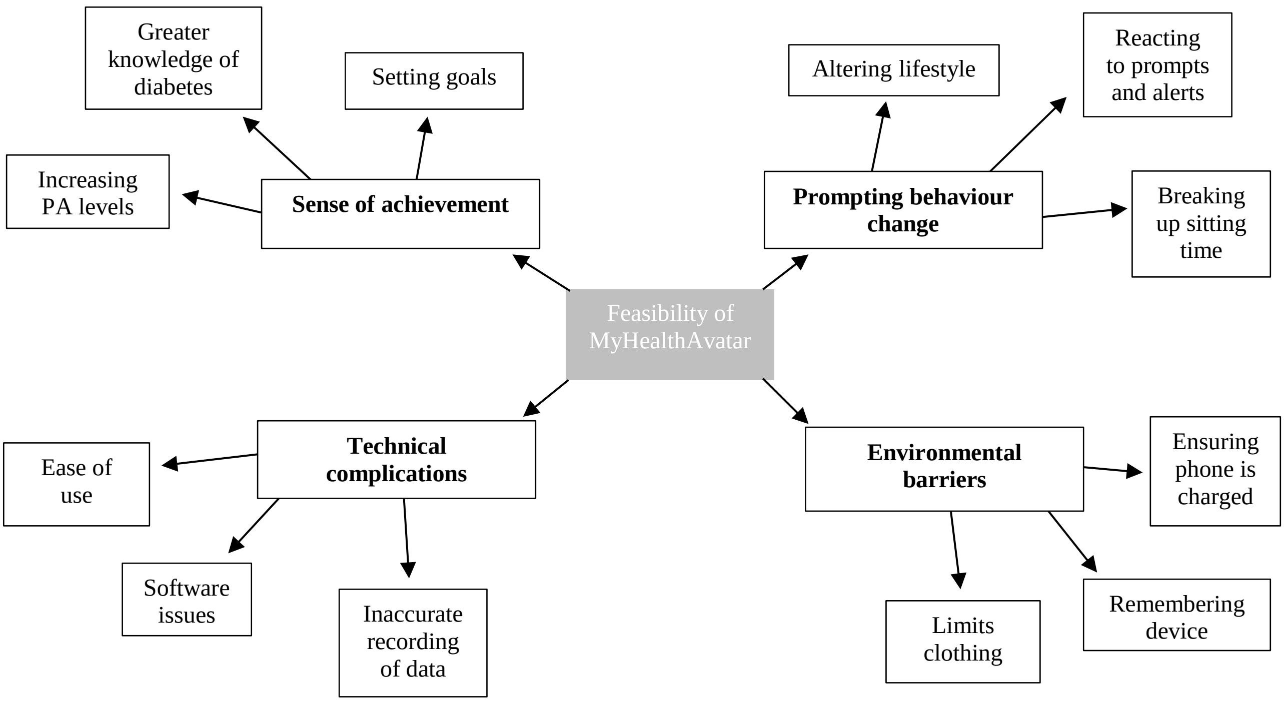

Figure 1 Thematic analysis maps following post-intervention interviews (See Appendix 10 for thematic analysis process)

Table 4 Psychological questionnaire data from baseline to follow up. Data presented as mean (SD).

Variable	Control baseline (n=7)	Control follow-up (n=7)	Mean difference	Intervention baseline (n=5)	Intervention follow-up (n=5)	Mean difference	Between-group mean difference from baseline to follow-up	Effect size (Cohen's d)
	Within-group difference							
Barriers	15.7 (3.9)	17.3 (1.8)	1.6 (3.2)	15.4 (4.9)	15.8 (2.7)	0.4 (3.4)	-1.2	0.48**
Attitudes	5.6 (1.6)	5.8 (1.7)	0.2 (2.0)	5.4 (0.3)	6.1 (0.6)	0.7 (0.8)	0.5	0.31*
Intentions	5.4 (0.6)	5.5 (0.9)	0.1 (0.9)	5.1 (1.1)	6.0 (0.3)	0.9 (1.4)	0.8	0.01
Subjective norms	4.5 (0.5)	4.7 (0.4)	0.2 (1.3)	4.9 (1.1)	4.6 (0.3)	-0.3 (1.1)	-0.5	0.48**
Perceived behavioural control	5.0 (0.7)	5.1 (0.4)	0.1 (0.5)	5.3 (0.8)	4.8 (0.7)	-0.5 (1.2)	-0.6	0.70**
Plans	1.5 (0.7)	2.1 (0.9)	0.6 (1.5)	1.5 (0.7)	2.8 (0.9)	1.3 (1.5)	0.7	0.69**
Wellbeing	49.6 (5.1)	48.9 (5.8)	-0.7 (2.6)	53.4 (8.8)	58.6 (5.7)	5.2 (12.6)	5.9	0.72**
Positive mood	35.1 (4.9)	32.7 (6.2)	-2.4 (3.4)	31.8 (8.7)	37.6 (4.1)	5.8 (11.8)	8.2	1.04***
Negative mood	17.8 (3.9)	16.3 (5.4)	-1.5 (5.2)	17.0 (8.7)	13.6 (2.3)	-3.4 (8.6)	-1.9	0.28*

*small effect size; ** medium effects size; ***large effect size

For questionnaire scoring, please refer to section 3.3.3 on page 23.

4.4.1 Prompting behaviour change

All participants in the intervention group demonstrated a decrease in total sedentary time at follow-up. Participants reported that this behavioural change came about due to the prompts and alerts installed into the app, reminding them to break up their sitting time every 30 minutes.

The most useful thing with the app is that it would vibrate every 30 minutes, which meant I didn't have to look at it, I just had it in my pocket and when I felt it vibrate, I would just automatically stand up. ***Male aged 44, white British.***

For many, in order to achieve this, a realisation of negative behaviours, such as prolonged sitting time was the first step. This was often followed by a change in their 'normal' behaviour and daily routines, in order to achieve their goal of reducing overall sedentary time.

It made me realise quite how many steps I wasn't doing just moving around the house. I have a hobby, which is siting, so what I'm trying to do now is do it standing up. ***Female aged 63, white British.***

It made me realise how often I do sit for exceptionally long periods of time, especially during the workday when you get engrossed in something and you don't leave, so having the app that did alert you was useful. ***Female aged 54, white British.***

4.4.2 Sense of achievement

Numerous participants reported how the app helped to increase their motivation to reach specific goals such as decreased sedentary behaviour and increased physical activity. This took into consideration individuals' lifestyles/habits and how they could be altered to reach the goal of decreased sedentary behaviour. Greater knowledge of diabetes and the negative effects of prolonged sedentary behaviour appeared to be imperative to behaviour change and an individual's feeling of a sense of achievement. The app had the ability to set specific goals and monitor how close participants were to achieving them and having real time feedback on behaviours allowed participants to track their progress throughout the day and over the course of the intervention period.

Goals were probably one of the best bits in the app; it showed you how many periods you had stood up for. ***Male aged 44, white British.***

It certainly made me think about how I sit all the time and my frame of mind has changed, I'm more positive now and I'm out walking with my sister. ***Female aged 63, white British.***

It also prompted me to look at the Diabetes UK website to find out a bit more myself. I think I've had quite a bit of conflicting information from medical people and so it can be confusing. ***Female aged 54, white British.***

4.4.3 Technical complications

The data gathered from the interviews highlighted the recurrence of a number of software issues experienced, which had the potential to decrease the likelihood of app usage. It was also clear that the app still required further updates to enhance the accuracy of the data produced, which further contributed to a lack of interest, compliance and trust in the app itself.

All these applications are good at tracking and helping and setting goals but the problem is you have to put in a lot of data to keep it up to date all the time. ***Male aged 44, white British.***

I didn't find it so accurate for the number of steps. ***Female aged 63, white British.***

Many individuals highlighted the need for the sitting reminder alarm to be reactive to the time spent sedentary, as opposed to a pre-set function to go off every half an hour. This may have increased individuals' motivation to comply with the breaks from sitting time to a greater degree.

Every half hour it bleeps at you rather than recording what you are doing and reacting to it. If you want people to get up every half hour, it needs to tell you when you have sat down. ***Male aged 65, white British.***

4.4.4 Environmental barriers

Alongside technical complications, environmental barriers to using the app were commonly discussed in the post-intervention interviews. Many reported environmental barriers such as ensuring the phone was charged in order to constantly monitor behaviour and remembering to have the phone with you and in your pocket at all times were identified. It was also noted that as the phone utilises inclinometry to detect posture changes it required the phone to be in a pocket, which limited clothing that could be worn. All of these issues had the potential to decrease use of the app and result in poor compliance over a prolonged period of time.

It's obviously an app so remembering to have it in your pocket all the time is a bit of a pain. ***Male aged 44, white British.***

Remembering to have it in my pocket and also it limits you to what you can wear, I wear a lot of these jeggings and they don't have the pockets (in order to carry the phone). ***Female aged 63, white British.***

Table 5 Interview participants' demographics

ID number	Gender	Age	Ethnicity
03	Male	44	White British
06	Female	54	White British
09	Female	63	White British
13	Male	65	White British
19	Female	63	White British

Chapter 5: Discussion

5.1 Feasibility of the trial

It seems that this trial was feasible in individuals with T2DM. The study itself was met with a relatively large amount of interest (50 individuals). Although a large proportion (40%) of those who showed initial interest did not respond to follow-up contact or declined to take part, there was no missing data for those who provided consent and thus retention rates over the 8-week study period was 100%.

The 12 participants in this study attended all of the visits to the laboratories (4) and complied with wearing the ActivPAL activity monitor at both baseline and follow-up, providing full physical activity and sedentary behaviour outcome data. The interviews conducted with participants in the intervention group suggested that the ActivPAL was a unique, non-invasive tool for measuring activity levels, which caused them little or no hassle. Full data was also obtained for all other variables, suggesting that it was feasible and could be included in a future study. With this in mind, it is to be expected that a future fully powered RCT would be feasible and achieve a high level of adherence and compliance.

5.2 Summary of main findings

The main findings of this study were that use of the MHA app was indeed feasible and accepted by the participants, individuals with T2DM. In addition, the intervention group's prolonged sedentary time, total sedentary time and 2 hour blood glucose all decreased following an 8 week intervention period. Total standing time, light physical activity and the number of breaks in sedentary time per day were also increased in the intervention group. An improvement in self-reported positive mood and wellbeing was experienced by the intervention group following the use of the MHA app. This may suggest a positive effect on sedentary behaviour, physical activity, glucose control, and mood and wellbeing in response to using the MHA app. Furthermore, although many of the participants experienced technical complications and environmental barriers regarding MHA use, all intervention participants reported they would recommend the app to others with T2DM, suggesting that it is a feasible self-management tool.

5.3 Total sedentary time

Total sedentary time was reduced in the intervention group following the study period. A similar study evaluating a mobile phone intervention to decrease sedentary time in overweight and obese individuals was associated with a reduction in total sedentary time (Bond et al., 2014). Bond et al. (2014) provided participants with an educational session prior to the commencement of the study on the rationale for reducing sedentary behaviour, including the risks of prolonged sedentary behaviour and potential benefits from reducing time in this behaviour. In the current study, education was solely provided within the app, with links to NHS websites and information surrounding the implications of sedentary behaviour built into the app's features. Therefore, education may play an important role in the reduction of total sedentary time. However, contrary to the current study, in which participants wore an ActivPAL for seven days at baseline and follow-up to monitor sedentary behaviour, Bond et al. (2014) used a SenseWear mini armband, which participants wore throughout the whole duration of the study. The implications of this being that results may have differed from using alternative tracking devices, the SenseWear mini armband did not detect participants' posture, unlike the ActivPAL and wearing the activity monitor throughout the whole study period may have influenced participant's 'normal' levels of sedentary behaviour as per the Hawthorne effect.

A recent review comparing studies involving both mobile phone and wearable devices to reduce sedentary behaviour reported that on average, this type of intervention was led to a 45 minute decrease in total sedentary time per day (Stephenson et al., 2017). This is similar to that of the current study and Arrogi et al. (2017) who assessed a smartphone intervention for reducing prolonged sedentary behaviour in healthy sedentary adults. Falconer et al. (2015) reported that in individuals with T2DM, 46% of their sedentary time is spent in prolonged bouts lasting > 30 minutes and it was suggested that the redistribution of this into regular 30-minute sedentary bouts could be the way forward in decreasing total sedentary time. With this in mind, individuals in this study's intervention group increased their number of sedentary bouts lasting 0-30 minutes compared with the control group, but, importantly, the intervention group decreased their number of prolonged sedentary bouts lasting 60-90 and >120 min. Similarly, Arrogi et al. (2017) reported a significant decrease in the number of prolonged sedentary bouts (> 30 minutes) in response to their smartphone intervention group. However, the study by Arrogi et al. (2017) was only two weeks in duration and participants wore an ActivPAL for the whole study duration, which could have influenced participant's behaviour, as well as the fact that participants were deemed as 'healthy sedentary' as opposed to T2DM as in this study. Comparable to the current study, the app used by Arrogi et al. (2017) allowed participants to review their sedentary behaviour as well as set goals that they wished to achieve.

Further research is still required to assess the changes in time spent in different duration bouts (e.g. 0-30, 30-60 minutes) of sedentary behaviour following a mobile phone app intervention. Much of the current research primarily focuses on total sedentary time rather than patterns of sedentary behaviour, making it difficult to compare results of the current study to previous investigations. However, this study provides a basis for future research evaluating the effect a mobile phone app on total sedentary time and different bout durations of sedentary behaviour.

5.3.1 Breaks in sedentary time

When compared to individuals with normal glucose metabolism, those with T2DM engage in significantly less breaks in sedentary time, leaving them at higher risk of additional health issues (Van der Berg., 2016). Individuals in the intervention group in this study successfully increased their number of breaks in sitting time. Arrogi et al. (2017) similarly assessed a smart phone app to reduce sedentary behaviour and also found an increase in the number of breaks from sitting in the intervention group. Both studies utilised an ActivPAL for measure sitting, stepping and standing time, however, Arrogi et al's. (2017) study did not have an activity tracker built into the smartphone, as this current study did. This could have influenced results, using MHA, with a built-in activity tracker could have produced greater change in the intervention groups' physical activity levels

Participants in a similar study reported that without the alerts and prompts to break up sitting time, they would have ended up continuing to sit for long periods of the day and therefore not show any improvements in either their sedentary behaviour or number of breaks in sedentary time (Pellegrini et al., 2015). Martin et al. (2017) found similar results during a study comparing the effects of feedback on stepping and standing time versus feedback on stepping and sitting (sedentary) time and highlighted the importance for individuals to be able to monitor their total sitting time in order to encourage increases in their number of breaks from sitting. Martin et al. (2017) reported that feedback on stepping and sitting time was most beneficial in increasing breaks in sedentary time. However, Pellegrini et al. (2015) reported a reduction in breaks in sitting time following a 1 month intervention of a smartphone to interrupt sedentary time in adults with T2DM and Cooper et al. (2012) who studied the effects of sedentary time, breaks in sedentary time and metabolic variables in T2DM at baseline and a six month follow up, also reported no differences in breaks in sedentary time.

The current study used a prompt every 30 minutes built within the MHA app, whereas Pellegrini et al. (2015) alerted individuals to every 20 minutes of consecutive sedentary behaviour. The alert in the Pellegrini et al. (2015) study allowed participants to respond in a number of ways, such as, 'ignore' or 'couldn't stand'. With these options, participants may have been less likely to comply with the prompts, resulting in a reduction in breaks in sitting time.

Martin et al. (2017) and Pellegrini et al. (2015) allowed individuals to monitor their sitting time and utilised alerts to prompt the participants to break up their sedentary behaviour. However, the device used in the study by Pellegrini et al. (2015) did not allow the individuals to monitor their time spent sitting down and instead were just reliant upon an alert going off following 20 minutes of continuous sedentary time. This may go some way to explaining the null effect reported in this study. The app used in the current study used reminders and alerts in an attempt to change sedentary behaviour. As described in the Behavioural Change Taxonomy v1 (Michie et al., 2013), prompts and cues are used in order to prompt a behaviour, such as breaking up sedentary behaviour. This is a positive feature of the app as it reminded individuals to break up their sitting time without the need to monitor it themselves. However, there is a danger that participants could become reliant upon the prompts and alerts and without the app, return to their usual sedentary behaviour.

It is clear that although prompts and alerts used in an attempt to increase breaks in sitting time may be beneficial in some cases, too many reminders may reduce compliance or may lead to the individual becoming too reliant upon the reminder, causing the behavioural change to be temporary. It is therefore suggested that individuals should have ownership as to the frequency of prompts, in addition to being able to dismiss alerts if necessary, this was highlighted as a potential development to the app MHA in the current study, in order to obtain greater compliance with the breaks when individuals are physically able to.

5.4 Physical activity

5.4.1 Total step count

An increase in step count is positively associated with an individual's overall health and wellbeing as suggested by De Cocker et al. (2009) who reported that an increase in total step count was associated with a reduced risk of CVD, hypertension and osteoporosis. A study using text messages to provide feedback on physical activity levels and pre-set goals to increase physical activity levels in T2DM found an increase in step count in months 3 and 4 of the intervention (Agboola et al., 2016). This is in contrast to the current study in which both the intervention and control group decreased their step count from baseline to follow-up, however, the reduction in step count was smaller in the intervention group. De Greef et al. (2010) utilised a cognitive-behavioural group intervention, with five cognitive behaviour sessions followed by participants wearing an accelerometer for five consecutive days. This intervention found an improvement in step count over a three-month period. These differing findings could be as a result of a number of factors, the main one being the study's primary focus not being on reducing sedentary behaviour but increasing step count.

Agboola et al. (2016) provided participants with two text messages daily, rather than the two per week as in the current study, which may have had an influence on total step count. Furthermore, the text messages received in Agboola et al. (2016) study were focused on increasing step count and physical activity levels rather than decreasing sedentary behaviour, as in the current study. Agboola et al. (2016) also incorporated the use of two-way text messages, allowing participants to respond, creating some level of participant engagement. In the current study, participants were asked not to reply to the text messages but to simply use them as a thought provoking prompt. Although De Greef et al. (2010) did not utilise text messages, the main focus of their cognitive-behavioural groups was also on increasing physical activity levels, rather than sedentary behaviour, which may explain the increase in steps observed in their study.

Although participants in the intervention group did not increase their total step count, they did increase their time spent standing, suggesting that participants replaced some of their sedentary behaviour with standing. However, is this beneficial to the health of individuals with T2DM? Previous research has found that breaking up sitting time with bouts of standing can produce benefits to health (Hamilton et al., 2007) as well as a reduction in mortality rates (Katzmarzyk, 2014). Similarly, a study supplementing six hours of sitting with 4 hours of walking and two hours of standing found an improvement in a number of health markers such as cholesterol and insulin (Duvivier et al., 2013). However, it is not clear as whether these favourable changes were as a result of the increase in walking or standing. A study in individuals with spinal cord injuries found an association between increased standing time and self-reported mood and wellbeing (Eng et al., 2001), suggesting that there are not only physiological benefits to be obtained from an increase in standing time. However, it was highlighted that for certain individuals, an increase in standing time could have negative implications due to underlying medical issues or injuries (Eng et al., 2001). This was further supported, with research (Tüchsen et al., 2005 & Halim et al., 2012) suggesting that extensive period of standing could result in muscle fatigue and an increased risk of varicose veins. Therefore, caution must be taken when implementing a standing intervention as to not cause more harm than good.

Much of the current research (De Greed et al., 2010 & Agboola et al., 2016) fails to report their data for changes in standing time and therefore comparison to similar studies is limited. This area still requires further research to determine whether increasing standing time can independently produce a positive influence on health and wellbeing.

Duration of the study could have impacted the results with both Agboola et al. (2016) and De Greef et al. (2010) utilising a longer intervention duration compared to the current study. Additionally, a specific algorithm may need to be implemented across the studies in order to standardise mobile phone app tracking abilities and obtain consistent and comparable results. Therefore, the differing methodologies, algorithms used in the tracking, text message content and engagement, study focus and duration potentially provides some level of justification for the lack of consistency in results. It is evident that MHA may not be effective in maintaining or increasing total step count and therefore, this may need further explorations in the future in order to optimise this response.

5.4.2 Light physical activity levels and standing time

The intervention group in the current study increased light physical activity levels compared with the control group during the study period. Substituting sedentary behaviour with light physical activity has the potential to improve metabolic markers associated with T2DM (Benatti & Ried-Larsen, 2015) and could be imperative in the battle to decrease the health risks associated with prolonged sedentary behaviour (Owen et al., 2010). Comparable to the current study, following a one month mobile phone app intervention to break up sitting time in individuals with T2DM, Pellegrini et al. (2015) reported a significant increase in light physical activity and a decrease in total sedentary behaviour in all but one participant. Agboola et al. (2016) additionally reported a significant increase in physical activity levels three months into an intervention; however, there was no significant difference between groups in light physical activity levels following the completion of the six-month text message and activity monitor intervention in T2DM. This may suggest that the duration of an intervention study may be important in terms of monitoring long-term compliance in response to app use.

However, in the study by Agboola et al. (2016), both the intervention and control group received an activity-tracking device for the study period, potentially invalidating comparisons between groups. In the current study, only members of the intervention group had access to an activity monitor (the app) for the 8-week period and the control group received no tools that may have encouraged them to increase their activity levels. Although there are inconsistencies in the magnitude of difference in light physical activity levels following a mobile phone app intervention it appears that mobile phone apps, such as MHA, can be effective in increasing light physical activity levels in T2DM.

5.4.3 Moderate-to-vigorous physical activity levels

MVPA has shown to assist with the management of T2DM (Hu et al., 1999), however, for individuals with a health complication such as T2DM this is seemingly unachievable due to physical incapabilities and a lack of time or motivation (Tucker et al., 2011). Similar to total step count, this study found a slight decrease in (MVPA) levels at follow-up in both groups in the current study. Similar findings were reported by (Helgadóttir et al., 2016) who also, following an intervention of light physical activity, found a reduction in MVPA levels. However, this study focused on depressed adults rather than those with T2DM. The same study reported no changes in MVPA following a vigorous exercise intervention, suggesting that perhaps the primary focus of the intervention is vital to the outcome. For example, a study focusing on sedentary behaviour is likely to see changes in sitting time but not MVPA, whereas a physical activity intervention would likely produce changes in variables such as light physical activity and MVPA. There was also a reduction in the control group's MVPA from baseline to follow-up; this therefore suggests that the intervention alone was not responsible for the reduction in MVPA. Pellegrini et al. (2015) found a minor, non-significant, improvement in MVPA levels following a smartphone intervention. Both studies were similar in terms of their primary aims of assessing the acceptability/feasibility of an app for breaking up sitting time in T2DM. However, Pellegrini et al. (2015) had a study period of 1 month and the smartphone technology was used to interrupt bouts of sedentary behaviour every 20 minutes, not every 30 minutes as in the current study.

A study utilising a dietary and physical activity intervention, through nurse consultation, effectively increased MVPA by 10 minutes per day in T2DM (Andrews et al., 2011). However, in comparison to the current study, Andrews et al's. (2011) main intervention focus was increasing MVPA by aiming to get participants to engage in '30 minutes of brisk walking per day' and therefore may explain the differing results to the current study. Additionally, as opposed to the technological intervention in the current study and that of Pellegrini et al. (2015), Andrews et al. (2011) used a face-to-face nurse intervention. Perhaps the use of an individual, whose opinion is well respected, such as a nurse, had a more influential effect on an individual's MVPA levels. Cooper et al. (2012) suggested that more research is required into interventions to increase MVPA in T2DM and the potential benefits that can be obtained.

5.5 Effect of sedentary behaviour interventions on health markers

A greater duration of time spent in a light physical activity state or an increase in the number of breaks in sedentary time is beneficially associated with an array of cardiometabolic markers, such as BMI, triglycerides, 2-hour glucose and waist circumference (Healy et al., 2008). Regular breaks from sedentary time increases carbohydrate oxidation and glucose uptake resulting in greater glucose metabolism and thus disease management (Benatti & Ried-Larsen, 2015). This was supported by Bailey and Locke, (2015) who reported that regular bouts of light physical activity, 2-minute bouts every 20 minutes, positively impacted postprandial responses. Similarly, Dunstan et al. (2012) found that, in overweight and obese individuals, short 2 minute bouts of treadmill walking every 20 minutes resulted in an improvement in glucose metabolism. The findings of the current study may complement the findings of various acute studies (Dunstan et al., 2012; Benatti & Ried-Larsen, 2015; Bailey and Locke, 2015) by showing that an intervention that achieved a reduction in sedentary time and an increase in breaks in sedentary time could potentially lead to a chronic glucose metabolism improvement.

The findings of this study suggest that a decrease in total sedentary time, increase in breaks in sedentary time, reduction in prolonged sedentary time and/or an increase in light physical activity levels may lead to a reduction in waist circumference. This finding was similar to that of a study aiming to assess the relationship between light physical activity levels and cardio metabolic risk factors, who found a decrease in waist circumference (WC) in correlation to an increase in light physical activity levels (Camhi et al., 2011). Although the main focus of Camhi et al. (2011) and the current study was different, both interventions resulted in a decrease in WC.

It is suggested that breaks in sedentary time could be utilised in an attempt to better control glucose levels in T2DM (Sardinha et al., 2017). This is due to the activation of substitute molecular signals, bypassing defective insulin signals (Standford & Goodyear, 2014). An addition of 10 breaks in sedentary time per day has shown to decrease FBG by 0.57% (Carson et al., 2014). However, this was not found in the current study with no difference in FBG from baseline to follow-up. This may be due to the change in breaks in sedentary time from baseline to post-intervention (4 per day) being too small to have an impact on FPG levels. However, there was a reduction in 2-hour glucose and this is a stronger predictor of CVD than FPG (Sardinha et al., 2017).

Heart rate is a strong predictor of CVD, myocardial infarction, hypertension and mortality levels (Cook et al., 2006). Although there was a decrease in heart rate in response to the intervention in the current study, other studies did not measure nor report their findings for this variable. More research is thus required into whether reducing sedentary time can positively influence heart rate. However, it appears that the behaviour changes that occurred in response to the MHA app were effective in improving this health marker in T2DM.

MHA app positively influences both sedentary behaviour and several health markers; however, more research is required to establish whether it is the reduction in sedentary time that positively affects T2DM health markers and/or the increase in physical activity levels.

5.6 Effect of sedentary behaviour interventions on mood and wellbeing

Wellbeing of the participants in the intervention group increased at follow-up in the current study, whereas the control group's wellbeing decreased. There is a significant lack of research regarding the psychological effects of a mobile phone intervention on mood and wellbeing. This study therefore provides important novel knowledge regarding the potential positive effects a mobile phone app intervention to reduce sedentary time may have on mood and wellbeing.

Both groups in the present study decreased their negative mood following the 8-week study period. However, the intervention group additionally increased their positive mood while positive mood decreased in the control group. Similarly, implementing a non-sedentary work style intervention and giving participants' feedback on their levels of sedentary behaviour has previously resulted in an improvement in mood (Matic et al., 2011). This was the first study to assess the effects of a sedentary behaviour intervention on mood. It has been reported that increased levels of sedentary behaviour are associated with an increased risk of suffering from mental health complications such as depression, low self-esteem and anxiety (Teychenne et al., 2015). With this in mind, it is evident that a decrease in overall sedentary time may be beneficial not only to an individual's metabolic health but also to their mental wellbeing.

There has been much previous research focusing on increasing physical activity to improve mood and wellbeing (Hogan et al., 2015), rather than the effects of reducing sedentary behaviour. Physical activity has shown to improve positive mood as well as decrease the risk of mental health issues (Hogan et al., 2015), such as anxiety and depression (Teychenne et al., 2015). It has also shown to be effective in the reduction of negative mood (Dubnov and Berry, 2000). This provides a potential new avenue for future studies to further examine the effects of a reduction in sedentary behaviour on mood and wellbeing to complement the findings of the present study.

5.7 Technological interventions for Type 2 diabetes management

5.7.1 Challenges with the use of technology

Although utilising a mobile phone app may be relatively simple for some individuals, others may struggle getting to grips with the concept and features. Certain individuals are not willing to take the time to learn how to use an app, which suggests that PHA's may not be appropriate for health care in all individuals (Tatara et al., 2009). The majority of the participants in the current study noted the simplicity of using the MHA app, however, one participant did find it challenging and not necessarily useful, suggesting that mobile phone technology may not be appropriate for reducing sedentary behaviour and improving health and wellbeing in all individuals with T2DM. Mobile phone apps appear to be a promising approach for management of T2DM based on the findings of this study but still require further development to ensure they are user-friendly for a variety of individuals (Faridi et al., 2008).

Individuals suffering from visual problems may struggle to effectively input data into a mobile phone (Rao et al., 2010). A study by Rami et al. (2006) required participants to utilise a mobile phone app every time they measured blood glucose levels, which caused some to report the use of a PHA as "too time consuming". In addition, it was reported that individuals often lack commitment to one particular app and usage levels are predominantly casual and sporadic (Schoeppe et al., 2016). This was frequently reported by members of the intervention group in the current study who suggested that the time taken to input data in order to keep the app up to date resulted in a lack of use in some instances.

Without consistent monitoring of sedentary behaviour, the effectiveness of an app is significantly reduced (De Greef et al., 2010). It is also crucial that the information and guidance that can be found within the app is accurate, reliable and true. Participants in a study by Abroms et al. (2011) reported that some of the current PHAs are providing misinformation. This could not only be dangerous to an individual's health if they were suffering from disease, but could also break the trust an individual could have formed with the app itself. This was a prevalent theme within the intervention group interviews in the current study with many being "put off" using the app through a lack of belief in its reliability and accuracy. Some participants felt the step count was producing inaccurate data. In many cases, if individuals had another tracking device such as an alternative phone or a Fitbit they would compare the two sets of data and notice discrepancies, thus making them doubt the accuracy of the app. With this in mind, it is important to educate individuals that alternative tracking devices use different algorithms, resulting in deviating data output. This was explained to the intervention participants, however, this issue was still often highlighted and strategies to overcome this barrier need to be explored. This issue was commonly highlighted amongst similar studies with nearly half of the participants questioning the reliability of the physical activity monitor in a study utilising a mobile phone app to promote physical activity and reduce sedentary behaviour (King et al., 2013). In addition, there is not yet a standardised method to monitor sedentary behaviour and physical activity through a PHA, thus producing discrepancies within the results. The app in the current study is the first app, to the author's knowledge, to utilise an inclinometer function to measure and provide feedback on sitting time and patterns. Even with this addition, the reliability and validity of the data produced still requires further clarity. Technology that allows individuals to track their physical activity and sedentary behaviour is becoming more frequently available (Lyons et al., 2014). However, little is known regarding the differences in the tools used to measure such behaviours and what influence this may have on the data reported (Lyons et al., 2014). Future research is required to determine the validity and reliability of PHAs for tracking these behaviours to aid in self-management of disease states.

In addition to user complications, with any form of technology there is always a possibility of technical difficulties, which could cause issues such as loss of data and inconsistency in results (Tatara et al., 2009). There is an additional risk of encountering difficulties due to loss, damage or miss-use of the device. Therefore, using an instant upload mechanism (to a server), such as in the app in the present study, would be most appropriate to ensure personal details are kept secure and data is stored throughout the day to reduce the potential loss of information (Stinson et al., 2008). However, several participants in the current study, in addition to other similar studies (Muntaner et al., 2015; Pellegrini et al., 2015), experienced technical complications. Frequent updates will need to be downloaded to ensure the individual has the newest version of the app, which can be time consuming and in some cases can come with a cost and loss of battery life (Muntaner et al., 2015). Participants who took part in a study by Pellegrini et al. (2015) described how constant use of the self-monitoring features in a PHA drained battery power making it hard to complete sufficient amounts of data collection and ensure the phone was charged throughout the day. During the current study, there were limited updates, however, it was reported that the having the app running constantly in the background utilised significant battery power, potentially resulting in inaccuracy and gaps within the data recorded due to the phone turning off.

A significant issue of using a mobile phone to monitor and store the data of a physical activity or behavioural change intervention is that the individual must keep it with them at all times in order to obtain the most accurate and reliable data. An integral implication of the current research and a similar study by Pellegrini et al. (2015) is that individuals would often forget and leave their phone on the desk or not have appropriate clothing to allow the phone to be in a pocket, thus being unable to utilise the inclinometer function effectively resulting in potentially inaccurate data for the user. This may explain why Jackson et al. (2005) reported mixed results, when reviewing numerous apps and management of HbA1c levels, with some studies reducing HbA1c levels and other finding no change or an increase. It was further stated that most of the current research on apps for self-management of health focuses primarily on management of Type 1 Diabetes, with T2DM thus requiring further research (Jackson et al., 2005).

PHAs have numerous features for encouraging self-management of health, for example, feedback, logbooks and goal setting. However, certain individuals in the current study found a number of these features to be burdensome and this appeared to have had a negative influence on app usage. In addition, participants in a similar study reported that prompts and reminders were annoying and demotivating (Dennison et al., 2013). Furthermore, participants in the current study received two text messages weekly based upon MI. This was in an attempt to trigger thought and assist the individuals with reaching their goals. Some participants felt the messages were thought provoking and a useful feature to the app, whereas others found them to be more an annoyance and over the duration of the study, began to ignore them. Dennison et al. (2013) suggested that in order to overcome this issue, the timing, message content and frequency of the prompts and alerts was imperative. In relation to the post-intervention interview feedback from this study, the lack of personalisation in the text messages was highlighted as an important factor to alter in order to make participants more likely to engage with the prompts.

5.7.2 Positive features of mobile phone applications for Type 2 diabetes

Although a number of technical and environmental issues were reported by individuals using the app in the current study, it was vital for individuals to focus on the effective and positive features of the app in order to successfully reach their individually set goals. Participants had to overcome the barriers to app use and focus on the potential benefits of self-management.

A number of participants reported that utilising the app resulted in a greater realisation of certain health behaviours, such as sedentary behaviour. This realisation came hand in hand with a greater knowledge of their diabetes and a link to the NHS diabetes care page built into the app allowed individuals to get up to date articles regarding their disease, receive information on the negative impacts of sedentary behaviour as well as data on a healthy BMI. Mobile phone apps allow individuals to receive information and disease management support throughout the day without the need to rely on the NHS services (Free et al., 2013). A study evaluating mobile phone interventions to assist individuals in giving up smoking allowed individuals to receive extra information and support when they required (Free et al., 2013). Although the current study did not have this feature, a constant link to the NHS website allowed participants to stay up to date with the latest news and health strategies regarding T2DM.

Although some research suggests that the use of reminders and alerts is a positive and helpful feature, it has been suggested that text message interventions are only appropriate for a short-term behavioural change and may not be effective as a long term management strategy (Fjeldsoe et al., 2009). In addition, Pellegrini et al. (2015) reported that participants ignored 48% of the prompts given to break up their sedentary behaviour. Although this means over half of the prompts were acted upon, there is still a need to increase the compliance to produce greater differences in sedentary behaviour. Similar responses were observed in the current study in which individuals suggested the prompts and alerts were beneficial at the start but later became annoying and they began to ignore them. It is therefore difficult to ensure participant adherence to reminders and alerts, questioning the fidelity of such studies.

The MHA app used in the current study had a number of positive features that benefited those in the intervention group. The ability to set and monitor personalised goals allowed participants to oversee their progression towards a goal, which participants reported to improve their motivation to achieve it. Constant access to the NHS website gave participants the opportunity to broaden their knowledge on T2DM without the need for extra doctor appointments. Participants also spoke highly of the constant activity-tracking feature of the app, in which they were not required to turn it on and off, reducing the likelihood of an individual forgetting to turn it on and thus not receive up to date information. Real time feedback was additionally reported to be a positive aspect of the app, allowing individuals the ability to survey their data. An additional feature of the app in the present study was that individuals could set a medication alarm and participants that used this element found it to be thoroughly useful and assisted them in their diabetes management. Many of these features should be implemented in to future studies as all were deemed to have a positive effect on participant's behaviour and compliance with the app.

All participants in the current study, regardless of any complications experienced, stated they would recommend the app to other individuals with T2DM to try, in an attempt to better manage their diabetes.

5.8 The use of Behavioural Change Techniques for disease management

It is evident from the participants' feedback following the intervention that many of the positive aspects to the app are those that are linked to a specific Behavioural Change Technique. As highlighted in Table 2, many of the features utilised in the app were underpinned with theory and BCTs. Direito et al. (2014) suggested that mobile phone apps are most beneficial to health when they are used in alliance with BCTs.

Providing feedback on performance is deemed the most beneficial BCT for improving health and psychological markers, such as wellbeing, depression and self-efficacy in individuals with T2DM (Van vugt et al., 2013). In the current study, this BCT allowed individuals to review and refer back to data on breaks in sedentary time, step count and health markers from previous days. This BCT has also been found to have an association with a reduction in HbA1c levels in T2DM (Cradock et al., 2017).

Participants using MHA could set their own personal goals and then monitor how close they were to achieving them. The use of goal setting decreased BMI in newly diagnosed T2DM by successfully increasing physical activity levels and decreasing dietary intake (Hankonen et al., 2014; Van vugt et al., 2013). However, unlike the current study, where goal setting was electronically set and measured through the app, Hankonen et al. (2014) utilised a face-to-face goal setting intervention, which resulted in a reduction of participant's BMI. With this in mind, electronic goal setting may not be effective for a reduction in BMI as the current study did not find a change in BMI in the intervention group. However, post intervention interviews from the current study suggested that goals were a useful feature of the app and allowed individuals to set specific goals as well as having the ability to monitor how close they were to achieving it.

Further research is required into the use of BCTs in intervention design as it has been reported that their effectiveness is often dependent upon individual differences and thus BCTs may need to be specifically tailored to an individual (Cradock et al., 2017). However, it is not feasible to specifically tailor BCTs to each individual and this would make it difficult to compare interventions across studies. In addition, Cradock et al. (2017) suggested that BCTs used in intervention studies were beneficial to physical activity over a short period of time (3-6 months), but were not sustained long term. Therefore, research is needed to assess how BCTs can be used for effective long-term behaviour change.

Utilising BCTs to develop mobile phone apps is a relatively new field of research and thus requires further evidence. However, Middelweerd et al. (2014) reported that although there is a lack of research, both BCTs and mobile phone app interventions have shown to have positive effect on a number of health behaviours such as physical activity levels, diet and sedentary behaviour and therefore combining the two may be equally, if not of greater, benefit. On average, mobile phone apps include five BCTs with feedback and self-monitoring being the most commonly used (Middelweerd et al., 2014), both of which were features of the app in this study. However, Cowan et al. (2013) reported that physical activity intervention apps often lack theoretical content, suggesting a greater need for app developers to incorporate underlying theories such as behavioural change techniques. This was however addressed in the current study, mapping BCTs to features within the app and should therefore be considered in future app interventions.

5.8.1 The theory of planned behaviour

According to the theory of planned behaviour, when an individual increases their PBC and intention towards a behaviour, it is more likely that they will achieve a behavioural change (Ajzen, 1991) such as reducing sedentary behaviour. In this study, individuals managed to reduce their prolonged sedentary behaviour, which was the primary aim of this study. However, individuals in the intervention group increased their intentions but PBC showed a decrease compared to the control group.

Trafimow et al. (2002) argued that it was not PBC that is influences intentions but perceived behavioural difficulty. Despite the intervention group decreasing their PBC, their perceived behavioural difficulty may have decreased resulting in a greater intention to perform a behaviour, leading to the reduction in total sedentary time and increased number of breaks in sedentary time. Considering this, new research taking into consideration the degree of difficulty an individual feels when adopting or attempting to adopt a behavioural change is needed to establish which component has the greatest impact on intention and behaviour. Additionally, Armitage and Conner, (2001) disclosed how and individual's intentions were a much better more accurate predictor of a behaviour than PBC, attitudes and SN.

SN is reported to be the weakest predictor of intentions and thus behaviour (Armitage and Conner, 2001), individuals in the intervention group of this study decreased their SN, meaning they felt less pressured to conform to their 'social norms' regarding sedentary behaviour.

Participants in the intervention group increased their attitude towards breaking up sedentary behaviour, from baseline to follow up. Although attitude has previously been thought to influence a behaviour (Armitage and Conner, 2001), LaPiere, (1934) questioned this relationship and reported a significant gap between an individual's attitude and their behaviour. There is a clear lack of research into the relationship between and individual's attitude and levels of sedentary behaviour. However, in terms of physical activity levels, Godin and Shephard, (1990) reported that attitude has a strong influence on an individual's physical activity levels. Taking Godin and Shephard's, (1990) findings into consideration, along with the findings of this study, an increase in attitude in line with a reduction in total sedentary behaviour, perhaps attitude does go some way to influencing behaviour, more specifically, sedentary behaviour.

McEachan et al. (2011) described how the TPB is most effective in the prediction of behaviour in a younger, healthy population and thus may not be appropriate for individuals in this study who were generally older with T2DM. In addition, Sniehotta et al. (2014) proclaimed that the TPB is not effective in designing interventions and the potential need for new, broader theories needs to be implemented.

5.9 Discussion synthesis

Although participants in the intervention group reported a decrease in PBC, suggesting they deemed the amount of time they spent in a sedentary state to be out of their control, their attitude towards breaking up and reducing sedentary behaviour increased. The intervention group's SN also decreased meaning individuals had a better attitude towards sedentary behaviour and felt under less social pressure to conform to 'social norms' such as prolonged bouts of sedentary behaviour. Additionally, following the study period, both groups of participants reported an increase in their belief to overcome barriers for reducing and breaking up sedentary time. However, the intervention group did increase their plans and intentions to break up prolonged sedentary behaviour. This resulted in numerous changes in participants' sedentary behaviour. Participants managed to increase their number of short sedentary bouts, breaks in sedentary time as well as decrease their prolonged sedentary bouts and total sedentary time.

Of high importance to an individual with T2DM, use of the MHA app led to beneficial changes in sedentary behaviour and a decrease in 2-hour blood glucose, suggesting greater glucose metabolism and improved diabetes self-management. In addition, a reduction in WC and heart rate was also observed,. In terms of psychological markers, with the MHA app led to an increase in positive mood and wellbeing and a decrease in negative mood. Although not all results were as expected, the findings of this study were instigated by the effective use of BCT coding within the app MHA and should therefore be considered in future app developments.

5.9.1 Strengths of the study

A strength of the current study is that it incorporated both quantitative and qualitative data to assess the feasibility, acceptability and potential effectiveness of the MHA app. In addition, of the 12 participants included in the study, all provided full data for the measures taken at both time points. This suggests that the study was feasible and participants accepted the intervention. Furthermore, this study utilised the ActivPAL activity monitor, which is relatively non-invasive and allows for 24 hour activity monitoring. Importantly, this activity monitor is a valid measure for all sitting related variables, imperative to this study. Finally, this study utilised both a control and intervention group, allowing for comparison between the two, eliminating the effect of external variables, other than that of the MHA app, increasing the reliability of the data collected.

5.9.2 Limitations of the study

One of the major limitations to this study was that the mobile phone app is only available on android devices and therefore, individuals with other phone models had to be provided with an additional device to use the app. Many participants reported this to be an issue, as they had to remember to carry and charge two devices. In order to overcome this issue, the app should be developed for use on all smartphone models to allow individuals to use their own devices and not have the burden of carrying a separate phone for the study period. Both the control and intervention groups wore an ActivPAL activity monitor at baseline and follow-up. Visser & Koster, (2013) suggest that wearing an activity-tracking device alone can influence levels of sedentary behaviour and physical activity, which may produce potentially biased or inaccurate data due to individuals being observed. This may partly explain the improvements in standing time and sedentary bouts lasting >120 minutes in the control group at follow-up. However, this would also be expected to occur in the control group and between-group comparisons should thus remain valid. In addition, the relatively short study period of 8 weeks may not have been long enough to have positive impacts on some health markers such as weight and blood pressure. Future study could assess the efficacy of the app over a longer study period in order to establish whether this could produce more substantial change on a larger range of health markers.

Recruitment for this study was difficult due to the target population (i.e. within 4 years of T2DM diagnosis) and took longer than anticipated, thus only twelve participants competed the study for inclusion in this analysis. A longer project duration would allow for more time spent on recruitment to increase sample size. Furthermore, in terms of the participant demographics, those that completed the study were all of a similar age and a large proportion being from the same ethnicity. Therefore, a study targeting a wider group with more diverse demographics would identify the potential impact that MHA may have on different types of individuals with T2DM.

5.9.3 Future Research

Further research is required into the effectiveness of mobile phone apps to reduce sedentary behaviour for the management of T2DM due to the lack of studies in this area. There is controversy as to whether the reduction in overall sedentary behaviour, increase in the number of breaks in sedentary time or increases in MVPA are most important factors for improving cardiometabolic markers (Cooper et al., 2012). Future studies should thus compare differences in cardiometabolic markers in response to interventions that focus on either reductions in overall sedentary behaviour, increases in the number of breaks in sedentary time or increases in MVPA. Additionally, there is limited research of the effects of sedentary behaviour interventions on mood and wellbeing. In terms of the use of BCT's, more research is required in order to identify the most effective techniques for implementing beneficial sedentary behaviour changes in T2DM. This could involve, for example, qualitative research to enable participants to highlight beneficial BCTs' that they felt attributed to a change in their sedentary behaviour patterns.

A potential next stage to this initial feasibility study could be to test the app's ability for participants to data share with their health practitioners. A study found that the ability to instantly download data from the devices allowed for more in-depth, quicker analysis, allowing for early detection of health issues or reoccurring symptoms an individual might be suffering from (Jacob et al., 2012). Similarly, utilising an automatic data downloading method allowed for greater patient-doctor communication and increased patient satisfaction and adherence (Aungst, 2013). Without this, participants may feel they are on their own and have no reassurance if they were to require it. Finally, future research should examine the long-term effects of the MHA app intervention on reducing prolonged sedentary behaviour and improving mood and wellbeing in T2DM in a fully powered RCT.

Chapter 6: Conclusion

The conclusion of this study is that it is feasible to conduct a trial utilising the MHA mobile phone app in individuals with T2DM with the aim of reducing prolonged sedentary time. This study found an a decrease in prolonged sedentary behaviour and an increase in standing time and light physical activity levels following an 8-week period of the MHA app usage. The intervention also led to an improvement in a number of psychological and physiological markers. The next step in this research programme would be to conduct a fully-fledged trail, using this feasibility study as a basis, to investigate further the potential benefits MHA can have on the management of T2DM.

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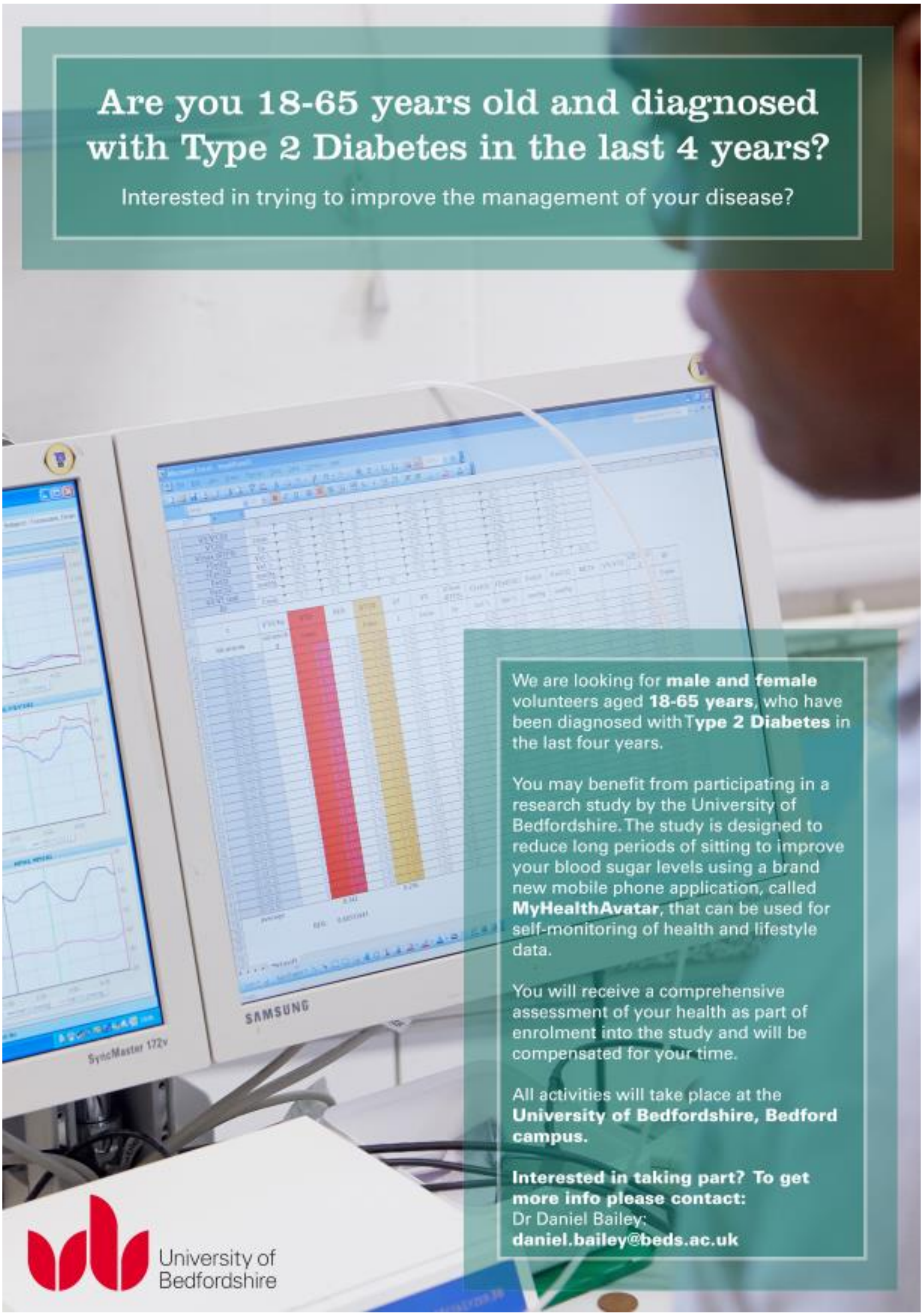
Chapter 8: Appendices

Appendix 1 – Leaflet poster for recruitment



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Appendix 2 – Participant information sheet

Participant Information Sheet

Evaluating how feasible a new mobile phone application is for reducing sitting behaviour and improving blood sugar levels in Type 2 diabetes

Thank you for showing an interest in the study. Below is the information regarding the investigation to be undertaken. Please read this information sheet carefully before deciding whether to participate.

What is the aim of the project?

Heart disease accounts for more than half of deaths in people with Type 2 diabetes and this is mostly due to increased blood sugar levels. Prolonged periods of sitting increase the risk of early death in people with Type 2 diabetes even if the person is active at other times. This means that even people who meet the government guidelines of 150 minutes of exercise per week may have a higher risk of heart disease if they spend long periods sitting. Breaking up prolonged sitting with regular short bouts of standing or walking improves blood sugar levels over a single day compared with uninterrupted sitting or a single continuous bout of exercise. The app we are testing has been developed by researchers at the University of Bedfordshire and can be used for self-monitoring of health and lifestyle data, including sitting time and physical activity. The user can enter and track health and lifestyle information related to Type 2 diabetes that encourages self-monitoring and self-management. The aim of the study is to evaluate whether this new mobile phone application is feasible in reducing prolonged sitting behaviour and improving blood sugar levels and wellbeing in people Type 2 diabetes.

What type of participant is needed?

We are looking for males and females aged 18-65 years, diagnosed with Type 2 diabetes within the last 4 years and in the first stage (single non-insulin blood glucose lowering therapy) or first intensification (dual treatment of metformin plus one other drug) of drug treatment or using a diet and exercise management strategy. All individuals must be able to stand and walk unassisted, not have any other diseases or disorders related to diabetes (e.g. heart disease, damage to the retina at the back of the eye, kidney problems, and infections, ulcers or reduced ability to feel pain in your feet), severe obesity (body mass index ≥ 40 kg/m^2), able to read and speak English, must not be pregnant, and have previous experience using a smart phone. If you think you have a blood borne infection then you should NOT take part in the study.

It is possible that other medical health problems not listed here may limit your ability to take part in this project. These may be identified on a health questionnaire we will ask you to complete and at that stage we will review your suitability for taking part in the project.

What will participants be asked to do?

For this study you will be randomly allocated to either the control group or intervention group (these are described below) and take part in the study for 8 weeks.

Testing visits: You will be asked to attend the University of Bedfordshire Sport and Exercise Science Laboratories in Bedford before and after the 8 week study period for a testing session. Each testing session will last approximately 2.5 hours. You will have height and waist circumference measured. Body fat levels and weight will be measured by standing on a scale with two metal plates. Blood pressure and heart rate will be measured by inflating a cuff around the arm and then letting the air out slowly using an automatic monitor. We will ask you to fast from the night before your visit so we can measure your fasting blood sugar levels when you arrive. We will then measure how well your body controls blood sugar levels by measuring your blood sugar again after you have consumed a drink of water containing 75 g of glucose. We will measure your blood sugar by taking a small finger prick blood sample. A total of 2 finger prick blood samples will be collected during each of your two testing visits.

Questionnaires: we will ask you to complete some questionnaires before and after the intervention to measure your psychological health and wellbeing and reasons that may explain your sitting time behaviours.

Sitting and activity monitoring: We will provide you with a small activity monitoring device that will be stuck to your right thigh to be worn for 8 consecutive days. It is attached to your thigh using medical dressing and this will keep the device waterproof. Therefore you can wear it continuously even when bathing or showering. **It is really important that you wear this activity monitor continuously every hour of every day throughout the 8 day monitoring period**. Without this data we will not know if the intervention has been successful.

What happens if I am in the intervention group?

Intervention procedures: we will ask you to use the mobile phone app for a total of 8 weeks. You will receive a detailed explanation and demonstration of the app at the end of your first testing visit, which will last approximately 30 minutes. The app is only available to Android phones. If you do not have an Android phone we will provide with one for you to use during the 8 week period.

The app: The app is used for self-monitoring of health and lifestyle data. The user can enter and track health and lifestyle information related to diseases, such as Type 2 diabetes, and encourages self-monitoring and self-management. The application has a variety of features to assist the user with their disease management such as:

- A suite for monitoring sitting time and activity levels (number of steps, amount of time being active, distance travelled, amount of time spent sitting, number of breaks from sitting time).
- Goal setting: patients can set personal short or long term goals relating to sedentary time, interruptions in sedentary time, physical activity (step counts), and body weight. These goals are monitored within the app.
- Reminders; the ability to set reminders to encourage individuals to meet daily goals for sitting behaviour and physical activity levels.
- Links to external NHS news and information websites related to the relevant patient disease to serve as an educational tool for the user.

During the 8 week intervention, you will also receive 2 text messages each week from the research team that will help support you in making changes to reduce your sitting time.

Interviews: after the 8 week mobile phone app intervention, you will be interviewed individually to so we can get feedback on your thoughts and feelings towards use of the app. All interviews will be voice recorded and a pseudonym (false name) will be used to ensure participant confidentiality. This will last approximately 30 minutes.

What happens if I am in the control group?

If you are randomly allocated to the control group you will not receive the intervention during the study. You will instead be asked to continue your normal behaviours. It is important that we have a control group so we can make comparisons to know if the intervention has been effective. At the end of the study, participants in the control group will be offered the opportunity to use the app for at least 8 weeks (you can use it for as long as you like if you have your own Android phone) so you have the opportunity to benefit as well. It is really important that you engage fully in the study if you are allocated to this group.

What are the possible risks of taking part in the study?

This study has been reviewed and approved by the Cambridge South NHS Research Ethics Committee.

Blood samples: There is a very small risk of contamination from blood sample collection finger prick blood sample will be taken to measure a number of physiological markers. This risk will be minimised by using screening all participants with a health questionnaires before you take part in the study. Individuals with any blood borne disease or virus will not be permitted to take part in the research. Only trained researchers will take blood samples and they will adhere to University of Bedfordshire standard operating procedure.

Activity monitor: There is a small chance of skin irritation from the adhesive dressing used to attach your activity monitor to your skin. If any discomfort or rash occurs, the activity monitor can be removed immediately and the problem discussed with the research team.

What are the possible benefits of taking part in the study?
It is to be hoped that the participants will benefit from reductions in prolonged sitting behaviour and increases in physical activity in response to using the app. The app also provides educational tools so you can be further educated around Type 2 diabetes, which could encourage adoption of lifestyle behaviours that could benefit the management of your condition and reduce heart disease risk and improve your wellbeing.

Participants who take part in the project and **provide full data before the intervention and after the intervention** will receive a **£10 shopping gift voucher**. These vouchers are redeemable in a variety of top stores.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice in accordance with the Data Protection Act (1998). All information and results collected will be held securely at the University of Bedfordshire and will only be accessible to senior members of the research team. Access to identifiable data (name, address etc.) will be limited to selected members of the research team and will be kept on secure University computers. This information and other personal details will not be included in analysis, or in publications or reports. All information collected during the study will be identified by a unique code so that you cannot be identified from it. All data will be kept on secure computer servers and in locked filing cabinets within a locked office at the University of Bedfordshire. The audio recorded interviews will be recorded on a password protected device accessible only to the research team. The data generated within the mobile phone app is stored in a highly secure server that only senior members of the research team will have access to. If you no longer want to use the app (you can continue using it after the study), you can close your account and request for all of your data generated within the app to be destroyed.

What if you decide you want to withdraw from the project?

At any stage of the study, you, as a participant, are free to withdraw and stop taking part completely in the research study. This can occur without any justification and you will be at no disadvantage if you chose to do so. All personal details will be destroyed and your anonymity will be maintained.

If you lose the capacity to consent during the study, you will be withdrawn from the study. Identifiable data already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

What will happen to the results of the study?
The results of the study will be used to assess the feasibility of the app in reducing prolonged sitting behavior and improving blood sugar levels. The results may be presented at academic conferences and/or published in academic journals. Everyone that takes part in the study will receive the results of the study once they are available.

How do I sign up to take part in this study?
If you would like to participate in this study then please complete the attached consent form and return it by email to Daniel.bailey@beds.ac.uk or by post to the address below. If you

have not been provided a consent form then please contact Daniel.bailey@beds.ac.uk to express your interest.

What if I have any questions?

Questions are always welcome and you should feel free to ask Daniel Bailey or Lucie Mugridge any questions at anytime. See details below for specific contact details.

Who do I contact if I have a problem?

If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact: Dr Andrew Mitchell, Acting Director, Institute for Sport and Physical Activity Research, University of Bedfordshire, Andrew.mitchell@beds.ac.uk, Tel: 01234 793363.

Many thanks,

Dr Daniel Bailey: daniel.bailey@beds.ac.uk, Tel: 07708 907861

Institute for Sport and Physical Activity Research

University of Bedfordshire

Polhill Avenue

Bedford

MK41 9EA

Miss Lucie Mugridge (MSc by Research student): lucie.mugridge@study.beds.ac.uk

University of Bedfordshire

Appendix 3 – Consent form

Title of Project: Evaluating how feasible a new mobile phone application is for reducing sitting behaviour and improving glucose (blood sugar) control in Type 2 diabetes

Please initial box

1. I confirm that I have read and understand the information sheet dated for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my data collected during the study may be looked at by individuals from the University of Bedfordshire, where it is relevant to my taking part in this research. ☐

4. I understand that if I am allocated to the intervention group, I will participate in an interview that will be audio recorded by the research team. ☐

5. I agree to take part in the above study ☐

____________________________ __________ ______________

Name of Participant Date Signature

Ethnicity:____________________ Age:__________________________

____

Address

____

Email

_________________________________ _______________________________

Telephone Mobile

________________________ __________ ______________

Researcher Date Signature

University of Bedfordshire

Appendix 4 – Pre study questionnaire and screening

PRE-STUDY MEDICAL AND SCREENING QUESTIONNAIRE

To be completed by all participants prior to taking part in the research

Name:___________________________

D.O.B:_______________ Gender: Male / Female

Please circle the appropriate response:

1) Are you able to read and speak in English? Yes / No

2) Do you have access to an Android phone? Yes / No

3) Do you have experience of using a smartphone? Yes / No

4) Do you have any planned trips outside of the UK in the next 3 months? Yes / No
If yes, please explain:

5) Have you been diagnosed with Type 2 diabetes? Yes / No

6) When were you diagnosed with Type 2 diabetes? __________month ________ year

7) Are you pregnant or have you been pregnant in the past 6 months? Yes / No

8) Are you suffering from any serious illnesses/accidents? Yes / No
If yes, please explain:

9) Are you recovering from any form of illness/operation? Yes / No
If yes, please explain:

10) Are you currently taking medication? Yes / No
If yes, please explain:

11) Are you currently taking part in any other research projects? Yes / No
If yes, please explain:

12) Have you taken part in any research projects in the past 6 months? Yes / No
If yes, please explain:

13) Do you suffer from chest pains at any time? Yes / No

14) Are you currently dieting or taking any weight loss supplements? Yes / No

15) Do you suffer or have you suffered from any of the following:
Respiratory conditions (asthma, bronchitis/others) Yes / No
Epilepsy Yes / No
High blood pressure Yes / No
Heart conditions (angina/ heart attack/varicose veins) Yes / No

16) Do you suffer from fainting/blackouts/dizziness? Yes / No

17) Is there any medical reason that you know of that could stop you from participating in this research study? Yes / No

DECLARATION

My replies to the above questions are correct to the best of my belief and I understand that they will be treated with the strictest confidence. The researcher has explained to my satisfaction the purpose of the experiment and possible risks involved.

I understand that I may withdraw from the experiment at any time and that I am under no obligation to give reasons for withdrawal or to attend again for experimentation.

I undertake to obey the research instructions, subject only to my right to withdraw declared above.

Name of Participant (please print) ____

Signature of Participant ________________________________ Date: ___________

Name of Researcher (please print)____

Signature of Researcher ___________________________ Date: __________

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Appendix 5 – Questionnaire booklet

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MyHealthAvatar

<u>Questionnaire booklet</u>

The information that you are about to give will help us to help you and others like you to manage their diabetes. Please answer **all** the questions as truthfully as possible.

If you have any queries please do not hesitate to ask.

Thank you for your involvement in this research project.

Determinants of sedentary behaviour questionnaire

Part 1: Overcoming barriers to sedentary behaviour

Sedentary behaviour means when you are sitting and not using up much energy, such as when watching TV, using the computer, or working at a desk. Below is a list of things people might need to overcome while trying to avoid long periods of sedentary behaviour. Please put a cross in one box for each item that best represents how certain you are that you could avoid long periods of sitting during these times.

	How certain are you that you could overcome the following barriers?	**Very uncertain**	**Rather uncertain**	**Rather certain**	**Very certain**
Q1	I can manage to avoid long periods of sitting even when I have worries or problems				
Q2	I can manage to avoid long periods of sitting even if I feel depressed				
Q3	I can manage to avoid long periods of sitting even when I feel tense				
Q4	I can manage to avoid long periods of sitting even when I am tired				
Q5	I can manage to avoid long periods of sitting even if I am busy				

Part 2 – Your attitudes towards sedentary behaviour

For the statements below please circle the number that you agree with most:

Q1) Avoiding long periods of sitting would be…:

Harmful	1	2	3	4	5	6	7	Beneficial
Boring	1	2	3	4	5	6	7	Interesting
Unenjoyable	1	2	3	4	5	6	7	Enjoyable
Unhealthy	1	2	3	4	5	6	7	Healthy

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Part 3 – Your intentions towards sedentary behaviour

For each statement below please circle the number that you agree with most:

Q1) I expect to avoid long periods of sitting over the next week:

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Q2) I want to avoid long periods of sitting over the next week:

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Q3) I intend to avoid long periods of sitting over the next week:

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Q4) I am confident that I can avoid long periods of sitting over the next week:

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Part 4 – Planned behaviour and social opportunity

For each statement below please circle the number that you agree with most:

Q1) Most people who are important to me think that I should avoid long periods of sitting over the next week:

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Q2) For me to avoid long periods of sitting over the next week will be:

Difficult 1 2 3 4 5 6 7 Easy

Q3) It is expected of me that I avoid long periods of sitting over the next week:

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Q4) The decision to avoid long periods of sitting over the next week is beyond my control:

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Q5) I feel under social pressure to avoid long periods of sitting over the next week:

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Q6) Whether I avoid long periods of sitting over the next week is entirely up to me:

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Part 5 - Your plans

Below are a number of statements. Please put a cross in one box for each of the six statements to indicate the extent to which you agree or disagree with that statement over the last week:

No.	During the last week…	Completely disagree	Somewhat disagree	Somewhat agree	Completely agree
		Please cross			
Q1	I have made a detailed plan regarding when to avoid long periods of sitting (e.g. watching TV, using the computer or at work)				
Q2	I have made a detailed plan regarding where to avoid long periods of sitting				
Q3	I have made a detailed plan regarding how to avoid long periods of sitting				
Q4	I have made a detailed plan regarding how often to avoid long periods of sitting				
Q5	I have constantly monitored whether I spent long periods sitting				
Q6	I have watched carefully that I interrupt long periods of sitting with standing or walking				

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Part 6 – Your feelings

Next we would like to ask you four questions about your feelings on aspects of your life. There are no right or wrong answers. For each of these questions please give an answer on a scale of 0 to 10, where 0 is 'not at all' and 10 is 'completely'. **Please circle only ONE response <u>for each question</u>**

Q1) Overall, how satisfied are you with your life nowadays?

Not at all satisfied										Completely satisfied
0	1	2	3	4	5	6	7	8	9	10

Q2) Overall, to what extent do you feel that the things you do in your life are worthwhile?

Not at all worthwhile										Completely worthwhile
0	1	2	3	4	5	6	7	8	9	10

Q3) Overall, how happy did you feel yesterday?

Not at all happy										Completely happy
0	1	2	3	4	5	6	7	8	9	10

Q4) Overall, how anxious did you feel yesterday?

Not at all anxious										Completely anxious
0	1	2	3	4	5	6	7	8	9	10

Part 7 – your wellbeing

Below are some statements about feelings and thoughts. Please tick the box that best describes your experience of each over the **last 2 weeks**.

	Your thoughts and feelings	None of the time	Rarely	Some of the time	Often	All of the time
No.		**Please mark your answers with a cross**				
Q1	I've been feeling optimistic about the future					
Q2	I've been feeling useful					
Q3	I've been feeling relaxed					
Q4	I've been feeling interested in other people					
Q5	I've had energy to spare					
Q6	I've been dealing with problems well					
Q7	I've been thinking clearly					
Q8	I've been feeling good about myself					
Q9	I've been feeling close to other people					
Q10	I've been feeling confident					
Q11	I've been able to make up my own mind about things					
Q12	I've been feeling loved					
Q13	I've been interested in new things					
Q14	I've been feeling cheerful					

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Part 8 – Your mood

Below are a number of words that describe different feelings and emotions. Please read each one and mark the number that best describes how you have been feeling **over the last week.**

Over the last week I have felt:	Very slightly or not at all 1	A little 2	Moderately 3	Quite a bit 4	Extremely 5
Interested	1	2	3	4	5
Distressed	1	2	3	4	5
Excited	1	2	3	4	5
Upset	1	2	3	4	5
Strong	1	2	3	4	5
Guilty	1	2	3	4	5
Scared	1	2	3	4	5
Hostile	1	2	3	4	5
Enthusiastic	1	2	3	4	5
Proud	1	2	3	4	5
Irritable	1	2	3	4	5
Alert	1	2	3	4	5
Ashamed	1	2	3	4	5
Inspired	1	2	3	4	5
Nervous	1	2	3	4	5
Determined	1	2	3	4	5
Attentive	1	2	3	4	5
Jittery	1	2	3	4	5
Active	1	2	3	4	5
Afraid	1	2	3	4	5

Appendix 6 – Activity monitor instructions and log

Thigh Monitor Instructions (ActivPAL)

How do I wear the monitor?

- The Thigh Monitor is attached directly onto the skin and positioned on the front of the thigh, roughly 1/2 of the way between hip and knee with the stick man standing up (see picture).
- Please wear the monitor **every day for 7 days**.

- **Please return you monitor to us on ______________________**

- Please wear the Thigh Monitor continuously (24 hours/day)
- The Thigh Monitor **can be** worn during sleep and is water resistant but please **do not wear it** when swimming or in the sea.
- The adhesive patch that sticks the Thigh Monitor to your skin may last up to 8 days but to avoid skin irritation you may want to change the adhesive patch.

Note: The Thigh Monitor will emit a green flash every 6 seconds. This is an indication that it is working and recording data.

How do I change the adhesive patch?

- You can watch this video for guidance on how re-attach your Thigh Monitor: https://www.youtube.com/watch?v=JcuFtFQ3auw&feature=youtu.be
- Remove the Thigh Monitor from your thigh and peel the adhesive patch off the Thigh Monitor. The monitor is covered in a waterproof sleeve and wrapped in one adhesive patch—please make sure that these remain on the monitor when you do this (they make the monitor waterproof).
- With an alcohol prep wipe provided, thoroughly wipe down the area of your leg where the Thigh Monitor was attached.
- Position the Thigh Monitor in the same spot as previously on your thigh (or on the other thigh if you have had a slight irritation), ensuring that the stick man on the front of the Thigh Monitor is standing up (head facing upwards).
- Peel the covering off an adhesive patch (provided in your pack) and place it over the Thigh Monitor. Press the patch onto your skin, starting from the middle out towards the edges peel back the top layer of the patch and smooth out the air bubbles and wrinkles as much as possible to ensure that the Thigh Monitor is firmly secured to your thigh.
- If you require assistance re-attaching your Thigh Monitor, or if you experience any skin irritation whilst wearing it, please call Ben Maylor on 07840 147734.

What else do I need to do?

- It is important that you fill in the **Daily Log** on the following pages every day for the 7 days while you are wearing the monitor.
- This helps us to look specifically at the data from when you were awake.

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ID Number:

How to fill in the daily activity monitor log

- The log is divided into 7 days. Please complete each question for all of the 7 days. Please try and be as accurate as possible—record the exact times if you can, or at least to the nearest 5 minutes of your estimated times.
- Start by writing the **date** in the top row.
- Record the time that you **woke up** and the time that you actually **got out of bed**. We ask for these two times because people sometimes spend time in bed before going to sleep or getting up and we are interested in distinguishing between actual sleeping time and time in bed before sleep or once awake, for example going to bed and watching TV for an hour before going to sleep.
- Please write **AM or PM** next to your times.
- Record the time that you **started** and **finished** work. This allows us to look at the data recorded whilst you were at work.
- Record what time you **got into bed** to go to sleep and the time that you actually **went to sleep time**. (i.e., the estimated time that you fell to sleep not the time that you got into bed). This is important as the monitor cannot tell the difference between asleep and awake times.
- Please record your sleep time first thing in the morning when you wake up along with recording your wake time and time that you got out of bed.
- If you remove either device for longer than 10 minutes during the day please note down the **time that you removed the device**, the **time length that the device is removed** and the **reason why you removed the device**. This is particularly important as we cannot tell from the data if you are you are lying down or whether you have removed the device and are just not wearing it (the data looks the same when we look at it).
- Being as accurate and thorough as possible when completing this log enables us to look at your data more accurately.
- If you have any questions about the log please contact Lucie Mugridge on 07783 322349 or lucie.mugridge@study.beds.ac.uk.

Day and date	Wake up	Got out of bed	Started work	Finished work	Got into bed	Went to sleep	Times during the day when I took my leg monitor off and why 	Any other comments
Example: Mon 17th Dec	*0700am*	*0715am*	*0900am*	*1700pm*	*2300pm*	*2330pm*	*1600pm for 45 minutes to go swimming*	
Date:								
Date:								
Date:								
Date:								
Date:								
Date:								
Date:								

Appendix 7 – Participant guidance sheet for using the MyHealthAvatar app

<u>Participant guidance sheet for using the MyHealthAvatar app</u>

Dear participant,

Thank you for agreeing to take part in our research project evaluating use of the MyHealthAvatar mobile phone application to reduce sitting behaviour and improve glucose control in people with Type 2 diabetes.

You have been randomly allocated to the intervention group of the study. We would like you to use the MyHealthAvatar phone app for the next 8 weeks. The instructions below will guide you through how to use the phone app.

If you are using a mobile phone provided by the University, the tariff includes data only so you can use the MyHealthAvatar app. Call or text allowances are not included.

What is it?

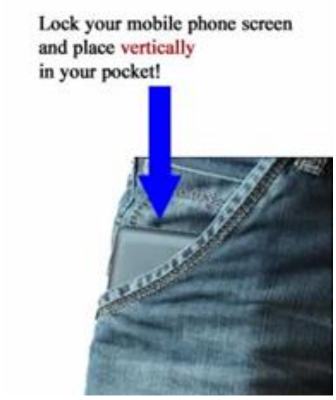
The mobile phone app you will be using is called “MyHealthAvatar”. We will help you download this onto your phone and set up an account.

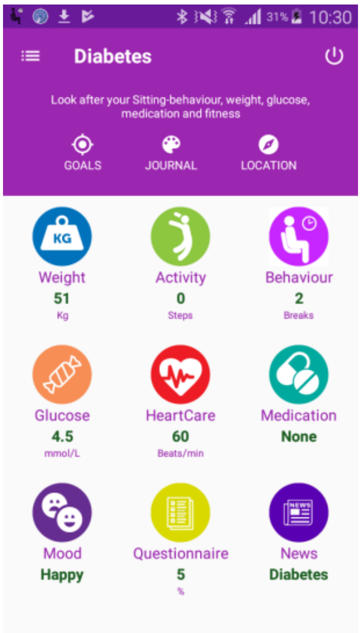
When to use the app?

Use the application on a daily basis, whenever convenient around your day to day activities.

How?

- Login to your account to record or monitor any data or information
- The built-in technology will monitor your sitting time and activity levels throughout the day **(IMPORTANT: please keep the phone in your pocket vertically and lock the screen to get the most accurate measurements)**

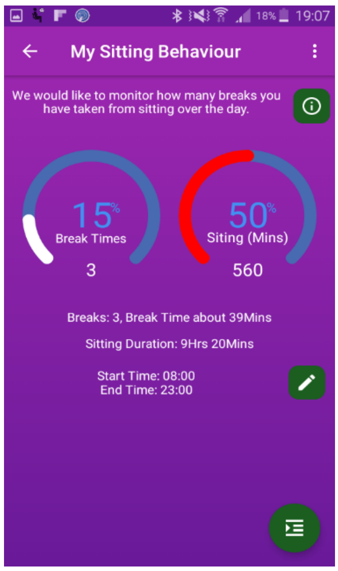


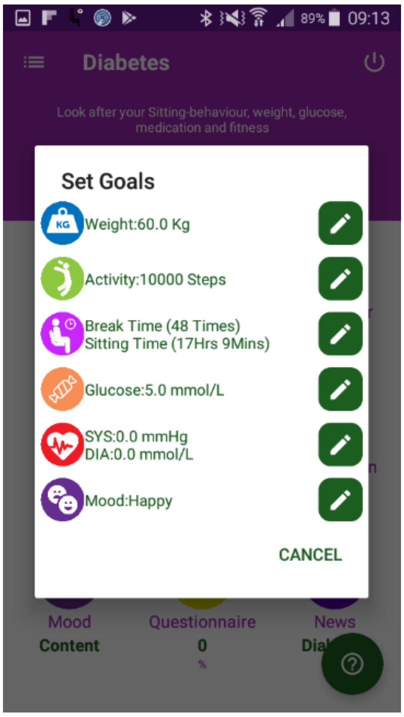


An overview of the home page of the app. Click on any of the boxes to access more information.

My sitting behaviour: Shows your sitting behaviour, including how long you have been sitting and how many breaks you take from sitting. Reducing long periods of sitting is important for managing glucose levels.

Start and end time of the behaviour monitoring can be altered to suit your lifestyle.



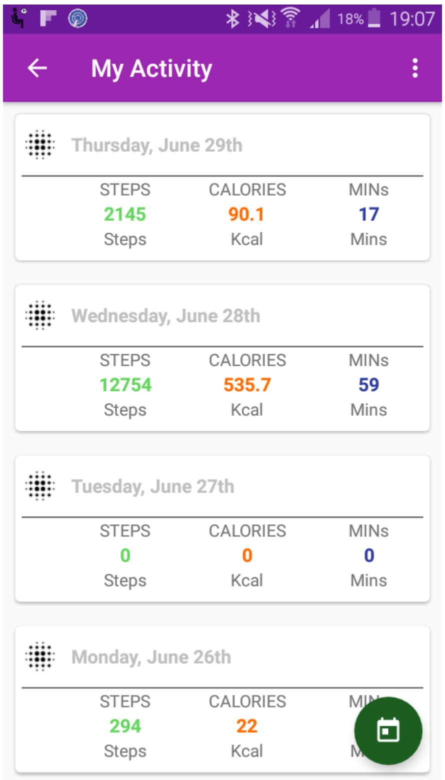


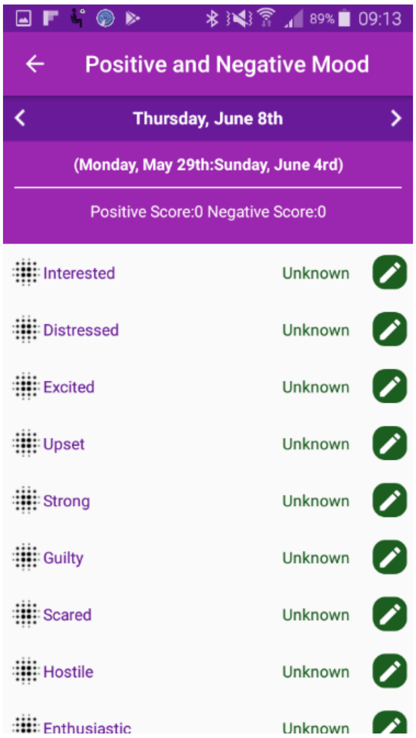
Goal setting: allows you to set a number of goals for various aspects of your behaviour.

Weight, activity levels, sitting time, breaks from sitting, glucose, blood pressure and mood.

My Activity: allows you to track your activity levels on a daily basis.

Comparison between dates/weeks can be seen and graphs show a weekly and monthly activity summary.

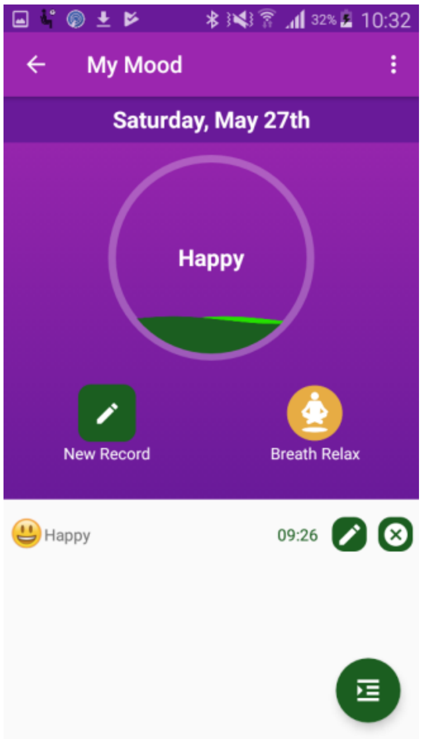




My Questionnaire: a positive and negative mood scale to be completed at your leisure.

Grade each word to your current feeling to receive a positive and negative mood state score.

My Medication: Allows you to enter data on your medicine with reminders, alerts and notes.



My mood: Allows you to input your mood and a breathing tool to help you relax.

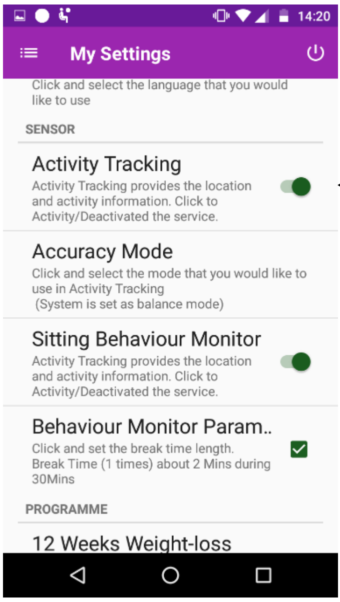
My NHS News: Links to the NHS news specifically for diabetes.

There are also other features within the app such as areas to monitor and manage your body weight and glucose levels. We encourage you to explore all features of the app.

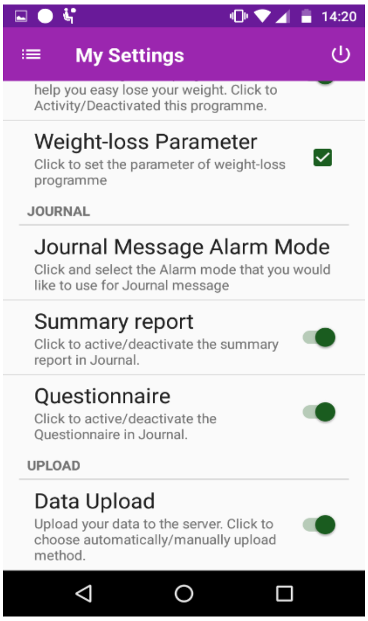
<u>**Making sure you have the correct settings**</u>

It is important you have your phone set so that data is enabled for use with the MyHealthAvatar app and that there are **no power saving options selected for the app – you will need to check your phone's setting to ensure it is not trying to save power by switching some of the app functions off**. This will result in your activity and sitting behaviours not recording all the time.

Within the app it is important you have the following settings selected:

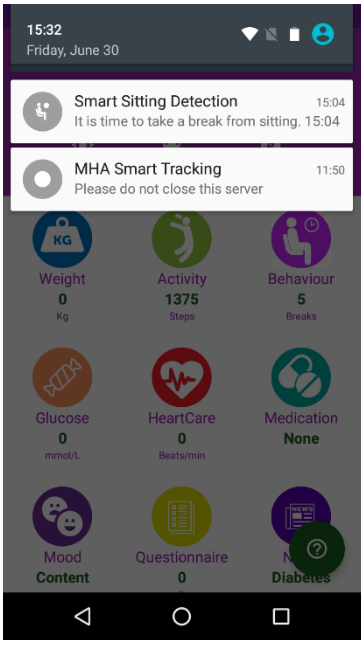


My Settings: Ensure that activity tracking and sitting behaviour monitor is always on to allow the app to measure your daily activity levels.



My settings: Turn on summary report and questionnaire to receive feedback in the journal page. However, you can save battery by turning it off if you do not want to use it.

Ensure Data upload is **ALWAYS** on to allow the data to upload to the servers



Notifications: in your notification drop down bar you should see these two notifications at **ALL TIMES.** If you do not then change "My settings" as above.

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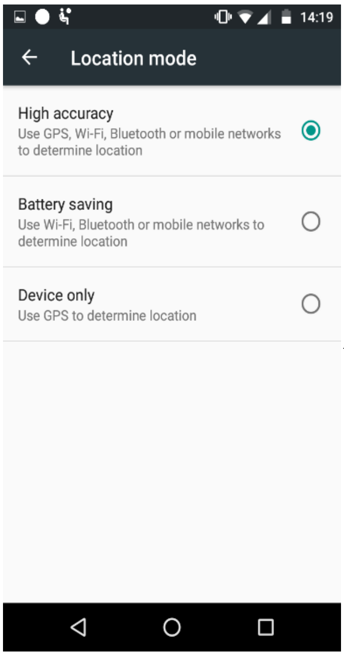
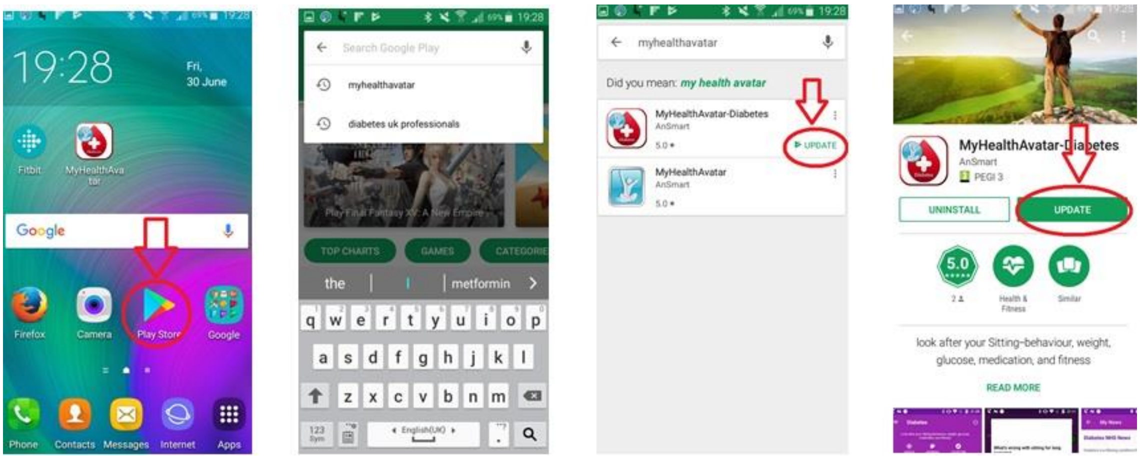


Phone settings: The phone's location settings should always be on **High accuracy** to permit the greatest data accuracy.

App updating: New versions of the app become available during the study to fix bugs and improve its data accuracy. Ensure you give the app permission to auto update. If not, you will need to go to the Google Play Store to update the app manually (follow the instructions below).



If you have any urgent issues regarding the phone app or the research project please contact Miss Lucie Mugridge on lucie.mugridge@study.beds.ac.uk or 07783 322349 or Dr Daniel Bailey (Principal Investigator) on daniel.bailey@beds.ac.uk.

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Appendix 8 – Text message support

Intervention Text Message Support

(Utilising Motivational Interviewing and the principles of the G.R.O.W - goal/reality/opportunity/will- model of Health Coaching)

Week 1- **G.**R.O.W

What sitting time goals do you hope to achieve?

- Sitting for shorter durations, sitting less throughout the whole day, getting up and moving around more often?

How can you make your goals SMART?

- Specific, Measureable, Achievable, Relevant and Timely

Week 2- **G.**R.O.W

How would sitting less benefit you?

- Better quality of life, more mobile, weight loss, better glucose control, something else?

What are the negative outcomes of sitting too much?

- Poor health/ fatigue/ weight issues/ low fitness

Week 3- G.**R.**O.W

What has stopped you from sitting less in the past?

- Time, opportunity, work, cost, motivation, something else?

What have you tried before to help you to sit less?

- Changing your environment, making plans to sit less, giving yourself cues/reminders to move

Week 4- G.**R.**O.W

What can you do differently going forward, to help you reach your goal of sitting less?

- Assign a certain day or time, set an alarm, get others involved, something else?

When will you know you have reached your intended goal?

- When I lose X amount of weight / when I complete X amount of steps per day

Week 5- G.R.**O.**W

What support is available to you to help you to sit less?

- Mobile phone app, internet, diabetes support groups, NHS website, something else?

Who can help you to reach your goal?

- Peers / family / friends / colleagues / support groups

Week 6- G.R.**O.**W

How does it feel when you are meeting your goal?

- Positive, happy, energetic

How can you continue to make positive changes?

- Make plans, ask friends to help

Week 7- G.R.O.**W**

On a scale of 0-10, how important is it for you to make changes to help you to sit less?

- What made you chose this number?

What are your next steps to maintaining and reaching new goals?

- Working with friends, SMART goals, something else?

Week 8- G.R.O.**W**

What barriers might you have to overcome to reach and maintain your goal?

- Work, time, money, transport, motivation, something else?

How will you reward yourself when you complete your intended goal?

- Buy a new outfit / book a holiday / take some time to relax / something else?

Appendix 9– Post-intervention interview questions

Post-intervention Interview Questions

Participant ID number:

Firstly, thank you for taking part in the research project, your participation is much appreciated. We intend to create the best possible mobile phone application for type 2 diabetes patients; therefore we require your feedback on using the app itself to find out what was beneficial and what could be improved for future users.

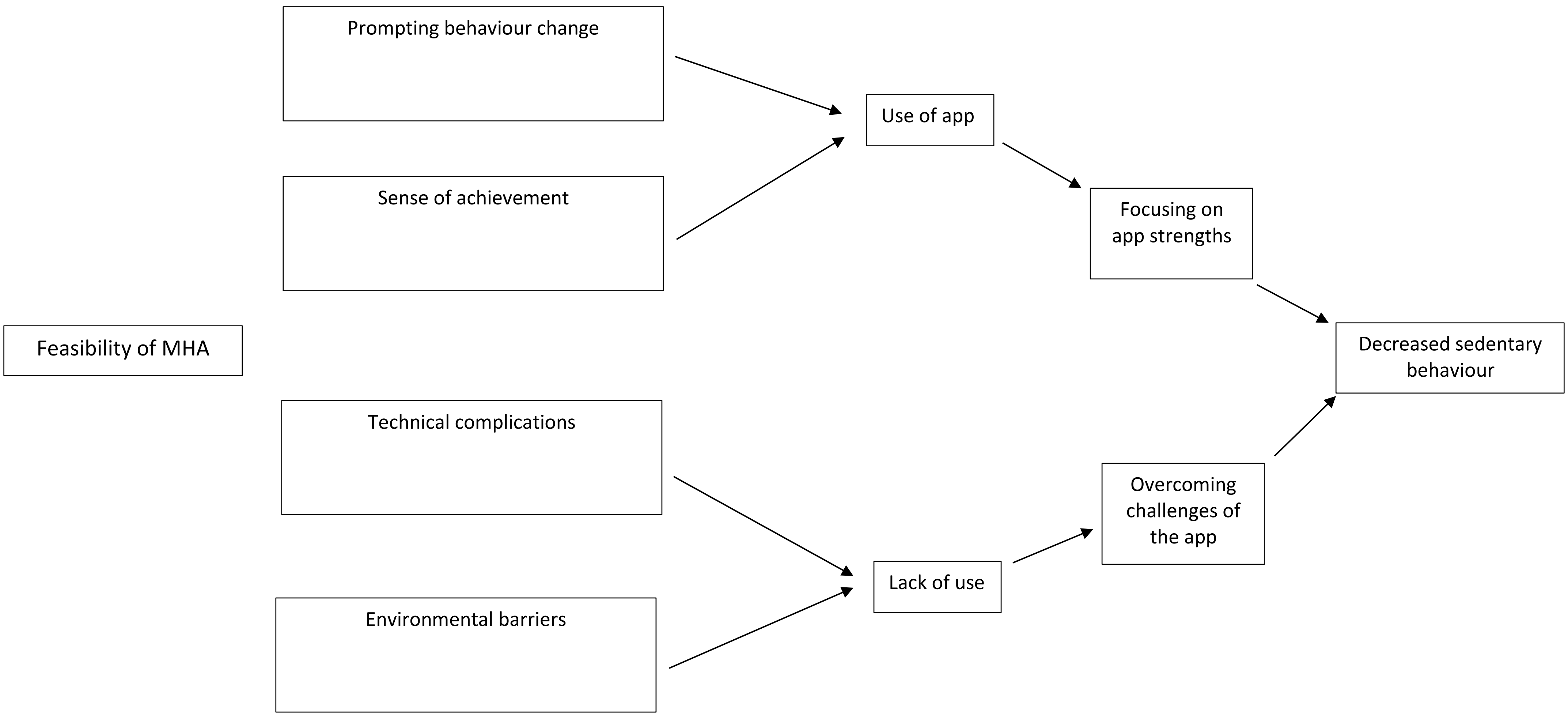
You will be asked a number of questions regarding the app, please answer honestly with as much detail as you feel relevant. The interview will be recorded to allow for analysis, with pseudonym (false names) put in place to protect your confidentiality at all times. Do you have any questions? If not we will begin with the first question.

1. What was your experience of using the app, MyHealthAvatar?
2. What were the most beneficial aspects to the app?
   a. Prompt: Which elements of the app did you find most useful?
3. What did you find hard about using the app?
   a. Prompt: What was challenging?
4. What changes have you made to your daily routine since using MyHealthAvatar?
   a. Prompt: Less time spent sitting/conscious of prolonged periods of sitting time/more active – higher number of daily steps
5. How do you think the app has influenced your health and wellbeing?
   a. Prompt: Feel fitter? More energy? Better mood? Glucose control?
6. Which elements of the app would you change?
   a. Prompt: why is this?
7. How did you find the break from sitting reminder/alerts?
8. Prompt: What about when you had already had a break from sitting? What would you say to other people with type 2 diabetes who are thinking of using the app?
   a. Prompt: Would you recommend it? Why?
9. What would have assisted you with using the app?
   a. Prompt: Information?
10. What would you add to the app to make it a more effective diabetes management tool?

Is there anything else that you want to add to help us evaluate the app that we haven't already covered?

Thank you for your ongoing involvement within this study, we hope you have benefitted from your experience and would be happy to accept any feedback positive or negative.

Appendix 10 – Thematic analysis maps



1st stage codes

- Software issues
- Setting goals
- Remembering device
- Breaking up sitting time
- Inaccurate recording of data
- Greater knowledge of diabetes
- Ease of use
- Ensuring phone is charged
- Limits clothing
- Increased PA levels
- Reacting to prompts and alerts
- Altering lifestyle

→

2nd stage codes

- Reacting to prompts and alerts
- Altering lifestyle
- Breaking up sitting time

- Ensuring phone is charged
- Remembering device
- Limits clothing

- Ease of use
- Software issues
- Inaccurate recording of data

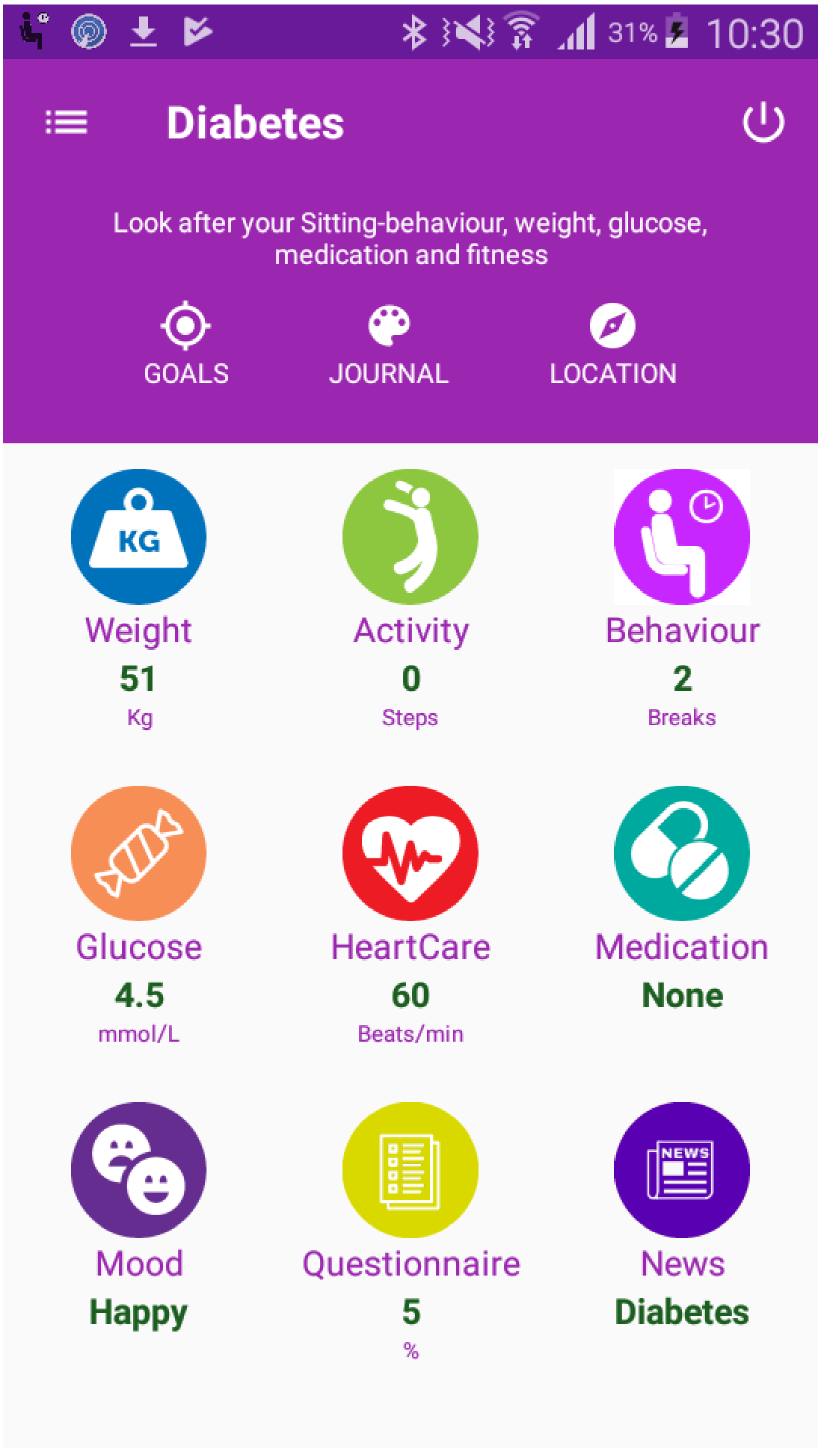
- Increased PA levels
- Setting goals
- Greater knowledge of diabetes

→

3rd stage themes

- Prompted behaviour change
- Environmental barriers
- Technical complications
- Sense of achievement

Appendix 11 – Coded screenshots of the app

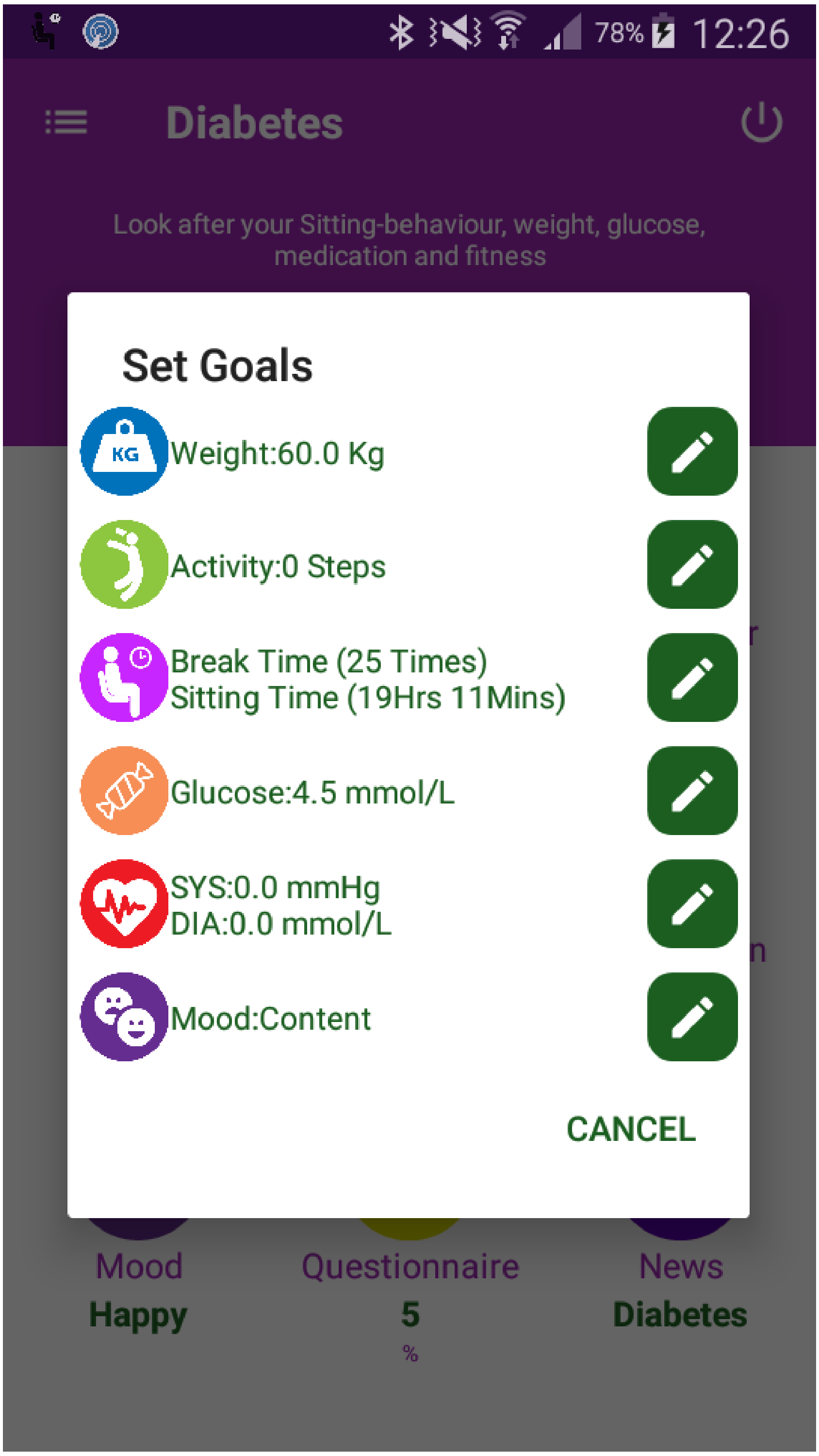


Codes;

2.2 Feedback on behaviour

2.7 Feedback on outcome(s) of behaviour

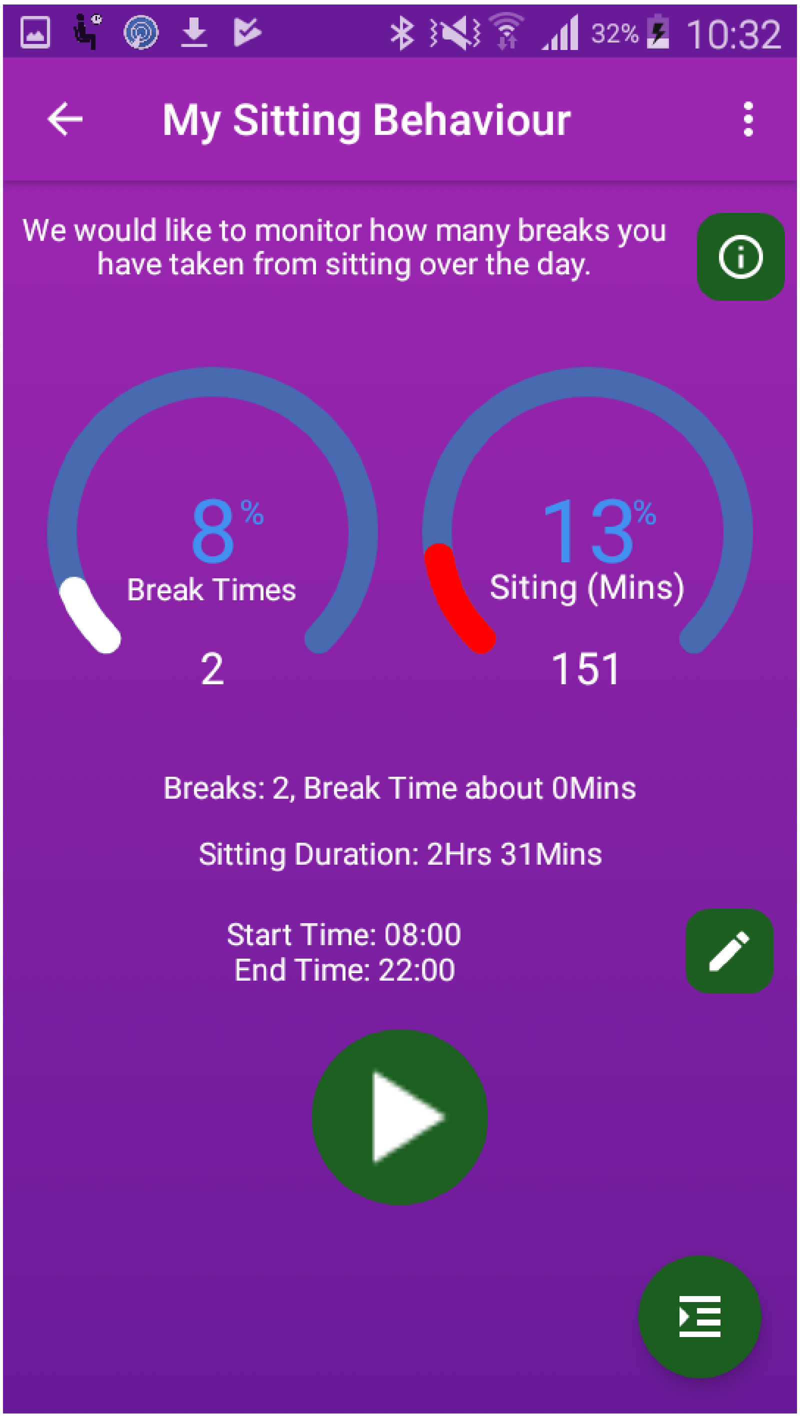
5.4 Monitoring of emotional consequences



Codes;

1.1 Goal setting (behaviour)

1.5 Review behaviour goal(s)

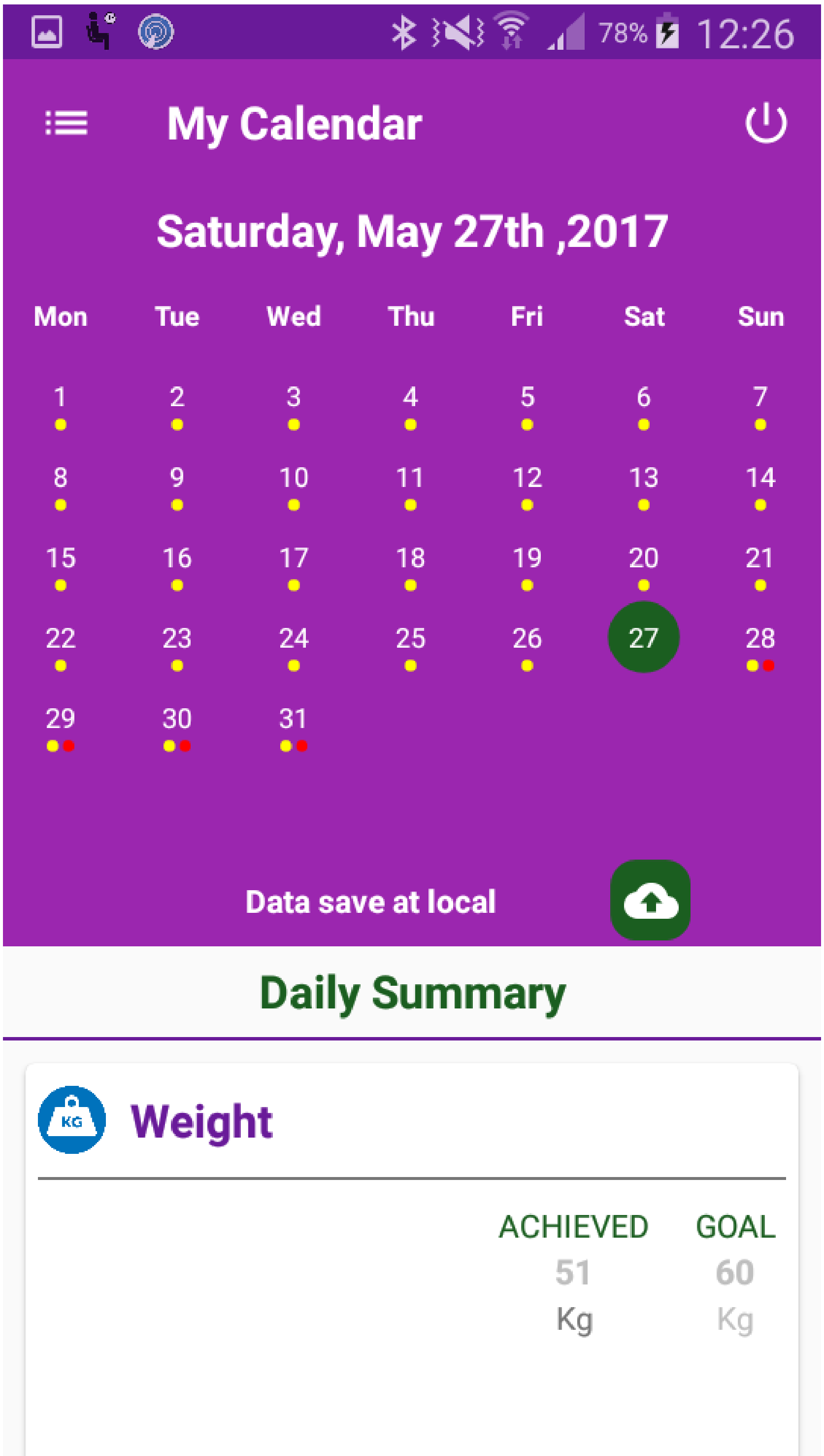


Codes;

1.6 Discrepancy between current behaviour and goal

2.2 Feedback on behaviour

2.3 Self-monitoring of behaviour

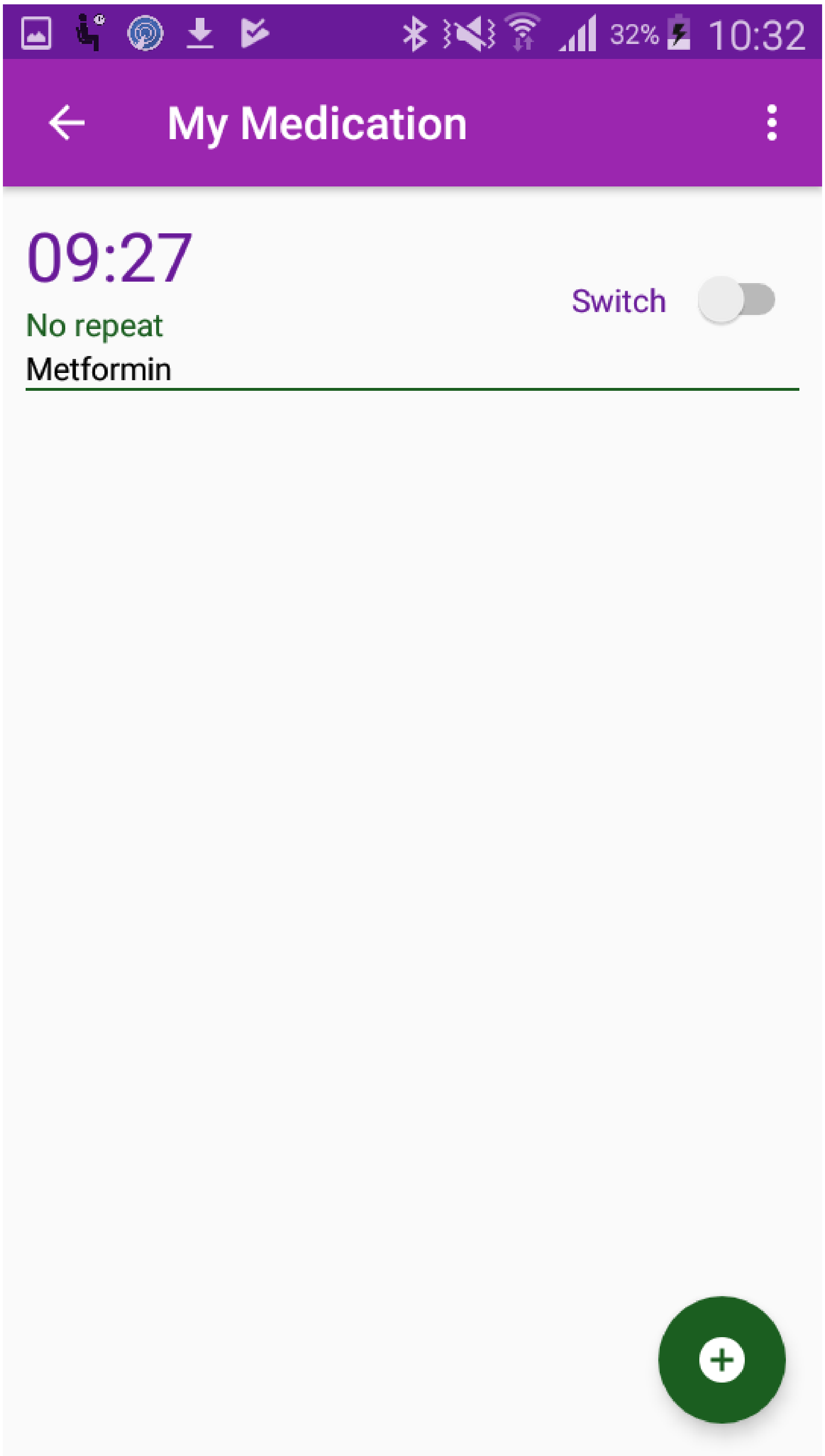


Codes;

1.4 Action planning

1.7 Review outcome goals(s)

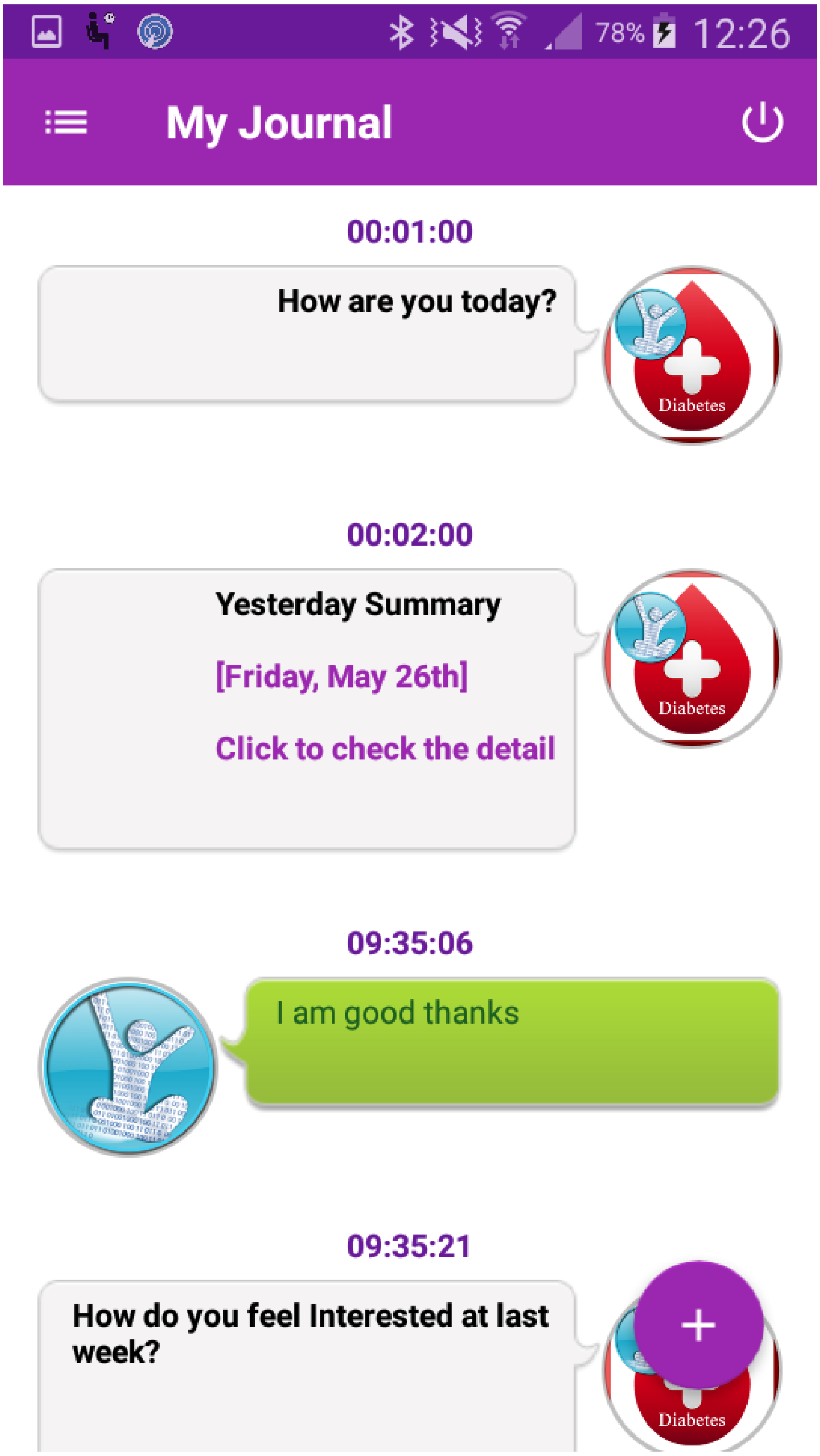
2.2 Feedback on behaviour



Codes;

1.4 Action planning

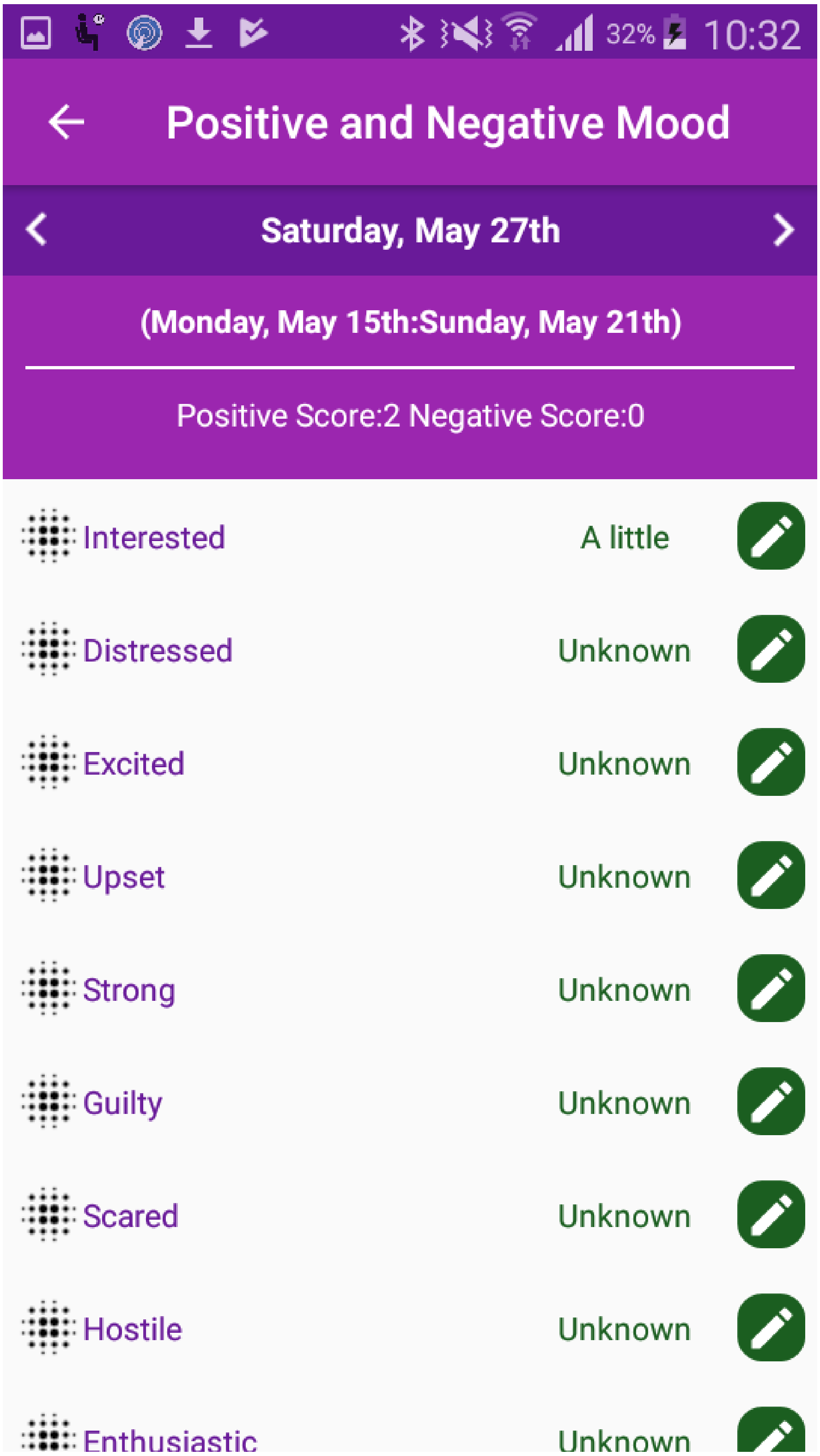
7.1 Prompt/cues



Codes;

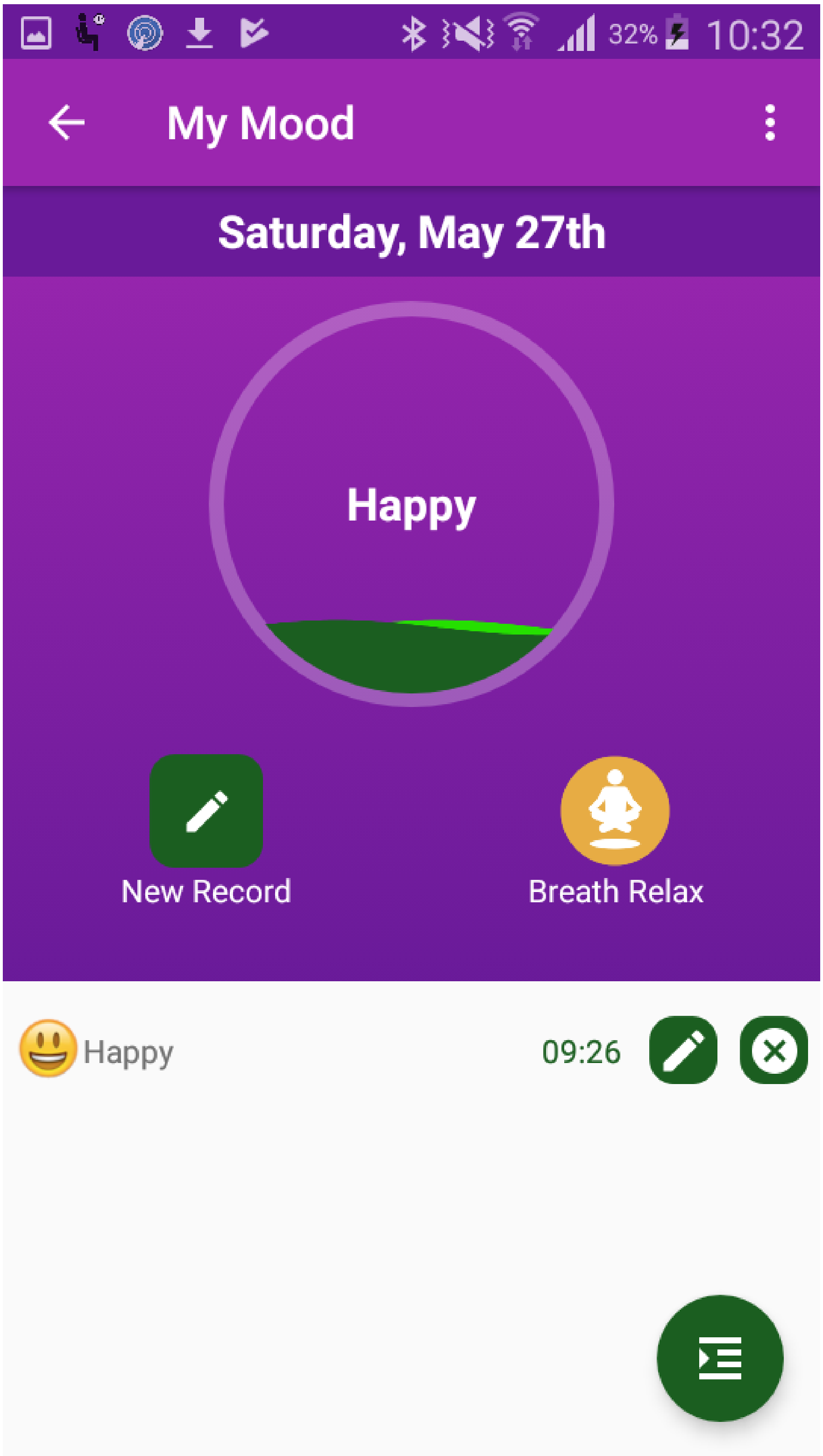
1.5 Review behaviour (goals)

3.1 Social Support (unspecified)



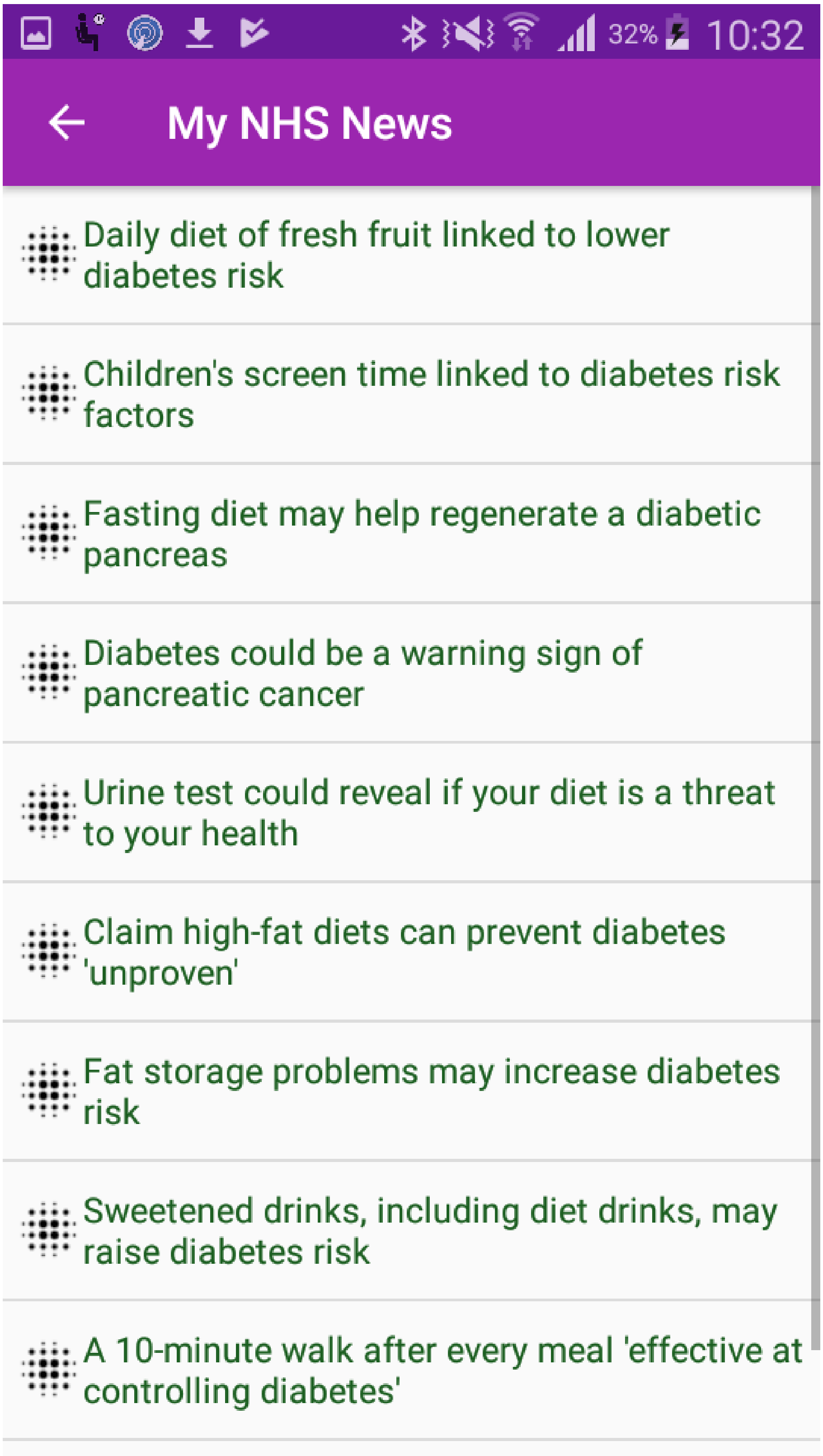
Codes;

2.4 Self-monitoring of outcome(s) of behaviour

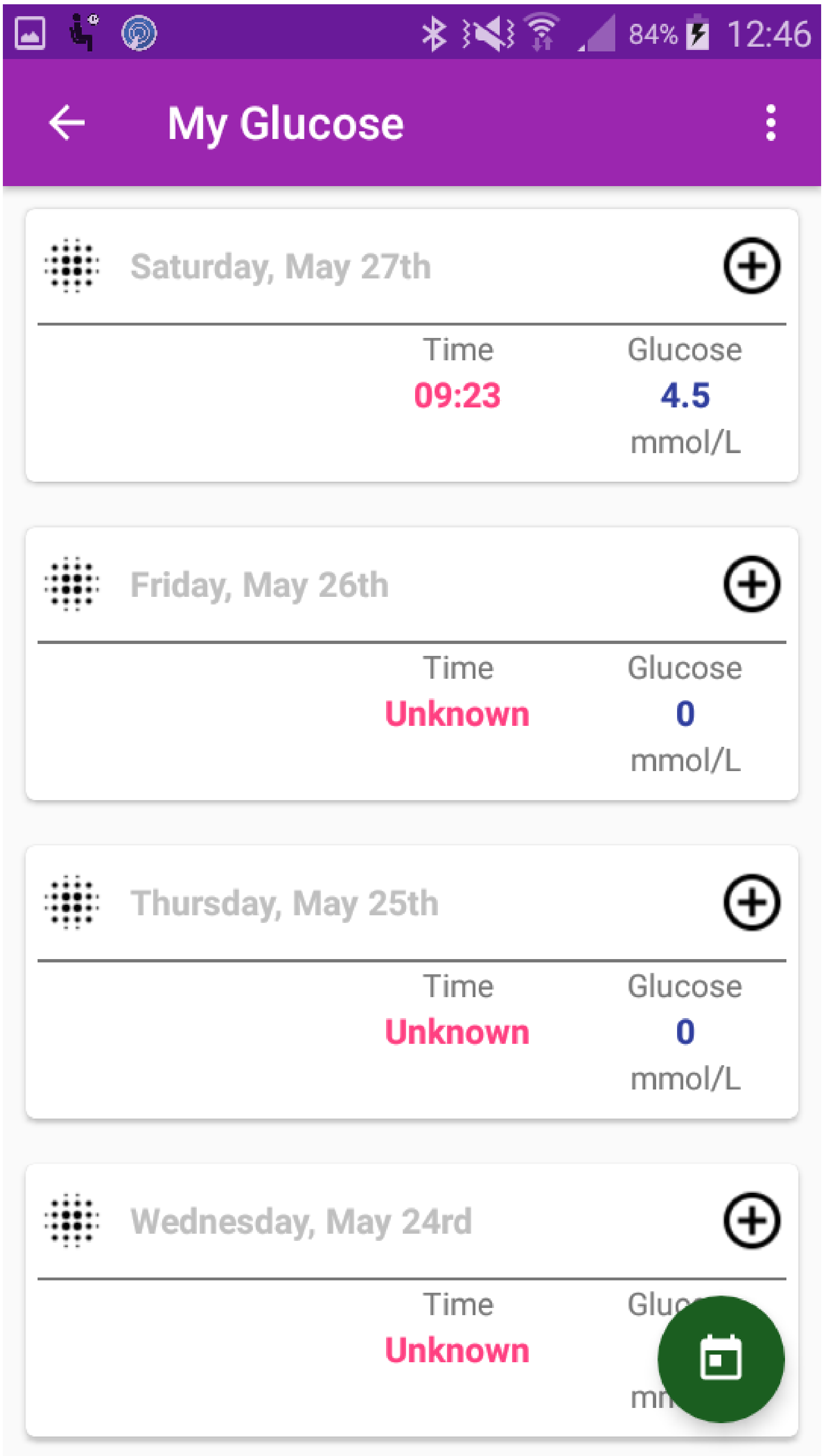


Codes;

2.4 Self-monitoring of outcome(s) of behaviour



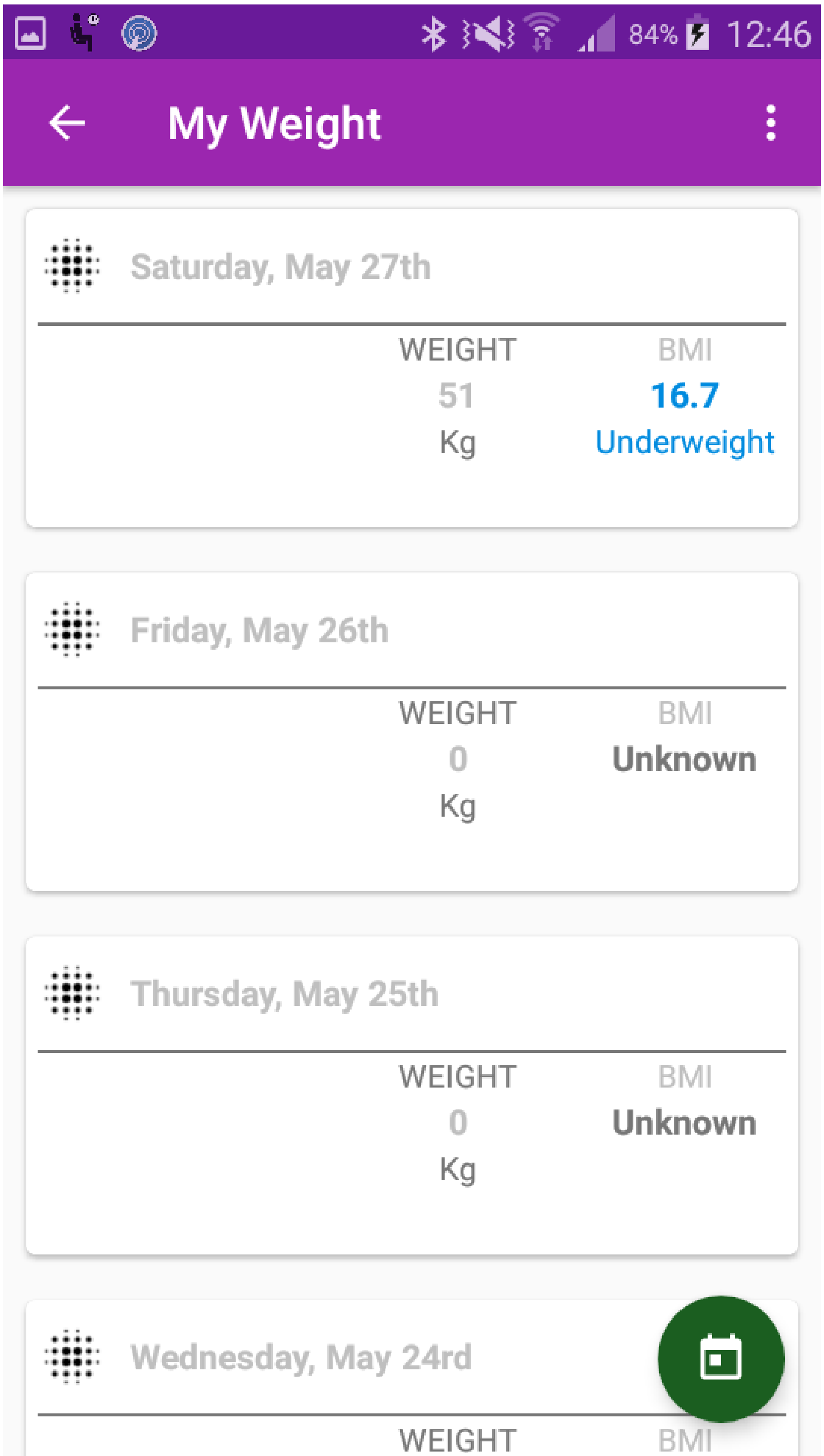
5.1 Information about health consequences



Codes;

2.4 Self-monitoring of outcome(s) of behaviour

2.7 Feedback on outcome(s) of behaviour



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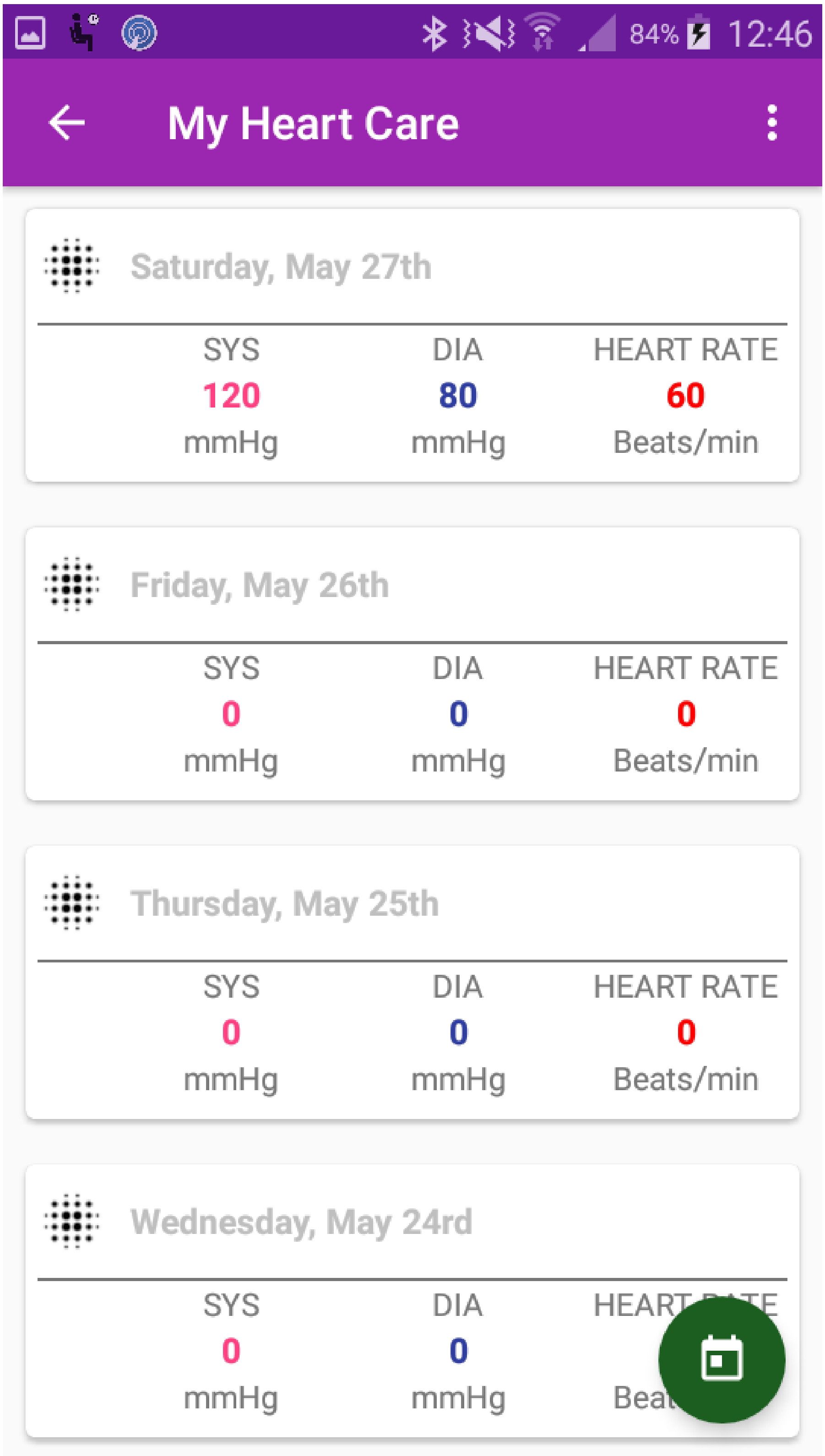
2.4 Self-monitoring of outcome(s) of behaviour

2.7 Feedback on outcome(s) of behaviour



Codes;

2.4 Self-monitoring of outcome(s) of behaviour

2.7 Feedback on outcome(s) of behaviour