

**DIABETES MELLITUS AND
HEALTH OUTCOMES:
THE ROLE OF POSITIVE AFFECT**

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In loving memory of

My Fuva, Dinker Patel (1946 – 2009)

My Nephew, Ryan Patel (2008 – 2009)

My Mama, Anil Patel (1957 – 2010)

My Kaka, Umesh Patel (1962 – 2011)

My Brother-in-law, Prajesh (Sid) Patel (1970 – 2012)

ABSTRACT

Accumulating evidence suggests that Positive Affect (PA) is beneficial in determining health-outcomes. Defined as ‘feelings that reflect a level of pleasurable engagement with the environment, such as happiness, joy and excitement’, PA has been associated with social and physiological factors as well as health practices. The work undertaken in this thesis aimed to investigate the relationship between PA and health-outcomes in people living with and without diabetes mellitus, independent of negative affect (NA).

Study one investigated the relationship between PA and cardiovascular (CV) reactivity and recovery in response to acute mental stress. It was unknown whether interventions to increase PA could improve reactivity to and recovery from acute mental stress and therefore this study sought to investigate if an intervention designed to increase PA could have a beneficial impact. This was a single blind randomised control study in design and recruited healthy individuals (N = 48) who attended two psycho-physiological sessions one week apart (before and after the intervention or control written exercise). The intervention maintained PA levels whereas in the control group, PA significantly decreased. There was no overall interaction between stress tasks, PA intervention and visit on blood pressure or heart rate reactivity or recovery.

Study two investigated the link between PA and HbA1c, self-care practices and diabetes quality of life independently of NA and other covariates. This was a questionnaire-based, cross-sectional study. It was completed by people living in the South East of England who were diagnosed with diabetes (N = 147). Measures included demographics, mood, coping style as well as diabetes-specific variables. Individuals with higher PA scores were twice as likely to follow a healthy eating plan independent of other known correlates. This was not independent of NA. Individuals who followed a healthy diet or avoided high fat foods had lower HbA1c levels. No direct link was found between PA and HbA1c, however following a healthy diet acted as a moderator in this relationship. PA predicted diabetes quality of life satisfaction independent of other known correlates.

Study three investigated the impact of a PA intervention in people with diabetes (N=40). Although, PA interventions have been investigated in chronic conditions, it was unknown whether a PA intervention could improve the management of diabetes. For these reasons, the aim of this study was to investigate a PA intervention and its effects on HbA1c, self-care practices and diabetes quality of life. This was a randomised control study which recruited individuals with diabetes, who were followed over a six month period (baseline, 1 week, 1, 3 and 6 months). Measures included demographic, mood and diabetes-specific variables. The PA intervention did not increase PA and therefore the sample was analysed as one sample (N=40). Bivariate analysis showed relationships between PA and quality of life at baseline, 3 months and 6 months, however, PA only predicted diabetes quality of life satisfaction at 6 months after controlling for NA and baseline diabetes quality of life satisfaction.

In conclusion, this thesis demonstrates that PA may have a beneficial impact on some health-outcomes, however interventions designed to increase PA had minimal efficacy. The randomised control studies that were implemented above were amongst the first to use an intervention designed to increase PA and investigate the impact on health outcomes such as HbA1c, self-care practices, quality of life and CV reactivity and recovery. Although no effects of the PA intervention on health outcomes were found, the relatively high levels of PA seen in volunteers participating in these studies may have influenced the results.

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List of the Main Abbreviations

BMI	Body Mass Index
BP	Blood Pressure
CD-RISC 10	Connor–Davidson Resilience Scale - 10
CES-D	Centre for Epidemiologic Studies Depression Scale
CV (D)	Cardiovascular (Disease)
DBP	Diastolic Blood Pressure
DM	Diabetes Mellitus
DQOL	Diabetes Quality of Life
EM	Early Memories
EMA	Ecological Momentary Assessment
HR	Heart Rate
NA	Negative Affect
OR	Odds Ratio
PA	Positive Affect
PS	Perceived Stress
PANAS	Positive and Negative Affect Scale
POMS	Profile of Mood State
PSS	Perceived Stress Scale
SBP	Systolic Blood Pressure
SDSCA	Summary of Diabetes Self Care Activities
SES	Socioeconomic Status
TGT	Three Good Things

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Declaration

I declare that the research contained in this thesis, unless otherwise formally indicated within the text, is the original work of the author. The thesis has not been previously submitted to this or any other university for a degree, and does not incorporate any material already submitted for a degree.

Meenal Raj Patel

Chapter One: Introduction

There is growing evidence linking positive psychological experiences, like subjective well-being to health outcomes ^[1]. Subjective well-being can be viewed as a collective term for factors such as optimism, PA, life satisfaction and happiness ^[2, 3] and goes beyond the scope of this review to cover all of the components of subjective well-being in relation to health. For this reason, the intention is to concentrate on PA as a predictor of health outcomes. The introduction also focuses on diabetes mellitus (DM), a chronic condition that affects millions of people worldwide ^[4]. Much of the psychosocial literature in relation to DM has investigated negative affective styles such as depression ^[5, 6] and stress ^[7]. In comparison, however, little attention has been placed on positive affective styles despite their emergence as important predictors of morbidity and survival in other chronic conditions ^[2, 8-10]. The main objective of this introduction is to explain the rationale for investigating the role of PA as a predictor of health-outcomes in people living with DM.

1.1 Positive Affect

Positive affect (PA) can be defined as “feelings that reflect a level of pleasurable engagement with the environment, such as happiness, joy, excitement, enthusiasm and contentment” ^[11]. The affect can either be long term, stable and disposition—like (trait PA), or represent more short-term bouts of positive emotion (state PA) ^[2].

There is already a large evidence base for the link between negative affect (NA) and ill health ^[12], and debate exists over the extent to which PA is independent from negative affect ^[13]. If they are bipolar opposites of the same scale, then the benefits of PA may simply reflect absence of NA. It seems that the literature of measurement is key in determining whether or not the affect has been measured on one or two scales ^[14]. Additionally, there is a growing body of research to show that PA can predict health outcomes even when NA is controlled for ^[2].

Trait affect (both PA and NA) is usually measured using self-report where a respondent states how they generally feel or by aggregating multiple measures of state affect ^[14, 15]. PA is typically measured through questionnaires where individuals are required to respond positively or negatively to a range of statements. Such measures include the Positive and Negative Affect Scale ^[11], the Global Mood Scale ^[16] and the PA subscale of the Center for Epidemiologic Studies Depression Scale ^[17]. Other techniques include Ecological Momentary Assessment ^[18] where individuals are required to state how they feel at times specified by the researcher i.e. via devices such as personal digital assistants ^[19], and Positive Emotional Style (PES) where participants are only asked how they feel once a day over a period of time as opposed to several times a day ^[20].

It is thought that trait PA and more long-term state PA i.e longer than one week, is more associated with health-outcomes such as the progression of chronic diseases or mortality due to the fact that emotions need to last long enough in order to influence behaviours or physiological responses ^[2, 21]. The emerging literature linking PA with health is still relatively small compared to the vast literature on negative affect (NA) ^[15]. Although NA is an important predictor of health, it is becoming more apparent that PA has an independent role in determining health outcomes. It goes beyond the scope of this thesis to provide a review of the influence of NA and health; for a review, please see Mayne (1993) ^[12].

1.1.1 Positive Affect and Health Outcomes

PA has been associated with longevity ^[22], reduced risk for cardiovascular diseases ^[23], lower blood pressure ^[24], lower cortisol levels ^[25] and reduced mortality ^[26]. In addition it has been linked to better self-reported health as well as improved functional status ^[2]. This section will focus on studies that have investigated PA in relation to mortality, survival and mobility in people with and without chronic conditions.

PA and Mortality

There is growing evidence to suggest that people who are psychologically more positive live longer. For instance, a longitudinal study of 180 Catholic nuns found that the emotional content of individuals' diaries predicted longevity to the extent that those who had written more positive emotional content in their twenties were more likely to have lived on average 10 years longer than the nuns who expressed the least positive emotions ^[22]. This type of correlational study cannot prove cause and effect and failed to assess the impact of other important correlates of longevity. However, other more comprehensive studies have replicated this finding while taking into account predictors such as age, negative affect and baseline health.

In a similarly designed longitudinal study, Xu and Roberts investigated the link between subjective well-being (including PA, NA and life satisfaction) and longevity in a sample of 6856 healthy individuals over a period of 28 years ^[27]. The findings showed that overall subjective well-being was related to a reduction in all cause mortality independent of age, gender, education and baseline physical measures. However, the effect of PA was not significant after NA had been accounted for, suggesting that NA plays a more important role in predicting mortality than PA. An alternative explanation is that PA and NA were not measured independently in this study and that they were measuring the same construct but just in reverse. For instance, the items used to measure affect were bipolar (i.e. 'bored' versus 'interested' to reflect NA versus PA) as opposed to independent items for each scale (i.e. 'not excited' to 'extremely excited' for PA and 'not nervous' to 'extremely nervous' for NA such as the PANAS). This highlights the importance of measuring PA and NA using a questionnaire that reflects the dimensions independently.

Addressing this issue, Steptoe and Wardle investigated PA and NA in relation to longevity in 3853 men and women aged between 52 and 79 years ^[28] using more independent measures. Data on mortality was obtained from a data registry and individuals were followed over an average of five years. The study found that people higher in PA were 35% at lower risk of mortality after controlling for demographic factors, NA, health behaviours and health indicators, thus suggesting that PA can independently predict mortality when other risk factors are taken into account.

It appears, however that the link between PA and mortality is less clear when current health status is controlled for. For instance, Kritji et al investigated the link between positive affect and survival in 4411 senior individuals aged 61 or older ^[29]. Mortality was assessed using electronic records and the average number of years that individuals were followed was 7.19 years. Using the CES-D scale to measure PA and NA, it found that individuals higher in PA were 7% at lower risk of mortality independent of gender, age, NA, socioeconomic status and lifestyle factors. However, this association did not remain after the addition of health status which included factors such as disability and prevalent diseases such as heart failure, stroke and cancer. It seems that PA may offer some increase in longevity in healthy populations but that the link with mortality is less clear in patient populations.

The majority of studies showing an independent link between PA and mortality have recruited healthy patients at baseline ^[22, 27, 30], however research conducted with patient populations has been more mixed. For instance, Van den Broek et al were interested in whether PA and NA predicted mortality in patients that have an implantable cardioverter defibrillator (ICD) ^[10]. Among the 591 individuals that were followed over a median period of 3.2 years, it was negative but not positive mood, as measured by the Global Mood Scale (GMS), that was statistically related to mortality rate, after controlling for demographic and clinical variables.

In contrast, Moskitwitz et al found that PA predicted mortality in patients with diabetes ^[26]. Among the 715 patients who were followed over 10 years, individuals that were higher in PA were 13% times less likely to be at lower risk of mortality. This result was not independent of NA, however, when analysing individual items of the CES-D PA, enjoyed life was a significant predictor of mortality independent of NA. In another study, Moskowitz et al found that PA also predicted mortality in patients with AIDS ^[26]. Four hundred and seven men who were HIV positive were followed over 3 years. The study reported that men higher in PA as measured by the CES-Depression Scale were 12% at lower risk of AIDS mortality at 12 months independent of illness progression markers and subscales of the CES-Depression (NA, somatic and interpersonal). Thereafter, at 24 months the effects were marginally significant ($p < .1$) and at 36 no effect was found in PA and AID mortality.

The finding that PA is linked to longevity has been replicated in both healthy and patient populations; however the association seems to be strongest in healthy populations. Chida and Steptoe conducted a systematic review to investigate the associations between positive psychological well-being and mortality on studies published between 1969 and 2007 in both healthy (35 studies) and diseased populations (35 studies) ^[30]. Higher positive psychological well-being (including PA, life satisfaction and optimism) was associated with lower mortality in 51.4% of the studies, independent of negative affective states in the healthy population studies. In contrast, only 31.4% of the studies with diseased populations demonstrated such a link. In addition they found that the link was stronger in older populations and where the follow-up was shorter. The authors consider the role of behavioural correlates such as smoking, diet and medication taking that might mediate the link but also demonstrate that positive well-being has an independent effect whilst controlling for such factors. This suggests that PA may influence health through the uptake of health protective behaviours as well as through other direct physiological pathways such as reduced cardiovascular response to stress.

Age has been shown to be a moderator of the PA-mortality relationship. For instance, Kritji et al report a significant interaction between age and PA which indicated that people who were less than 70 years old were 8% at lower risk of mortality and this was independent of gender, age, NA, socioeconomic status and lifestyle factors and health status. No such benefit was found for people over 70. In contrast, Chida and Steptoe found a stronger association between well-being and lower mortality in healthy people over 60 than in the general healthy population ^[30]. They point out that this finding may be due to there being higher mortality rates in the older group and thus a statistically stronger association. If age does moderate the PA-mortality relationship, it might suggest that there is a threshold in relation to survival where, in older individual's health status might impede on psychological well-being and the protective effects of PA are no longer significant.

Generally PA has predicted lower mortality and greater survival, and the effects have shown to be stronger in the healthy population. This highlights the importance to investigate interventions that are designed to increase PA ^[30]. In addition, individuals

diagnosed with or at increased risk of developing serious diseases often have lower PA compared to individuals who are healthy ^[2]. Future studies should investigate the role of PA in people with existing chronic conditions.

PA and Morbidity

Studies have reported associations between PA and more favourable health outcomes in people with existing medical conditions. These studies have entailed either self reported outcomes ^[8, 31] or objective outcomes ^[32-35] which will now be discussed.

There is evidence to suggest that individuals who are higher in PA and have experienced a pain related illness report fewer pain symptoms. For instance, Fisher et al recruited 1084 Mexican Americans with arthritis who were over 65 years of age ^[36]. Individuals with higher PA were 54% less likely to self-report a disability 2 years later, independent of baseline socio-demographic variables, medical conditions and negative affect.

Similarly, Berges et al investigated PA in relation to self-reported pain ratings in 917 adults aged over 50 years who have had a stroke ^[8]. Pain ratings were categorised into high, medium and low and the study found that individuals higher in PA were 14% less likely to be categorised into high pain rating group after three months independent of baseline discharge pain ratings, NA, demographic and clinical factors. Negative affect was not associated with pain ratings at 3 months follow-up. This study again was based on self-report data and therefore the relationship between PA and self-reported health might be expected as more positive people may be more inclined to report that they feel better. The self-reported data is problematic as it is possible that people who are more positive simply report fewer symptoms ^[37, 38].

PA has also been shown to predict incidence of stroke while controlling for age, education, marital status, BMI, smoking status, history of heart attack and DM and NA ^[31]. Ostir et al investigated the incidence of stroke in 2478 individuals that were over 65 years of age ^[31]. The incidence of stroke was captured through follow-up interviews over six years. Individuals higher in PA at baseline had a lower incidence of stroke. The association was stronger in men than women, such that for every unit increase in PA

there was a decreased incidence of stroke of 44% for men and only 18% for women. NA as measured by the CES-D-NA subscale was not linked to incidence of stroke. The results of this study are based on a relatively large sample followed up over 6 years and are thus relatively reliable however; the incidence of stroke was still based on a self-report. Whilst it is unlikely that someone would lie about having had a stroke, alternative methods that use objective outcome measures might be more convincing.

Using objective outcome measures, Fredman et al found that among 432 elderly patients over the age 65, higher PA was related to better recovery after hip fracture over two years ^[32]. In particular improvements were found in speed of walking and performing one chair-stand as measured by the number of seconds taken to rise from and sit back down into a chair compared to people who exhibited depressive symptoms. The results of this study are based on performance and importantly measured objectively as opposed to subjective reporting.

Additionally, Bhattacharyya et al have shown that PA can predict heart rate variability in patients who are suspected of coronary heart disease ^[33]. The Day Reconstruction Method (DRM) was used to measure PA such that participants are instructed to recall their experiences during the monitoring period and then in addition to self-report how they felt during each episode. This study found that among the 88 patients recruited for this study, higher PA was found to be associated with more controlled heart rate variability independent of age, gender, medication and coronary artery disease status. When depression scores were added in as a covariate (as measured by the Beck Depression Inventory) the effect of PA remained significant. This study showed the effects of PA were independent of depression and not NA and therefore the findings cannot confirm if PA was independent of NA in predicting heart rate variability.

There is evidence to suggest that people who are high in PA are less likely to contract the common cold ^[34, 35]. For instance, Cohen et al recruited volunteers (n = 334) aged between 18 and 54, measured their emotional style and exposed them to a virus. They were quarantined for five days where the signs and symptoms of the illness were monitored. During post exposure (over five days), individuals were asked if they had a cold to rate how they felt on a scale of 1 – 4. Furthermore, daily mucus production as

well as nasal mucociliary clearance was aggregated over five days by collecting tissues in a sealed bag and weighing them and through dye administered through the anterior nose ^[35]. Positive emotional style was linked to lower incidence of illness ratings independent of antibody level, demographics, body mass index, season and virus type. In an additional study, Cohen et al ^[34] found that individuals high in positive emotional style were 2.34 times more like to not to develop the common cold ^[34].

Many studies suggest that PA is linked to longevity, mortality and morbidity. However, as no studies have shown causal links, the relationship between PA and outcome measures might be influenced by other factors. It is possible that PA may be associated with healthier lifestyles and behaviours such that people higher in PA are more likely to exercise and have better social support, additionally PA might influence health through more direct physiological pathways. For these reasons, it is important like the studies above, to control for baseline measures as well as measure risk factors that may influence the relationship.

PA and Biological Factors

Many studies investigating the relationship between PA and biological factors such as cortisol, inflammatory markers and cardiovascular reactivity/recovery have recruited individuals through the Whitehall II Study ^[24, 25, 39]. The Whitehall II longitudinal study was set-up in 1985 ^[40]. The sample cohort consisted of 10, 308 London-based civil servants aged between 35 and 55 years of age ^[40]. The initial aim of this study was to investigate the socioeconomic gradient in health and disease and was further broadened to investigate demographic, psychosocial and biological risk factors of health and disease over several years ^[24, 25, 39-45]. At present the Whitehall II study is in its 11th phase of data collection.

Psycho-physiological stress testing is a technique that has been used to investigate the association between PA and biological under controlled conditions ^[9]. Individuals are subjected to behavioural tasks that elicit a stress response which is then used to investigate reactivity and recovery. Studies that have recruited individuals from the Whitehall II cohort will now be discussed in relation to PA.

Steptoe et al investigated the relationship between PA and (i) cortisol, (ii) blood pressure (BP) and (iii) heart rate^[25] in 227 men and women over one working day and evening. This relationship was also tested among 228 men and women in another study by Steptoe and colleagues in response to acute mental stress^[24]. Both of these studies found that PA, as measured by EMA, was inversely associated with cortisol over the working and non working day after adjusting for age, grade of employment, smoking status, BMI and general health measures^[24, 25]. PA was not linked to cortisol awakening response (CAR) or BP, however, higher PA was associated with lower heart rate in men but not in women^[24].

Steptoe and Wardle re-examined the data between PA and the biological factors at 3 years^[25] and the association between positive affect and (i) cortisol and (ii) heart rate remained, suggesting that trait positive affect is relatively stable and is associated with more favourable health-outcomes. The results showed that higher levels of positive affect were associated with lower systolic blood pressure.

Cortisol levels can be affected by mood state and for this reason Steptoe et al investigated if the relationship between PA and cortisol was independent of depressed mood^[39]. In addition chronic inflammation markers were also investigated (C-reactive protein and interleukin-6). As found in the previous study^[24], PA was not associated with CAR, however among the 4609 men and women aged between 35 and 55 lower cortisol levels over the working day were linked to higher PA and still remained significant after the addition of depression scores (as measured by the CES-D) as a covariate.

Studies recruiting from different populations have also found associations between PA and health related neuroendocrine and cardiovascular outcomes. For instance, Bostock et al measured PA using PES in relation to cortisol levels and cardiovascular reactivity/recovery in response to mental stress and found that PES was associated with better diastolic blood pressure, post-stress recovery and lower cortisol post task independent of age, BMI and NA.^[20] Measurements were taken at various time-points; BP and heart rate were taken continuously throughout the experimental procedure from

which averages were obtained. Cortisol samples were obtained at baseline, post-task and recovery. No associations were found between heart rate and PES.

Steptoe et al also investigated PA by measuring it using EMA and the PANAS questionnaire ^[46] in relation to (i) cortisol (ii) blood pressure and (iii) heart rate in response to acute mental stress and found that EMA scores were more strongly associated with biological factors compared to PANAS scores. This study differed from the others as data was collected over two time-points and the scores were averaged. Although, this is better than collecting data at one single time-point it still does not determine causality. A method in which this could have been addressed was to have investigated a PA intervention whereby, during the intervening period, participants could have been instructed to complete a PA intervention. This would have enabled the study to investigate the effect of PA on physiological responses using an experimental design. No studies have investigated PA interventions in relation to PA and biological measures in response to stress and therefore this is an area that needs further attention.

Although previous studies do suggest that there is a link between PA and biological stress factors, these studies failed to incorporate a no-stress control group so although CV reactivity was significantly different from baseline readings, it is not possible to say with certainty that it was the stress manipulation that elicited a stress response and not some other confounding factor that resulted in higher reactivity.

Dowd et al have used a no-stress control group and compared a speech task (stressful condition) to silent reading (control). Here, the stress manipulation did elicit a stress response ^[47]. The sample population consisted of 56 women who were between 17 and 35 years of age. To measure PA and NA, participants were asked to complete the PANAS using the time frame “right now” before and after the experimental tasks. Participants were either asked to complete a speech task (stress group) or read a magazine silently (no stress group). During these tasks, blood pressure was measured at 1, 2.5 and 4 minutes and post stress recovery was measured 5 minutes after the experimental task at 1, 2.5 and 4 minutes. Results showed a reduction in PA and an increase in NA after the completion of the experimental task. There was a significant interaction between affect and stress group, such that there was a reduction in PA scores

and an increase in NA for individuals in the stress group but not for individuals in the no stress group. Importantly the interaction between stress and time showed that the effects of stress on NA was much stronger accounting for 32.2 % compared to the effect on PA where the accounted variance was only 7.2%. Despite the reduction in PA scores, the study showed that higher levels of PA at baseline predicted greater systolic BP reactivity to stress but also greater systolic recovery from stress. The mean baseline PA score for this study was 2.79 which is higher than the study conducted by Steptoe and colleagues (PA score = 2.55) ^[46]. Individuals with higher PA scores might have seen the stress task as a challenge as opposed to a threat which might explain the heightened reactivity. In relation to NA, the interaction between NA and stress group on systolic blood pressure reactivity showed that higher baseline NA scores predicted less diastolic BP reactivity for the control group but not the stress group. In terms of diastolic blood pressure, there was an interaction between PA and stress group such that individuals showed a reduction in diastolic blood pressure reactivity and recovery in the no stress group but not for the stress group. This study provides evidence that stress affects PA and NA differently and that it is important to investigate these dimensions independently.

All of the studies that suggest there is link between PA and CV measures ^[20, 24, 48-50] are all limited in that they are all cross-sectional in design and therefore cannot provide evidence of causality. At present there are no studies that have experimentally investigated the link between PA and CV measures in response to interventions to improve reactivity and recovery to stress.

PA and Health Practices

Health practices are important behaviours that can prevent, treat and manage chronic illnesses. They include behaviours such as attention to diet, exercise, taking medication, sleep patterns, alcohol intake and smoking status. PA has been associated with better health practices such as improved sleep ^[51], diet ^[52] and physical exercise ^[53]. Health practices are important factors in managing chronic conditions and this is especially true for people living with Diabetes Mellitus (DM) which will be discussed in section 1.2.2.

While very little research has specifically investigated the association between PA and self-care practices in people with DM, the following section will review the research which has investigated PA in relation to health practices more generally.

There is evidence to suggest that people who are high in PA are more likely to self-report that they engage in physical activity ^[51, 53], for instance, Kelsey et al investigated the impact of a health promotion programme for blue-collar women (n = 1093) who worked in one of five rural areas in the south-eastern United States of America and found that higher PA (as measured by the PANAS) predicted physical exercise independent of body mass index (BMI), age and education ^[53]. However the results were based on self-reported data and therefore might be subjected to response biases. ^[53].

Similarly, Garcia et al investigated PA in relation to exercise but focused more on the effect of high compared to low activation of PA on exercise frequency. The relationship was investigated in four different study populations; study 1 recruited 635 adults, study 2 recruited 311 adolescents, study 3 recruited 135 adolescents and study 4 recruited 150 adults. Studies 1 -3 found that PA (as measured by the PANAS) was linked to increased frequency in physical activity independent of age and gender. BMI was included as an additional covariate in study 2; however the association between PA and physical activity still remained. Study 4 did not find an association between exercise frequency and PA; however this might be because the study used an instrument that reflected low activation levels on opposed to high activation levels. This might suggest that high activated emotions (as found in the PANAS) are more strongly linked to exercise than low activation. The results from all 4 studies were based on self-reported data and therefore it is possible that individuals might have reported lower weight and height. Furthermore, as this study was cross-sectional in design, it cannot be concluded whether PA is directly linked to physical exercise, or whether people who exercise more frequently report that they are happier.

There is evidence to suggest that PA is associated with better sleep ^[51]. This was supported in the four studies conducted by Garcia et al where they found PA was negatively associated with sleep problems.

In a similar study, Steptoe et al ^[51] also found that among 736 individuals who were aged between 58 and 72 years, PA (as measured by EMA) was associated with good sleep, independent of age, gender, household income, work status and self-rated health. Sleep as well all other measures used were based on self-reported data. .

In Cohen et al's studies linking PES to the common cold ^[35], participants high in PES were found to report better sleep quality and efficiency, report higher dietary zinc levels and report to do more exercise.

Interestingly all of these studies used different methods to measure PA and all found favourable associations in relation to exercise and sleep. However, these studies were limited to (i) the outcomes being based on self reported data and (ii) the studies being all cross-sectional in design therefore it might be possible that people who have better sleep are more likely to report that they feel better. To address the issue of self-reporting data, studies could incorporate a mixture of self-reporting questionnaires as well as objective measures. For instance, instead of people reporting the frequency of exercise, individuals could be given a pedometer that captures the amount of steps a person actually carries out. The second issue regarding causality could be addressed by investigating the link between PA and health practices in response to interventions to improve adherence.

In summary, there is supporting evidence that suggests there is a link between PA and health outcomes. This has been conceptualised into two models that have been proposed by Pressman and Cohen ^[2]. In using a theoretical framework, it might help to design experimental studies and also address the issue of causality which has not been addressed in many studies.

1.2 Models of Positive Affect

There is accumulating research suggesting that PA does have a beneficial impact on health outcomes. Pressman and Cohen have proposed two theoretical models linking PA to the onset and progression of disease ^[2]. The "*direct effect model*" (see Figure 1.1), suggests that PA influences the onset and progression of disease through health

practices, social factors as well as biological factors such as the autonomic nervous system (ANS) and hypothalamic–pituitary–adrenal (HPA) axis activation ^[2].

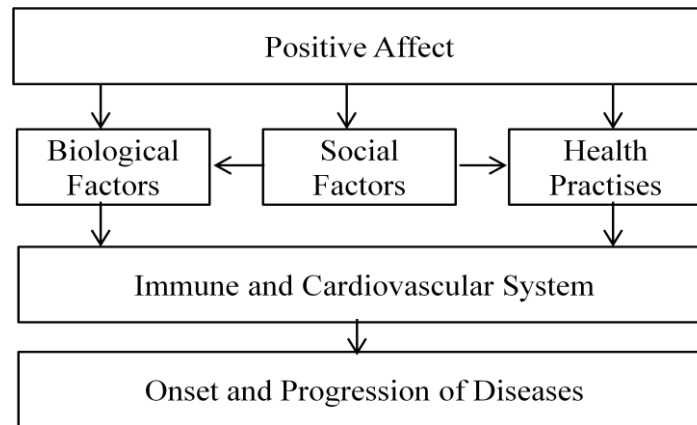


Figure 1.1 Direct effect model adapted from Pressman, S. D., & Cohen, S. (2005).

Does Positive Affect Influence Health? ^[2], Direct affect model illustrating how positive affect can influence the onset and progression of diseases through behavioural, biological and social factors.

The second model (Figure 1.2) referred to as the “*stress buffering model*” suggests that PA influences the onset of diseases through the same mechanism as the direct effect model; however it additionally acknowledges the effects of stress, social, psychological and physical resources ^[2]. Stress stimulates the HPA axis and continuous elevated levels of stress can have a major impact on health.

Positive resources may buffer the adversity of stress and this is what the stress buffering model describes ^[2]. It builds upon Frederickson’s ^[54] broaden-and-build theory which suggests that positive emotions can be broadened based on personal resources which include social resources such as friendship, psychological resources such as resilience and physical resources such as health ^[55]. The model suggests that people who experience more positive emotions have the ability to deal with stress as they are able to use their personal resources and as a result are able to regulate their negative emotional experience ^[55]. Fredrickson’s theory suggests that by broadening a person’s mindset, it

can over time build psychological resources and inevitably promote physical and emotional well-being.

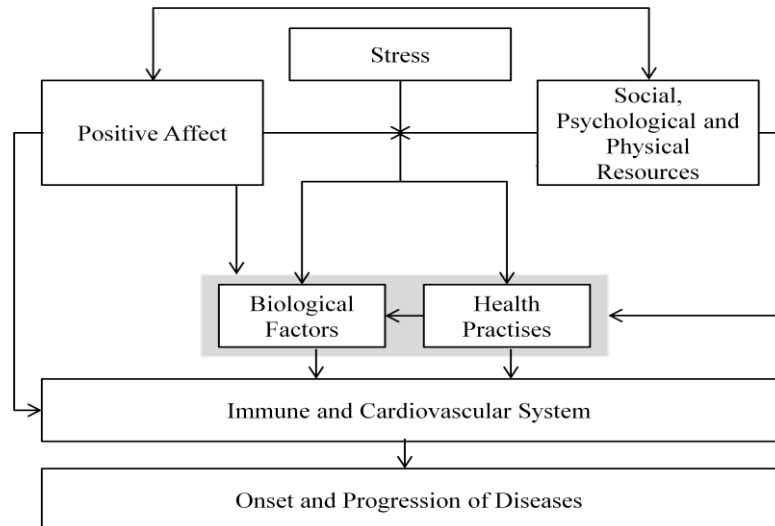


Figure 1.2 Stress buffering model adapted from Pressman, S. D., & Cohen, S. (2005).

Does Positive Affect Influence Health? ^[2]. Stress buffering model illustrating how positive affect could potentially buffer the impact of adverse stress on the onset and progression of diseases

In summary, PA has been linked to better health through various mechanisms as proposed by Pressman and Cohen ^[2]. The implications of these models can form the basis of designing future studies that address the issue of causality which many studies have lacked in. For example based on these models, future studies could investigate the links between PA and health in response to interventions.

1.3 Positive Affect Interventions

Interventions that promote positive experiences have the ability to encourage individuals to learn how to increase their positive emotions, cognition and behaviour

^[56]. Interventions designed to increase PA are based on the philosophy of Positive Psychology (PP). PP has been defined as “*the conditions and processes that contribute to the flourishing or optimal functioning of people, groups and institutes*” ^[62]. In addition, interventions from positive psychology are self administered, cost effective and can be delivered with ease. This is advantageous as it helps individuals to treat themselves by actively improving their mood without the need of psychological or professional assistance ^[56].

There is evidence to suggest that positive psychology interventions are beneficial in increasing well-being and alleviating depression in both depressed and non-depressed populations ^[3, 57, 58].

For instance, Seligman et al investigated interventions designed to increase happiness ^[57] and found two in particular to have significant long-term effects on happiness (see methods section 2.5). This online study recruited 577 individuals who were predominantly white, two thirds of whom were aged between 35 and 54. Seventy-one percent (411) of the study population completed the study over a 6 month period and were randomised to one of five intervention tasks or to a control task. Both the Three Good Things (TGT) and the Signature Strengths (SS) exercises’ showed significant improvements in happiness and decreases in depression for up to six months by the end of the study. The TGT intervention asked individuals to write three good things that happened in their day and to provide a brief explanation about the good thing. Individuals were instructed to complete the exercise every night for 7 days. The SS intervention asked individuals to complete an online questionnaire which then provided feedback on their personal signature strengths. Individuals were then instructed to use their top three strengths in a new way. This study showed that the intervention had relatively long term effects of increased happiness; however the population was slightly biased in that the individuals who participated were mildly depressed at the start of the study. In addition the study did not measure any other health related factors.

The few PA interventions studies that have investigated health outcomes have led to favourable outcomes. For instance, Charlson et al have investigated the effect of PA interventions in chronic conditions over a series of studies ^[59-63]. The researchers investigated behavioural interventions and their impact on people with coronary artery

disease (n =246), asthma (n =246), and hypertension (n =262) ^[59]. The study investigated the effects of a PA intervention, which was a combination of PA and self affirmation. Self affirmation can be defined as *“the active use of positive statements or memories about ones accomplishments or successes to build self confidence. Self-affirmation enhances the ability to overcome any negative expectations of one’s ability by drawing on previous experiences of success such as overcoming obstacles”* ^[59].

The methodologies of the three studies were similar ^[59-63]. Patients provided consent and had baseline data collected and thereafter were randomised to either the control or intervention group. Patients in both groups received educational work books. In addition, individuals in the PA intervention were taught how to induce positive affect and self affirmation. There were three components to the PA intervention; a work book which focused on the construct of PA and self affirmation, bimonthly telephone calls and small gifts which were sent to participants every 2 months. Over the 12 months, generic and more disease-specific questionnaires were completed.

The first study investigated medication adherence in African Americans with hypertension ^[61]. Disease-specific measures included adherence and this was measured using the Morisky Medication Adherence Questionnaires and pill monitors. In addition to measuring adherence, the study recorded blood pressure which was obtained from patient medical records over 12 months. The study found that individuals in the PA intervention group had better medication adherence compared to patient education alone. Despite this however, the effect was not the same for blood pressure, such that the change in both systolic and diastolic blood pressure after 12 months was the same for both groups. This is interesting as we would have expected a change in BP as there was an increase in adherence to medication. Although it is appreciated that there are other factors that might affect blood pressure, it must be noted that medication was self-reported and it might be that people who reported that they were taking medication might not have been. It is also possible that people who received gifts felt obliged to report that they have taken their medication. This highlights that in addition to self-reporting measures, objective measures must also be included.

The second and third study investigated physical activity in patients who had either undergone percutaneous coronary intervention (PCI) ^[63] or had asthma over 12 months. These studies measured physical activity using the Paffenbarger Index, and the scores obtained were converted into energy expenditure in kilo-calories per week. The PCI patients were asked to complete the “Living with Heart Disease: Taking control After Angioplasty” workbook. Patients in both studies received a pedometer where they were asked to report the number of steps completed in a day. After 12 months, the PCI study found that patients in the PA intervention group were almost twice as likely to increase their energy expenditure compared to the control group. In contrast however, the study in relation to asthma found that although there was an increase in energy expenditure for both groups, no differences were found between the groups. Importantly, there was also no decline in the severity of the asthma. Interestingly, the PCI patients in the PA intervention group were 2.58 times more likely to recover from elevated baseline depressive symptoms, thus supporting that PA intervention do not only alleviate depressive symptoms but can also have an impact on health outcomes.

These studies provide valuable insight to the efficacy of PA interventions on health outcomes; however they were limited to the data being self reported. Although the set-up of these studies does advance the current literature, in addition to self-report measures, biological measures might also want to be incorporated or alternatively participants are asked to visit a surgery where they perform certain tasks where they can be objectively measured.

PA interventions have shown to be beneficial in predicting health outcomes ^[59-61, 63], whether it has been improvements in or in maintaining positive behaviours. However, it must be appreciated that these interventions are time and resource intensive, such as giving gifts and telephone calls. Therefore, other methods need to also be explored. A method that could address this issue is to use positive psychology exercises. These exercises are cost effective and convenient to deliver, and most importantly have shown to affect mood ^[56]. Furthermore, these interventions might increase PA in populations that have chronic illnesses and consequently have a beneficial effect on health-outcomes.

Conclusion

The first half of this introduction has demonstrated that there is evidence to suggest that PA is linked to health. However one chronic condition that has received little attention is diabetes mellitus (DM). The next part of this introduction aims to give an overview of DM, the importance of self-management as well as demonstrate the reasons why the relationship between PA and DM is an important avenue for further research.

1.4 Diabetes Mellitus

1.4.1 Epidemiology, Incidence and Prevalence of Diabetes Mellitus

Diabetes Mellitus (DM) (thereafter referral to as ‘diabetes’) is a chronic disease affecting millions of individuals worldwide and is a condition that is characterised by chronic hyperglycaemia if untreated ^[64]. Hyperglycaemia can be the result of either insulin deficiency, impaired effectiveness of insulin action or a combination of both ^[65]. Insulin is a hormone that is secreted from pancreatic beta cells in response to elevations in blood glucose concentrations ^[66]. Its main function is to facilitate the uptake of glucose from the blood into cells ^[67]. The prevalence of diabetes is increasing at alarming rates worldwide ^[68]. In 2011, it was estimated that worldwide 336 million were diagnosed with diabetes and this figure is estimated to rise to 552 million by 2030 ^[4].

There are three main types of diabetes which include type 1 diabetes, type 2 diabetes and gestational diabetes. Type 1 diabetes is an autoimmune disorder that results in complete beta cell destruction ^[69]. It is characterised by insulin deficiency or complete lack of insulin production which can result in severe hyperglycaemia, coma or death if left untreated ^[69]. Treatment for people with type 1 diabetes is insulin. Type 2 diabetes affects approximately 90-95% of people with diabetes ^[69, 70] and is predominately due to genetic disposition, excess body weight and physical inactivity ^[69]. Unlike type 1 diabetes, people with type 2 diabetes are not always reliant on insulin therapy. The first

line of treatment for people who are diagnosed with type 2 diabetes is diet and exercise. However, lifestyle modifications may not work alone in people who are diagnosed with type 2 diabetes and therefore drug therapy is usually introduced. Although some people with type 2 diabetes may require insulin eventually, in most cases oral anti-diabetic agents are used.

There are different types of oral drug treatments available which are classified into groups by their pharmacological response. The most frequently used glucose lowering agents are the biguanides (such as Metformin), which decrease the amount of glucose produced by the liver and as a result the body will need less insulin to control the blood glucose levels. Other treatments work by either stimulating the beta cells to secrete more insulin or by increasing the muscle, fat and liver's sensitivity to insulin^[71]. These include the sulfonylureas, thiazolidinediones and DPP-4 inhibitors. Gestational diabetes is a condition that is associated with glucose intolerance that occurs during pregnancy. Treatment for gestational diabetes is either insulin or lifestyle modifications^[69, 72].

The main indicator of diabetes is an elevation in blood glucose levels, which can lead to serious complications if left uncontrolled^[69]. Furthermore it can lead to coma and death for people with type 1 diabetes. Common symptoms include increased thirst, polyuria, fatigue, weight loss and persistent or recurrent infections^[73]. Individuals presenting with such symptoms would be tested in line with the World Health Organisation (WHO) recommendations. The criterion for diagnosing people with diabetes should be confirmed via a glucose measurement performed in an accredited laboratory on a venous plasma sample. The diagnosis of diabetes can be confirmed when an individual has either (i) a fasting plasma glucose concentration (FPG) of ≥ 7.0 mmol/l (≥ 126 mg/dl), (ii) a two hour post plasma glucose concentration of ≥ 11.1 mmol/l (≥ 200 mg/dl) after 75g anhydrous glucose in a oral glucose tolerance test (OGTT) or (iii) a random plasma glucose concentration of ≥ 11.1 mmol/l (≥ 200 mg/dl)^[72].

Individuals diagnosed with diabetes must manage the condition by adhering to various health practices such as diet and exercise to maintain blood glucose levels, blood pressure and lipid levels within healthy bounds^[69]. The next part of this introduction

focuses on the importance of diabetes self-management and the detrimental consequences of poorly controlled diabetes.

1.4.2 Self-management and Diabetes Mellitus

The management of diabetes is complex and it has been reported that 95% of diabetes management is down to the individual ^[74, 75]. It involves adherence to diet, exercise, clinic appointments and medication regimes ^[70, 76]. Adherence is defined as “*the extent to which a patient’s behaviour matches agreed recommendations from the prescriber*” ^[77]. Adherence to medication in chronic conditions generally is estimated to be low at around 50% ^[78], and adherence to the self-care practices, often recommended in diabetes, is reported to be even lower ^[77]. Adhering to treatment regimes is a process that requires the combination of several behaviours as opposed to just one ^[79]. Delamater reports adherence rates of 65% for diet compared to only 19% for exercise ^[80]. This highlights that the reasons for adherence to physical activity may differ from reasons for adherence to following a healthy diet ^[79]. In addition, Harris et al suggest that the majority of people with diabetes do not measure their blood glucose levels more than once a month ^[81]. Among the 1480 patients with type 2 diabetes, 58.9% either had only measured their blood glucose levels less than once a month or reported that they have never measured it ^[81].

Khattab et al investigated which factors were associated with poor glycaemic control in 917 patients with type 2 diabetes ^[82]. This study found that although the majority of patients (91.9%) reported that they adhered to their medication, in comparison, adherence to other self-care behaviours was very low. For example 81.4% of patients did not follow a meal plan and 67.9% of patients did not participate in physical exercise. Furthermore the study also reported that people who did not follow self-care behaviours such as diet, 30 minutes of exercise, blood glucose monitoring and medication adherence were more likely to have worsened glycaemic control. Causality could not be determined and the measures used were all based on self-report. This study focused on the risk factors of diabetes such as duration, negative attitudes to diabetes and barriers of adherence.

The complexity and demands of treatment regimes for people with diabetes are potential causes of non-adherence ^[77, 79]. The consequences of non-adherence can result in waste of medication, reduced quality of life, the development of co-morbid diseases ^[76, 77, 79] as well as increased costs towards medical resources such as patient hospitalisation ^[70, 77, 79, 83, 84].

There are a number of factors that can influence adherence such as age, social factors and the relationship between the patient and physician, all of which may potentially lead to a decrease in patient satisfaction ^[79]. Beliefs about medication and the underlying condition have shown to be strong predictors of adherence ^[85, 86] where a lack of perceived necessity for the medication and raised concerns about the side-effects is linked to higher non-adherence rates. ^[87]. This may be especially true for people with type 2 diabetes where the complications of diabetes are not present at the start and hyperglycaemia may not cause severe symptoms. Additionally, a lack of understanding of the importance of good control and what role medication plays has been shown to lead to non-adherence ^[87].

In addition to the associations shown between beliefs and adherence, affect has also been shown to relate to adherence. For instance, there is evidence to suggest that depression can have a negative impact on the management of diabetes ^[88]. The prevalence of depression in people with diabetes is high and increasing ^[89, 90]. It is estimated that depression occurs in 27% of people with type 2 diabetes and the prevalence is higher in women (28%) than in men (18%) ^[91].

Gonzales et al found that a higher baseline level of depressive symptoms was a significant predictor of non-adherence to medication in 879 people with type 2 diabetes ^[88]. This study used a self-reporting depression questionnaire (Harvard Department of Psychiatry/National Depression Screening Day Scale (HANDS)) to assess the symptoms of depression and found that one point increase in the HANDS was associated with a 1.12 increase in individuals missing at least one dose of medication over the previous 7 days ^[88]. Similarly, it has also been reported that those who are depressed are three times more likely to be non adherent with medical treatment recommendations ^[5].

People with diabetes who are severely depressed have been shown to have a poorer diet, be more non-adherent to medication, have higher health costs and greater functional impairment compared to diabetics who were less depressed ^[92, 93]. The impact of non-adherence can lead to the development of diabetes complications, lower quality of life and increased healthcare cost ^[93]. To alleviate depressive symptoms, an approach that combines both medication and referral of psychotherapy such as cognitive behavioural therapy (CBT) might be required. CBT has shown to ease symptoms for various health problems including depression ^[94].

Whilst it has not been investigated in people with diabetes, PA has been shown to independently predict adherence in people with hypertension. For instance, Cuffe et al investigated happiness and adherence to antihypertensive medication in 573 African Americans ^[58]. Logistic regression analysis showed that compared to people with low happiness scores (as measured by Subjective Happiness Scale) people who had higher happiness scores were twice as likely to report better adherence to medication. The correlational nature of this study means that causality could not be determined and the use of self-report limits the validity of the study.

Utilising an experimental design however, Ogedegbe et al investigated a PA intervention in African-Americans who also were diagnosed with hypertension ^[61]. Participants who were randomly assigned to the PA intervention did see an increase in medication adherence; however there were no differences in blood pressure over 12 months (see section 1.3).

In summary, successful management of diabetes often requires adherence to dietary, exercise and medication regimes. Rates of adherence in other conditions have been shown to be linked to positive as well as negative affect but little work has been conducted in a diabetes population. If adherence is improved it can have a positive impact on patient health which can ultimately improve the management of diabetes and reduce the cost burden on the health care system ^[70, 76, 77, 79]. In addition it can also reduce the physical and traumatic burden to the patient who develops a serious complication. The following sections review important biochemical factors that need to be controlled as well as factors that help aid the management of diabetes.

Glycaemic Control

The management of blood glucose control is crucial for people with diabetes as continuously elevated levels of blood glucose can lead to the onset of complications ^[95]. At present, the most accurate way of monitoring a person's blood glucose control over a period of time is to measure their glycated haemoglobin (HbA1c) levels which is represented in either mmol/mol or as a percentage ^[96]. HbA1c is an indication of blood glucose control over the past two to three months. It represents the amount of red blood cells that are glycated and so it is indicative of blood glucose levels over three months, the lifetime of red blood cells. A greater HbA1c level is an indication of poor diabetes control over the past two to three months. Despite this however, glycation is a reversible process and so improving blood glucose control can result in improved HbA1c.

NICE guidelines ^[97] on glycaemic control recommend an HbA1c target $\leq 6.5\%$ for people with diabetes; however this is dependent on the person's circumstances and therefore healthcare professionals are required to adapt to individual needs. HbA1c levels are normally monitored every three to six months. However once a person with type 2 diabetes has reached a stable target with or without pharmacological assistance, it is normally measured annually ^[98].

Blood Pressure

The control of blood pressure (BP) is important for people with or without diabetes as continuous levels of elevated BP can lead to hypertension which, in the USA alone, affects approximately 64 million individuals ^[99-102]. Hypertension affects approximately 70% of people with diabetes, however this is dependent on age, ethnicity and obesity ^[103, 104] and they are at greater risk of stroke, heart failure and kidney failure compared to people with hypertension alone ^[100]. Furthermore it is estimated that over 65% of all people with diabetes will die from cardiovascular diseases ^[99]. For this reason the management of BP is paramount for people diagnosed with diabetes.

NICE guidelines for people living with type 2 diabetes ^[97] suggests that individuals should aim to maintain a systolic pressure of <140 mm Hg and a diastolic pressure <80 mmHg . Individuals who have kidney, eye or cerebrovascular damage, targets for BP have been lowered to <130 mmHg for systolic pressure and < 80 mmHg for diastolic pressure. BP is very difficult to control in diabetes and often requires multiple agents to achieve normal BP. These include diuretics, angiotensin-converting enzyme inhibitors (ACEI), angiotensin 2 receptor blockers (A2RB), α blockers, β blockers and calcium channel blockers (CCB). The prevalence of diabetes and co-morbid hypertension still remains high even though well established treatments are available. Possible reasons for this are lack of education, non-adherence to treatment regimes and side effects of prescribed medication ^[105].

Blood Lipids

Lipids consist of cholesterol and triglycerides that circulate in the blood. Total cholesterol levels should be <4 mmol/l, however, they are sub divided further into high density lipoproteins (HDL) and low density lipoproteins (LDL). Elevated blood levels of LDL (>2 mmol/l) and triglycerides (>1.7mmol/l) can lead to increased risk of cardiovascular disease (CVD) ^[106] which is a risk factor of diabetes. Despite this, some fats such as HDL can protect against heart disease and levels should be \geq 1.0mmol/l in men and \geq 1.2mmol/l in women ^[107]. If targets are not reached, statins are common agents that are prescribed ^[106]. Other pharmacological agents that are also available include the fibrates, resins and ezetimibes ^[107].

Self-care Behaviours

As previously mentioned adherence to treatment regimes might help to reduce the development and progression of complications ^[84]. Diet and exercise are common self-care practices that can promote better health, however among people with diabetes, more specific self-care practices are required such as blood glucose monitoring and regular checking of feet. Glucose monitoring is important for people with diabetes as it can inform individuals how well they are controlling their blood glucose levels and also whether they are at risk of hypoglycaemia. Neuropathy is a common diabetes complication which can result in loss of sensation in the feet. This is the reason why it

is important that shoes and feet are checked regularly, as a person that has neuropathy or at risk of developing it, might not realise that they have injured their foot which can potentially lead to infections or amputation.

1.4.3 Complications of Diabetes Mellitus

People living with diabetes may develop complications due to extended periods of hyperglycaemia. Hyperglycaemia can cause damage to blood vessels, major organs and the nerves ^[69]. Complications from diabetes can be divided into one of two groups; macrovascular and microvascular. Macrovascular complications include coronary heart disease, peripheral arterial disease and stroke ^[108]. Cardiovascular diseases (CVD) are the major cause of mortality in people living with diabetes ^[109] and individuals with diabetes are two to four times more likely to develop CVD than those without diabetes and this risk increases if the management of glucose control worsens ^[110]. Microvascular complications of diabetes include diabetic retinopathy which can cause blindness ^[64, 69, 111], neuropathy which can lead to loss of sensation in the toes, feet, legs, hands and arms ^[112, 113] and nephropathy which can lead to end stage renal disease which results in dialysis, kidney transplant or death ^[64].

There is evidence to suggest that depression might be linked to complications, for instance, a Meta-analysis of 27 studies conducted by de Groot et al reported a significant link between diabetes complications and depressive symptoms ^[114]. Furthermore, statistical significance was found between depression and more specific diabetes complications such as retinopathy, neuropathy, nephropathy and sexual dysfunction. Many of the studies reviewed in this meta analysis were cross-sectional in design and therefore no conclusions can be drawn in terms of the causal link between depression and diabetes complications.

In contrast, improvements in glycaemic control and blood pressure have shown to be the most effective way of preventing diabetes complications ^[104, 108, 115-117] and this has been shown through landmark studies for both type 1 and type 2 diabetes. These studies include the Diabetes Control and Complications Trial (DCCT) ^[117], the Epidemiology of

Diabetes Interventions and Complications (EDIC) study and the UK Prospective Diabetes Study (UKPDS) ^[104].

In summary, diabetes complications have been linked with risks that are modifiable and therefore health care professionals should emphasise the importance of diabetes management and the impact it can have in preventing diabetes complications. However, although HbA1c levels, BP and lipid levels might seem to be the main objective for health care providers, glycaemic control will not improve if health practices are not adhered to. For this reason, shifts towards patient empowerment as well as the set up of educational programmes that assist patients to successfully manage their DM have been introduced.

Patient Education and Empowerment

The NHS Diabetes Framework strongly advises that educational courses are made available to people with diabetes by their GPs. Educational programmes such as the Dose Adjustment For Normal Eating (DAFNE) and the Diabetes Education and Self Management for Ongoing and Newly Diagnosed (DESMOND) ^[118] assist patients to make informed decisions about their diabetes using problem solving techniques ^[119, 120].

DESMOND is aimed at people who are newly diagnosed with type 2 diabetes, preferably within twelve weeks of diagnosis. The programme was developed to ensure that it could be integrated into routine care and have the ability to target a wide range of people with diabetes. Health-care professionals are given formal training to ensure that the programme is delivered to the same standard nationally ^[121]. The six hour pre-written curriculum focuses on issues such as lifestyle factors, food choices, exercise and risk factors. Davis et al evaluated the DESMOND programme in a twelve month randomised control trial (RCT). They found that individuals newly diagnosed with type 2 diabetes who attended the DESMOND programme in addition to the routine care showed a significant reduction in body weight and triglyceride levels compared to a control group. In addition, the intervention group were less likely to be smoking at twelve months as well as showing significant improvements in the (i) understanding, (ii) taking responsibility and (iii) seriousness of their diabetes. Furthermore there was also a significant reduction in depression scores for the intervention group ^[119].

DAFNE is an educational programme aimed at people with type 1 diabetes ^[120]. The objective of this five day training course is to teach and provide individuals with the skills that are required to understand factors such as carbohydrate counting, monitoring of blood glucose, insulin regimens, hypoglycaemia and exercise. Like the DESMOND programme, the initiative is to discuss experiences and share ideas that are facilitated by trained health care professionals but to also acquire specific skill sets that teach people with type 1 diabetes to inject the right amount of insulin to match the carbohydrates that they are consuming.

The management of diabetes relies heavily on patients having the ability to set goals as well as make informed daily decisions. The set-up of these education programs moves away from the notion that healthcare professionals are the only experts. Instead, they provide a safe environment consisting of small groups where the day to day management of diabetes can be discussed. It is an opportunity for patients to raise questions and gives patients the confidence to make informed decisions. This notion has led to a shift towards patient empowerment.

A movement towards patient empowerment, which can be seen as “a process to facilitate self-directed behaviour change” ^[122], can help encourage patients to make informed decisions about the management of their diabetes ^[123]. Interventions designed to increase empowerment can increase an individual’s ability to make self-directed decisions ^[122]. It is vital that health care providers motivate individuals so that self efficacy becomes an integral part in changing behaviour which can ultimately lead to better diabetes management ^[123, 124].

Anderson et al designed a six week programme with one week intervals to investigate the impact of a patient empowerment programme on self-efficacy, attitudes towards diabetes and glycaemic control ^[125]. This randomised control study recruited 64 predominantly middle aged women (mean age 50) who were overweight, well educated and already felt that their diabetes was managed well. The intervention group were assigned to the empowerment program and the control group were put on a waiting list. Blood samples were drawn to measure HbA1c. After the six week session, individuals were asked to complete a questionnaire. The study found a significant reduction in

HbA1c and improvements in self efficacy, however there were limitations to this study such that the sample population was already motivated to take part in the study. Furthermore, the follow-up sessions between the two groups were not a direct comparison due to the fact that measurements were taken from the intervention group at 12 weeks and compared to the control group where measurements were taken at 6 weeks.

In summary, the objective of empowerment does not involve persuading an individual to change, but instead to focus on forming a partnership that encourages and supports individuals to reflect on their experience of living with diabetes ^[122]. The patient is an integral part of their diabetes management team and should be empowered ^[126], through appropriate training to prevent or treat their diabetes. Consequences of a poor patient-healthcare provider relationship could lead to poor management and subsequently the development of complications.

The link between people with diabetes and the ability to successfully self manage may be mediated by various psychosocial factors ^[123]. The implications of depression on the adverse effects of self management were discussed previously (see section 1.4.1 and 1.4.2). However, there are other psychosocial factors that might also affect diabetes management such as stress and quality of life.

1.5 Diabetes Mellitus Positive Affect and Psychosocial Factors

Stress and Coping

The onset and progression of living with a chronic disease such as diabetes can be seen as stressful ^[127]. Stress has been hypothesised to affect diabetes through physiological mechanisms as well through uptake of health behaviours ^[127].

Stress is a pattern of physiological, behavioural, emotional and cognitive responses to stimuli that are perceived as threats or challenges. Stress can lead to either confronting a situation or escaping it otherwise known as the “fight or flee response” ^[128]. These stimuli are normally aversive and are referred to as stressors. Stressors can range from

being very serious such as being in an earthquake to not so serious such as waiting for a delayed train. In response to a stressor the hypothalamus sends signals to both the autonomic nervous system and the pituitary glands which results in the body's organs becoming stimulated. As a result of this, blood pressure as well as heart rate increases. In addition blood glucose levels rise and blood vessels become dilated. The negative consequences of stress can have detrimental effects on health and therefore it is paramount that individuals learn to control it ^[129].

Stress can have serious repercussions for people with diabetes as cortisol, a stress-related hormone, triggers glucose production ^[130]. Long-term exposure to high levels of cortisol ^[130] can be very dangerous for people with diabetes as it becomes more difficult to control blood glucose levels ^[26] and as a consequence it can lead to poor control of the disease ^[130]. Stress may also affect glycaemic control by affecting behaviours around medication-taking, diet and exercise. These changes in self-care behaviours can consequently lead to poor management of the condition ^[127]. In addition, stress can lead to increased smoking and alcohol use which can impact cardiovascular parameters and blood glucose ^[75]. Stress can also impact other factors such as quality of life so therefore reducing the adverse effects of stress might also improve other diabetes related outcomes.

Coping strategies may mediate the link between stress and diabetes-related outcomes ^[131]. Engaging in more problem-focused coping strategies, for instance, has been shown to lead to lower HbA1c in non-diabetic women ^[132], and training in stress-management has been shown to be linked to reduced HbA1c in people with type 2 diabetes ^[133].

Quality of Life

Quality of life (QOL) is a measure of physical, social and emotional wellbeing ^[134]. It is a collection of subjective as well as objective experiences in relation to health. People diagnosed with chronic illnesses have been shown to manage their condition better if they have a better quality of life in terms of satisfaction, social networks and overall well-being ^[135]. These elements have the potential to motivate individuals to manage their illness successfully. There are two broad approaches in measuring QOL, generic

and disease specific ^[136]. Generic quality of life and well being instruments illustrate an overall picture of health and illness where as disease specific QOL instruments focus on the specific problems associated with that disease ^[134].

The daily challenges of diabetes can substantially impact an individual's QOL ^[137, 138]. This can lead to unfavourable outcomes such as poor management of self-care practices which can impact physiological variables like glycaemic control which can result in the onset of complications ^[134, 139]. The onset of complication has shown to reduce QOL; in particular, the presence of two or more diabetes-related complications has been associated with poorer QOL ^[134]. For these reasons, QOL is often reported to be lower in people with diabetes than those without ^[139].

Paddison et al investigated the relationship between psychosocial factors, HbA1c and quality of life in 615 people with type 2 diabetes ^[139] and showed that lower HbA1c was associated with better perceived quality of life as measured by a single item from the Audit of Diabetes-Dependent Quality of Life (ADDQOL) questionnaire.

1.6 Positive Affect in People with Diabetes Mellitus

In a recent review ^[140], Robertson et al investigated the associations between positive emotional health and outcomes in adults with diabetes. The review focused on three specific areas of positive emotional health that were published between 1970 and 2011; they were well-being, PA and resilience. In comparison to the studies investigating well-being (n = 13), there were far fewer in relation to PA (n= 5) and resilience (n = 4). The next part of this introduction will briefly summarise the main findings for well-being and resilience and then focus on the PA studies.

Among the thirteen studies reviewed in relation to positive well-being, the findings indicated that it was linked to better diet, exercise and lower HbA1c. In addition, higher positive well-being was associated with higher education and not being on insulin. Well-being was generally measured as an outcome and either measured using the Well-Being Questionnaire (long and short form) or the WHO Five Well-being Index. The study designs varied within these studies from cross-sectional to randomised control

studies. Out of all the studies reviewed only one study found a negative link between positive well-being and HbA1c.

In relation to resilience, studies either used several instruments to measure various constructs such as self efficacy, purpose in life and locus of control or alternatively only used one instrument which was the Connor-Davidson Resilience Scale. The findings suggest that resilience predicted HbA1c after 1 year and that high resilience dampened the effect of worsened HbA1c and self-care behaviours in response to increased distress. Furthermore it was linked to improvements in empowerment.

The handful of studies that have investigated the relationship between PA and diabetes related factors ^[26, 140-143] have used various methods to measure PA, these include the Positive and Negative Affect Scale (PANAS) ^[141], the Affect Balance Scale (ABS) ^[143], the Mood Adjective Checklist (MACL) ^[142] and the PA subscale of the Centre for Epidemiological Studies Depression Scale (CES-D) ^[26]. Outcomes ranged from self-care practices such as exercise and glucose monitoring to physiological parameters such as HbA1c and have found mixed results.

For instance, Moskitwitz et al investigated whether PA could predict mortality in people with diabetes ^[26]. This was a longitudinal study that followed a sample population that consisted of people with diabetes (n = 715) or without a chronic condition (n = 2,673). Among the 715 patients who were followed over 10 years, individuals that were higher in PA were 13% times less likely to be at lower risk of mortality. This result was not independent of NA, however, when analysing individual items of the CES-D PA, 'enjoyed life' was a significant predictor of mortality independent of NA.

In addition to investigating the relationship between PA and mortality over a ten year period (1982 – 1992), Moskitwitz et al also investigated the stress buffering theory such that it was hypothesised that PA would be strongly associated with mortality among people with diabetes compared to people with no chronic conditions. The authors proposed that having a chronic condition adds an extra burden of stress that people without a chronic condition do not have. Interaction analysis between PA and perceived stress in people with diabetes and in people without chronic condition who were over 65 years old showed no associations in people with diabetes but did show an association in

people without chronic conditions such that the protective effects of PA on mortality were much stronger in those who reported greater levels of stress. The study found no link when directly comparing people with diabetes and people without chronic conditions. A possible reason that might explain why there was no interaction between PA and stress on mortality in people with diabetes is that the 4 items used to measure stress were taken from the General Well-being Schedule and therefore might have not been as sensitive compared to a questionnaire such as the Perceived Stress Scale (PSS) which is specifically aimed to measure perceived stress.

Skaff et al investigated the relationship between affect (PA and NA) and blood glucose levels in people with type 2 diabetes ^[141]. This study instructed participants to measure their glucose for 21 days every morning as soon as they woke. To measure PA and NA, participants were instructed to complete the PANAS every evening (time frame used - last 24 hours). Individuals who had higher NA levels across the 21 days had higher morning blood glucose levels. However this relationship was no longer significant after it was adjusted for covariates (HbA1c, treatment and time since diagnosis). No links were found between PA and blood glucose. Within-person analysis showed that when men but not women had higher NA levels compared to their average state, blood glucose levels would be higher the following morning. A possible reason to why this study found no relationship between PA and fasting blood glucose is that individuals had to continue to take measurements on a daily basis for 21 days and this might have been burdensome to the participant. HbA1c might be a better measure as it is an indication of long term glucose control over the past two to three months. It only involves taking one sample and can be correlated with PA and NA by adjusting the time frame.

In summary, there are only a handful of studies that have investigated PA in relation to diabetes outcomes. These studies used a range of methods in measuring PA and it can be argued that not all of these instruments actually measured PA as a construct independent from NA. Importantly, however, this review highlights that PA is related to some favourable outcomes. Therefore, PA should also be targeted in intervention studies in order to fully explore if increases in PA can further improve the management of diabetes.

An understanding of the role of PA and how it can be enhanced will help to identify what types of resources are needed to enhance PA. This is key to the development of new interventions. At present, there are no studies that have investigated PA interventions on the relationship between PA and diabetes outcomes (as measured by HbA1c, quality of life and self-care practices).

1.7 Aims of the Project

The stress-buffering model suggests the effects of stress can be buffered by PA. Studies have shown that people higher in PA react less to and recover faster from stress compared to people with low PA; however, these studies have yet to investigate the effect of this relationship using a PA intervention.

PA has been associated with chronic conditions ^[2, 9], however, there are relatively few studies that have investigated the relationship between PA and diabetes related measures. Diabetes mellitus is a long-term, complex condition that involves intensive management to avoid or delay the onset and progression of complications. The impact of a PA intervention is yet to be investigated in people with diabetes and therefore the role of PA needs further investigation.

PA interventions are starting to emerge as methods to increase PA and have shown to lead to improvements in health measures in patients with chronic conditions such as hypertension and asthma. The Three Good Things exercise is an intervention that has led to significant improvements in happiness; however the effect of this intervention has not been investigated on health measures such as HbA1c, self-care practices, quality of life and cardiovascular reactivity and recovery.

The aims of the project intends to fill the gaps in the existing literature and entail designing three research studies

Aim 1: Investigate the stress-buffering hypothesis of PA

Aim 2: Investigate the relationship between PA and diabetes related measures

Aim 3: Investigate the effect of a simple PA intervention on PA and health measures

Chapter Two: General Methods

This chapter addresses two areas, as well as detailing a general description of the psychological and physiological measures that have been used at various stages of this research; it also justifies the reasoning to why we have chosen the Positive and Negative Affect Scale (PANAS) to measure PA throughout this thesis.

2.1 Mood Related Measures

2.1.1 Positive and Negative Affect Scale

General Overview

The Positive and Negative Affect Scale (PANAS) was developed by Watson, Clark, & Tellegan (1988) and is designed to measure two primary facets of mood, positive and negative affect^[11]. It contains 10 Positive Affect (PA) items (*interested, excited, strong, enthusiastic, proud, alert, inspired, determined, attentive and active*) and 10 Negative Affect (NA) items (*distressed, upset, guilty, scared, hostile, irritable, ashamed, nervous, jittery and afraid*). Participants are asked to rate each item on the extent to which it describes them^[144]. Items are rated as 1 (very slightly or not at all), 2 (a little), 3 (moderately), 4 (quite a bit), and 5 (extremely). For each mood facet, total scores can range from 1 to 50 or, alternatively, mean scores can range from 1 to 5, with the higher scores indicating greater affect^[144]. The PANAS has demonstrated good reliability with Cronbach's Alpha for PA and NA ranging from 0.83 to 0.90 and .84 to .93 respectively^[11]. The inter-correlation between PA and NA are normally reported low to moderate and negative ranging from -.12 to -.23^[145]. A number of timeframes have been used with the PANAS including "today", "the past year" and "generally".

Rationale

The Positive and Negative Affect Scale (PANAS) is a widely used questionnaire that attempts to measure PA and NA independently^[2, 46, 47, 144]. It has been used in many

studies including areas such as health practices ^[53], chronic pain ^[146] and cardiovascular reactivity/recovery ^[46, 47].

There is some debate, however, over the extent to which PA is independent of NA ^[2, 11, 147]. It is of reasonable assumption that people would think that these measures of affect are bipolar because the claim that PA and NA are independent, suggests that the words positive and negative are not opposite when in actual fact they are ^[14].

Although, the items used within the PANAS are based on independence, the dimensions still correlate. Watson and Clark suggested that the correlation between PA and NA is very small and consistent regardless of the time frame that is chosen ^[11], however when Schmukle et al investigated the correlation and timeframe between PA and NA ^[147], the results showed that when using the time frame “generally” the relationship between PA and NA was relatively independent, however when individuals were asked to respond to “right now” the association between the two dimensions was quite correlated. These findings suggest that there is a level of independence between PA and NA on a trait level but not for a state level ^[147].

To address this issue, Russell and Carroll suggested that if affect activation levels are categorised, it might remove bipolarity, such that if activation levels of affect are grouped [(i) PA: high activation (ii) PA: medium activation (iii) PA: low activation (iv) NA: high activation (v) NA: medium activation and (vi) NA: low activation] ^[14], by removing the group that is 180 degrees away from the corresponding group of interest, the presence of bipolarity could be removed. For example if PA: high activation items were used then you would not use NA: low activation (see Figure 2.1). The PANAS uses high activated emotions to measure PA such as ‘excited’ and ‘enthusiastic’, as well as high activated NA items such as ‘upset’ and ‘hostile’. This, according, to Russell and Carroll removes bipolarity ^[14].

Another factor that can influence the independence of PA and NA is how individuals respond to a question. For example, if individuals were asked to rate how happy they are and then rate how sad they are using the same scale that ranges from extreme sadness to neutral to extreme happiness, then it is highly likely that the ratings obtained will be opposite to one another. To address this issue, PA and NA need to be scored

separately using the same scale that does not adopt a negative-neutral-positive continuum. Instead, a response scale that starts at 0 for both dimensions could reduce bipolarity. The response format of the PANAS ranges from not at all to extremely, and does not include a neutral point. Therefore if individuals scored low on PA subscale, it would be an indication of low NA activation such as tired and bored. On the contrary if individuals scored low on the NA subscale, it would be an indication of low PA such as calm.

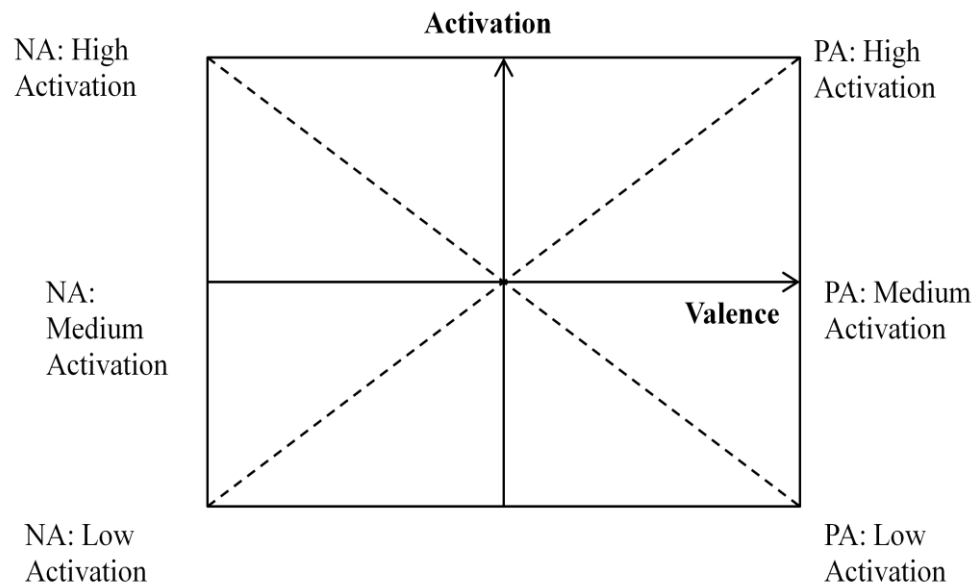


Figure 2.1 Affect categorised by valence and activation (PA = positive affect; NA = negative affect) ^[14]

Based on the reasons above, the PANAS will be used in this thesis to measure PA independently from NA. In addition, in using this instrument we can hypothesise that the PANAS will measure PA independently from NA.

2.1.2 Perceived Stress Scale

The Perceived Stress Scale (PSS) was developed by Cohen & Williamson (1988) ^[148, 149]. It contains 10 items and is designed to measure the degree to which an individual appraises the situations in their life ^[150]. The standard response time-frame is “during the last month” for example “*In the last month, how often have you been upset because of something that happened unexpectedly?*” and “*In the last month, how often have you found that you could not cope with all the things that you had to do?*” The PSS has been used in studies that have investigated health behaviours such as sleeping, drinking and exercising ^[150, 151]. Furthermore it has also been used in studies that have investigated biochemical markers such as cortisol ^[152, 153]. The PSS has demonstrated good reliability with Cronbach’s Alpha (coefficient to rate internal consistency) ranging from 0.84 - .86 ^[149]. Items are rated as 0 (never), 1 (almost never), 2 (sometimes), 3 (fairly often), and 4 (very often), however, items 4, 5, 7 and 8 are reversed scored. Scores can range from 0 – 40, with the higher scores indicating greater perceptions of stress ^[148].

2.1.3 Profile of Mood State

The Profile of Mood Scale (POMS) was developed by McNair et al (1971) ^[154] and is suitable for both research and therapy purposes ^[155]. The instrument has 72 items which are divided into 8 mood subscales; these are anxiety, depression, anger, vigour, fatigue, confusion, friendliness and elation ^[156]. Participants are asked to rate each item on the extent to which it describes them at that moment in time. Items are rated as 0 (not at all), 1 (a little), 2 (moderately), 3 (quite a bit), and 4 (extremely) with higher scores indicating a greater degree of that mood state ^[156].

2.2 Diabetes Related Measures

2.2.1 Diabetes Quality of Life

The Diabetes Quality of Life Scale (DQOL) was developed by Jacobson et al (1988)^[157] and is designed to assess diabetes related quality of life in individuals with type 1 or type 2 diabetes. The DQOL contains 60 items; 13 of which are specific to children and adolescents with diabetes. These 13 items were not incorporated into the questionnaire as none of the sample populations were children/adolescents. The DQOL provides four subscales which are satisfaction with treatment, impact of treatment, social worries and diabetes related worries^[157]. Items are rated on a five-point Likert scale and consist of two general designs. The first half of the instrument asks individuals how satisfied are they with their diabetes, for example, “*How satisfied are you with the flexibility you have in your diet?*” and is scored from 1 (very satisfied) to 5 (very dissatisfied). The second half of the instrument asks about the frequency of the negative impact of diabetes or of the diabetes treatment, for example, “*How often does your diabetes interfere with your family life?*” and is rated from 1 (never) to 5 (all the time). The DQOL has been shown to have good internal consistency ($r = 0.78-0.92$), test retest reliability ($r = 0.78-0.92$), and convergent validity for all subscales for people with type 1 and type 2 diabetes^[158]. For the present studies, scoring of the DQOL was transformed^[159] so that a higher score indicated a more positive quality of life for all of the subscales. Participants’ scores were reversed (apart from Impact items 8 and 16) and summed to form a raw score for each subscale. This score was used to calculate a transformed score (see Figure 2.1).

In the present studies and following Jacobson et al^[157, 159], total sub-scale scores were only calculated where there was enough valid data for a case. Therefore total subscales scores were not calculated for social worries and diabetes related worries if two or more items were missing; for impact, if five or more items were missing and for satisfaction, if four or more items were missing.

$$\text{Transformed Scale} = \left[\frac{\text{Participant raw score} - \text{lowest possible raw score}}{\text{Raw score range}} \right] * 100$$

Figure 2.2 Diabetes Quality of Life transformation calculation.

Equation to calculate the transformed scale for each DQOL subscale ^[157]

2.2.2 Summary of Diabetes Self Care Activities

The Summary of Diabetes Self Care Activities (SDSCA) was developed by Toobert et al (2000) ^[160]. It contains 12 items and measures diabetes related self-care practices over a seven day period which includes diet, exercise, blood glucose monitoring, feet checks and smoking status. The SDSCA is a self-report measure which is brief, reliable, valid and multidimensional measure of diabetes self-management behaviours ^[160]. Individuals report how many of the last seven days they engaged in a certain self-care activity, for example, “*on how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?*” Mean scores are calculated for each self-report measure. Due to the fact that the distribution of responses for each self-care practice was bimodal, with most individuals either engaging fully or not at all to self care activities, parametric analysis could not be justified. For this reason two groups were formed ≥ 5 days and < 5 days ^[161].

2.3 Personality Related Measures

2.3.1 Connor–Davidson Resilience Scale - 10

The Connor-Davidson Resilience Scale 10 (CD-RISC 10) ^[162] is a self-report questionnaire designed to measure an individual’s perception of their own resilience ^[162]. It contains 10 items which assess individuals’ perceptions of their abilities to adapt to change, deal with unexpected events, cope with illness, handle unpleasant

feelings and also maintain positivity in the face of stress ^[162]. The CD-RISC 10 has demonstrated good reliability with a Cronbach's Alpha of 0.85 ^[162]. Examples include "*I can stay focused under pressure*" and "*I can deal with whatever comes*". Items are rated as 0 (not true at all), 1 (rarely true), 2 (sometimes true), 3 (often true), and 4 (true nearly all the time). Scores range from 0 to 40 with the higher scores indicating greater resilience ^[162]. The CD-RISC-10 was chosen over the original 25-item version as it reduces participant burden and has been shown to be highly correlated with the 25-item version (the correlation co-efficient between the 25-item and 10-item scales has been shown to be $r = .92$ in previous research indicating a strong relationship) ^[162].

2.3.2 Coping Styles

The Brief COPE scale is designed to measure a range of coping responses among adults for all diseases ^[163]. Within this instrument there are fourteen dimensions with each dimension having two items ^[164]. These include self-distraction, active coping, denial, substance use, use of emotional support, use of instrumental support, behavioural disengagement, venting, positive reframing, planning, humour, acceptance, religion and self blame. The two dimensions that were selected for the present studies were active coping and instrumental support ^[164]. These were selected as they have been previously used in a diabetes population and have been associated with positive affect ^[132]. Active coping is the process of taking active steps to try and reduce or remove the stressor or having the ability to recognise the effects of the stressor ^[165, 166]. Instrumental support is the extent to which an individual seeks help, advice or information ^[165, 166]. Both of these coping strategies are forms of problem focused strategies ^[164]. Items are rated on a four point Likert scale ranging from 1 (I haven't been doing this at all) to 4 (I have been doing this a lot) with higher scores indicating greater use of these coping strategies by the individual. Active coping and instrumental support have demonstrated good reliability with Cronbach's Alpha's of .71 and .64 respectively ^[164].

2.4 Physiological Measures

2.4.1 Blood Pressure and Heart Rate

Blood pressure (BP) and heart rate (HR) measurements were taken using a digital blood pressure monitor (exact model will be displayed in the appropriate chapter). The cuff was positioned around the upper left arm so that the edges were parallel and the cuff was mildly snug but still admitted a finger under it. The lower edge was one inch above the bend of the elbow, if physically possible. The hose was positioned over the brachial artery just to the inside of the midline of the elbow crease. When the arm was relaxed the start button on the monitor was pressed. Measurements obtained were (i) systolic pressure (ii) diastolic pressure and (iii) heart rate.

2.4.2 Body Mass Index

Body mass index (BMI) was calculated using weight and height measurements. Participants were asked to remove any outdoor clothing and footwear i.e. coats, jackets, heavy outerwear and shoes/boots. Participant's weight was measured using calibrated weighing scales in kilograms. Height was measured in meters using a height measuring stick (Leicester Height Measure, SKU: SMSSE-0260, Model: Leicester). From these measurements the BMI was calculated using the following equation (*Weight (kilograms) / Height² (metres)*).

2.4.3 HbA1c Determination

HbA1c was measured self-reported and objectively within this thesis. Participants were asked to either self-report their most recent HbA1c reading or alternatively it was measured objectively using the Bio-Rad machine which will be explained in more detail below. HbA1c levels fluctuate every 2-3 months and therefore the self-report measure must be taken with slight caution as the reading would not directly correlate with the responses to questions.

BioRad Clinical Procedure

The Bio-Rad in2it Analyzer was used to determine HbA1c levels. The procedure was followed in line with the BioRad In2it (I) Instruction Manual to ensure accurate performance of the product. Prior to the test procedure, system checks were always performed using the In2it System Check Cartridge. This occurred (i) before the samples were tested, (ii) if the Analyzer was moved, (iii) if there were concerns that the test result may be incorrect or (iv) after an error message. Once completed participants were asked to sit down and the finger prick site was cleaned with an alcohol swab. When the area was dry, a sterile lancet was used to make the finger puncture. The finger was gently massaged to allow a blood drop to form. Using the blood key provided by Bio-Rad, blood was drawn into the key. Once completed, the blood key was immediately inserted into the Bio-Rad cartridge and there after immediately placed into the Analyzer. The analysis took ten minutes to complete. Once the test was finished, the HbA1c percent was displayed and recorded. The cartridge was then disposed of as biohazardous waste. The participant was given a small ball of cotton wool to put over the puncture for a few minutes to stop the bleeding and a plaster was applied if needed.

Equipment

281-0000EX	in2it (I) Analyzer, Model 501122R.1
281-0001EX	in2it (I) A _{1c} Test Cartridge
281-0002	in2it System Check Cartridge
281-0003	Blood Keys
281-0012	Cartridge Work-stand
AT1004	Owen Mumford, Unistik® 3 Normal, Single Use Safety Lancets

Information taken from the Bio-Rad in2it Analyzer manual states that the method used to separate the glycated fraction from the non-glycated fraction was boronate affinity chromatography. The in2it Analyzer (I) used was a fully automated system incorporated with a single-wavelength (440nm) photometer ^[167]. Each test cartridge that was used contained a sample reagent (boronate affinity resin, surfactant, sodium azide (0.1%) and buffer) as well as wash solution and elution buffer. Once the cartridge was in the

Analyzer, the analysis was automated to calculate a glycated absorbance as well as a non-glycated absorbance ^[167].

Storage

Test cartridges were stored in their protective packaging until they were ready to use and were stored between 2-8 °C. The operating temperature of the test was between 18 and 27 °C and therefore the cartridges were allowed to reach room temperature before they were used.

2.5 Positive Affect Intervention and Control Exercise

The interventions and control exercises that were given to participants were based on established methods that have been used in the largest randomised control trial in this area ^[57]. The intervention exercises: *three good things (TGT)* have been shown to have long term effects on mood. The intervention exercises have shown to increase happiness and decrease depression up to six months while the control exercise, *early memories (EM)* did not show to have such effects ^[57]. A note book and pen was given to each participant. Based on the work of Seligman et al (2005), they were instructed to spend 10 minutes on their allocated exercise and to complete it daily over seven consecutive days.

2.5.1 PA Intervention Exercise

Three Good Things

Participants were asked to write down three good things that happened each day and also write down why each thing went well. The following instructions were given to participants

“We think too much about what goes wrong and not enough about what goes right in our lives. Of course, sometimes it makes sense for us to analyse bad events so that we can learn from them and avoid them in the future. However, people tend to spend more time thinking about what is bad in life than is helpful. Worse, this tendency to focus on bad events sets us up for anxiety and depression. One way to keep this from happening is to develop our ability to think about the good in life. Most of us are not nearly as good at analysing good events as we are at analyzing bad events, so this is a skill that needs practice. As you become better at focusing on the good in your life, you will likely become more grateful for what you have and more hopeful about the future. So let’s get started.

- *Every night for one week, set aside 10 minutes before you go to bed. Use that time to write down three things that went really well during that day and why they went well. Write about these events in the notebook that we have given to you.*
- *Next to each positive event, answer the question “Why did this good thing happen?”*
- *It is important that you keep a physical record of what you have written. It is not enough to do this exercise in your head.*
- *Writing about “why” the positive events in your life went well may seem awkward at first, but please stick to it. It will get easier!*
- *Do this every night for 7 days*
- *After 7 days, look back at what you have written in your notebook*

The three things in your list can be relatively small in importance or they can be relatively large in importance to you. For example you could write “My children cooked me a lovely meal, I thought this was very thoughtful and caring”

2.5.2 Control Exercises

Two different control exercises were employed and these are described below.

Early Memories

Participants were asked to think about their earliest memories and write about them at the end of each day for seven days. The following instructions were given to participants

“Consider for a moment your earliest memories. Out of all the experiences of a lifetime, we only hold onto a few in the form of early memories. A careful consideration of our earliest memories may help us better understand who we are today.

- *Every night for one week, set aside 10 minutes before you go to bed. Use that time to think about an early memory and write it down in as much detail as possible.*
- *Try to remember what you were doing at that time, who you were with and what you were feeling (please do not worry if you cannot remember some of the details, that is OK, just write down what you can remember).*
- *Write about these events in the notebook that we have given you.*
- *It is important that you keep a physical record of what you have written. It is not enough to do this exercise in your head.*
- *Do this every night for 7 days*
- *After 7 days, look back at what you have written in your notebooks. Do you notice any similarities or patterns across the memories?”*

Statistical Writing

Participants were instructed to copy chunks of text taken from an introductory statistics textbook ^[168] over a seven day period. The following instructions were given to participants

Dear Participant

You have been chosen at random to do the following task. Please follow the instructions for the exercise below. In this envelope there are 7 pieces of paper. Each paper corresponds to a day of the week. Day 1, Day 2, Day 3 etc

Every night, for 7 days, set aside 10 minutes before you go to bed to complete this exercise.

***On day 1**, please copy the text that corresponds to day 1 into the notebook provided*

***On day 2**, please copy the text that corresponds to day 2 into the notebook provided*

***On day 3**, please copy the text that corresponds to day 3 into the notebook provided*

***On day 4**, please copy the text that corresponds to day 4 into the notebook provided*

***On day 5**, please copy the text that corresponds to day 5 into the notebook provided*

***On day 6**, please copy the text that corresponds to day 6 into the notebook provided*

***On day 7**, please copy the text that corresponds to day 7 into the notebook provided*

After completing the writing task, all pieces of paper can be placed back inside the envelope

It is important that you keep a physical record of what you have written. It is not enough to just read the exercise.

Please do not spend more than 10 minutes on this exercise

DAY 1

The next level of measurement moves us away from categorical variables and into continuous variables. A continuous variable is one that gives us a score for each person and can take on any value on the measurement scale that we are using. The first type of continuous variable that you might encounter is an interval variable. This hypothesis is the opposite of the alternative hypothesis.

DAY 2

Ratio variables go a step further than interval data by requiring that in addition to the measurement scale meeting the requirements of an interval variable, the ratios of values along the scale should be meaningful. For this to be true, the scale must have a true and meaningful zero point. In our lecturer ratings this would mean that a lecturer rated as 4 would be twice as helpful as a lecturer rated with a 2.

DAY 3

Continuous variables can be, well, continuous but also discrete. This is quite a tricky distinction. A truly continuous variable can be measured to any level of precision, whereas a discrete variable can take on only certain values on the scale. Our example in the text of rating lecturers on a 5-point scale is an example of a discrete variable. The range of the scale is 1–5, but you can enter only values of 1, 2, 3, 4 or 5.

DAY 4

Things like reaction times and physiological measures are valid in the sense that a reaction time does in fact measure the time taken to react and skin conductance does measure the conductivity of your skin. However, if we're using these things to infer other things then they will be valid only if there are no other factors other than the one we're interested in that can influence them.

Day 5

This method is the one described above, in which different groups of people take part in each experimental condition. The second method is to manipulate the independent variable using the same participants. The mean is the measure of central tendency that you are most likely to have heard of because it is simply the average score and the media are full of average scores.

DAY 6

Randomization is important because it eliminates most other sources of systematic variation, which allows us to be sure that any systematic variation between experimental conditions is due to the manipulation of the independent variable. Interval data are considerably more useful than ordinal data and most of the statistical tests in this book rely on having data measured at this level.

Day 7

This works very nicely when we have an odd number of scores but when we have an even number of scores there won't be a middle value. Let's imagine that we decided that because the highest score was so big, we would ignore it. We have only 10 scores now. As before, we should rank-order these scores: 22, 40, 53, 57, 93, 98, 103, 108, 116, and 121. We then calculate the position of the middle score.

Chapter Three: A single blind, randomised control study to investigate the impact of a positive affect intervention on cardiovascular reactivity and recovery

3.1 Introduction

The relationship between Positive Affect (PA) and stress has been described through a stress buffering model (see Figure 1.4) which proposes that the effect of stress on health is buffered by PA levels. The objective of this study was to test the stress buffering hypothesis using an experimental design.

A number of studies have investigated how physiological indicators such as blood pressure (BP) and heart rate (HR) change in response to acute mental stress [20, 24, 39, 42, 46, 48, 49]. These studies have generally found that individuals higher in PA react better to and from laboratory stressors such that they have lower reactivity and faster recovery. Changes in BP and HR in response to stress are typically measured as cardiovascular reactivity and recovery. Heightened reactivity and delayed recovery to acute mental stress can predict future changes in cardiovascular parameters such as BP and HR [23, 169-171]. This area of research is important as continuous elevated changes in response to stress can lead to the onset and progression of cardiovascular diseases (CVD).

Cardiovascular reactivity is defined as an increased elevation in BP or HR in response to acute mental stress which involves tasks that may be challenging, aversive, or engaging [170]. Cardiovascular recovery is defined as the time it takes for BP and HR to return to baseline after a stress-induced task or, alternatively, the extent of elevation that remains during the post-task recovery period [171].

Chida and Steptoe [169] conducted a meta analysis on the association between cardiovascular responses in response to acute mental stress and cardiovascular risk status which included factors such as elevated blood pressure, hypertension and

coronary calcification. The analysis found that heightened reactivity and delayed recovery were linked longitudinally to poorer cardiovascular status.

Previous studies have investigated the relationship between PA and physiological measures such as cardiovascular, neuroendocrine and inflammatory markers [9, 15, 20, 24, 25, 39, 46-49, 172]. Generally, studies have found associations between PA and cardiovascular parameters such that high levels of PA have been linked to lower BP and HR reactivity to stress and better recovery from stress [20, 24, 48-50]. However, such studies have yet to investigate whether PA interventions designed to increase PA could improve reactivity to and recovery from acute mental stress. The three good things (TGT) intervention has been shown to increase PA after one week and up to six months [57]. In view of this, this study aimed to first see if the TGT intervention could show the same efficacy in a healthy population and then secondly, whether the manipulation could have a beneficial impact on reactivity and recovery in response to acute mental stress.

As mentioned at the start of this chapter, the relationship between PA and stress has been described through a stress buffering model (see section 1.4). In relation to acute mental stress, individuals with higher PA are predicted to be resilient to the effects of the stress tasks and as a consequence the effect on BP recovery and reactivity will be more adverse for someone with lower PA. For this study we hypothesise that participants in the intervention group will react less and recover more quickly in response to the stress tasks after a one-week intervention compared to those in the control group.

Another area that this study addressed was the relationship between PA and NA. Previous research has criticised the methods with which PA has been measured. One questionnaire in particular is the PANAS which, although has been extensively used, is often criticised for measuring current mood state and memory recall. Nevertheless, as reviewed in the methods chapter, the items in the PANAS (section 2.1.1) are designed so that PA and NA are independent of each other. Therefore if the TGT intervention can effectively manipulate PA, then it should not have any effect on NA, when measured by the PANAS. Therefore the second aim of the study was to see if levels of

PA and NA change independently following the PA intervention. It is hypothesised that participants undergoing the TGT intervention will have a greater increase in PA scores compared to the control participants.

Most studies that have investigated the relationship between PA and CV measures have been cross-sectional in design and therefore causality cannot be determined [20, 24, 25, 49]. For this reason, this was a single blind randomised control study and adds to the current body of research. Furthermore these studies have failed to incorporate a control group to show that a stress response actually did occur. Although the studies showed significant increases from baseline, it is still important to compare it to a control group, as without one, any changes can be attributed to the passage of time alone. For this reason the study design also included a non stress group and it was hypothesised that individuals randomised to the stress group would react more compared to people in the no stress group.

In conclusion, based on the literature above it is hypothesised that (i) the TGT exercise would induce an increase in PA; (ii) the PA intervention would not change negative affect; (iii) individuals who completed the stress task would have higher systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR) and perceived stress (PS) compared to the no stress group; (iv) the PA intervention (TGT) would reduce SBP/DBP/HR/PS reactivity; and (v) the PA intervention (TGT) would speed post-stress recovery.

3.2 Ethical Approval

The study proposal was submitted to the Faculty of Science and Engineering Research Ethics and Governance Committee (FREGC) at the University of Brighton for review. Approval was granted on 1st June 2011 (see appendix A).

3.3 Methods

3.3.1 Study Design

This was a randomised single blind control study and was conducted in the Clinical Research Laboratories in the School of Pharmacy and Biomolecular Sciences at the University of Brighton. Participants were randomly allocated to one of four independent groups; (i) no stress: neutral (ii) no stress: three good things (TGT) (iii) stress: neutral and (iv) stress: TGT. Although the researcher was aware of whether individuals were randomised to the stress or no stress tasks, she was blinded to the tasks designed to alter PA or control. This ensured that none of the researcher's beliefs or expectations about the exercise would affect the results. An independent person arranged appropriate packs that corresponded to the different conditions. They were in charge of randomising which condition participants were allocated to. They also blinded the packs that were given to the participants by the researcher. If any participant required further information about the exercise, the researcher explained both exercises to them again. At the end of the study the researcher was given access to the study codes for analysis.

Stress Tasks

Participants in the stress groups were asked to complete two behavioural tasks ^[173]. Participants were asked to prepare a speech defending themselves in a role play accusation. These were randomly assigned to one of the following (threat of unemployment, a shop lifting accusation, or an incident involving a close relative living in a nursing home). They were given two minutes preparation time and then were instructed to talk about the situation for a further 3 minutes in front of a video camera (in reality the camera did not record volunteers performance, but participants were not informed of this until debriefing at the end of the study).

The second task involved a mirror tracing exercise whereby participants were asked to trace a star that could only be seen in a mirror using a metal stylus. If the participant traced outside the star, a loud beep was emitted indicating a mistake. An element of competition was also included whereby participants were told that their score would be marked against other participants. In addition, on their second visit, they were asked to

try to beat their first visit personal score. These tasks have previously been shown to elicit a stress response ^[20, 46, 173].

No Stress Tasks

Participants in the no stress groups were asked to read an academic journal for 5 minutes ^[47]. The second task also involved a mirror tracing exercise, however, participants were asked to trace the star with a metal stylus without the mirror or shield present and there was no element of competition.

Sample Size

The sample size was based on a power analysis for an effect size of 0.30 where $n = 48$ with repeated measures gives power (1-beta err prob) of 0.93 (Gpower v 3.1).

3.3.2 Participants

People were considered eligible for inclusion in this study if they fulfilled all of the following criteria, (i) gave written informed consent to take part in the study (ii) had a BMI between 18.5 and 29.9 (iii) were aged between 18 and 40 years and (iv) had the ability to read and write English fluently. Volunteers were excluded from the study if they were a current smoker, were diagnosed with any heart related problems, were on medication or were receiving any treatment for mental health problems. Furthermore, females who were pregnant or breastfeeding, or who thought they may be pregnant were excluded. All data were regarded as confidential. Participant's age and randomly assigned experimental number were used as identification and no individual data was reproduced.

3.3.3 Measures

Predictor

The PANAS was used to measure PA. Two timeframes were used for the purpose of this study. At visit one, the timeframe used was “*generally*” and for visit two the timeframe used was “*during the past week*” (see section 2.1.1).

Cardiovascular Measures

The primary measures which were taken using a validated blood pressure monitor (see section 2.4.1) were systolic blood pressure, (SBP) diastolic blood pressure (DBP), heart rate (HR) and perceived stress (PS) whereby participants were asked to rate how stressed they were feeling. These measures were taken at baseline, during (on tasks) and after the tasks (post tasks). The *on task* reading for SBP, DBP, HR and PS was calculated by averaging the scores that were obtained from the two stress tasks or two no stress tasks.

From these CV measures, CV reactivity and recovery were calculated and these served as the main outcome measures. To measure reactivity, the difference between the on task reading and the baseline reading was calculated, with a higher positive value indicating greater reactivity. To measure recovery, the difference between the post task reading and the on tasks reading was calculated, a higher positive score indicated better recovery.

Demographic Factors

Participants were asked to report their age, gender, ethnic background and education. Participants’ weight and height were measured from which BMI was calculated (see section 2.4.2)

Psychosocial Factors

Participants were asked to complete the following validated questionnaires: the PSS and CD-RISC which were used to measure perceived stress and resilience respectively. These validated questionnaires have been used extensively in other research areas and were chosen for their demonstrated reliability and validity (see section 2.1.2 and 2.3.1).

3.3.4 Procedure

On arrival at the laboratory at visit one, participants height and weight were measured and then they were asked to complete three questionnaires (PANAS, PSS and CD-RISC-10). The blood pressure monitor was then attached to the non-dominant hand of the participant. Participants were instructed to sit quietly and after 10 minutes, three BP and HR readings were taken and then averaged to represent baseline levels. Participants were asked to report on a scale of 1- 7 how stressed they felt at that moment in time (1 indicating not stressful at all and 7 indicating very stressed)

Participants were then randomly assigned to either complete two stress tasks or two no stress tasks (see section 3.3.1). The duration of each task was 5 minutes and BP and HR readings were recorded at 3 minutes for each task. After each task participants were asked to report on a scale of 1- 7 how stressed they felt (1 indicating not stressful at all and 7 indicating very stressed)

After completing the second task, participants were then instructed to sit quietly for 10 minutes. BP and HR readings were taken at 5 minutes and again at 10 minutes. Participants were then asked again to report on a scale of 1- 7 how stressed they felt (1 indicating not stressful at all and 7 indicating very stressed)

At the end of visit one, the participant's were given a sealed envelope containing either the PA intervention or the control exercise. Participants were instructed to complete the written task and to come back after 7 days to complete visit two.

The laboratory procedure completed by participants at visit one was repeated at visit two. At the end of the study participants were fully debriefed about the study. The procedure is summarised in Figure 3.1.

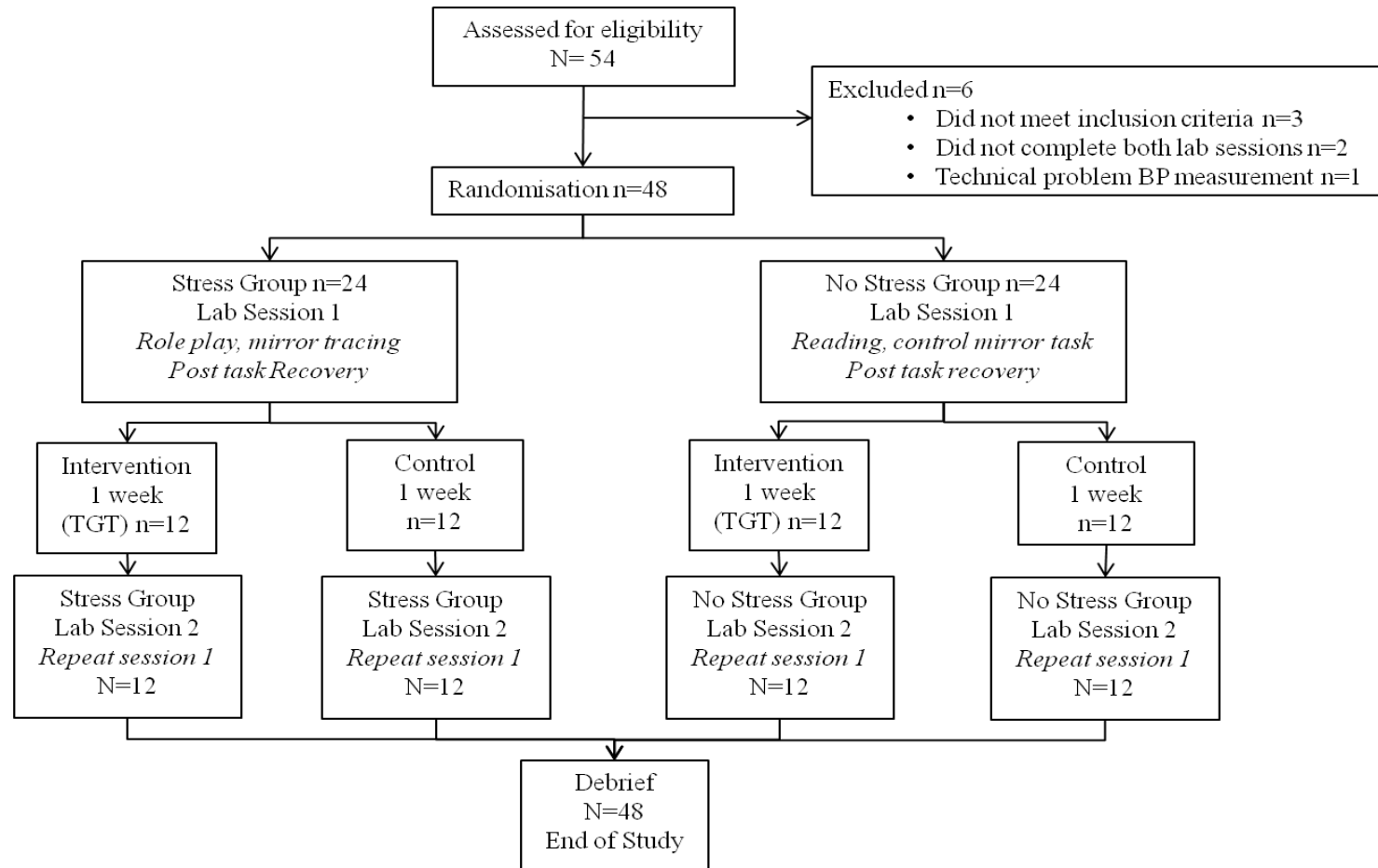


Figure 3.1 Flow diagram illustrating order of events for visit one and visit two. TGT = Three Good Things

3.4 Data Analysis

The statistical software used for all analysis was PASW Statistics 18. Normality tests were performed using the Kolmogorov-Smirnov and Normal Q-Q plots. Non-parametric tests were used if variables did not show normality after transformation.

Data analysis was conducted in three steps; first descriptive statistics were calculated for all measures across the four independent groups (i) no stress: neutral group (ii) no stress: three good things (TGT) group (iii) stress: neutral and (iv) stress: TGT.

Then a series of ANOVA's were conducted on these measures to assess if there were any differences between the four independent groups in baseline BP, HR, PA, NA, Resilience and Perceived Stress Scale). Where differences were found, the scores were included as covariates in the subsequent analysis.

Finally, a series of mixed ANCOVA's were conducted to assess the impact of the positive affect intervention (TGT vs. neutral group) and the stress manipulation (stress vs. no stress) on (i) PA scores (ii) NA scores, (iii) reactivity to tasks for SBP, DBP, HR, PS and (iv) recovery from tasks for SBP, DBP, HR and PS across the two visit time-points (visit one vs. visit two) while controlling for any significant covariates and NA¹. Furthermore, to analyse recovery data, the mean reactivity score at visit two was included as a covariate if there was a main effect of reactivity at visit one. For all outcomes a p-value < .05 was considered to be statistically significant.

¹ NA was used as a covariate regardless of whether or not there was a difference at baseline; this is because we wanted to investigate PA independent of NA and to show that PA is not the bipolar opposite of NA when measured by PANAS.

3.5 Results

3.5.1 Sample Characteristics

The number of individuals who completed the study was 48 of whom 60% were female and the mean age was 22 years ($SD = 4.52$). All of the participants had either a college or university degree and 59% of individuals were white/white British.

Table 3.1 shows the differences in demographics, PA, NA, PSS and CD-RISC scores across the four groups at visit one. Significant differences were found in age ($F(3, 44) = 4.74, p = .006$) and years of education ($F(3, 44) = 3.77, p = .017$). Post-hoc comparisons indicated that the mean scores for participants in the no stress: neutral group were significantly older than individuals in the (i) stress: control group and (ii) stress: TGT group. In addition, Post-hoc comparisons also indicated that the mean scores for participants in the no stress: neutral group had significantly higher number of years of education than individuals in the stress: control group. Age, education and NA will therefore be used as covariates in any subsequent analysis.

Table 3.1 Comparison of four randomised groups (i) no stress: neutral group (ii) no stress: three good things (TGT) group (iii) stress: neutral and (iv) stress: TGT. Mean scores (standard deviation).

	No stress: neutral	No stress: TGT	Stress: neutral	Stress: TGT	<i>p</i> value
Age (years)	25.08 (6.16)	23.08 (4.87)	19.67 (1.56)	20.17 (1.34)	.006
Education (years)	11.79 (3.39)	10.58 (2.68)	8.58 (1.44)	9.42 (2.02)	.017
BMI	23.91 (3.57)	22.11 (3.59)	22.65 (2.48)	23.83 (2.60)	.411
PA	3.67 (.50)	3.63 (.52)	3.48 (.53)	3.58 (.48)	.813
NA	1.81 (.39)	1.79 (.65)	2.00 (.45)	1.68 (.57)	.522
PSS	2.28 (.30)	2.03 (.31)	1.95 (.42)	2.15 (.36)	.130
CD-RISC	3.10 (.51)	3.05 (.42)	3.00 (.34)	2.98 (.45)	.899

BMI: Body Mass Index. PA: Positive Affect. NA: Negative Affect. PSS: Perceived Stress scale. CD-RISC: Connor Davidson Resilience Scale-10.

3.5.2 Positive Affect Intervention

Positive Affect

Figure 3.2 shows the mean positive affect scores at visit one and visit two independent of age and number of years of education. There was no significant main effect of visit ($F(1, 42) = .29, p = .591$, partial eta squared $.01$) indicating that PA scores were generally the same after the one week interval. The main effect of the stress manipulation was also not significant, ($F(1, 42) = .93, p = .927$, partial eta squared $< .001$), indicating no difference in PA scores between the stress task and no stress task groups. The main effect of the PA intervention, however, was significant, ($F(1, 42) = 5.39, p = .025$, partial eta squared $= .11$), indicating that higher PA scores were observed in the intervention group (TGT mean = 3.63, SE = .10; neutral group mean = 3.30, SE = .10).

Importantly, there was a significant interaction between the PA intervention and visit, ($F(1, 42) = 13.81, p = .001$, partial eta squared $.25$) indicating that PA scores decreased at visit two for the control group (visit one mean = 3.56 SE = .10; visit two mean = 3.03 SE = .13) but not for the intervention group (visit one mean = 3.61, SE = .10; visit two mean = 3.64, SE = .13). There was no significant interaction between the stress manipulation and visit ($F(1, 42) = .006, p = .520$, partial eta squared $= .01$) indicating that PA scores decreased at visit two for both the stress task and the no stress task.

There was no significant interaction between the stress task, PA intervention and visit ($F(1, 45) = .006, p = .940$, partial eta squared $< .001$) indicating that the decrease in PA scores for the control intervention was the same for both the stress and the no stress group. The results therefore showed that the TGT intervention prevented the decline in PA that occurred in the control groups, regardless of whether or not participants were in the stress/no stress groups. For this reason Hypothesis 1 cannot be supported: the TGT exercise did not show an increase in PA.

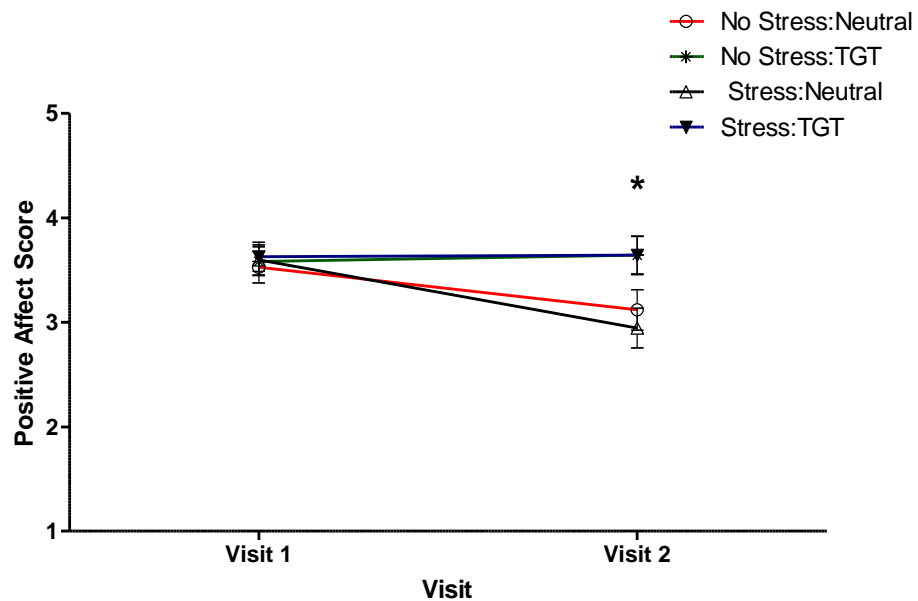


Figure 3.2 Mean positive affect scores at visit one and visit two in participants randomised to either (i) no stress: neutral group (ii) no stress: three good things (TGT) group (iii) stress: neutral and (iv) stress: TGT.

Error bars represent standard error of mean; adjusted for age and years of education. $N = 12$ per group. $*p < .05$

Negative Affect

Figure 3.3 shows the mean NA scores at visit one and visit two independent of age and number of years of education. The main effect of the PA intervention was not significant, ($F(1, 42) = 1.78, p = .189$, partial eta squared = .04), indicating no differences in NA scores between the TGT groups and the control group. The main effect of the stress manipulation was also not significant, ($F(1, 42) = 2.49, p = .123$, partial eta squared = .06), indicating no differences in NA scores between the stress task and the no stress task. There was also no significant main effect of visit ($F(1, 42) = .23, p = .635$, partial eta squared = .01), indicating that NA scores were generally the same after the one week interval.

There was no significant interaction between the PA intervention and visit, ($F(1, 42) < .001$, $p = .996$, partial eta squared $< .001$), indicating that the lack of change in NA scores was similar in both the control group and the intervention group. There was no significant interaction between the stress manipulation and visit ($F(1, 42) = 1.28$, $p = .264$, partial eta squared = .03) indicating that the lack of change in NA scores was similar for participants in the stress task and the no stress task groups.

There was no significant interaction between the stress tasks, PA intervention and visit $F(1, 42) = .01$, $p = .815$, partial eta squared = .001 indicating that the lack of change between the two visits is the same amongst the four groups (see Figure 3.3).

The results therefore indicate that the TGT intervention did not influence NA scores, regardless of whether or not participants were in the stress/no stress groups. This therefore supports Hypothesis 2; the PA intervention did not change NA.

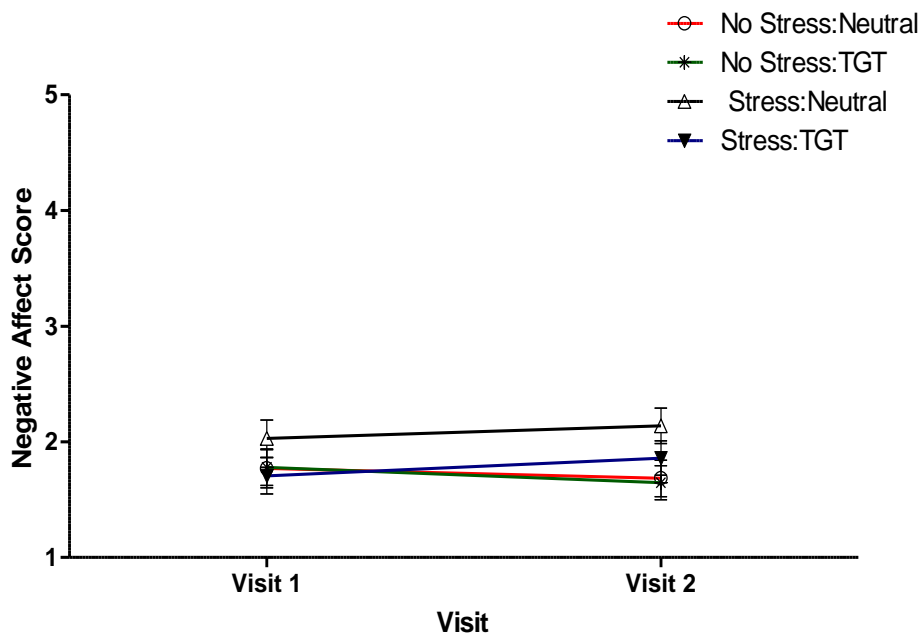


Figure 3.3 Mean negative affect scores at visit one and visit two in participants randomised to either of the following groups (i) no stress: neutral (ii) no stress: three good things (TGT) (iii) stress: neutral or (iv) stress: TGT.

Error bars represent standard error of mean; adjusted for age and years of education. $N = 12$ per group.

3.5.3 Cardiovascular and Perceived Stress Responses

Systolic Blood Pressure Reactivity

Figure 3.4 shows the systolic blood pressure (SBP) reactivity scores at visit one and visit two independent of age, years of education and NA. The main effect of the PA intervention was not significant ($F(1, 41) = .64, p = .428$), indicating no differences in SBP reactivity between the TGT group and the control group. As expected there was a significant main effect of the stress manipulation ($F(1, 41) = 66.54, p < .001$, partial eta squared = .62), indicating that SBP reactivity to tasks was higher in the stress group compared to the no stress group. There was a significant main effect of visit on SBP reactivity ($F(1, 41) = 5.21, p = .028$, partial eta squared = .11) indicating a decrease in SBP reactivity scores after the one week interval (visit one mean = 10.94 SE = .88; visit two mean = 7.74 SE 1.01).

There was no significant interaction between the PA intervention and visit ($F(1, 41) = 1.01, p = .322$), indicating that change in SBP reactivity scores was similar in both the control group and intervention group. There was no significant interaction between the stress manipulation and visit ($F(1, 41) = .39, p = .537$), indicating that the change in SBP reactivity was similar for participants in the stress group and the no stress group.

There was no overall interaction between stress task, PA intervention and visit ($F(1, 41) = .36, p = .550$), indicating the pattern of change between the two visits was the same amongst the four groups (see Figure 3.4).

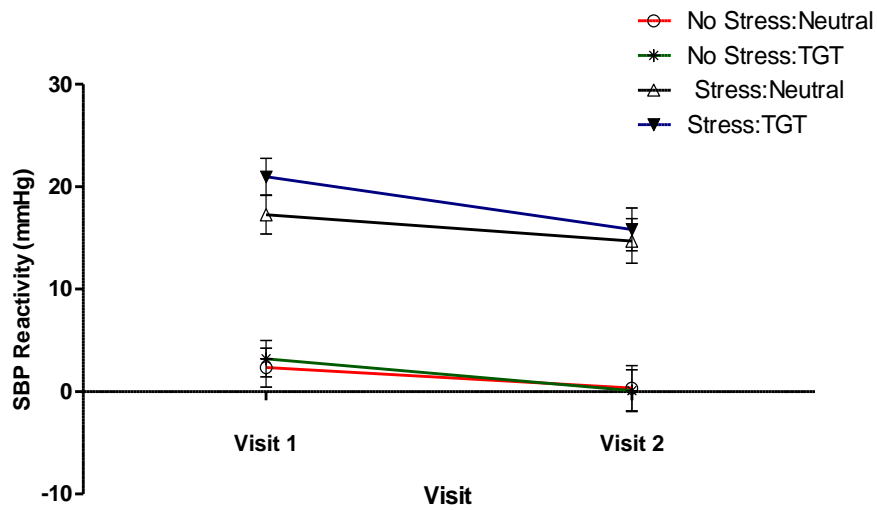


Figure 3.4 Systolic Blood Pressure (SBP) reactivity to tasks for participants at visit one and visit two across the four groups (i) no stress: neutral group (ii) no stress: three good things (TGT) group (iii) stress: neutral and (iv) stress: TGT.

Error bars represent standard error of mean; adjusted for age, years of education and negative affect. $N = 12$ per group.

Systolic Blood Pressure Recovery

Figure 3.5 shows SBP recovery scores at visit one and visit two independent of mean reactivity scores at visit two, age, years of education and NA. The main effect of the PA intervention reached near significance ($F(1, 40) = 3.75, p = .060$), suggesting that there might be a trend in SBP recovery scores between the TGT group and the control group. There was no significant main effect of the stress manipulation ($F(1, 40) = 1.83, p = .183$), however there was a significant interaction between the stress manipulation and exercise such that individuals in the TGT group had reduced recovery but not for the control group ($F(1, 40) = 5.75, p = .021$). There was no significant main effect of visit on SBP recovery ($F(1, 40) = 1.63, p = .210$), indicating that SBP recovery scores were generally the same after the one week interval.

There was a significant interaction between the PA intervention and visit ($F(1, 40) = 8.34, p = .006$, partial eta squared = .18), indicating slower recovery at visit 2 compared

to visit one for the TGT group (visit 1 mean = 13.03, SE = 1.22; visit 2 mean = 6.91, SE = 1.32) but not for the control group (visit 1 mean = 7.55, SE = 1.58; visit 2 mean = 7.11, SE = .73). There was a significant interaction between the stress manipulation and visit ($F(1, 40) = 8.47, p = .006$, partial eta squared = .18), indicating that recovery was similar between visit one and visit two for the no stress group (visit one mean = 7.37, SE = 1.64; visit two mean = 7.94, SE = .98) but not for individuals in the stress group (visit 1 mean = 13.96, SE = 1.64; visit 2 mean = 6.25, SE = .98).

There was no overall interaction between stress task, PA intervention and visit ($F(1, 40) = 2.31, p = .14$), indicating the pattern of change between the two visits was the same amongst the four groups (see Figure 3.5).

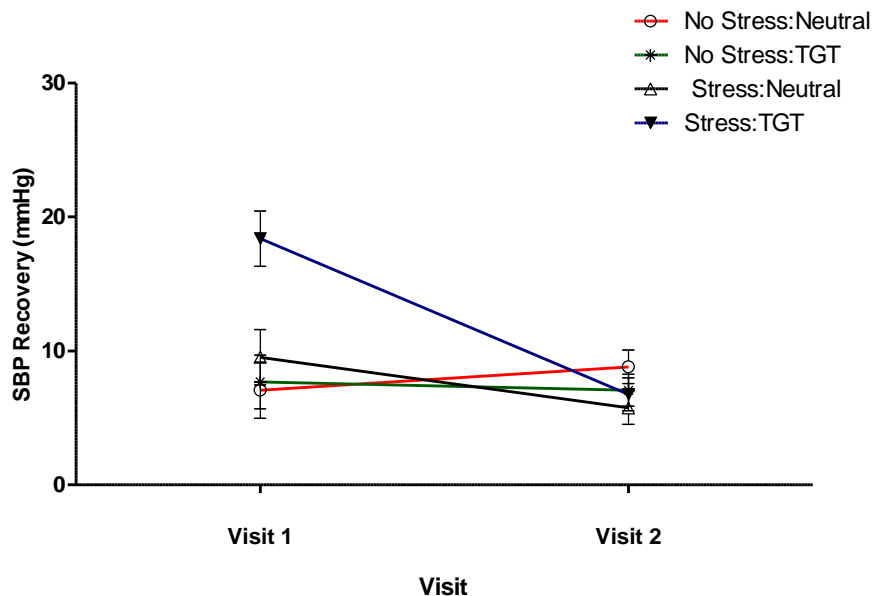


Figure 3.5 Systolic Blood Pressure (SBP) recovery from tasks for participants at visit one and visit two across the four groups (i) no stress: neutral group (ii) no stress: three good things (TGT) group (iii) stress: neutral and (iv) stress: TGT.

Error bars represent standard error of mean; adjusted for mean reactivity scores at visit two, age, years of education and negative affect. A higher score indicates a faster recovery. $N = 12$ per group.

In summary, the results in relation to SBP reactivity showed that individuals who completed the stress tasks had heightened SBP, regardless of whether or not participants were in the TGT/control groups. Therefore this supports Hypothesis 3; the stress tasks did indeed lead to heightened SBP reactivity compared to the individuals completing the no stress tasks. In addition, individuals in the TGT groups had higher levels of PA compared to the control group at visit two (see Figure 3.2). However, Hypothesis 4 could not be supported; the TGT groups showed no additional reduction in SBP reactivity after the one week interval.

The results showed that individuals in the TGT group had reduced SBP recovery at visit two compared to visit one. For this reason, Hypothesis 5 could not be supported, since it was predicted that the Stress: TGT group would have increased post stress recovery after the intervention.

Diastolic Blood Pressure Reactivity

Figure 3.6 shows the diastolic blood pressure (DBP) reactivity scores at visit one and visit two independent of age, years of education and NA. The main effect of the PA intervention was not significant ($F(1, 41) < .001, p = .967$), indicating no differences in DBP reactivity between the TGT group and the control group. Unsurprisingly, there was a significant main effect of the stress manipulation ($F(1, 41) = 60.53, p < .001$, partial eta squared = .60) indicating that DBP reactivity to tasks was higher in the stress group compared to the no stress group. There was no significant main effect of visit on DBP reactivity ($F(1, 41) = .06, p = .806$) indicating no changes in DBP reactivity after the one week interval.

The interaction between visit and the PA intervention was not significant ($F(1, 41) = .03, p = .869$), such that the lack of change in DBP reactivity was similar in both the control groups and intervention groups. The interaction between visit and the stress manipulation was also not significant ($F(1, 41) = .28, p = .597$), indicating that the lack of change in DBP reactivity between visit one and visit two was the same for the stress groups as the no stress groups.

There was no interaction between stress task, PA intervention and visit ($F(1, 41) = .01$, $p = .910$), indicating the pattern of change between the two visits was the same amongst the four groups (see Figure 5.6).

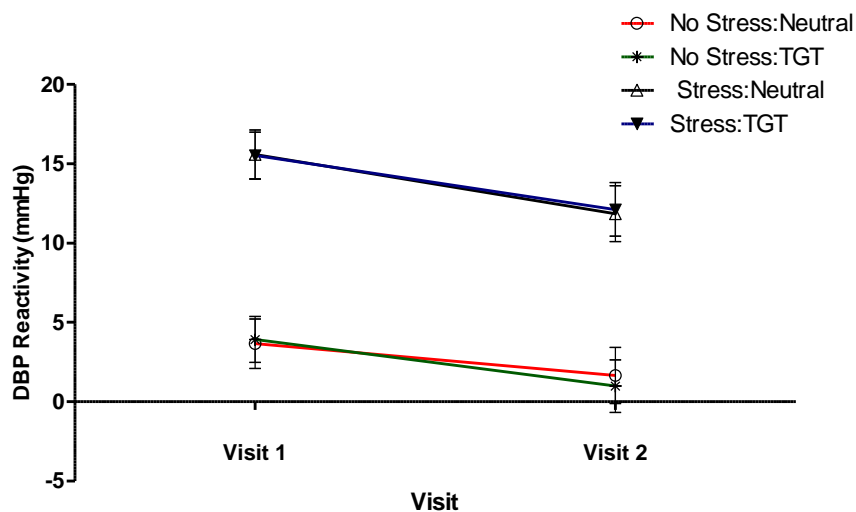


Figure 3.6 Diastolic Blood Pressure (DBP) reactivity to tasks for participants at visit one and visit two across the four groups (i) no stress: neutral group (ii) no stress: three good things (TGT) group (iii) stress: neutral and (iv) stress: TGT. Error bars represent standard error of mean; adjusted for age, years of education and negative affect. $N = 12$ per group.

Diastolic Blood Pressure Recovery

Figure 3.7 shows DBP recovery scores at visit one and visit two after adjusting for age, years of education and NA. There was no significant main effect of the PA intervention ($F(1, 41) = .29, p = .591$), indicating no differences in DBP recovery scores between the TGT group and the control group. There was, however, a significant main effect of the stress manipulation ($F(1, 41) = 46.89, p < .001$, partial eta squared = .53), indicating that DBP recovery values were larger in the stress group compared to the no stress group. This difference is not surprising as there was a main effect of the stress manipulation for reactivity and therefore individuals in the no stress groups had less to recover from. The main effect of visit on DBP recovery scores was not significant ($F(1, 41) = 2.44, p = .126$) such that there were no differences in recovery scores between visit one and visit two.

There was no significant interaction between the PA intervention and visit ($F(1, 41) = .15, p = .704$), indicating that the lack of change in DBP recovery scores between visit one and visit two was similar in both the control group and intervention group. There was no significant interaction between the stress tasks and visit ($F(1, 41) = .02, p = .890$) indicating that the lack of change in DBP recovery scores was similar for participants in the stress groups and the no stress groups.

There was no interaction between stress task, PA intervention and visit ($F(1, 41) = 1.35, p = .252$), indicating the pattern of change between the two visits was the same amongst the four groups (see Figure 3.7).

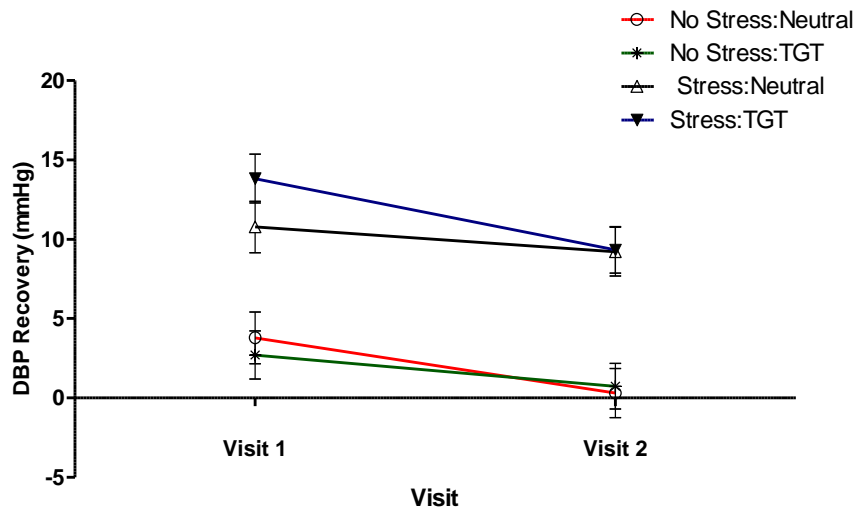


Figure 3.7 Diastolic Blood Pressure (DBP) recovery from tasks for participants at visit one and visit two across the four groups (i) no stress: neutral group (ii) no stress: three good things (TGT) group (iii) stress: neutral and (iv) stress: TGT.

Error bars represent standard error of mean; adjusted for baseline DBP, age, years of education and negative affect. $N = 12$ per group.

In summary, the results in relation to DBP showed that individuals who completed the stress tasks had heightened DBP reactivity, regardless of whether or not participants were in the TGT/control groups. Therefore this supports Hypothesis 3, the stress tasks did indeed lead to heightened DBP reactivity compared to the individuals completing the no stress tasks.

As mentioned before, individuals in the TGT groups had higher levels of PA compared to the control group at visit two (see Figure 3.2). Despite this, the results showed that there was no reduction in DBP reactivity. For this reason, Hypothesis 4 could not be supported, given that the TGT groups showed no reduction in DBP reactivity after the one week interval.

The results showed that PA intervention did not alter recovery from stress. For this reason, Hypothesis 5 could not be supported; given that the Stress: TGT group did not have improved post stress recovery after the one week interval.

Heart Rate Reactivity

Figure 3.8 shows heart rate (HR) reactivity scores at visit one and visit two, after adjusting for age, years of education and NA. The main effect of the PA intervention was not significant ($F(1, 41) = .20, p = .654$), indicating no differences in HR reactivity between the TGT group and the control group. There was a significant main effect of the stress manipulation ($F(1, 41) = 16.17, p < .001$, partial eta squared = .28), indicating that HR reactivity to tasks was higher in the stress group compared to the no stress group. There was no main effect of visit on HR reactivity scores ($F(1, 41) = 1.17, p = .286$) indicating that there was no change in HR reactivity scores at visit one and visit two.

The interaction between visit and the PA intervention was not significant ($F(1, 41) = < .001, p = .986$), such that the lack of change in HR reactivity was similar in both the control group and intervention group. The interaction between visit and the stress manipulation was also not significant ($F(1, 41) = 1.41, p = .242$), indicating that the lack of change in HR reactivity between visit one and visit two was the same for the stress groups and the no stress groups.

There was no interaction between stress task, PA intervention and visit ($F(1, 41) = .04, p = .848$), indicating the pattern of change between the two visits was the same for the four groups (see Figure 3.8).

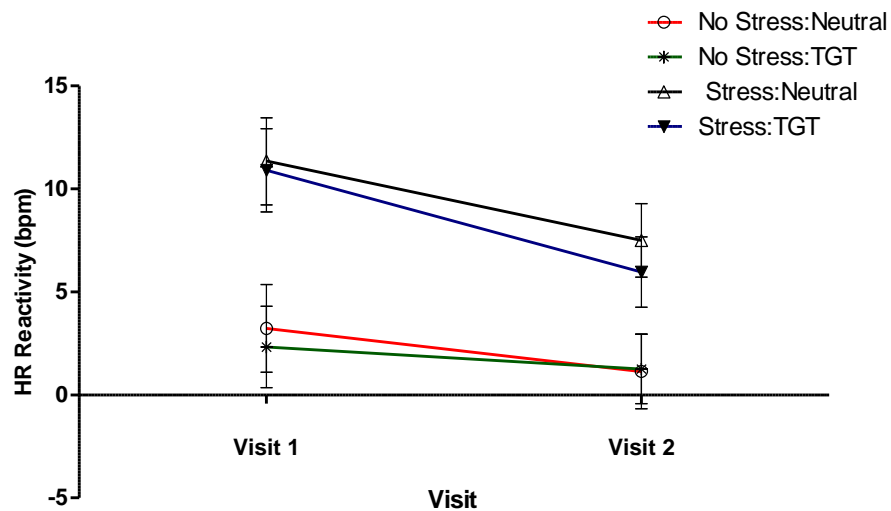


Figure 3.8 Heart Rate (HR) reactivity to tasks for participants at visit one and visit two across the four groups (i) no stress: neutral group (ii) no stress: three good things (TGT) group (iii) stress: neutral and (iv) stress: TGT.

Error bars represent standard error of mean; adjusted for baseline HR, age, years of education and negative affect. $N = 12$ per group.

Heart Rate Recovery

Figure 3.9 shows HR recovery scores at visit one and visit two after adjusting for age, years of education and NA. There was no significant main effect of the PA intervention ($F(1, 41) = .09, p = .771$), indicating no differences in HR recovery scores between the TGT groups and the control groups. There was a significant main effect of the stress manipulation ($F(1, 41) = 10.19, p = .003$, partial eta squared = .20), indicating that HR recovery values were larger in the stress group. This difference is not surprising as there was a main effect of the stress manipulation for HR reactivity and therefore individuals in the stress group would have needed to recover more. There was no significant main effect of visit in HR recovery ($F(1, 41) = .18, p = .673$), indicating that HR recovery scores were generally the same after the one week interval.

There was no significant interaction between the PA intervention and visit ($F(1, 41) = .23, p = .636$), indicating that the lack of change in HR recovery scores between visit one and visit two was similar in both the control group and intervention group. The interaction between visit and the stress manipulation was also not significant ($F(1, 41) = .37, p = .546$), indicating that the lack of change in HR recovery scores was similar for participants in the stress group and the no stress group.

There was no interaction between stress task, PA intervention and visit ($F(1, 41) = .34, p = .562$), indicating the pattern of change between the two visits was the same amongst the four groups (see Figure 3.9).

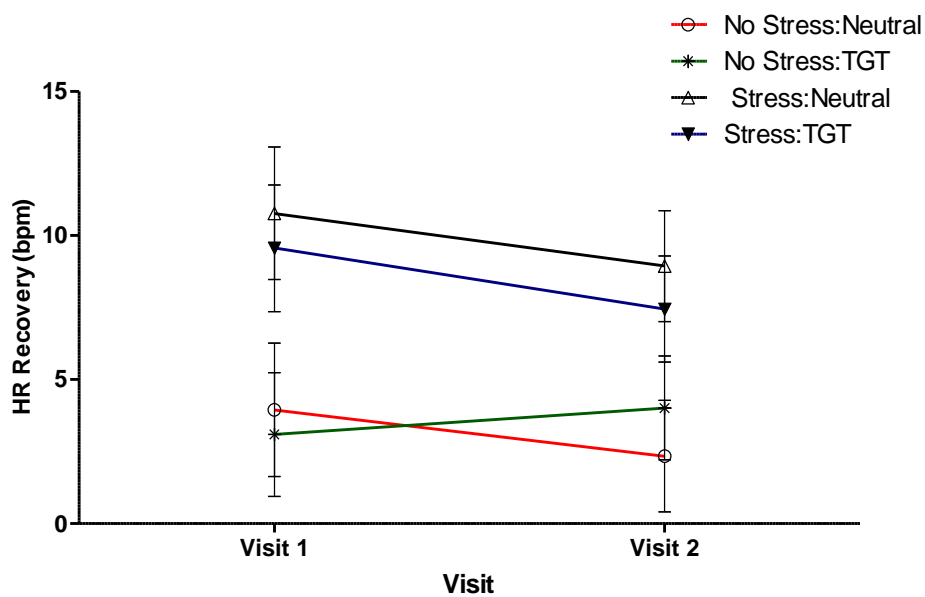


Figure 3.9 Heart Rate (HR) recovery from tasks for participants at visit one and visit two across the four groups (i) no stress: neutral group (ii) no stress: three good things (TGT) group (iii) stress: neutral and (iv) stress: TGT.

Error bars represent standard error of mean; adjusted for baseline HR, age, years of education and negative affect. $N = 12$ per group.

In summary, the results in relation to HR showed that individuals who completed the stress tasks had heightened HR, regardless of whether or not participants were in the TGT/control groups. Therefore this supports Hypothesis 3, the stress tasks did indeed lead to heightened HR reactivity compared to the individuals completing the no stress tasks.

As mentioned before, individuals in the TGT groups had higher levels of PA compared to the control group at visit two (see Figure 3.2). Despite this, the results showed that individuals across all four groups did not show a reduction in HR reactivity. For this reason, Hypothesis 4 could not be supported; the TGT groups showed no reduction in HR reactivity after the one week interval.

Similar to other measures, HR data provided no evidence of faster recovery after the PA intervention. Hypothesis 5 could not be supported, given that the TGT groups did not show improved post stress recovery after the one week interval.

Perceived Stress Reactivity

Figure 3.10 shows how individuals perceived the stressfulness of the task (PS) at visit one and two after adjusting for age, years of education and NA. There was no significant main effect of the PA intervention ($F(1, 41) = .66, p = .420$), indicating that there was no difference between the TGT group and the control group in how stressful the task was perceived to be. There was a significant main effect of the stress manipulation ($F(1, 41) = 33.08, p < .001$, partial eta squared = .45), indicating that the stress tasks more were more perceived as such. There was no significant main effect of visit in PS scores ($F(1, 41) = 2.64, p = .112$), indicating that there was no change in the perceived stressfulness of the tasks after the one week interval.

There was no significant interaction between the PA intervention and visit ($F(1, 41) = .06, p = .817$), indicating that the lack of change in which individuals perceived the stressfulness of the tasks between visit one and visit two was similar in both the control group and intervention group. The interaction between visit and the stress manipulation was also not significant ($F(1, 41) = 3.22, p = .080$), indicating that the lack of change in

which individuals perceived the stressfulness of the tasks was similar for participants in the stress group and the no stress group.

There was no interaction between stress tasks, PA intervention and visit ($F(1, 41) = .76$, $p = .388$), indicating the pattern of change between the two visits was the same for the four groups (see Figure 3.10).

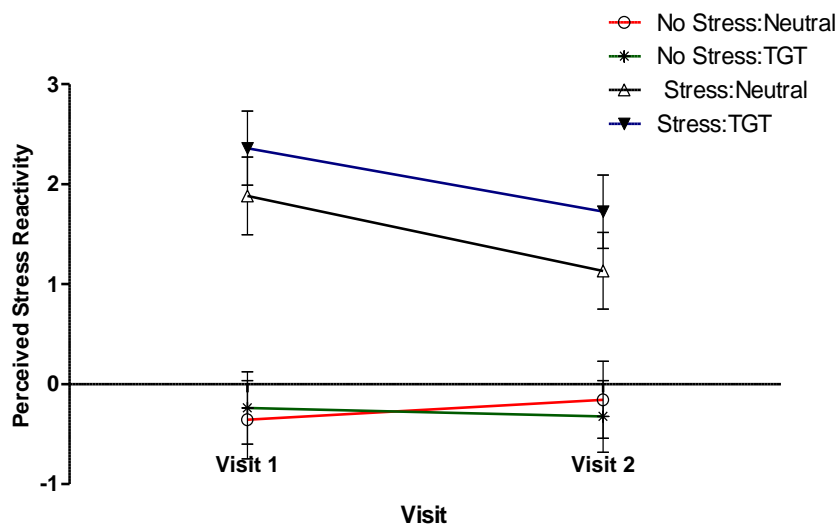


Figure 3.10 Perceived stress (PS) scores (reactivity) from tasks for participants at visit one and visit two across the four groups (i) no stress: neutral group (ii) no stress: three good things (TGT) group (iii) stress: neutral and (iv) stress: TGT. Error bars represent standard error of mean; adjusted for age, years of education and negative affect. $N = 12$ per group

Perceived Stress Recovery

Figure 3.11 shows the recovery scores of perceived stress at visit one and visit two after adjusting for age, years of education and NA. There was no significant main effect of the PA intervention ($F(1, 41) < .001, p < .971$), indicating that there was no difference between the TGT group and the control group in recovery from the perceived stressfulness of the tasks. There was a significant main effect of the stress manipulation ($F(1, 41) = 30.12, p < .001$, partial eta squared = .42), indicating that recovery scores were greater in the stress group compared to the no stress group. This difference is not surprising as there was a main effect of the stress manipulation for how individuals perceived the stressfulness of the tasks and therefore individuals in the stress tasks would have needed to recover more in the stress tasks. There was no main effect of visit in PS recovery scores ($F(1, 41) = 2.52, p = .120$) indicating that there was no change across time.

There was no significant interaction between the PA intervention and visit ($F(1, 41) = .31, p = .580$), indicating that the lack of change in recovery between visit one and visit two was similar in both the control group and intervention group. The interaction between visit and the stress manipulation was also not significant $F(1, 41) = .99, p = .326$, indicating that the lack of change in which individuals recovered from their perceived stressfulness of the tasks was similar for participants in the stress group and the no stress group.

There was no interaction between stress task, PA intervention and visit ($F(1, 41) < .001, p = .976$), indicating the pattern of change between the two visits was the same amongst the four groups (see Figure 3.11).

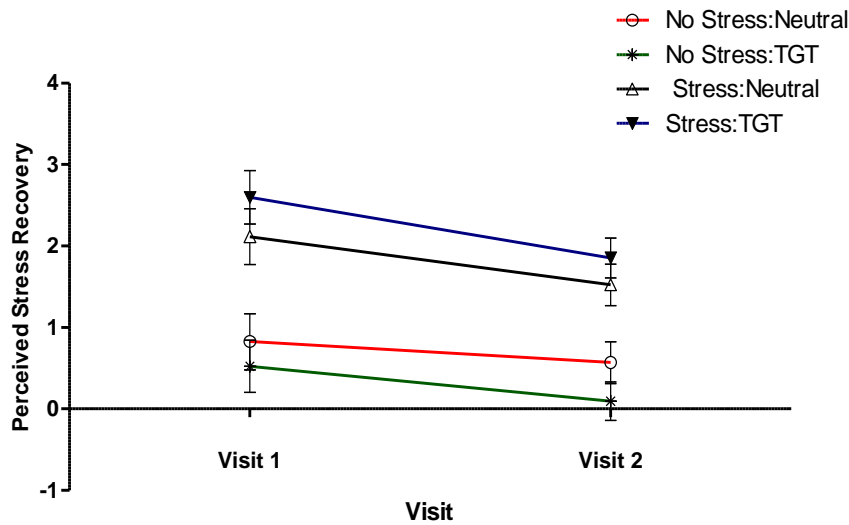


Figure 3.11 Perceived stress (PS) scores (recovery) from tasks for participants at visit one and visit two across the four groups (i) no stress: neutral group (ii) no stress: three good things (TGT) group (iii) stress: neutral and (iv) stress: TGT. Error bars represent standard error of mean; adjusted for age, years of education and negative affect. $N = 12$ per group

In summary, the results in relation to how individuals perceived the stressfulness of the tasks showed that participants who completed the stress tasks perceived the tasks as more stressful, regardless of whether or not they were in the TGT/control groups. Therefore this supports Hypothesis 3; the stress tasks did indeed lead to greater perceived stress.

Despite the higher levels of PA in the TGT groups at visit two (see Figure 3.2) there were no reductions in how stressful tasks were perceived. For this reason, Hypothesis 4 could not be supported, the TGT groups showed no additional reduction in PS reactivity after the one week interval.

The results also indicated that PA was not linked to post stress recovery. For this reason, Hypothesis 5 could not be supported.

3.6 Discussion

A number of studies have investigated the association between PA and CV reactivity and recovery in healthy samples ^[9, 20, 24, 48, 174]. However, our study contributes to the existing literature by designing an experimental study to investigate the effects of a PA intervention on CV reactivity and recovery. This study had three key objectives: to investigate if the TGT exercise would increase PA independent of NA, to carry out a controlled study with an effective stress manipulation and to extend the research from cross-sectional studies suggesting that PA is associated with better CV reactivity and recovery in response to mental stress.

The present study found that the PA intervention did not increase PA levels over the one week time-frame. Interestingly, however the PA intervention was able to maintain PA levels compared to the control group where PA levels significantly decreased. The study also found that the tasks used were able to elicit a clear stress response as measured by SBP/DBP/HR/PS parameters. No changes were observed in DBP/HR reactivity and DBP/HR recovery between the two visits. Differences were observed however in SBP reactivity over the two visits, but were not dependent on the PA intervention. SBP recovery was slower for individuals in the PA intervention group following the one week interval. No changes were found in how individuals perceived the stressfulness of the tasks between the two visits.

There are several reasons that might explain the lack of effect of the PA intervention. Firstly, the relatively high levels of PA seen in participants. Based on the high levels of PA found across the four groups at baseline, the results might indicate a “ceiling effect” where the scores are so high on the scale that there is little room for improvement. The consequence of the lack of effect meant that we could not investigate the causal link between PA and CV reactivity and recovery. Nevertheless, the results from the current study did give us the ability to compare different levels of PA that represented high and low PA (3.04 v 3.64) respectively at visit two. It is worth pointing out however, when Steptoe et al ^[46] compared high and low PA using a median split, what might have been considered as low PA for our study was categorised as the high PA group in their study (Median high PA > 2.55).

The alternative explanation is that our study recruited healthy volunteers, however, the TGT intervention that was originally developed by Seligman et al ^[57] was completed by individuals who were already mild to moderately depressed at baseline. This supports the findings of Sin and Lyuburksy who found that PA interventions are more effective in increasing well-being in people who exhibit depressive symptoms ^[3].

Another possibility is that the intervention required more time. In previous research the TGT showed most effect after one month. However participants were only instructed to do the intervention for one week to show an effect which did show an increase in happiness after the one week ^[57].

Alternatively, it could be because we used a different instrument to measure PA. Seligman et al used the Steen Happiness Index (SHI) to measure happiness which is considered to be extremely sensitive to changes in happiness ^[57, 175], however, it can be argued that this is only because it measures happiness using a scale that ranges from extreme sadness to neutral to extreme happiness ^[14]. In comparison we used the PANAS, where the response format ranges from not at all to extremely, and does not include a neutral point therefore addressing the issue of bipolarity.

Despite PA scores not changing in the PA intervention group after the one week interval, they significantly decreased in the control group. It could be argued that during the intervening week, the control group experienced something stressful and that is what brought a decline in PA for the control group but not the intervention group. However, this is unlikely since participants were randomly allocated to groups, plus there were no differences in scores for perceived stress and NA using validated questionnaires at visit one or visit two.

The findings that the stress tasks were associated with increased SBP/DBP/HR/PS were expected. Although, laboratory mental stress tasks have been shown to elicit a stress response, previous studies have not always incorporated a control group to statistically ensure that the stress manipulation was effective ^[20, 28]. By including an appropriate control group, this study (i) demonstrated that the tasks used did indeed produce a clear stress response and (ii) enabled determination of any specific interactions with a

stressor, rather than non-specific changes in CV parameters, or change just due to habituation to the stressor.

It was anticipated that at visit two, participants who had higher PA would be more resilient to the stress tasks and as a result their reactivity would be lower. The present study found no interaction between stress task, PA intervention and visit for SBP/DBP/HR/PS reactivity such that the pattern of change between the four groups was generally the same after the one week interval. The only main effect of visit was for SBP reactivity, whereby there was a decrease in reactivity scores at visit two but this was not dependent on the PA intervention. It is possible that the lower reactivity score was because individuals knew what to expect. Although we did try to address this issue by giving the individuals different tasks/or an additional element to complete at visit two, the procedure did not differ.

One possibility is that the tasks used in the present study were inherently less stressful than those used in both previous studies. The average reactivity to the stress task for the present study was 17.24mmHg and 15.59mmHg at visit 1 and 20.95mmHg and 15.52mmHg at visit 2 for SBP and DBP respectively. Although this was significantly greater than the control group, in comparison to other studies it was relatively low. For instance, Steptoe et al reported reactivity of 30mmHg for SBP and 20.7mmHg DBP and Dowd et al reported 26.72mmHg for SBP and 25.75mmHg for DBP. However, we followed the protocols of the experimental tasks used in both studies. An alternative explanation is that the participants found that the tasks less stressful. Indeed, the stress-buffering model would predict that with higher levels of PA observed in our sample, we might expect to find less reactivity to the stressor across the sample. That we cannot detect a relationship between PA and reactivity might be due to 'floor effects' where all participants are relatively resilient to the stressor.

The present study found that PA was not associated with better recovery for DBP, HR or PS. Our finding does support other studies that have not found any association between PA and BP or HR recovery ^[24, 48]. However there was an interaction between the intervention and visit for SBP recovery such that individuals had slower recovery at visit two compared to visit one in the PA intervention group but not in the control

group. Participants in the PA intervention group recovered less quickly following the stressor than participants who did not have the intervention. This contradicts previous research that has shown individuals high in PA to recover more quickly from a stressful event. A possible explanation for the differences in recovery might be that high PA individuals were more engaged at visit two and saw the tasks as a challenge as opposed to a threat, they were still reacting even though they were in the recovery period. Some might argue that this might be an indication of rumination; however, with the high levels of PA seen in this study, Frederickson's broaden and build theory^[54] suggests that positive emotions such as joy and excitement have the ability to broaden a person's thinking and as a result this would build resources such as positive psychosocial factors like the ones described above as well as overcome challenges and develop new skills. Furthermore, if individuals were dwelling on the stress experience, then there could have been a difference in perceived stress recovery scores at the end of the study.

In contrast to the current study, previous studies have found a link between high PA and SBP recovery^[46, 47, 58] while some have not found any associations^[24, 176]. Papousek et al used the PANAS to investigate CV recovery^[176] and although reactivity scores were much lower, they used a different method to elicit a stress response which could explain the low reactivity scores in response to stress. The results of this study found that higher PA as measured by the PANAS was associated with better diastolic BP recovery but not systolic BP recovery^[176].

The results of this study did replicate some of the findings from Steptoe et al^[46] who investigated PA using both the PANAS and EMA. They found no links between PA (as measured by PANAS) and (i) diastolic blood pressure and (ii) heart rate. The results of this study do not support the stress-buffering model of PA. However it is likely that a ceiling effect occurred and future studies should investigate individuals with lower PA to optimise the efficacy of the intervention and establish its effect on CV reactivity and recovery.

3.6.1 Limitations

The sample population was relatively young (22 years, SD = 4.52) and age might have an impact on CV reactivity and recovery scores. For instance, Gasperin et al found that people aged over 46 were twice as likely to have greater increases in blood pressure in response to stress^[177]. In addition, all of the participants were under taking a university degree or had completed one, and over half the population were white/white British, therefore the results might not generalise to other groups.

Compliance with the written tasks was down to the individual and completed in their own time and therefore it was not possible to measure if individuals actually did complete the exercise. Individuals were asked if everything was ok in completing the written tasks and in response, none of the participants reported having any problems. However, this was based on self-report and therefore we can still not be certain. In an effort to avoid on the Hawthorne effect^[86], where people's behaviour changes in response to being monitored, objective measures of task completion were felt to be inappropriate. Future studies, however could measure compliance to the exercise by instructing individuals to complete it online.

BP and HR measurements were taken using a calibrated BP monitor; three measurements were taken to represent baseline levels, however only one measurement was taken during each task and then finally another three further readings were obtained to measure recovery. Although they do represent reactivity and recovery, previous studies have used a Finapres instrument to measure BP and HR; this instrument measure BP and HR continuously^[9, 24, 49] which is advantage as once it is attached to the individual, the researcher does not have to intervene during the experimental procedure.

3.7 Conclusion

This study was the first to use a PA intervention and investigate the effect on stress, CV reactivity and recovery. Furthermore, it is also one of few studies that have used a control group for the stressor. Although, the intervention prevented a decline in PA, it

did not alter CV stress responsivity. This might be because individuals who participated had relatively high levels of PA making it difficult to detect the impact on CV responsivity.

The present study recruited healthy volunteers; however, there is accumulating research towards investigating PA in populations that have chronic conditions. One reason for this is that dealing with the effects of any chronic condition can be stressful, and as proposed by Pressman and Cohen ^[2], PA might dampen the effects of stress which can lead to more favourable health measures.

This thesis intends to focus on diabetes. Diabetes is a stressful chronic condition and therefore as proposed by Pressman and Cohen, PA might dampen the effects that stress has on important diabetes related factors. At present, there is no evidence to confirm if there is a relationship between PA (as measured by the PANAS) and diabetes outcomes (as measured by HbA1c, self care practices and quality of life) independent of NA, and secondly there are at present no studies that have investigated a PA intervention among people with diabetes.

For the reasons stated above, the next two chapters will investigate the relationship between PA and diabetes related outcomes in people with diabetes. This will determine whether there is a link between PA and diabetes outcomes and also the efficacy of using an intervention designed to increase PA in people with diabetes.

Chapter Four: A cross-sectional study to investigate the relationship between positive affect and health outcomes in people with diabetes mellitus

4.1 Introduction

Diabetes Mellitus is a complex condition that requires life-long management. Three important diabetes related measures are HbA1c, self-care practices and quality of life. This is because these outcomes are fundamental in preventing or reducing the onset of complications ^[115, 157, 178].

Mood state can affect diabetes-related factors, however, the majority of published studies have focused on negative affective states, such as depression ^[6, 179, 180] and stress ^[127], which have long been accepted as predictors of increased illness susceptibility and mortality ^[26, 140]. Despite a growing evidence base for PA being an independent predictor of health-outcomes in other chronic conditions, there has been very little research to date to explore the relationships between PA and health-outcomes in people with diabetes.

Depression has been linked to poor glycaemic control as well as adherence to treatment regimes ^[6, 179, 180]. Gonzalez et al ^[93] conducted a meta analysis to examine the relationship between depression and treatment non adherence in individuals with type 1 and type 2 diabetes. Higher baseline levels of depressive symptoms were significantly linked to non-adherence to medication in people with type 2 diabetes. Non-adherence to self-care practices such as medication, blood glucose monitoring, diet and exercise can affect physiological parameters such as HbA1c ^[181], blood pressure and cholesterol levels ^[181]. Depression has also been shown to affect quality of life and studies have generally shown that people living with diabetes have a poorer quality of life compared to healthy individuals ^[139, 159, 182]. This is perhaps because diabetes can often be burdensome and potentially impact multiple outcomes, all of which can lead to increased complications ^[183].

Studies have also shown that protective factors such as well-being ^[182] and problem focused coping strategies ^[184] can assist the management of diabetes ^[185].

Huang et al ^[185] investigated the effect of both protective factors for diabetes as well as risk factors for diabetes such as age and diabetes symptoms on glycaemic control, quality of life and self care behaviours in people with type 2 diabetes. The study found that social and behavioural factors such as physical activity, coping strategies and social support were related to better diabetes-related outcomes but surprisingly found no relationship between risk factors of diabetes and diabetes-related measures. Although this study could not determine causality, it did suggest that protective factors can play a role in favourable diabetes health-outcomes. This study measured diabetes-related emotional distress as a risk factor of diabetes, but failed to measure positive affect as a protective factor as well as NA as a risk factor. This is a limitation as there is growing evidence that PA is an important predictor of health independent of NA ^[140].

Robertson et al's systematic review ^[140] on studies published between 1970 and 2011 in relation to PA and diabetes outcomes found that PA was linked to lower mortality, better exercise and lower perceived treatment burden. The studies that investigated HbA1c found no associations between PA and glycemic control. Despite there being a growing body of literature linking psychosocial factors to diabetes related factors ^[50, 134, 135, 186], more studies are needed to explore the relationship between PA and diabetes related factors (HbA1c, self-care practices and quality of life) independent of NA.

Tsenkova et al ^[132] investigated the relationships between PA, coping strategies and NA on glycaemia control and found that the relationship between coping and HbA1c was moderated by PA. The study recruited older women without diabetes and collected data at baseline and at 2 years. Glycaemic control is an important indicator for diabetes, however the findings from this study were based on people without diabetes. The Mood and Anxiety Symptom Questionnaire (MASQ) was used to measure PA independently from NA and coping was measured using the Coping Styles Inventory ^[164]. HbA1c was measured using a fasting blood glucose sample taken by a nurse and this was monitored by individuals staying overnight at a general clinical research centre. Multiple regression analysis showed that problem solving coping strategies predicted HbA1c

levels at 2 years and showed that the strongest effects were found with active coping and instrumental coping. Positive affect was also a predictor of HbA1c at two years and moderated the relationship between (i) active coping (ii) instrumental coping and (iii) suppressing competing activities. Women with high PA scores who reported lower problem focused coping scores had lower levels of HbA1c compared to people with low PA. Based on this evidence it would be beneficial to investigate the relationship between problem-focused coping and PA when investigating diabetes related outcomes.

This study aims to fill the gap in the existing literature by investigating the relationship between PA (as measured by PANAS) and (i) HbA1c, (ii) quality of life and (iii) self-care practices in people with diabetes independent of NA and other known risk factors.

Protective resources such as coping mechanisms and social support might be able to buffer the negative effects of diabetes. Positive psychological resources have been shown to promote better health. According to Fredrickson^[187] these resources are built over time in response to experiencing positive emotions which can broaden an individual in terms of behaviour, social integration and cognition. Therefore people who exhibit high PA should have built up resources that could potentially dampen the adverse negative effects on health. This study focuses firstly on coping strategies, in particular problem solving techniques such as active and instrumental coping strategies. As mentioned earlier, these techniques have already been associated with PA in relation to HbA1c in women without diabetes^[132]. In view of this, the aim is to extend the existing knowledge on the handful of studies investigating PA by investigating whether PA and coping strategies are linked to HbA1c and also other diabetes related factors such as self-care practices and quality of life in individuals with diabetes independent of NA and other known risk factors.

In conclusion, based on the literature above it is hypothesised that (i) PA will be related to lower HbA1c, better quality of life and better engagement in self-care practices, (ii) higher PA will moderate the effect that stress has on HbA1c, quality of life and self-care practices, and (iii) PA and coping strategies (active and instrumental) will be related to lower HbA1c, as well as better quality of life and better engagement to self-care practices.

4.2 Ethical Approval

The study proposal was submitted to the School of Pharmacy and Biomolecular Science Research Ethics Committee at the University of Brighton for review. Approval was granted on 8th September 2010 (see appendix B).

4.3 Methods

4.3.1 Study Design

This study was cross-sectional and was conducted in South East England. Data was collected using a self-report questionnaire and was designed to investigate the relationship between PA and (i) glycaemic control, (ii) quality of life and (iii) self-care practices in people living with diabetes. Participants either completed a paper format or an online version of the questionnaire (via SurveyMonkey).

Sample Size

Using a conservative estimate of detecting a small effect size ($d = .20$), a correlational model with a 2-sided 5% significance level and a power of 80%, a minimum sample size of 191 people was required (G Power 3.1). In total 147 respondents completed the self-report questionnaire.

4.3.2 Procedure

Participants were recruited using an advertisement which was distributed through email, the intranet and magazines. It was sent to Brighton University, Brighton and Sussex Medical School, Diabetes UK support groups in the South East region and Brighton and Hove City Council. Snowball sampling technique (whereby participants are encouraged to ask eligible associates to also complete the questionnaire) was used to maximise recruitment. Once recruited, participants were asked to complete the questionnaire either online via a “SurveyMonkey” link or alternatively participants had the option to complete a paper copy.

The questionnaire took approximately 15 to 20 minutes to complete². The first page contained information about the questionnaire and also informed participants about the content and the rationale. If participants were willing to complete the questionnaire, they were asked to press the “I accept” button (displayed at the end of screen/page). This allowed the participant to complete the questionnaire. Participants that completed the paper copy were asked to read the cover page which was exactly the same as the online version. Completing the questionnaire was an indication of consent. On completion, they were instructed to send it back to the research student using the free post envelope that was provided. If participants completed the questionnaire, with permission they were put into a prize draw to win an IPOD Touch. Recruitment period for this study was between 1st September 2010 and 31st January 2011.

4.3.3 Participants

People were considered eligible for inclusion in this study if they fulfilled all of the following criteria; (i) had a self-reported diagnosis of diabetes (i) were over 18 years of age and (iii) had the ability to read and write English fluently. All data were regarded as confidential. Participant’s age and a randomly assigned experimental number were used as identification and no individual data was reproduced.

4.3.4 Measures

Below is a summary of the measures (predictor, outcomes and covariates) that were included in the questionnaire.

Positive Affect

The PANAS was used to measure PA (see section 2.1.1)

Diabetes-Related Health Outcomes

The three primary outcomes for this study were HbA1c, self-care practices and Diabetes Quality of Life (DQOL). Participants were asked to self-report their HbA1c. To assess

² A copy of the questionnaire can be found in Appendix B (pg 194)

DQOL and self-care practices, participants were asked to complete the DQOL and SDSCA questionnaire (see section 2.2).

Demographic Factors

Participants were asked to report on their current housing situation by selecting one of the following options '*owned - with a mortgage to pay, owned – with no mortgage to pay, rented from council or rented from private landlord*'. They were also asked about their level of education and instructed to select one of the following options '*GCSEs / O-levels, A-levels, degree, postgraduate qualification, no qualification or other*'. Ethnic background (White (British, Irish, Other White background, All white groups) Black or British Black (Caribbean, African, Other Black background, All Black groups) Mixed (White and Black Caribbean, White and Black African, White and Asian, Other mixed background) Asian or British Asian (Indian, Pakistani, Bangladeshi, Other Asian background, All Asian groups) Chinese or Other Ethnic Group (Chinese, Other ethnic group, All Chinese groups) or All Ethnic Groups) and marital status (married/civil partnership, cohabitating, separated, divorced or single) were also categorised whereby participants were instructed to select the category that they felt best represented them. Participants were asked to report their age in years.

Psychosocial Factors

Participants were asked if they had ever been diagnosed with depression and if they were currently taking medication for depression. Perceived stress was measured using the PSS ^[148, 149] and coping strategies were measured using the COPE inventory ^[164]. These validated questionnaires have been used extensively in other research areas and were chosen for their demonstrated reliability and validity (see section 2.1.2 and 2.3.2). Individuals were asked to report on alcohol use and data was obtained using 2 items from the Alcohol Users Disorders Identification Test ^[188], individuals who reported that they drank alcohol were asked to report how often which was scored as follows; less than a month (1) 2 -4 times per month (2) 2 – 3 times per week (3) 4+ times per week (4). Then individuals were asked to report how many units which was scored as follows 1-2 (0) 3-4 (1) 5-6 (2) 7-8 (3) 9+ (4). These scores were added together to form a score that ranged from 1 to 8 with higher scores indicating greater units per week of alcohol

intake. Smoking status was assessed by asking participants how many cigarettes they had smoked in the last week ^[160].

Diabetes and Health Related Factors

Participants were also asked to report more specifically on certain diabetes-related factors such as type of diabetes (*type 1, type 2 or gestational*), duration of diabetes (*years: 0-2, 2-5, 5-10, 10-20, 20-30, 30+*), medication, diabetes related co-morbidities and other complications. Furthermore they were also asked if they had attended social support groups or/and an NHS educational programme related to their diabetes. Participants were asked to report their weight and height from which BMI was calculated (see section 2.4.2, Figure 2.2).

4.4 Data Analysis

The statistical software, PASW Statistics 18, was used for all analyses. Descriptive statistics, means, standard deviations, frequencies and percentages were calculated for all measures. Normality tests were performed using the Kolmogorov-Smirnov and Normal Q-Q plots. In addition, further analysis was carried out to ensure that there was no violation of the assumptions of multicollinearity. To determine the presence of multicollinearity two values were calculated, tolerance and variance inflation factor (VIF). Tolerance is an indicator of how much variability of the specified predictor is not explained by the other predictors. Values less than .10 were considered to be very low and an indication of multicollinearity. VIF is the inverse of tolerance and values greater than 10 indicated presence of multicollinearity. Non-parametric tests were used if variables did not show normality after transformation. All data for the diabetes quality of life subscales were transformed so that a positive quality of life was equivalent to a higher score ^[157]. For example, individuals who scored highly on the impact subscale reported that diabetes did not negatively impact their lives. For all outcomes a p-value < .05 was considered to be statistically significant. Effects size's were based on Eta squared where .01 is small, .06 is medium and .138 is considered large ^[189].

Relationships between all continuous variables were initially investigated with either Pearson's or Spearman's *Rho* correlations. To investigate differences between the

categorical variables on diabetes related outcomes, a series of t-tests, Man-Whitney tests and Chi squares were used.

Depending on the level of measurement and the parametric quality of the data, multiple linear or logistic regression analysis was used to investigate the relationship between PA and diabetes related outcomes (as measured by HbA1c, self-care practices and diabetes quality of life). Hierarchical multiple regression was used to predict HbA1c, DQOL satisfaction, DQOL impact, DQOL diabetes related worries and DQOL social worries whilst taking into account NA and other significant covariates as identified by the correlational analysis. All factors that significantly correlated with the outcome were entered in step one. To test if PA made a unique prediction, mean PA was then included in step two. When mean NA did not significantly correlate as a covariate with the outcome, it was added at step three.

For interaction analysis between PA and (i) coping strategies or (ii) perceived stress, two-way between-groups ANOVA's were used for all DQOL subscales and HbA1c. Direct logistic regression was used for self-care practices. The main effect predictors were added at step one and then the interaction terms were entered at step two.

4.5 Results

4.5.1 Sample Characteristics

In total 147 respondents completed the self-report questionnaire. One hundred and four respondents completed the questionnaire online and 43 respondents completed it using the paper format. Table 4.1 and Table 4.2 show the descriptive statistics for all variables. Self-care behaviours are also summarised in Table 4.3.

Table 4.1 Descriptive statistics for demographic, psychosocial and diabetes variables

Continuous Measures	N	Mean (\pmSD)	Minimum –Maximum
Age (years)	140	53.69 (15.23)	20 – 84
Body mass index (kg/m ²)	132	29.24 (7.47)	17.0 – 58.88
Mean Positive Affect	138	3.04 (0.77)	1– 4.50
Mean Negative Affect	137	1.96 (0.79)	1– 4.00
COPE: Active	145	1.45 (1.02)	0 – 4
COPE: Instrumental	145	1.97 (1.00)	0 – 4
Mean PSS score	146	1.68 (0.75)	0 – 3.30
Alcohol (units per week)	110	3.52 (1.90)	1 – 8
HbA1c	87	7.35 (1.34)	4.30 – 12
DQOL Satisfaction	147	63.85 (17.57)	23.33 – 100
DQOL Impact	145	66.67 (11.05)	36.11 – 100
DQOL Diabetes Related Worries	127	67.54 (24.95)	8.33 – 100
DQOL Social Worries	57	73.68 (24.58)	4.76 – 100
Number of complications	145	2.03 (1.80)	0 – 8

DQOL = Diabetes Quality of Life, PSS = Perceived Stress Scale

Table 4.2 Descriptive statistics for categorical demographics, diabetes related variables and depression status

	n (%)
Gender (n = 141)	
Male	71 (50.4)
Female	70 (49.6)
Marital status (n = 144)	
Married/civil partnership	85 (59.0)
Separated	8 (5.6)
Widowed	6 (4.2)
Single	21 (14.6)
Divorced	10 (6.9)
Cohabiting	14 (9.7)
Housing (n = 140)	
Owned with a mortgage to pay	55 (39.3)
Owned with no mortgage to pay	50 (35.7)
Rented from Council	12 (8.6)
Rented from Private Landlord	23 (16.4)
Ethnic Background (n = 147)	
White/White British	127 (86.4)
Other	20 (13.6)
Type of Diabetes (n = 144)	
Type 1	47 (32.6)
Type 2	97 (67.4)
Duration of diabetes (years) (n = 144)	
0 – 2	23 (16.0)
2 – 5	34 (23.6)
5 – 10	35 (24.3)
10 – 20	23 (16.0)
20 – 30	13 (9.0)
30 +	16 (11.1)
Clinical diagnosis of depression (n = 137)	
Yes	27 (19.7)
No	110 (80.3)

Table 4.3 Percentage of sample engaging in specific self-care behaviours

	n (%)
Self-care Practices (engaged \geq 5 days)	
Healthy Diet	75 (51.0)
Specific Diet	68 (46.3)
Exercise	40 (27.2)
Blood glucose testing	47 (32.0)
Feet checks	22 (15.0)
Treatment (n = 146)	
Diet and Exercise	18 (12.3)
Oral Medication	31 (21.2)
Diet, Exercise and Oral Medication	25 (17.1)
Insulin	47 (32.2)
Oral Medication and Insulin	21 (14.4)
Oral Medication, Insulin, Diet and Exercise	4 (2.7)
Taking other medication	
Antihypertensive (n = 146)	77 (52.7)
Statins (n = 144)	88 (61.1)
Anti platelet (n = 143)	42 (29.4)
Attendance	
Attend NHS educational course (n = 131)	48 (36.6)
Attend regular support groups (n = 131)	50 (38.2)

4.5.2 HbA1c

The mean HbA1c for the total sample was 7.35% (SD = 1.34; min – max = 4.3 – 12).

Correlations/associations with demographic factors

No associations were found between self-reported HbA1c and any of the demographic factors (age, log BMI, gender, marital status and ethnic background).

Correlations/associations with psychosocial factors

Alcohol was positively correlated with HbA1c ($\rho = .24$ $p = .056$) suggesting higher levels of alcohol consumption was related to higher levels of HbA1c. However no other association were found between HbA1c and (i) PA (ii) NA (iii) perceived stress and (iv) coping strategies (see Table 4.4).

Correlations/associations with diabetes-related factors

As expected participants with type 1 diabetes had higher levels of HbA1c than people with type 2 diabetes ($U = 607$, $z = -2.63$, $p = <.01$ $r = .28$ $n = 87$) (type 1 diabetes median = 7.5, IQR = 6.8-8.2; type 2 diabetes median = 6.9, IQR = 6.4-7.48), however for all other diabetes-related factors (support groups, education programme, diabetes medication and number of complications) no significant differences were found in levels of HbA1c.

Table 4.4 Correlation matrix of demographic, psychosocial and diabetes related factors on diabetes related outcomes³

Diabetes Outcomes		Demographics		Psychosocial Factors					Diabetes Related Factors
		Age	Body Mass Index	Positive Affect	Negative Affect	Perceived Stress	Active Coping	Instrumental Coping	Number of Complications
HbA1c	<i>r/rho</i>	-.08	-.13	-.10	-.13	-.03	-.01	-.20	-.04
	<i>n</i>	85	83	84	84	87	87	87	86
DQOL Satisfaction	<i>r/rho</i>	.38**	-.29**	.37**	-.56**	-.53**	.07	.19*	-.10
	<i>n</i>	140	132	138	137	146	145	145	145
DQOL Impact	<i>r/rho</i>	.38**	-.01	.10	-.46**	-.34**	-.10	-.12	-.19*
	<i>n</i>	139	131	136	135	145	144	144	143
DQOL Diabetes Related Worries	<i>r/rho</i>	.41**	-.11	.18*	-.46**	-.42**	-.04	-.01	-.19*
	<i>n</i>	121	115	119	118	127	127	127	125
DQOL Social Worries	<i>r/rho</i>	.61**	.19	.16	-.63**	-.62**	.001	-.08	-.11
	<i>n</i>	54	50	55	54	57	57	57	56

Note *r/rho* = Figures here represent either the *r* or *rho* statistic as some of the data was not normally distributed. ** $p < .001$ * $p < .05$. *n* = number of participants

³ A more detailed version of results is provided in Appendix B (pg 193)

4.5.3 Diabetes Quality of Life

Correlations/associations with demographic factors

Bivariate analysis (Table 4.4) indicated that all subscales of the DQOL (satisfaction, impact social worries and diabetes-related worries) negatively correlated with age suggesting that older individuals reported higher quality of life. Individuals who were married/cohabitating scored higher on the DQOL satisfaction and DQOL social worries subscales than people who were not married/cohabitating, suggesting that people who were married/cohabitating were more satisfied with their diabetes treatment ($t(142) = 2.40, p = .018, r = .039$) (married/cohabitating mean = 66.09, SD = 17.50; not married/cohabitating mean = 58.63, SD = 16.89) and reported that the social worries associated with their diabetes did not affect their lives adversely ($U = 158.5, z = -3.79, p < .001, r = .51$) (married/cohabitating median = 85.71, IQR = 66.67-100.00; not married/cohabitating median = 66.67, IQR = 33.33-80.95).

DQOL satisfaction negatively correlated with log BMI (see Table 4.4) and were more likely to report that they were not smokers ($t(126) = -2.22, p = .029, r = .038$) (smoker mean = 52.56, SD = 15.15; not smoker mean = 65.26, SD = 17.56). This indicates that people who smoked and had higher BMI reported that they were less satisfied with their diabetes treatment.

Correlations/associations with psychosocial factors

DQOL satisfaction negatively correlated with instrumental coping and PA (see Table 4.4) indicating that people who reported higher PA and who engaged in instrumental coping strategies were more likely to report that they were satisfied with their diabetes.

Bivariate analysis (Table 4.4) indicated that all subscales of the DQOL (satisfaction, impact social worries and diabetes related worries) negatively correlated with perceived stress and NA suggesting that individuals who reported less stress and had lower NA reported a better DQOL.

Significant differences were found in the following DQOL subscales (satisfaction, impact and social worries) in depression status. Unsurprisingly, people who reported that they had a clinical diagnosis of depression (DQOL satisfaction: $t(135) = -2.27, p =$

.025, $r = .037$) (DQOL impact: $U = 1036.5$, $z = -2.32$, $p = .02$, $r = .20$) (DQOL social worries: $U = 77.00$, $z = -3.15$, $p = .002$, $r = .43$) reported a lower quality of life for all three DQOL subscales (i) satisfaction (depression mean = 57.27 SD = 17.94; no depression mean = 65.80, SD = 17.41), (ii) impact (depression median = 65.00 IQR = 55-70; no depression median = 69.59, IQR = 61.39-73.75) and (iii) social worries (depression median = 55.95, IQR = 0-66.67; no depression median = 80.95, IQR = 67.86-95.24).

Individuals who attended support groups scored higher on the DQOL satisfaction, DQOL impact and DQOL diabetes related worries subscales than people who did not attend, suggesting that people who attended support groups were more satisfied with treatment ($t(129) = -3.57$, $p < .001$, $r = .09$) (support group mean = 71.15 SD = 16.56; no support group mean = 60.27, SD = 17.16), reported that their diabetes did not impact their lives adversely ($U = 1311.5$, $z = -3.15$, $p = .002$, $r = .28$) (support group median = 72.50, IQR = 65.13-75.00; no support group median = 66.25, IQR = 56.88-72.47) and had fewer diabetes related worries ($U = 1016.5$, $z = -2.40$, $p = .016$, $r = .23$) (support group median = 83.33, IQR = 66.67-89.58; no support group median = 66.67, IQR = 43.75-83.33).

Correlations/associations with diabetes-related factors

As expected, individuals who had type 1 diabetes reported a lower quality of life on all three subscales (DQOL satisfaction: $t(113) = -2.07$, $p = .041$, $r = .044$) (DQOL impact: $U = 1633.5$, $z = -2.51$, $p = .012$, $r = .21$) (DQOL diabetes related worries: $U = 1250.5$, $z = -2.67$, $p = .008$, $r = .24$): (i) satisfaction (type 1 diabetes mean = 60.30 SD = 14.55; type 2 diabetes mean = 66.16, SD = 18.43), (ii) impact (type 1 diabetes median = 65.63 IQR = 58.13-71.56; type 2 diabetes median = 70.00, IQR = 62.32-75.00) and (iii) diabetes related worries (type 1 diabetes median = 58.33, IQR = 42.36-81.94; type 2 diabetes median = 77.78, IQR = 56.25-91.67).

4.5.4 Self-care Behaviours

Individuals who followed a healthy diet for more than 5 days reported engaging in more instrumental coping strategies ($U = 1988.5$, $z = -2.57$, $p = .01$, $r = .21$) (≥ 5 days median = 2.00, IQR = 1.5-3.0; ≤ 5 days median = 2.00, IQR = 1.0-2.13) and also had higher levels of PA ($t = (136) = -2.73$, $p = .007$, $r = .052$) (≥ 5 days mean = 3.21 SD = .69; ≤ 5 days mean = 2.86, SD = .82).

Individuals who avoided high fat foods for more than 5 days reported engaging in both more instrumental ($U = 2056.5$, $z = -2.26$, $p = .002$, $r = .26$) (≥ 5 days median = 2.00, IQR = 1.63-3.0; ≤ 5 days median = 2.00, IQR = 1.0-2.25) and active coping strategies ($U = 1839$, $z = -3.15$, $p = .024$, $r = .19$) (≥ 5 days median = 1.75, IQR = 1-2.5; ≤ 5 days median = 1.00, IQR = .5-2.0).

Not surprisingly, individuals who reported exercising for more than 5 days had lower log BMI ($U = 1313.5$, $z = -2.12$, $p = .034$, $r = .18$) (≥ 5 days median = 1.42, $n = 36$; ≤ 5 days median = 1.45, $n = 96$) and reported engaging in active coping strategies ($U = 1312.5$, $z = -3.42$, $p = .001$, $r = .28$) ($U = 1839$, $z = -3.15$, $p = .024$, $r = .19$) (≥ 5 days median = 2.00, $n = 39$; ≤ 5 days median = 1.00, $n = 106$).

Individuals who reported monitoring their blood glucose levels for more than 5 days were younger ($t = (138) = 2.50$, $p = .014$, $r = .043$) (≥ 5 days mean = 49.17, SD = 15.22; ≤ 5 days mean = 55.89, SD = 14.82), more likely to be married ($\chi^2 (1, n = 144) = 7.03$), had lower log BMI ($t = (143) = 2.17$, $p = .032$, $r = .035$) (≥ 5 days mean = 1.43 SD = .09; ≤ 5 days mean = 1.47, SD = .11), had type 1 diabetes ($\chi^2 (1, n = 144) = 39.49$), reported taking antidiabetic medication ($\chi^2 (1, n = 145) = 10.39$) and reported engaging in instrumental coping strategies ($U = 1793.5$, $z = -2.20$, $p = .028$, $r = .18$) (≥ 5 days median = 2.00, $n = 47$; ≤ 5 days median = 2.00, $n = 98$).

No other significant demographic, psychosocial or diabetes related factors were found with self-care practices.

4.5.5 Associations between Diabetes Related Outcomes

A Chi-square test for independence (with Yates Continuity Correction) indicated an association between following a healthy diet and avoidance of high fat foods ($\chi^2 (1, n = 147) = 24.01, p < .001$). There was an association between individuals who reported exercising more regularly and who reported following a healthy diet ($\chi^2 (1) = 6.91, p = .009$) and who avoided high fat foods ($\chi^2 (1) = 8.84, p = .003$). There was also an association between individuals who reported exercising and monitoring their glucose levels for more than five days ($\chi^2 (1) = 9.39$). Furthermore, in relation to HbA1c, as expected individuals who reported following a healthy diet ($U = 625.5, z = -2.69, p = .007$) (≥ 5 days median = 6.80, $n = 47$; ≤ 5 days median = 7.40, $n = 40$) or avoiding high fat foods ($U = 617.5, z = -2.77, p = .006$) (≥ 5 days median = 6.80, $n = 41$; ≤ 5 days median = 7.40, $n = 46$) for more than five days had lower HbA1c.

Individuals who monitored their glucose levels had higher diabetes related worries ($U = 1253, z = -2.82, p = .005$) (≥ 5 days median = 66.67, $n = 43$; ≤ 5 days median = 77.78, $n = 84$) and had lower DQOL impact scores ($U = 1744, z = -2.27, p = .023$) (≥ 5 days median = 65.00, $n = 46$; ≤ 5 days median = 70.00, $n = 99$).

It is not surprising that individuals who scored highly on the DQOL satisfaction subscale scale also reported that their diabetes did not impact their lives negatively ($\rho = .54, n = 145, p < .001$) had fewer social worries ($\rho = .45, n = 57, p < .001$) and diabetes related worries ($\rho = .60, n = 127, p < .001$). Furthermore a positive correlation between DQOL impact and (i) DQOL social worries ($\rho = .54, n = 57, p < .001$) and (ii) diabetes related worries ($\rho = .66, n = 126, p < .001$) suggests that individuals who reported that their diabetes did not impact their lives negatively also reported fewer social and diabetes related worries.

In summary, PA was associated with DQOL satisfaction, DQOL diabetes related worries and diet. This provides support for parts of Hypothesis 1, given that people who reported higher PA had better DQOL satisfaction, fewer diabetes related worries and were more likely to report following a healthy diet. No support was found for Hypothesis 2, PA was not found to be associated with HbA1c, diabetes impact, avoiding high fat foods, monitoring glucose levels, engaging in regular exercise and

checking feet. These outcomes do not support Hypothesis 1, given that no associations were found between people who reported higher PA and lower HbA1c, better diabetes impact and most self-care practices.

The next part of this results section focuses on the diabetes health-outcomes (HbA1c, DQOL satisfaction, DQOL diabetes related worries and following a healthy diet) that were related to PA. The objective is to see whether PA can independently predict the health-outcomes independent of NA as well as other factors that significantly correlate with the outcome.

4.5.6 Positive Affect and Diabetes Related Outcomes

PA and HbA1c

Although there was no significant correlation between HbA1c and PA, both factors showed significant associations with following a healthy diet for more than 5 days. For this reason, a two-way between-groups analysis of variance was conducted to investigate any interaction effects between PA and following a healthy diet on HbA1c. The main effect for healthy diet ($F(1, 82) = 7.02, p = .010$) was significant however the main effect for PA ($F(1, 82) = .64, p = .426$) was not. The interaction effect between following a healthy diet and PA on HbA1c was significant ($F(1, 82) = 4.65, p = .034$) suggesting that the relationship between PA and HbA1c was different for people who reported following a healthy diet and those who did not. It should be noted Levene's test did show heterogeneity of variances and therefore the result should be treated with caution.

Figure 4.1 shows no direct association between PA and HbA1c ($r = -.10, p = .344$). For individuals who reported not following a healthy diet for more than five days, higher PA levels were associated with lower levels of HbA1c (reaching near significance) ($r = -.27, p = .092$). No such association was found for individuals who reported following a healthy diet ($r = .20, p = .181$). This suggests that in the absence of healthy eating PA might have a positive impact on HbA1c.

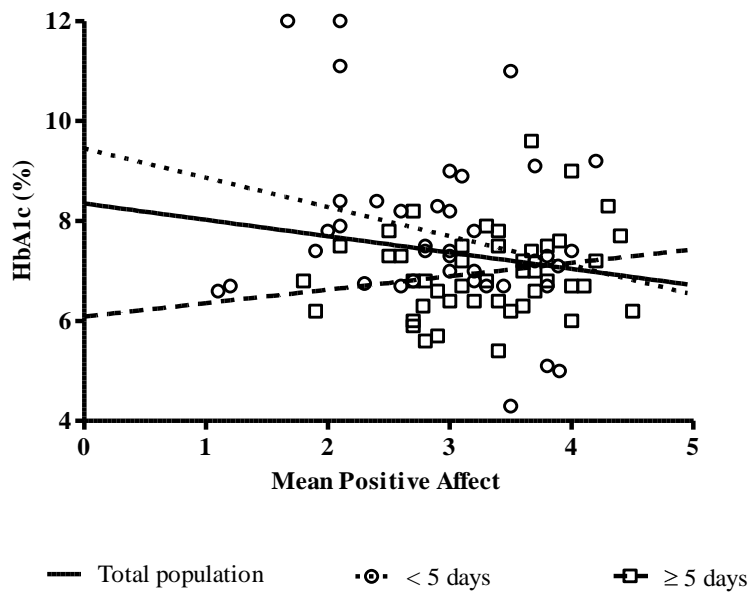


Figure 4.1 Interaction plot between Positive Affect (PA), HbA1c and following a healthy diet

PA and DQOL Satisfaction

Hierarchical multiple regression was used to assess the ability of PA to predict DQOL satisfaction after taking into account the variance explained by the other factors (see Table 4.5). DQOL diabetes social worries was initially included in this model, however was removed due to small sample size ($n = 57$) and the presence of multicollinearity (Model 1: tolerance value = .02 and VIF = 39.72). The covariates that correlated significantly with DQOL satisfaction were entered at step 1, explaining 58.2% of the variance in DQOL satisfaction, ($F(12, 96) = 11.12, p < .001$). After entry of PA at step 2, the total variance explained by the model as a whole was 59.7%, ($F(13, 95) = 10.82, p < .001$). PA explained an additional 1.5% of the variance in DQOL satisfaction after controlling for type of diabetes, age, log BMI, marital status, NA, perceived stress, depression and smoking status, instrumental coping, attending support groups, DQOL diabetes worries and DQOL impact (R^2 change = .015, F change (1, 95) = 3.61, $p = .060$).

Table 4.5 Hierarchical multiple regression analysis for factors predicting DQOL satisfaction

Variable	Step 1			Step 2		
	<i>B</i>	<i>SE B</i>	β	<i>B</i>	<i>SE B</i>	β
Log body mass index	-31.31	12.61	-0.18*	-30.64	12.45	-0.18*
Age	0.02	0.11	0.02	0.03	0.11	0.02
Marital status	-0.73	2.64	-0.02	0.06	2.64	0.00
Mean perceived stress	-4.11	2.34	-0.18	-2.55	2.45	-0.11
Mean negative affect	-4.49	2.25	-0.20*	-4.78	2.23	-0.21*
Depression status	-0.72	3.32	-0.02	-0.45	3.28	-0.01
Mean instrumental coping	3.32	1.24	0.19**	2.84	1.25	0.16*
DQOL – impact	0.32	0.16	0.20*	0.35	0.16	0.22*
DQOL - diabetes worries	0.15	0.07	0.21*	0.13	0.07	0.18*
Attend support groups	1.95	3.00	0.05	1.82	2.96	0.05
Type of diabetes	5.24	3.06	0.14	5.17	3.02	0.14
Smoking status	2.55	4.52	0.04	3.14	4.47	0.05
Mean positive affect				3.27	1.72	0.14
R squared			.58**¹			0.60²

Note. * $p < .05$. ** $p < .01$.

¹ This *R* squared value relates to Step 1 and includes covariates only. ² This *R* squared value relates to Step 2 and includes covariates and PA.

PA and DQOL Diabetes Related Worries

Hierarchical multiple regression was used to assess the ability of PA to predict DQOL diabetes worries after taking into account the variance explained by the other factors (see Table 4.6). Although the DQOL social worries subscale was initially included in this model, it was removed due to small sample size ($n = 57$). The covariates that correlated significantly with DQOL diabetes worries were entered at step 1, explaining 57.8% of the variance in DQOL diabetes worries, ($F(9, 102) = 15.55, p < .001$). After entry of PA at step 2, the total variance explained by the model as a whole was 58.1%, ($F(10, 101) = 14.01, p < .001$). PA explained an additional .3% of the variance in DQOL diabetes worries after controlling DQOL satisfaction, DQOL impact, glucose

monitoring, type of diabetes, total complications, attend support groups, age (years), negative affect, and perceived stress (R squared change = .003, F change (1, 101) = 651, $p = .422$). Therefore PA did not significantly predict DQOL diabetes worries once the other factors had been accounted for.

Table 4.6 Hierarchical multiple regression analysis for factors predicting DQOL diabetes related worries

Variable	Step 1			Step 2		
	<i>B</i>	<i>SE B</i>	β	<i>B</i>	<i>SE B</i>	β
Age	0.28	0.16	0.17	0.29	0.16	0.18
Mean perceived stress	-2.61	3.21	-0.08	-1.72	3.40	-0.05
Mean negative affect	0.32	3.12	0.01	-0.01	3.15	0.00
Complications	-1.58	1.05	-0.11	-1.56	1.05	-0.11
DQOL – impact	1.03	0.19	0.46**	1.05	0.20	0.47**
DQOL - satisfaction	0.30	0.13	0.21*	0.28	0.13	0.19*
Attend support groups	-0.45	4.13	-0.01	-0.59	4.14	-0.01
Type of diabetes	-2.88	4.59	-0.05	-3.02	4.60	-0.06
Glucose Monitoring	-7.55	4.26	-0.14	-7.89	4.29	-0.15
Mean positive affect				1.94	2.40	0.06
R squared		.58**¹			0.58*²	

Note. * $p < .05$. ** $p < .01$.

¹ This R squared value relates to Step 1 and includes covariates only. ² This R squared value relates to Step 2 and includes covariates and PA.

PA and General Diet

As shown in Table 4.7, the logistic regression model at step two contained four predictor variables. The full model at step two was statistically significant ($\chi^2(4, n = 136) = 34.67, p < .05$) indicating that it was able to distinguish between individuals who reported following more than 5 days of healthy eating than those who did not. The model at step two as a whole explained 30.0% (Nagelkerke R squared) of the variance in following a healthy diet and correctly classified 75% of cases. Both PA and following a specific diet made significant contributions at step two. The strongest predictor of following a healthy diet was specific diet (avoiding high fat foods) with an odds ratio of 5.24. This suggests that people who avoided high fat foods were 5.24 times more likely to follow a healthy diet. Respondents who reported higher levels of PA were almost twice as likely to follow a healthy diet for more than five days after controlling for all other factors in the model (odds ratio 1.74).

When NA was included at step three, although the model remained statistically significant as a whole ($\chi^2(5, n = 136) = 37.32, p < .05$), PA did not make a unique contribution in following a healthy diet ($p = .089$).

Table 4.7 Logistic regression predicting the likelihood of following a healthy diet for more than five days

Variable	Step 1				Step 2				Step 3			
	<i>B</i>	<i>WALD</i>	<i>OR</i>	<i>CI</i>	<i>B</i>	<i>WALD</i>	<i>OR</i>	<i>CI</i>	<i>B</i>	<i>WALD</i>	<i>OR</i>	<i>CI</i>
Mean instrumental coping	0.30	2.30	1.35	.92-1.99	0.21	1.04	1.23	.82-1.85	0.25	1.39	1.28	.85-1.94
Specific diet	1.61	16.41**	4.98	2.29-10.83	1.66	16.47**	5.24	2.36-11.66	1.73	17.01**	5.62	2.48-12.67
Exercise	0.58	1.61	1.79	.73-4.38	0.57	1.45	1.76	.7-4.43	0.63	1.79	1.88	.74-4.78
Mean positive affect					0.56	4.32*	1.74	1.03-2.94	0.47	2.89	1.60	.93-2.74
Mean negative affect									-0.43	2.58	0.65	.38-1.10

Note. * $p < .05$. ** $p < .01$. OR. Odds Ratio. CI. Confidence Interval
 Step 1. Covariates only; Step 2. Covariates and PA; Step 3. Covariates, PA and NA.

4.5.7 Positive Affect and Coping Interactions on Diabetes Related Outcomes

A series of two-way between-groups ANCOVAs were conducted to assess the relationship between coping strategies (active and instrumental) and PA on (i) HbA1c and (ii) DQOL. To test this interaction on self-care practices, logistic regression was used. Using a median split, two groups were calculated for PA (high vs. low). Levene's test of equality of error variances was conducted for each outcome. If in the instances the variance of outcomes was not equal, caution was taken when evaluating the results.

HbA1c

The main effect for both PA ($F(1, 82) = .139, p = .241$) and active coping ($F(1, 82) = .06, p = .815$) on HbA1c did not reach statistical significance. The interaction effect between active coping and PA on HbA1c was not statistically significant ($F(1, 82) = .36, p = .550$).

The main effect for both PA ($F(1, 82) = .02, p = .899$) and instrumental coping ($F(1, 82) = .62, p = .435$) on HbA1c did not reach statistical significance. The interaction effect between instrumental coping and PA on HbA1c was not statistically significant ($F(1, 82) = .37, p = .546$).

DQOL Satisfaction

There was a statistically significant main effect of PA on DQOL satisfaction ($F(1, 135) = 21.20, p < .001$), furthermore the effect size was large (partial eta squared .137). The main effect of active coping ($F(1, 135) = .00, p = .983$) did not reach statistical significance. The interaction effect between instrumental coping and PA on DQOL satisfaction was not statistically significant ($F(1, 135) = .02, p = .876$).

There was a statistically significant main effect for PA on DQOL satisfaction ($F(1, 135) = 21.67, p < .001$), furthermore the effect size was large (partial eta squared .140). The main effect for instrumental coping ($F(1, 135) = 1.34, p = .248$) did not reach

statistical significance. The interaction effect between instrumental coping and PA on DQOL satisfaction was not statistically significant ($F(1, 135) = .2.17 p = .143$).

DQOL Impact

The main effect for both PA ($F(1, 134) = 2.31 p = .131$) and active coping ($F(1, 134) = .51 p = .475$) on DQOL impact did not reach statistical significance. The interaction effect between active coping and PA on DQOL impact was not statistically significant ($F(1, 134) = .08 p = .776$).

The main effect for both PA ($F(1, 134) = 2.40 p = .123$) and instrumental coping ($F(1, 134) = .1.15 p = .286$) on DQOL impact did not reach statistical significance. The interaction effect between instrumental coping and PA on DQOL impact was not statistically significant ($F(1, 134) = .71 p = .401$).

DQOL Diabetes Related Worries

The main effect for both PA ($F(1,117) = .11 p = .738$) and active coping ($F(1,117) = 1.22 p = .272$) on DQOL diabetes related worries did not reach statistical significance. The interaction effect between active coping and PA on DQOL diabetes related worries was not statistically significant ($F(1, 117) = 2.44 p = .121$).

The main effect for both PA ($F(1,117) = .18 p = .672$) and instrumental coping ($F(1, 117) = .70 p = .404$) on DQOL diabetes related worries did not reach statistical significance. The interaction effect between instrumental coping and PA on DQOL diabetes related was not statistically significant ($F(1, 117) = .85 p = .36$).

DQOL Social Worries

The main effect for both PA ($F(1, 59) = 1.98 p = .165$) and active coping ($F(1, 59) = .02 p = .894$) on DQOL social worries did not reach statistical significance. The

interaction effect between active coping and PA on DQOL social worries was not statistically significant ($F(1, 59) = .12$ $p = .728$).

The main effect for both PA ($F(1, 59) = 1.47$ $p = .23$) and instrumental coping ($F(1, 59) = .01$ $p = .940$) on DQOL social worries did not reach statistical significance. The interaction effect between instrumental coping and PA on DQOL social worries was not statistically significant ($F(1, 59) = .11$ $p = .747$).

Self-care Practices

At step one the main effect predictors were entered in the model ((i) mean PA and median active coping or (ii) mean PA and median instrumental coping). At step two the interaction effect was added. The overall model at step two for specific diet, exercise, blood glucose monitoring and foot checks did not reach statistical significance. Therefore the model was not able to distinguish between individuals who did or did not report to following more than 5 days of a certain self-care practice.

Only healthy diet was able to distinguish whether individuals did or did not report following more than 5 days of healthy eating. However the interaction effect at step two between (i) mean PA and median active coping and (ii) mean PA and median instrumental coping did not reach significance.

In summary, no interactions were found between PA (high and low) and (i) active or (ii) instrumental coping on (i) HbA1c, (ii) DQOL satisfaction (iii) DQOL diabetes related worries, (iv) diabetes social worries and (v) following self-care practices respectively. Although there was a relationship between instrumental coping and DQOL satisfaction, PA did not influence this relationship. For these reasons, Hypothesis 2, could not be supported.

4.5.8 Positive Affect and Perceived Stress on Diabetes Related Outcomes

A series of two-way between-groups ANCOVAs were conducted to explore the impact of perceived stress and PA on (i) HbA1c and (ii) DQOL. To test this interaction on self-care practices logistic regression was used. Using a median split, two groups were calculated for PA (high vs. low). Levene's test of equality of error variances was conducted for each outcome. If in the instances the variance of outcomes was not equal, caution was taken when evaluating the results.

HbA1c

The main effect for both PA ($F(1, 82) = .22$ $p = .641$) and perceived stress ($F(1, 82) = .55$ $p = .461$) on HbA1c did not reach statistical significance. The interaction effect between perceived stress and PA on HbA1c was not statistically significant ($F(1, 82) = .003$ $p = .958$).

DQOL Satisfaction

There was a statistically significant main effect for perceived stress on DQOL satisfaction ($F(1, 135) = 37.21$ $p < .001$), furthermore the effect size was large (partial eta squared .219). The main effect for PA ($F(1, 135) = .08$ $p = .776$) did not reach statistical significance. The interaction effect between perceived stress and PA on DQOL satisfaction was not statistically significant ($F(1, 135) = 1.92$ $p = .168$).

DQOL Impact

There was a statistically significant main effect for perceived stress on DQOL impact ($F(1, 134) = 24.07$ $p < .001$), furthermore the effect size was large (partial eta squared .154). The main effect for PA ($F(1, 134) = 2.93$ $p = .09$), however did not reach statistical significance. The interaction effect between perceived stress and PA on DQOL impact was statistically significant ($F(1, 134) = 4.65$ $p = .033$), however this finding must be taken with caution as homogeneity of variances were unequal.

Figure 4.2 shows a negative relationship between perceived stress and DQOL impact ($\rho = -.343, p < .001$). Furthermore, whilst looking at the sample as a whole, PA acted as a moderator. For individuals who had low PA, higher stress was strongly associated with lower quality of life ($\rho = -.436, p < .001$). However, for individuals high in PA, the association was weaker between DQOL impact and perceived stress ($\rho = -.285, p < .05$). This suggests that levels of stress did not impact DQOL as negatively for people with high PA. This result offers some support for the stress buffering theory whereby levels of stress had a decreased impact on QOL for individuals with high PA compared to individuals with low PA.

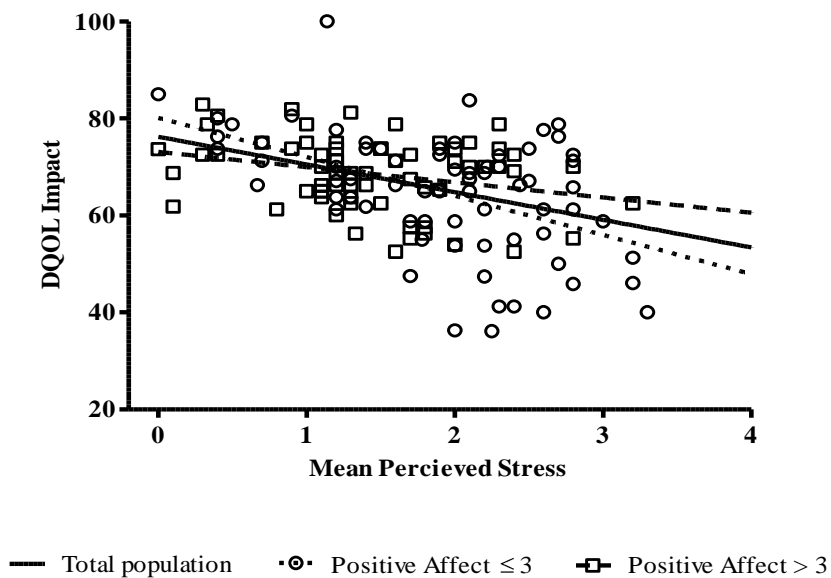


Figure 4.2 Interaction plot of perceived stress and Positive Affect on DQOL impact
PA scores represent median PA, DQOL = Diabetes Quality of Life

DQOL Diabetes Related Worries

There was a statistically significant main effect for perceived stress on DQOL social worries ($F(1, 117) = 23.16, p < .001$), furthermore the effect size was large (partial eta squared .168). However the main effect for PA ($F(1, 117) = .05, p = .817$) did not reach statistical significance. The interaction effect between perceived stress and PA on DQOL social worries was not statistically significant ($F(1, 117) = .57, p = .453$).

DQOL Social Worries

There was a statistically significant main effect for perceived stress on DQOL social worries ($F(1, 59) = 27.87, p < .001$), furthermore the effect size was large (partial eta squared .328). However the main effect for PA ($F(1, 59) = .37, p = .546$) did not reach statistical significance. The interaction effect between perceived stress and PA on DQOL social worries was not statistically significant ($F(1, 59) = .14, p = .708$).

Self-care Practices

At step one the main effect predictors were entered in the model (median PA and mean perceived stress). At step two the interaction effect between median PA and mean perceived stress was entered. The overall models at step two for all self-care practices failed to reach statistical significance. Therefore the model was not able to distinguish between individuals who did or did not report to following more than 5 days of a certain self-care practice.

In summary, no associations were found between perceived stress and (i) HbA1c and (ii) following self-care practices, regardless of whether or not participants had high or low PA. Hypothesis 3 therefore could not be supported.

Conversely, there were associations between perceived stress and all of the DQOL subscales, indicating that higher perceived stress was associated with lower quality of life (see Table 4.3). These associations remained the same for DQOL satisfaction,

diabetes related worries and diabetes social worries, regardless of whether or not individuals had high or low PA. Hypothesis 3 therefore could not be supported.

The association between perceived stress and diabetes impact was dependent on whether or not participants had high or low PA. Therefore this is the only finding that supports Hypothesis 3, given that the relationship between perceived stress and diabetes impact differed depending on levels of PA (see Figure 4.2).

4.6 Discussion

This study had three key objectives: to investigate the relationship between PA and diabetes factors (HbA1c, DQOL satisfaction, impact, diabetes related worries and social worries and self-care practices); to investigate the relationship between PA and perceived stress on those factors; and to investigate the relationship between PA and coping strategies in people with diabetes.

The present study found significant relationships between PA and (i) following a healthy diet, (ii) DQOL satisfaction and (iii) DQOL diabetes related worries therefore supporting parts of Hypothesis 1. Individuals higher in PA were more likely to follow a healthy diet, have better DQOL satisfaction and fewer diabetes related worries. Although, these relationships described were significant, the main objective was to assess whether PA predicted these outcome measures independent of other important factors (demographic, psychosocial and diabetes and health related) that also correlated with the outcome at baseline and for this reason hierarchical and logistic regressions were conducted.

The study found that individuals higher in PA were twice as likely to follow a healthy diet independent of instrumental coping, exercise and avoiding high fat foods, although this relationship was not independent of NA. Following a healthy diet was the only self-care practice that was related to PA, however in previous studies PA has been associated with exercise independent of NA but in individuals without a chronic

condition ^[53, 190]. The management of diabetes involves an array of self-care behaviours; therefore this taken together with the results of this study might suggest that PA is linked with a greater tendency to engage in certain health behaviours like healthy eating.

HbA1c did not correlate with any of the measured demographic or psychosocial factors. This was unanticipated as factors such as stress and depression have previously been associated with poor glycaemic control ^[6]. There is considerable literature suggesting that stress is linked to worsening HbA1c ^[127, 133]. Studies have shown that stress can have a physiological impact on glycaemic control ^[130], such that continuous increases in cortisol can lead to poor management of glucose levels which over time can lead to worsening HbA1c and consequently the onset of complications. Depression has also been widely published in relation to diabetes (see section 1.3) ^[179], individuals are less likely to adhere to medication, follow self-care practices and more likely develop complications ^[92, 93, 114]. The fact that we found very little in relation to HbA1c might be due to the findings being based on self-report readings rather than obtaining blood samples. Another possible explanation is that the individuals who chose to complete the questionnaire might have been interested in their diabetes and therefore might have been more likely to follow self-care behaviours and consequently have better HbA1c.

The relationship between PA and HbA1c was found to be moderated by healthy diet. PA levels were not correlated with HbA1c in people who did follow a healthy diet, as it was expected that they would already have relatively good glycaemic control as good self-care practices such as following a healthy diet have been shown to improve glucose control in prior research ^[191]. This was supported by the findings of the present study such that people who followed a healthy diet or/regularly avoided high fat foods for more than 5 days per week had lower HbA1c. However, the association between PA and HbA1c was statistically significant in individuals who did not follow a healthy diet. Therefore although PA might have buffered the effects of not following a healthy diet on HbA1c, individuals who exhibit lower PA that do not engage in healthy eating might

be at risk. The study highlights that if we can test an intervention designed to increase PA, it might help people with diabetes that do not follow a healthy diet.

Delamater reported that people with diabetes might adhere more to one self-care practice compared to another^[80]. Fifty one percent of our study population adhered to a healthy diet. This means that about half of our study population did not follow a healthy diet and had significantly higher HbA1c. The NICE guidelines recommend that people should engage in a healthy and balanced diet^[192]. Diet is important for people with diabetes, since any food that is consumed will affect the management of the disease.

This study recruited individuals with type 1 and type 2 diabetes. Although, the main goal of both types of diabetes treatment is to maintain blood glucose levels within healthy bounds, the treatments that are available and the repercussions of not adhering differ significantly. For instance, the implications of a person with type 1 diabetes not adhering to their medication can be fatal, whereas a person with type 2 diabetes does not face such severe short term consequences. In the present study, we addressed this issue by including the 'type of diabetes' as a covariate if it significantly correlated with any of the diabetes outcomes. The present study found a difference between type of diabetes and glucose monitoring where people with type 1 diabetes were more likely to monitor their glucose levels more often. This result was expected as a person with type 1 diabetes needs to continually monitor their glucose levels as they are at an increased risk of becoming hypoglycaemic or hyperglycaemic. Individuals with type 1 diabetes also had higher levels of HbA1c; this result might also be expected as a person with type 1 diabetes has no circulating insulin whereas a person with type 2 would still be producing insulin which could help in maintaining blood glucose levels. As expected people with type 2 diabetes had a higher BMI, a risk factor of type 2 diabetes^[193].

The relationship between PA and DQOL satisfaction neared significance ($p = .06$) after controlling for age, BMI, marital status, perceived stress, NA, depression status, instrumental coping, diabetes impact, diabetes related worries, attendance of support groups, type of diabetes, and smoking status. In addition, there were also other factors

that made a statistically significant contribution ($p < .05$) in predicting DQOL satisfaction. There were in order of importance, DQOL impact (beta = .22), NA (beta = -.21), BMI (beta = -.18), DQOL diabetes worries (beta = .18) and instrumental coping (beta = .16).

The fact that PA reached near significance and that NA was a significant predictor of DQOL satisfaction in the same model might suggest that both PA and NA can independently predict diabetes quality of life satisfaction. This supports the view that PA and NA might not be bipolar and can be seen as orthogonal constructs ^[11]. Individuals who report more negative affect might have a more negative attitude towards their diabetes and therefore report a lower quality of life. Generally quality of life is lower in people with a chronic disease and this has been shown to also be true for people with diabetes ^[183].

Higher BMI also remained significant after adjusting for other covariates in the DQOL satisfaction model. Individuals with higher BMI reported lower diabetes quality of life satisfaction but no other relationships were found between BMI and the remaining diabetes quality of life subscales. This finding supports other studies that have shown that people who have a high BMI do have a lower quality of life ^[194]. Obesity is a complex disease that has reached epidemic levels ^[194]. Excess weight is directly linked with insulin resistance ^[193] and develops from a combination of genetic, metabolic and psychosocial factors ^[194]. It is estimated that 90% of people with type 2 diabetes are overweight or obese ^[193]. For the reasons above in relation to obesity, it is recommended (according to NICE guidelines ^[97]) that lifestyle modifications such as losing weight are the first line of treatment.

A possible explanation as to why both diabetes impact and diabetes related worries predicted DQOL satisfaction is that although the subscales investigated separate factors they all measure quality of life of people with diabetes. Therefore if people are satisfied with their diabetes treatment they are probably highly unlikely to feel that their diabetes adversely impacts their lives.

PA did not predict diabetes related worries after adjusting for age, perceived stress, NA, complications, attendance of support groups, type of diabetes, glucose monitoring, diabetes impact and DQOL satisfaction. In the final model, only two control measures were statistically significant, with diabetes impact being more important than DQOL satisfaction which might suggest that they do correlate.

Some demographic factors correlated with DQOL. Individuals who were older reported better quality of life for all four DQOL subscales. However when evaluating it as a model to predict DQOL satisfaction, age did not make a significant contribution in predicting DQOL satisfaction. This partly supports Rubin and Peyrot who found no 'meaningful' link between age and quality of life in their systematic review ^[134]. When they specifically looked at physical functioning however, they did find that older individuals are more likely to report lower scores on physical and social functioning compared to younger people. Although this contradicts our findings, these studies did not use specific diabetes questionnaires whereas the diabetes quality of life instrument is a specific instrument that does address aspects of physical and social functioning ^[134]. Interestingly, Redekop et al investigated 1162 individuals with type 2 diabetes in relation to diabetes treatment satisfaction using a specific instrument (Diabetes Treatment Satisfaction Questionnaire) and found that individuals who reported higher diabetes satisfaction were older, had lower HbA1c and were not on insulin therapy compared to individuals who reported lower satisfaction ^[195].

Individuals who were married or cohabitating were more satisfied and had fewer diabetes related worries. This is also supported by Jacobson who found that individuals who were not married or cohabitating experienced lower levels of quality of life as measured by the Diabetes Quality of Life instrument ^[159]. Individuals who attended support groups were more satisfied, had fewer diabetes related worries and felt that their diabetes did not impact their lives adversely. Attending social support groups increases networks and therefore might be linked to better access to information such as diagnosis, management, expectations and possible complications of diabetes which can lead to more favourable health outcomes ^[196, 197]. Individuals who attend such groups

might have the opportunity to gain personal advice given by health care professionals or from their peers who also have diabetes. Although we asked individuals whether they attended social support groups, we did not measure how they perceived the support. Despite this, we did find differences in quality of life scores and therefore it might be possible to speculate that those who attended support groups perceived the support in a more positive way. Gilden et al found that men with type 2 diabetes that attended support group sessions had better diabetes knowledge and quality of life ^[198].

Perceived stress was negatively associated with all four DQOL subscales indicating that individuals who had reported lower perceived stress were more likely to report better quality of life. As mentioned earlier, stress can have adverse effects on health and in particular in people with diabetes as it does not only impact physiologically but also psychologically ^[127]. For instance the daily demands of living with diabetes, as well the constant worry of being at risk of becoming dangerously hyper or hypoglycemic and also the fears of developing or living with complications, can all be extremely stressful which can have an adverse impact quality of life.

The stress buffering theory was also tested in this study. It was hypothesised that people higher in PA would be more resilient to stress and therefore this would result in more positive outcomes compared to people who have low PA. PA was shown to moderate the relationship between perceived stress and diabetes impact and offers some support for Hypothesis 2. Individuals who perceive their diabetes to have impacted their lives more adversely might be less likely to adhere, have increased stress and develop more complications. Conversely, people who have higher PA are more likely to accumulate more positive gains so that when they are faced with a stressor like the negative impacts of diabetes they are able to use these resources and become more resilient to the stressor ^[54, 55].

No interaction effects were found between PA and (i) active coping nor (ii) instrumental coping on any of the diabetes related factors and therefore do not support Hypothesis 2. This contradicts previous research which shows coping to be a positive resource in

improving health outcomes ^[129]. For instance, Tsenkova et al found that coping strategies are linked to lower HbA1c levels in a non-diabetic population ^[132]. In the present study, this was investigated for the first time in patients with diabetes along with two further measures; diabetes quality of life and self-care practices. Although coping strategies were not associated with HbA1c or diabetes quality of life; they were linked to better engagement to self care practices. People who engaged in active coping strategies were 5.41 times more likely to exercise for more than five days after controlling for healthy diet, specific diet, blood glucose testing, body mass index, positive affect and negative affect.

Generally, problem-focused coping strategies are associated with more successful health outcomes such that they have been associated with better self-care, glycaemic control and well-being ^[199]. The present study measured active and instrumental support as ways of coping. These problem solving strategies have the potential to help individuals manage their diabetes effectively. With epidemic levels of obesity rising ^[200] and its association with insulin resistance, exercise is an important self-care practice that could help to reduce this.

4.6.1 Limitations

There were some limitations to the study. Firstly, the desired sample size ($n = 191$) was not reached. Post hoc power analysis showed that with an alpha set to .05 and with 147 participants who completed the questionnaire, this study had 80% power to detect an effect size of $d = .23$. For two of the diabetes related factors (HbA1c ($n = 87$) and DQOL social worries ($n = 57$)), this study had 80% power to detect an effect size of $d = .29$ and $d = .35$.

HbA1c was self-reported and therefore may have posed further limitations; firstly individuals may not have known this figure and therefore did not report it ($n = 60$) or reported it incorrectly. Beard et al recruited 83 individuals to assess their understanding

of HbA1c in relation to engaging in self-care practices and reported that only 26.5% of people had a good understanding of their HbA1c ^[96]. Secondly, HbA1c levels fluctuate over a period of 2-3 months (Diabetes UK); most individuals with diabetes would normally have their HbA1c tested either every 6 months or once a year (Diabetes UK) so individuals may not have reported an accurate or up-to-date reading when completing the questionnaire.

The questionnaire was based on self-reported data and therefore might have been subjected to response biases. Despite this however, the benefit of self-reporting data is that it does give us an opportunity to acquire more respondents. However, to investigate relationships more robustly, studies should try to employ more objective measures.

In this study, PA was investigated at only one time point and also it was not manipulated; therefore the causal relationship between PA and diabetes related factors could not be determined. To elucidate the direction of this relationship, it will be necessary to use interventions designed to increase PA and investigate whether it can have a beneficial impact on diabetes related outcomes such as HbA1c, self-care practices and quality of life. This has not yet been explored in a diabetes population.

4.7 Conclusion

These results offer further support to the suggestion that PA is related to certain health factors in individuals living with diabetes. In summary, this study suggests that people high in PA are more likely to follow a healthy eating plan and that it might (based on nearing significance) be linked to better DQOL satisfaction. The study contributes to the current literature by showing that the relationship between HbA1c and PA does not appear to be straight forward in people with diabetes and that it may be moderated by eating a healthy diet.

This study investigated the relationship between PA (as measured by PANAS) and diabetes related outcomes (as measured by HbA1c, self-care practices and quality of life) in a diabetes population, however, because this study could not determine causality, the next stage of this research is to employ an experimental design.

Chapter Five: A six month, randomised control study to investigate the impact of a positive affect intervention on health outcomes in people with diabetes

5.1 Introduction

The results from Chapter 4 indicated that individuals high in PA were more likely to follow a healthy diet and report better DQOL satisfaction. In addition the study found that PA moderated the relationship between following a healthy diet and HbA1c such that individuals higher in PA who reported not following a healthy diet for more than 5 days reported lower HbA1c. However, due to the correlational nature of the study, causality cannot be determined. Therefore the next stage of this research was to design a study that experimentally manipulates PA and to investigate the impact on diabetes related factors as measured by HbA1c, self-care practices and diabetes quality of life.

Ismail et al conducted a systematic review to investigate the effectiveness of psychological interventions in improving glycemic control in people with type 2 diabetes ^[201]. The studies included in this review were all randomised controlled trials of a psychological intervention. Glycemic control was the main outcome, as well as blood glucose concentrations, weight and psychological distress which focused on problems such as depression, binge eating and stress. Interventions that were chosen in the analysis included cognitive behavioural therapy or a similar strategy to that such as relaxation, goal setting or self monitoring of behaviours. In addition to this counselling was also investigated. These interventions were generally compared to usual care, education or waiting lists. In total there were 12 studies that were reviewed in relation to HbA1c, 8 were blood glucose related, 9 were weight studies and 5 were related to psychological distress. The findings showed that psychological interventions resulted in a .76% reduction in HbA1c. No improvements were found in weight or blood

glucose concentrations. However, interventions were effective in reducing psychological distress. Although there are various psychological interventions being used, PA interventions have yet to be tested in people with diabetes. As discussed in chapter 4, PA might be related to some diabetes related factors and therefore interventions designed to increase PA might be another type of intervention that might help people with diabetes and therefore should be addressed.

A randomised controlled trial by Pouwer et al^[182] investigated whether monitoring and discussing psychological well being in addition to standard care, would have an effect on mood, HbA1c and QoL. Outpatients with diabetes were randomly assigned into one of two groups; standard care or standard care plus additional monitoring which involved diabetes research nurses discussing the individuals' well-being. To evaluate psychological well-being, the study used a more general questionnaire (as opposed to a diabetes specific questionnaire) and therefore was unable to address the emotional aspects of diabetes, such as the fear of hypoglycaemia. Results showed that in addition to routine standard care, discussing psychological well-being can have an impact on the mood of patients. However it did not affect HbA1c levels, one possible reason for this is that the sample population already had relatively good glycaemic control (7.4%) and therefore may have been unable to detect a significant difference as there was little room for improvement. This study showed that well-being can be improved through psychological monitoring, and although the study investigated HbA1c, it did not investigate the significance of improved well-being on factors such as health practices and diabetes quality of life.

The studies^[60, 61, 63] that have investigated PA interventions in other chronic conditions have incorporated both positive affect and self affirmation, which can be defined as enabling an individuals' ability to acknowledge past accomplishments that make them proud^[63]. As reviewed in the introduction in more detail (section 1.2), these studies investigated medication adherence and physical activity. The findings suggested that enhancing patient education with a PA intervention could result in more favourable health outcomes in patients with hypertension and also in patients who have undergone

percutaneous coronary intervention (a non-surgical procedure to treat atherosclerosis) but not for people with asthma.

Although these studies have shown that PA combined with self affirmation can have favourable effects on health practices, it must be appreciated that it involved many resources such as telephone calls and gifts over a prolonged period of time. These interventions can be costly and the feasibility of delivering such interventions might be difficult to incorporate into a clinical setting. Furthermore it is difficult to distinguish the specific elements of the intervention to locate what is having the biggest effect. Nevertheless, these studies do add to the growing literature that positive affect interventions may play a role in promoting health behaviours.

PA interventions have been investigated in relation to health outcomes, however studies have yet to explore whether PA interventions might serve as a way to improve the management of diabetes. Therefore the main objective of the study is to see whether a PA intervention could lead to increases in PA and as a result show improvements in diabetes related factors such as HbA1c, self-care practices and quality of life.

This study aims to fill the gap in the existing literature by implementing a simple intervention that has been shown to increase PA and see if it can benefit people with diabetes. The Three Good Things intervention was used for two specific reasons: first the intervention has shown long term increases in happiness up to 6 months^[57], this is an advantage because trait PA is associated with better health outcomes (see section 1.1). Secondly, the implementation of this intervention is simple; the instructions are self explanatory and do not require a facilitator and therefore the cost of implementation is minimal.

It was hypothesised that (i) participants assigned to the PA intervention (TGT) would report greater increases in PA following the intervention than participants assigned to the control exercise and (ii) PA would be associated with lower HbA1c, better engagement with self-care practices and better diabetes quality of life up to 6 months.

In addition, the PA intervention was also investigated in relation to whether or not it independently affected NA.

5.2 Ethical Approval

The study proposal was submitted to Brighton University Faculty Research Ethics Governance Committee (FREGC) for review. After approval, it was forwarded to Brighton and Hove NHS Research Ethics Committee (REC). Brighton and Hove NHS REC approval was received on 25th June 2009. The study also required Research and Development (R&D) approval from Brighton and Hove City Primary Care Trust (PCT) and this was granted on 27th August 2009. To maximise recruitment, additional PCTs were contacted and approval was granted for Hastings and Rother PCT, East Sussex Downs and Weald PCT and West Sussex PCT on 19th January 2010 (see appendix C for all ethical approval letters for this study).

5.3 Methods

5.3.1 Study Design

This was a randomised control study and was conducted in South East England. Data was collected at five time-points over six months (baseline, 1 week, 1 month, 3 months and 6 months). Participants were randomised (using the online random allocator random.org) into one of two independent groups. Participants in the control group were asked to complete the Early Memories (EM) exercise and participants in the PA intervention group were asked to complete the Three Good Things (TGT) exercise (see section 2.5).

Sample Size

Previous studies with non diabetic populations have shown similar interventions to produce moderate to large effects on measures of PA ^[3, 57] and adherence to treatment ^[62]. Using a conservative estimate of detecting a moderate effect size ($d = .50$), an

independent samples t-test with a 2-sided 5% significance level and a power of 80% requires a minimum sample size of 64 people in each of the two conditions (the intervention group and the control group).

5.3.2 Procedure

Participants were initially recruited through GP surgeries, posters and the Brighton University intranet. To maximise recruitment, three diabetes clinics were approached in East Sussex; (i) River Lodge Surgery, (ii) Anchor Field Surgery and (iii) Newick Surgery.

Figure 5.1 illustrates the study procedure and what information was obtained during the study. Individuals that consented and were eligible to take part in the study were instructed to complete various questionnaires at the start of the study (baseline). These included the Positive Affect and Negative Affect Scale (PANAS), The Summary of Diabetes Self-Care Activities (SDSCA), Diabetes Quality of Life (DQOL) and the Profile of Mood States (POMS). Physiological factors that were measured were HbA1c, blood pressure (BP), weight and height.

Once baseline data was obtained, the instructions to the allocated task (either PA intervention or control) were given to participants at random and they were instructed to read them. Participants were then asked to complete the Profile of Mood States again.

The participant took their randomly allocated written task home and completed it for seven consecutive days. Thereafter, data was collected at five different time-points; at 3 months and 6 months participants were asked to attend their GP surgery. At these time-points participants completed questionnaires the research student obtained physiological measures. At 1 week and 1 month, the PANAS and SDSCA were sent to participants home where they were instructed to complete the questionnaires. Participants returned the questionnaires using a free post envelope addressed to the research student. At the end of the study, participants were debriefed about the study.

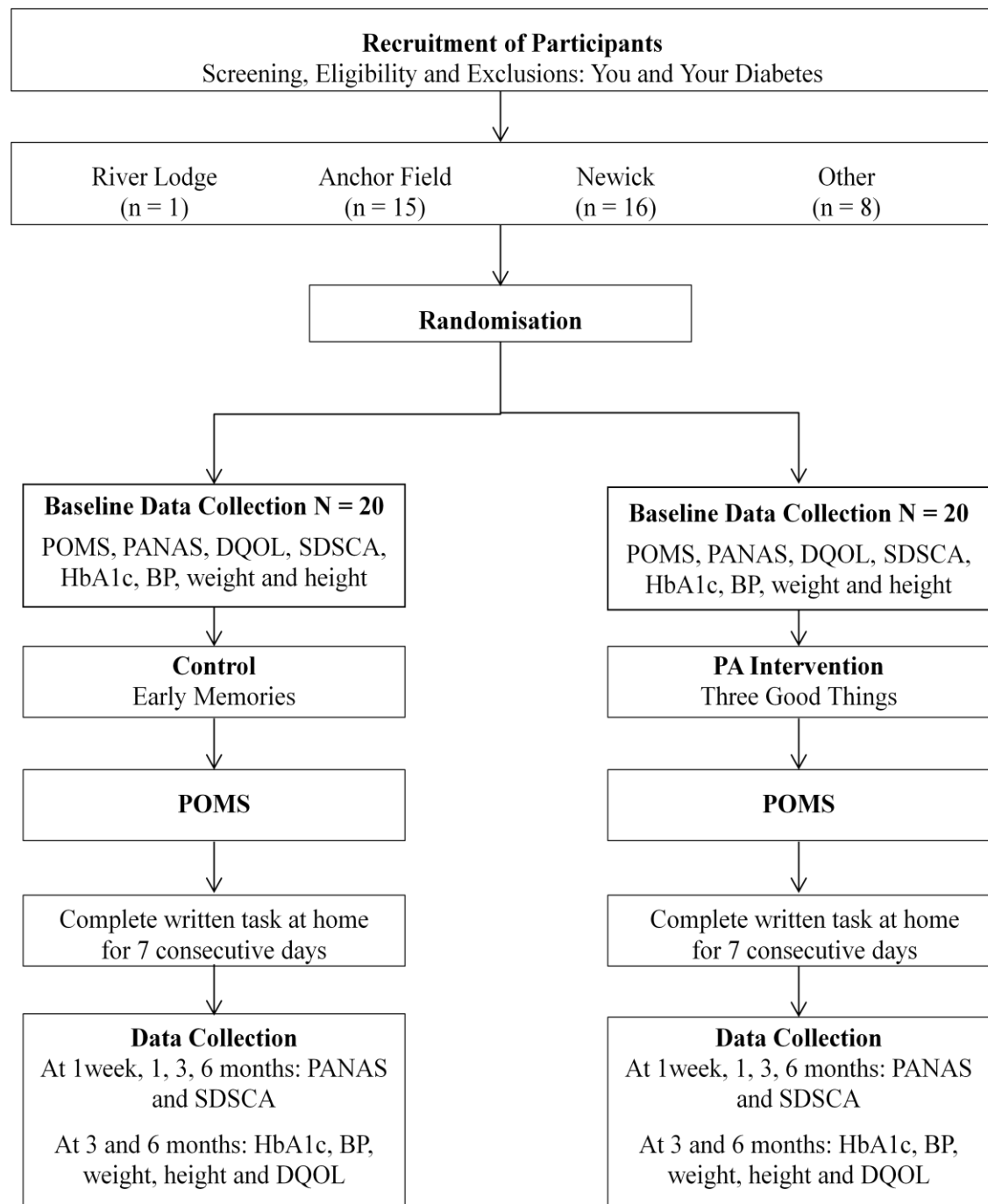


Figure 5.1. Flow diagram of study procedure.

PANAS = Positive Affect and Negative Affect Scale. SDSCA = Summary of Diabetes Self-Care Activities. DQOL = Diabetes Quality of Life. POMS = Profile of Mood States. BP = Blood Pressure.

5.3.3 Participants

Inclusion eligibility was assessed using a form that included questions about participant demographics (age, gender) and diabetes related information (duration of diabetes, type of diabetes) and a question on depression. This was referred to participants as the “You and Your Diabetes” questionnaire.

People were considered eligible for inclusion in this study if they fulfilled all of the following criteria, (i) gave written informed consent to take part in the study (ii) had a diagnosis of diabetes (iii) were over 18 and (iv) had the ability to read and write English fluently. Personal data for all participants were regarded as confidential. Participant’s age and randomly assigned experimental number were used as identification and no individual data was reproduced. The design of the study was aimed at targeting mood, therefore people who were taking medication to enhance mood or who had a psychological disorder that was mood related were excluded from the study. People were not considered suitable for the study if they had (i) experienced, been previously diagnosed or were having treatment for depression (CBT/medication) (ii) treatment for any other psychiatric disorders and (iii) serious cognitive problems. At baseline 20 individuals were recruited into each group.

5.3.4 Measures

Mood or Affect

The PANAS was used to measure PA (see section 2.1.1). The time frames selected for this questionnaire varied according to the time the data was collected. Therefore at baseline, the time frame used was “*generally*”, at 1 week the time frame was “*in the past week*” at 1 month the time frame used was “*in the last month*”, at 3 months the time frame used was “*in the last 3 months*”, and at 6 months the time frame used was “*in the last 6 months*”. The PANAS and POMS were used to assess NA and current mood states respectively.

Diabetes-Related Health Outcomes

The primary measures for this study were HbA1c levels, self-care practices (< 5 days or ≥ 5 days) and DQOL scores (satisfaction, impact, diabetes related worries and social worries). HbA1c was measured using the BioRad Analyzer (see section 2.4.3). To assess self-care practices and DQOL, participants were asked to complete the SDSCA and DQOL respectively (see section 2.2). The time frame used for the SDSCA was “in the past 7 days”. The time frames used for the DQOL were “*currently*”, “*over the past 3 months*” and “*over the last 6 months*” depending on the time the data were collected.

Demographic Factors

Information on demographic factors were recorded from the “You and Your Diabetes” form (age, BMI, gender, ethnic background and marital status). Participants were asked to report on diabetes related factors such as type of diabetes and duration of diabetes. If medical records ($n = 32$) were obtained then information regarding medication was recorded. BP was measured using a calibrated BP monitor (A&D Medical, Compact Desk Top Monitor, Digital Blood Pressure Monitor, Model No. UA-705) (see section 2.4.1).

5.4 Data Analysis

The statistical software package, PASW Statistics 18 was used for all analyses. Normality tests were evaluated using the Kolmogorov-Smirnov and Normal Q-Q plots. Non-parametric tests were used if variables did not show normality after transformation. For all outcomes a p-value < .05 was considered to be statistically significant. Descriptive statistics, means, standard deviations, frequencies and percentages were calculated for all measures between the two independent groups ((i) Three Good Things (TGT) and (ii) Early Memories (EM).

To investigate if the PA intervention had an immediate effect, paired T-tests were conducted for both groups (before and after) using the scores from the Profile of Mood States (POMS) subscales.

A two-way ANOVA was conducted to investigate the impact of the PA intervention (TGT vs. EM) on (i) PA scores and (ii) NA scores across two time-points (baseline vs. 1 week). Repeated measures ANOVA's were then carried out to investigate the effect of the PA intervention on the diabetes outcomes (HbA1c, quality of life and self care practices). Where there was no effect of the intervention, the sample population was combined and further analyses were conducted to focus on scientific questions that were generated from the results of Chapter 4. This will involve conducting correlational analysis to investigate the associations between PA and HbA1c, healthy diet and DQOL satisfaction across the various time points. Then hierarchical regression to assess the ability of PA to predict DQOL satisfaction after taking into account the variance explained in baseline scores and NA.

5.5 Results

5.5.1 Sample Characteristics

Forty individuals participated in this study, with 20 in each group. Tables 5.1 and 5.2 list the means (\pm SD) and percentage distribution for all variables and Table 5.3 presents the number of individuals that engaged in various self-care practices.

Table 5.1 Descriptive statistics for demographic and diabetes related variables at baseline

	Control: Early Memories (n = 20)	PA Intervention: Three Good Things (n = 20)	<i>p</i> value
Gender (N = 40)			
Male	10	10	1.00
Female	10	10	
Marital status (N = 40)			
Married/civil partnership	19	10	.019
Other	1	10	
Ethnic Background (N = 39)			
White/White British	19	19	1.00
Other White background	1	0	
Type of Diabetes (n = 39)			
Type 1	3	4	1.00
Type 2	16	16	

Table 5.2 Descriptive statistics for demographic, psychosocial and diabetes related variables at baseline.

Data represents mean scores (SD)

	Control: Early Memories (n = 20)	PA Intervention: Three Good Things (n = 20)	<i>p</i> value
Age (years)	66.0 (8.31)	68.4 (11.78)	.461
Body mass index (kg/m ²)	29.82 (6.30)	30.97 (7.54)	.603
Mean positive affect	3.59 (.48)	3.34 (.78)	.231
Mean negative affect	1.29 (.28)	1.62 (.63)	.038
Duration of Diabetes (years) ¹	7.96 (2.74)	7.78 (2.47)	.941
HbA1c (%)	7.0 (.94)	7.64 (1.15)	.062
DQOL Satisfaction	77.14 (13.34)	71.75 (15.28)	.242
DQOL Impact	80.73 (9.36)	72.56 (10.07)	.016
DQOL Diabetes Related Worries	78.09 (14.45)	71.39 (18.70)	.228

DQOL = Diabetes Quality of Life

¹ Data presented from log values

Table 5.3 Percentage of sample engaging in specific self-care behaviours at baseline.

Data represents the number of individuals and (%)

	Control: Early Memories (n =20)	PA Intervention: Three Good Things (n = 20)	<i>p</i> value
Self-care practice (engaged \geq 5 days) (N= 40)			
Healthy Diet	13 (68.4)	16 (80)	.645
Specific Diet	6 (31.6)	9 (47.4)	.507
Exercise	6 (30)	11 (55)	.201
Blood glucose testing	8 (40.0)	6 (30)	1.00
Feet checks	4 (20.0)	6 (30)	.715
Diabetes Treatment (N = 24)			
Diet and Exercise	1	1	
Oral Medication	7	9	
Insulin	1	3	
Oral Medication and Insulin	2	0	.376
Taking other medication			
Antihypertensive (N = 16)	5	11	
Statins (N = 17)	10	7	
Anti platelet (N = 3)	0	3	

The two groups differed on marital status, baseline NA and baseline DQOL impact, such that the TGT group had higher NA scores and reported lower DQOL impact at baseline compared to the control group. A greater proportion of people were found to be married in the control group.

5.5.2 Positive Affect Intervention

The Profile of Mood State questionnaire (POMS) was completed before and after the instructions to the task was given to the individuals. Table 5.4 shows the mean/median scores before and after the randomised exercise was given to participants. The PA intervention showed more statistical reductions in the negative affect states compared to the control group. There was a reduction in friendliness ratings in the PA intervention group (see Table 5.4). Although there were some changes in the in the subscales of the POMS, this questionnaire was not administered after this point and therefore no further analysis could be conducted in relation to the POMS.

Table 5.4 Comparison of POMS subscales before and after the randomised exercise was given to participants

	Control Early Memories (n = 20)		PA Intervention: Three Good Things (n = 20)	
	Before	After	Before	After
Vigour¹	2.38 (.80)	2.49 (.79)	2.28 (.69)	2.17 (.78)
Friendliness¹	3.05 (.52)	3.01 (.62)	2.96 (.53)	2.73 (.61)*
Elation¹	2.18 (.88)	2.38 (.82)	1.90 (.80)	1.86 (.77)
Anxiety²	-.11 (-.33- .33)	-.33 (-.44- -.11)*	.28 (-.19- 1.33)	-.11(-.33- .83)*
Depression²	.07 (0 - .32)	.00 (0- 2.75)*	.27 (.10- .80)	.20 (.02- .57)*
Anger²	.17 (0- .31)	.08 (0- .25)	.42 (0- 1.25)	.08 (0- .56)*
Confusion¹	.08 (.42)	-.21 (.23)*	.54 (.86)	.28 (.74)*
Fatigue¹	.90 (.77)	.51(.62)*	1.50 (1.09)	1.10 (1.07)*

¹ Paired T test, data represent means (standard deviations). ² Wilcoxon Signed Rank Test, data represent medians (inter quartile range 25th and 75th percentiles).

* $p < .05$ Vs 'before' time-point

Positive Affect

Figure 5.2 and Table 5.5 show the mean Positive Affect scores at baseline and the follow-up time points and the corresponding mixed design ANOVA output respectively. At 1 week, 1 month and 3 months there was no main effect of time indicating that the pattern of change in PA scores was the same. However at 6 months, there was a significant main effect of time ($F(1, 22) = 10.51, p = .004, \text{partial eta squared} = .32$) such that PA scores were lower at the 6 months interval compared to baseline (baseline mean = 3.48 SE = .13; 6 month mean = 3.44 SE = .10). There was no main effect of the PA intervention at any of the specified time points indicating that there were no differences in PA scores between the two groups.

There were also no significant interaction between the PA intervention and time, therefore indicating that the pattern of change in PA scores was the same for both the control group and the intervention group between baseline and the specified time points.

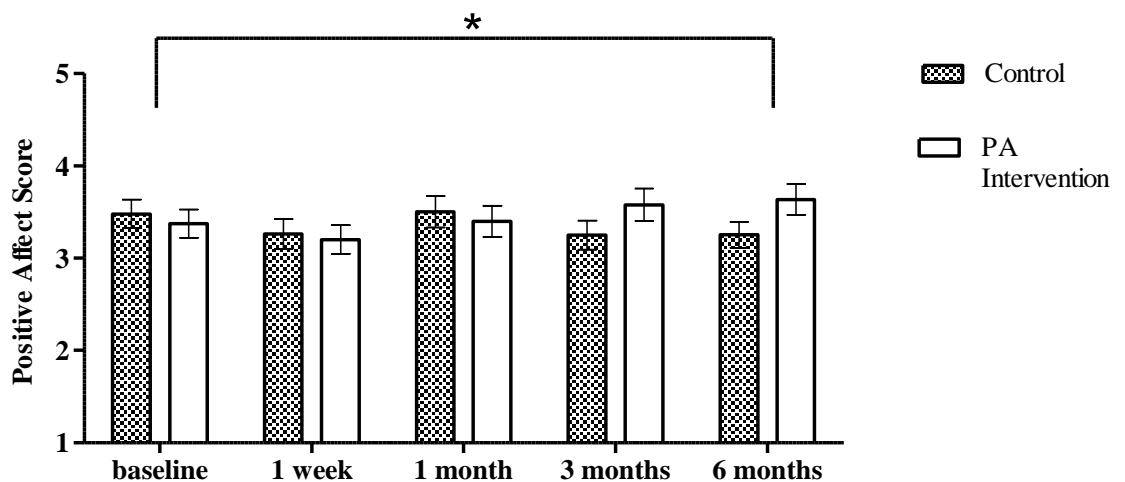


Figure 5.2 Mean Positive Affect scores at each time point in participants from the PA intervention or the control group.

Asterisks correspond to a statistically significant ($p < .05$) difference in time between the specified time point and baseline. Error bars represent standard error of mean; adjusted for baseline Negative Affect and marital status.

Table 5.5 The effects of time point, PA intervention and time point*PA Intervention interaction between the Positive Affect baseline score and the specified time point score

Time point	Effect	Degree's of Freedom	F statistic	p value
1 week	Time point	1,33	.23	.632
	PA intervention		.95	.338
	Time point *PA Intervention		.14	.716
1 month	Time point	1.30	1.54	.224
	PA intervention		.31	.638
	Time point *PA Intervention		.04	.845
3 months	Time point	1,29	2.88	.101
	PA intervention		.60	.445
	Time point *PA Intervention		2.20	.149
6 months	Time point	1,22	10.51	.004
	PA intervention		1.04	.319
	Time point *PA Intervention		.18	.079

Negative Affect

Figure 5.3 and Table 5.6 shows the mean Negative Affect (NA) scores at baseline and the follow-up time points and the corresponding mixed design ANOVA output respectively. There was no significant main effect of time, PA intervention or interaction between the PA intervention and time at 1 week and 1 month, 3 months or 6 months.

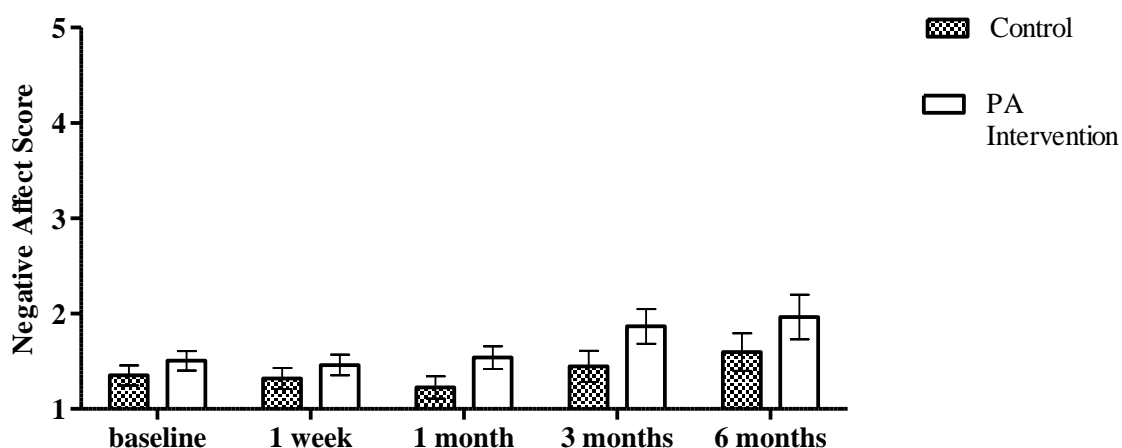


Figure 5.3 Mean Negative Affect scores between the PA intervention group and the control group at each point in time.

Error bars represent standard error of mean; adjusted for marital status.

Table 5.6 The effects of time point, PA intervention and time point*PA Intervention interactions on Negative Affect baseline score and the specified time point score

Time point	Effect	Degree's of Freedom	F statistic	p value
1 week	Time point	1,34	.08	.776
	PA intervention		1.07	.308
	Time point *PA Intervention		.01	.919
1 month	Time point	1.31	1.96	.172
	PA intervention		2.97	.095
	Time point *PA Intervention		.77	.388
3 months	Time point	1,30	.24	.627
	PA intervention		2.84	.102
	Time point *PA Intervention		.97	.332
6 months	Time point	1,23	.06	.805
	PA intervention		1.58	.222
	Time point *PA Intervention		.35	.560

5.5.3 HbA1c

Figure 5.4 and Table 5.7 show the mean HbA1c levels at baseline and the follow-up time points and the corresponding mixed design ANOVA results respectively. There was no significant main effect of time at either 3 or 6 months indicating no changes in HbA1c levels. There was no main effect of the PA intervention at any of the follow-up time points indicating no differences in HbA1c levels between the intervention and control group.

There were also no significant interaction between the PA intervention and time, indicating the lack of change in HbA1c levels was the same for both the control group and the intervention group between baseline and the specified time points.

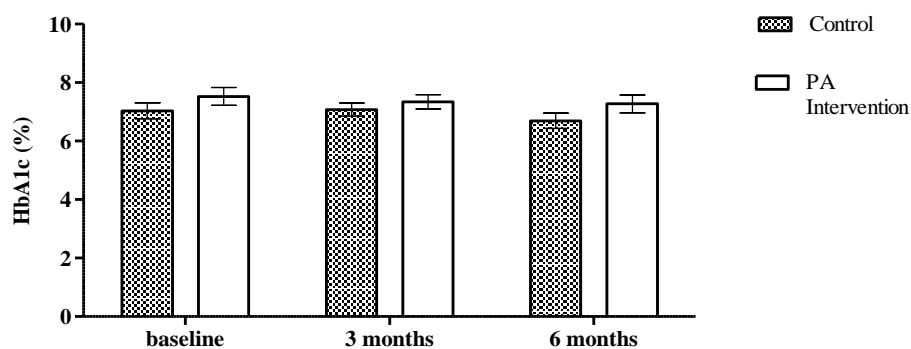


Figure 5.4 Mean HbA1c scores between the PA intervention group and the control group at each point in time.

Error bars represent standard error of mean; adjusted for baseline Negative Affect and marital status.

Table 5.7 The effects of time point, PA intervention and time point*PA Intervention interactions on HbA1c and the specified time point score

Time point	Effect	Degree's of Freedom	F statistic	p value
3 months	Time	1,29	1.17	.287
	PA intervention		1.07	.309
	Time*PA Intervention		.56	.462
6 months	Time	1,24	1.39	.251
	PA intervention		2.49	.129
	Time*PA Intervention		.35	.560

5.5.4 Self-care practices

A series of Chi-square tests were conducted to see if individuals in the PA intervention group were more likely to follow self-care practices for more than five days (healthy diet, specific diet, glucose monitoring, exercise and feet checks).

Figure 5.5a-e shows the percentage of individuals that followed the specified self-care practice for more than 5 days at each time point. No differences were found between the PA intervention group and control in following any of the self-care practices at any of the specified time-points (Chi Square $p > .05$)

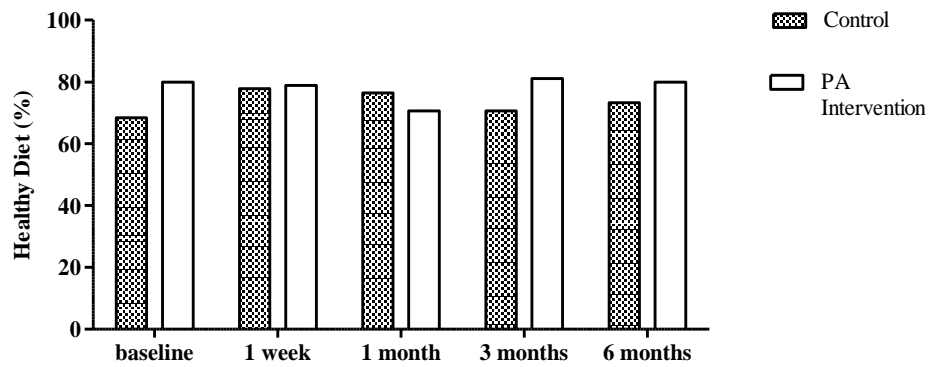


Figure 5.5a Percentage of individuals following a healthy diet for more than 5 days in the PA intervention group and the control group at each point in time

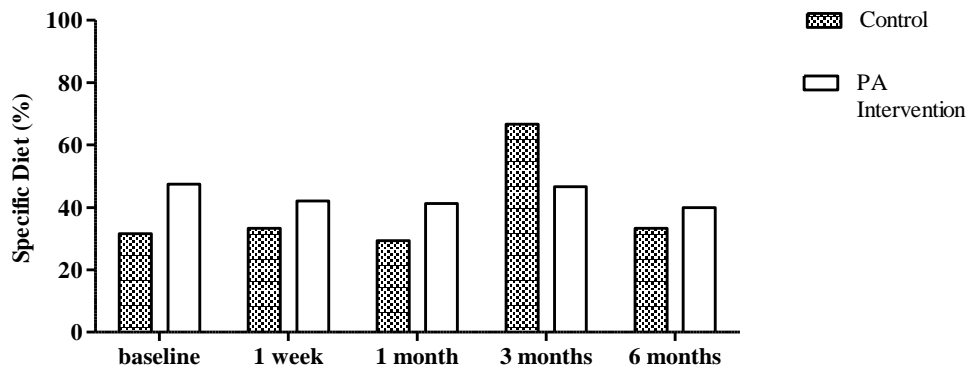


Figure 5.6b Percentage of individuals who avoided high fat foods for more than 5 days in the PA intervention group and the control group at each point in time

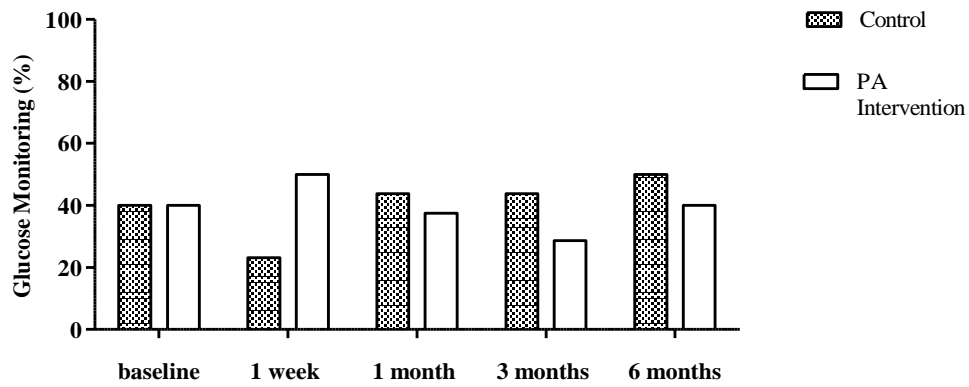


Figure 5.7c Percentage of individuals who monitored their glucose levels for more than 5 days in the PA intervention group and the control group at each point in time

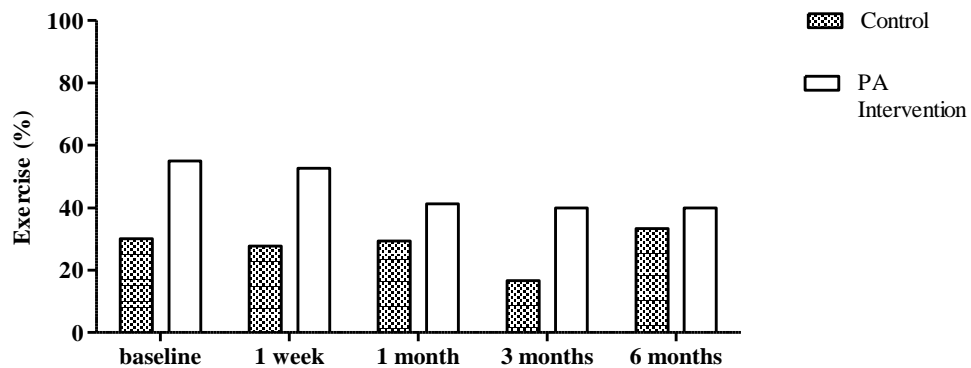


Figure 5.8d Percentage of individuals following exercise for more than 5 days in the PA intervention group and the control group at each point in time

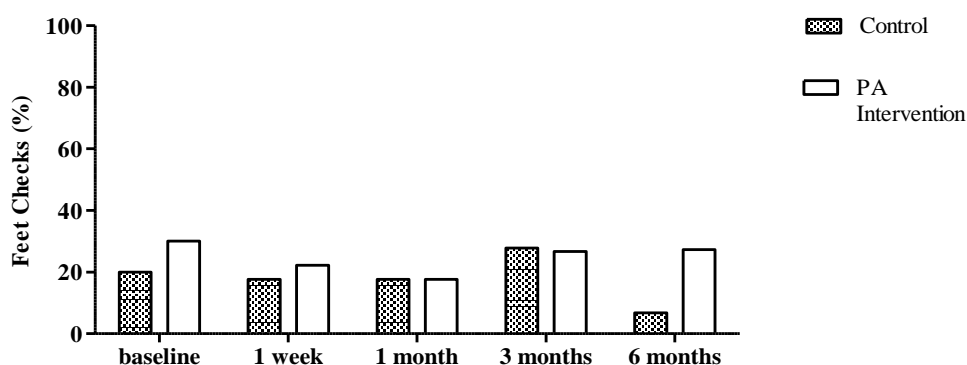


Figure 5.9e Percentage of individuals following foot checks for more than 5 days in the PA intervention group and the control group at each point in time.

5.5.5 Diabetes Quality of Life

Figure 5.5 and Table 5.8 show the mean Diabetes Quality of Life Scores (satisfaction, impact and diabetes related worries) at baseline and the follow-up time points and the corresponding mixed design ANOVA output respectively. There was no significant main effect of time at both 3 and 6 months such that there was no difference between baseline Diabetes Quality of Life Scores for satisfaction, and diabetes related worries and the specified time points. However, for diabetes impact, there was a main effect of time at 3 months ($F(1, 20) = 4.72, p = .042, \text{partial eta squared} = .19$) such that diabetes impact scores increased after 3 months (baseline mean = 78.11 SE = 1.79; 3 month mean = 78.61 SE = 1.41). However at 6 months, the main effect of time did not remain significant.

There was no main effect of the PA intervention nor was there a significant interaction between the PA intervention and time at any of the follow-up time points indicating that there were no differences in Diabetes Quality of Life Scores (satisfaction, impact and diabetes related worries) between the intervention and control group.

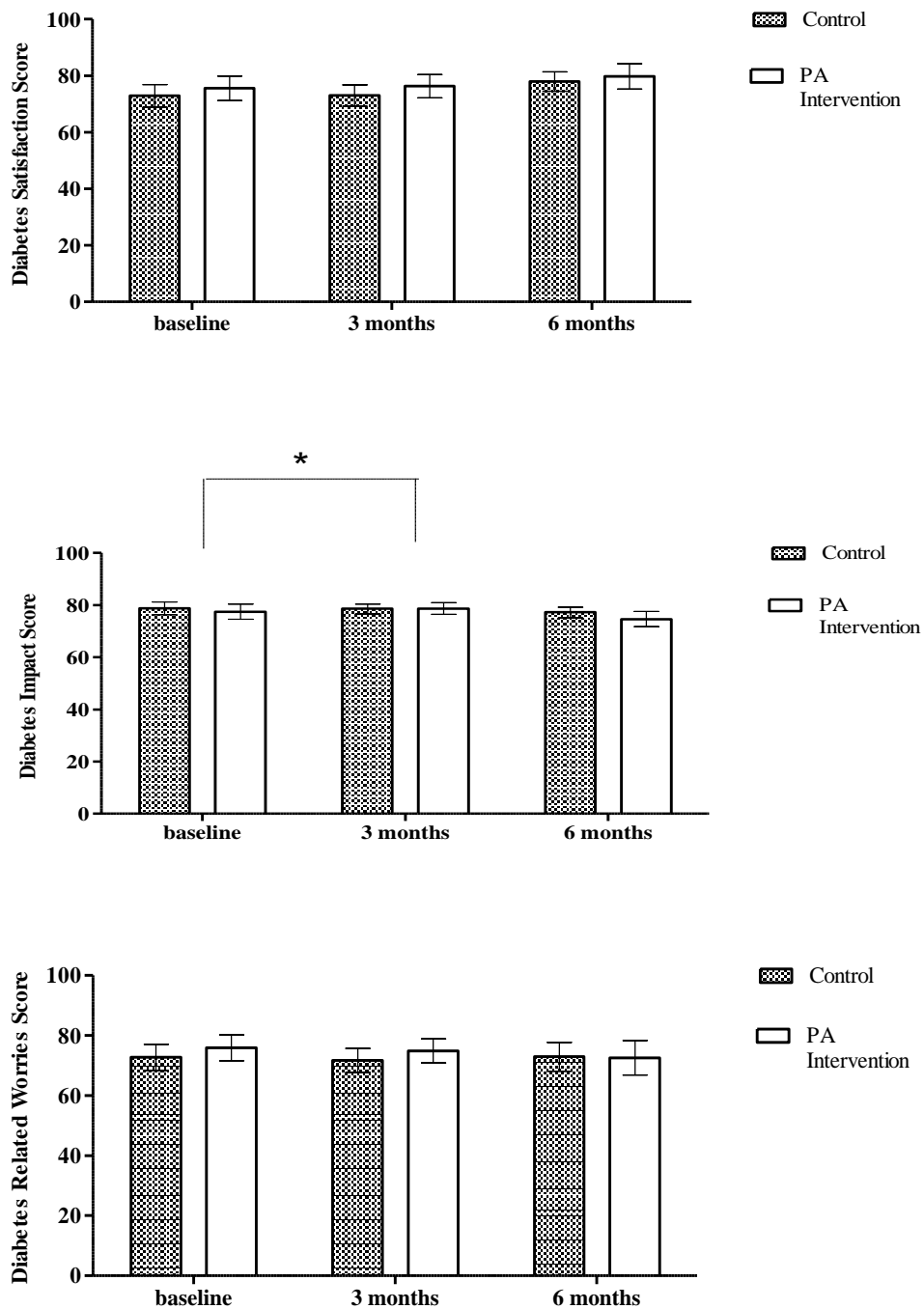


Figure 5.10 Mean Diabetes Quality of Life Scores (satisfaction, impact and diabetes related worries) between the PA intervention group and the control group at each point in time.

Asterisks correspond to a statistically significant ($p < .05$) difference between the intervention group at that point in time and baseline. If no asterisk is shown, the intervention group and the control group did not differ. Error bars represent standard error of mean; adjusted for baseline Negative Affect and marital status.

Table 5.8 The effects of time point, PA intervention and time point*PA Intervention interactions on Diabetes Quality of Life (satisfaction, impact and diabetes related worries) baseline score and the specified time point score

	Time point	Effect	Degree's of Freedom	F statistic	p value
Diabetes Satisfaction	3 months	Time	1,24	.09	.768
		PA intervention		.26	.616
		Time*PA Intervention		.05	.830
	6 months	Time	1,20	.34	.565
		PA intervention		.14	.712
		Time*PA Intervention		.01	.933
Diabetes Impact	3 months	Time	1,20	4.72	.042
		PA intervention		.03	.867
		Time*PA Intervention		.63	.437
	6 months	Time	1,17	4.37	.052
		PA intervention		1.88	.189
		Time*PA Intervention		1.40	.253
Diabetes Related Social Worries	3 months	Time	1,20	.56	.462
		PA intervention		.41	.528
		Time*PA Intervention		<.001	.987
	6 months	Time	1,20	.35	.559
		PA intervention		.18	.680
		Time*PA Intervention		.23	.636

The above analysis illustrates that there were no significant interactions between the PA intervention and time-points suggesting that the pattern of change between the two groups was the same for PA, NA, HbA1c, and quality of life.

For this reason, the two groups will now be combined and the data will be analysed as one sample (N = 40). This will enable important questions that were raised in chapter 4 to be answered.

Firstly, this study measured HbA1c objectively as opposed to self report (as measured in chapter 4) and therefore the present study can investigate the relationship between PA and HbA1c. Secondly the results generated in Chapter 4 did not determine causality and the data for the study was only collected at one time. Although we will still not be able to determine causality, we can analyse the data while controlling for baseline measures as it was collected over a series of time-points.

The next part of this chapter will focus on scientific questions that were generated from the results of chapter 3. This will further investigate the relationship between PA and diabetes outcomes. First PA levels will be investigated to see if there are any differences at the specified time-points and then following questions will be addressed.

1. Is there an association between HbA1c and PA and does baseline PA predict HbA1c at 3 and 6 months?
2. Does diet moderate the relationship between PA and HbA1c?
3. Does PA predict DQOL satisfaction at 3 and 6 months after controlling for baseline DQOL satisfaction?

5.5.6 Positive Affect

The mean PA scores at baseline for the total sample was 3.47 (SD = .65; min – max = 1.70 – 4.60). Figure 5.11 shows the mean Positive Affect scores for the total sample population at baseline and the follow-up time points independent of NA. There were no main effects of time indicating that PA scores stayed fairly stable across the six months. This shows therefore that PA scores did not change significantly from baseline throughout the study and therefore PA baseline scores will be use from this point forward in all analysis.

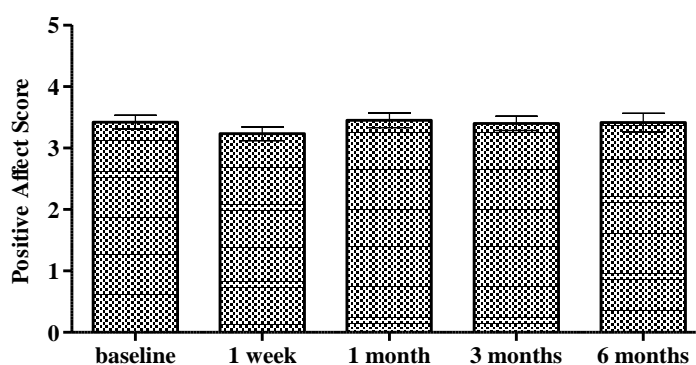


Figure 5.11 Mean Positive Affect scores at each time point for participants taking part in the study

Error bars represent standard error of mean; adjusted for baseline Negative Affect

5.5.7 Positive Affect, Healthy Diet and HbA1c

The mean HbA1c for the total sample was 7.32% (SD = 1.09; min – max = 5.60 – 9.50). Seventy four percent of individuals followed a healthy diet for more than five days. Pearson's correlations found no associations between PA and HbA1c at baseline, 3 months or 6 months ($p > .05$). No differences were found between people who followed a healthy diet and those who did not in their PA levels or HbA1c levels.

As there are no associations between these three variables no further analysis will be conducted.

5.5.8 Positive Affect and Diabetes Quality of Life Satisfaction

DQOL Satisfaction

Table 5.9 shows the correlation coefficients between DQOL satisfaction and affect at baseline, 3 months and 6 months. At baseline, although no association was found between PA and DQOL satisfaction, the relationship between PA and DQOL satisfaction neared significance ($p = .064$). At 3 months and 6 months, individuals who had higher PA scores were more satisfied with their diabetes.

Individuals with higher NA scores at all three time-points were less satisfied with their diabetes.

Table 5.9 Correlation matrix between *DQOL satisfaction* and affect at baseline, 3 months and 6 months

	Baseline (40)	3 Months (28)	6 Months (24)
Positive affect	.296	.609**	.466*
Negative affect	-.357*	-.481*	-.412*

** $p < .001$ * $p < .05$.

Hierarchical multiple regression analysis was used to assess the ability of PA to predict DQOL satisfaction at 3 and 6 months after taking into account the variance explained by baseline DQOL satisfaction and NA.

For *DQOL Satisfaction at 3 Months*; baseline DQOL satisfaction and NA were entered at step 1, explaining 79.3% of the variance in DQOL satisfaction at 3 months ($F(3, 24) = 30.68, p < .001$). PA explained no additional variance in DQOL satisfaction after controlling for NA and baseline DQOL satisfaction (R squared change $< .001, F$ change $(1, 24) = .04, p = .838$).

For *DQOL Satisfaction at 6 Months*; baseline DQOL satisfaction and NA were entered at step 1, explaining 57.2% of the variance in DQOL satisfaction at 6 months, ($F(3, 20) = 13.60, p < .001$). PA explained an additional 10% of the variance in DQOL satisfaction after controlling for NA and baseline DQOL satisfaction (R squared change $< .001, F$ change $(1, 20) = .6.04, p = .023$). This result indicates that baseline PA provided independent prediction of DQOL satisfaction scores at 6 months.

5.6 Discussion

This study aimed to see if the TGT exercise would increase PA independent of NA in a diabetes population and to see if this impacted physiological and behavioural health related measures. In addition, important questions in relation to PA, healthy diet, HbA1c and DQOL satisfaction that were raised in chapter 4 were also investigated.

The present study found that the PA intervention did not increase PA at 1 week, 1 month or 3 months independent of NA and marital status. This supports the findings of Chapter 3. Surprisingly, PA scores went down after 6 months; however this decline was not dependent on the PA intervention and was observed in both groups. In addition, no differences were found between the PA intervention group and control group in HbA1c, self care practices, DQOL satisfaction and diabetes related worries across after adjusting for NA and marital status at all time-points suggesting that these outcomes for individuals were relatively the same across all time-points. Diabetes quality of life impact was the only outcome measure that saw an increase after 3 months; however the pattern of change was the same for both groups.

There are a number of reasons which might explain why the PA intervention was not effective in this study. One of the main reasons is that the sample recruited for this study exhibited high levels of PA at baseline (3.65) and therefore it is possible that the PA intervention could not increase PA scores any further. The high levels of PA seen in this study might also explain the good glycemic control found in this study (mean HbA1c: control group = 7.0%; PA intervention group = 7.64%). Pouwer et al ^[182] recruited individuals with diabetes who had a mean HbA1c of 7.8% in both groups and similar to the findings of our study, they found no differences in HbA1c between the

intervention group and control group after 6 months and 12 months ^[182]. In light of these findings, future studies might want to consider recruiting individuals who have relatively high HbA1c levels in order to see an effect ^[182].

There are other reasons that might have affected the efficacy of the PA intervention and should also be addressed. This study was the first to test the TGT intervention in people with diabetes and therefore it is possible that a simple PA intervention might not be effective in people with diabetes. Managing a chronic condition such as diabetes involves adhering to a multi-complex treatment regime and therefore future studies involving interventions might need to incorporate other elements. For instance, Moskowitz et al investigated a similar intervention to the TGT intervention in patients who were newly diagnosed with HIV ^[202]. They referred to the written exercise as a “positive event” where participants were instructed to write down one or more positive things that happened that day. In addition they were also asked to report how they felt, what they did in relation to that response and whether they amplified on it. The major difference from the current study is that the intervention included other components that were either facilitated or completed at home. In addition the study did not investigate any health factors and therefore all outcomes were based on self-reported data. Although the sample size was small (n = 9), the study is interesting because writing positive events like the TGT might be beneficial in people with a chronic condition but importantly, Moskowitz et al highlights that it might not be effective on its own and therefore future studies might want to investigate a combination of PA inducing factors as opposed to only one.

The relatively high levels of PA seen in this sample population may have influenced the results by introducing a ‘ceiling effect’. If individuals have high PA scores prior to the intervention, then it can be extremely difficult to demonstrate any positive effects of the intervention. For this reason, future studies should consider recruiting individuals with low PA by using a screening questionnaire prior to a person consenting to the study. To further investigate whether the effect was down to the study population having diabetes, multiple interventions could be tested ^[202] or a specific intervention that is tailored to a specific chronic condition ^[60, 61, 63] as opposed to more generic based intervention as used in the present study.

The PA intervention had no effect on the diabetes related measures and therefore the sample population was combined. No differences were found in PA scores across the specified time-points when the sample was studied as a whole. The study showed that PA levels at baseline were predictive of DQOL satisfaction up to six months later independent of NA; however no associations were found between PA, HbA1c and healthy diet in people with diabetes.

In contrast to Chapter 4, the present study found no associations between HbA1c, PA and healthy diet. The relationship between diet and HbA1c was not anticipated as previous studies have shown that engaging in a healthy diet is associated with lower HbA1c ^[191]. Engaging in self-care activities is an integral part of the successful management of diabetes. Although, this study did not find any associations between PA and self-care practices, over 70% of people reported engaging in a healthy diet and therefore this level of adherence suggests that we may have recruited a more adherent group. Although, previous studies have not reported as high rates of adherence to diet, in comparison our findings are consistent with other studies on poor adherence rates to other self-care practices ^{[80] [132] [203]}.

The non significant associations found between PA, diet and HbA1c might indicate that the variability of these outcomes were restricted and therefore it would be difficult to detect an association. This is partly because of the small sample size and partly because the majority of respondents reported being more adherent, had higher PA scores and relatively good glycemic control.

We found that PA predicted DQOL satisfaction at 6 months. This result shows that even after controlling for baseline DQOL satisfaction, PA was predictive of DQOL satisfaction. This finding provides strong evidence that PA might contribute to better quality of life in terms of DQOL satisfaction in people with diabetes over time. Furthermore, this result was independent of NA and therefore provides further support that PA and NA are independent.

5.6.1 Limitations

There are several limitations to the methodology of this study which must be considered when interpreting the results of this study. Recruitment was a major limitation; at the time of planning this study, the required sample size was 64 people in each of the two conditions, however recruitment was very challenging. Between August 2009 and August 2010, only six participants were recruited and this was why additional PCTs were approached for approval. Although all GP surgeries and pharmacies were sent a letter regarding the study, the response rate was less than 1%. In addition, during the initial stages of recruitment, there was an outbreak of swine flu and thereafter severe weather became a hindrance. Many GP's and pharmacies quoted these as reasons for not participating. Despite this, some GP surgeries were willing to help, however, they requested that information should be sent out to eligible participants on their behalf as access to patient details was not authorised. For this to happen, an additional document was produced by the researcher which required NHS and R&D approval through a substantial amendment. In order to increase participant numbers, it was decided by the research team to (i) reduce the original study from 18 months to 6 months, (ii) reduce the number of outcome measures and (iii) get permission to approach potential participants at GP surgeries and take measurements on site. This amendment received approval on 23rd June 2010. For the reasons above, the anticipated sample size required for this study was not reached and therefore this will have reduced the power to detect significant associations. Furthermore, it is less likely to find significant relationships in the data especially when the effect sizes are small.

In addition, there was a substantial attrition rate such that of the forty participants who completed baseline measures, only twenty-six (65%) completed the entire study. It is possible that the final sample differed in some important way from the initial sample, however, individuals who dropped out of the study did not differ from those who remained in the study at baseline on any measured factors (all baseline characteristic $p > .05$).

Patients who had a psychological disorder that was mood related were excluded from the study. This was intentional, firstly because we did not want medication or

psychological treatments influencing the results and secondly we wanted to investigate the effects of the intervention first, on people with diabetes without depression.

This study shows that the intervention might not be effective in people with high PA. We did not anticipate seeing such high levels of PA, partly because in comparison to previous literature PA scores were much lower and partly because diabetes is a chronic condition, so although people might not have a psychological disorder, we assumed that their affect would be lower. Therefore based on these reasons we hypothesised that an intervention might have an effect on PA scores in people with diabetes.

There is evidence to suggest that the TGT intervention does alleviate depressive symptoms and therefore it will be interesting to extend this research by investigating a diabetes population that is depressed. Studies that have investigated diabetics with depression have shown to have significantly higher levels of HbA1c ($> 8\%$) [204, 205] which would address the issue of recruiting people who already have good glycaemic control.

Compliance to the PA intervention for the full seven days was not monitored and therefore we cannot confirm the effectiveness of the PA intervention. In an attempt to avoid on the Hawthorne effect [86], we did not want our study participants to think that because we were recording their behaviour, they were required to report in a certain way. On the contrary, individuals were informed about the study and understood that they would have to complete a written task for ten minutes for seven days and therefore if they were not prepared to commit to the study; it is likely that they would not have consented to the study.

To keep the burden of respondents to a minimum, the study did not measure other important variables that may have influenced the relationship. Adaptive factors such as coping strategies and social support may have a crucial role in the mediating the link between PA and diabetes measures, however the present study did not incorporate them. Despite this, it would have been difficult to carry out more complex analysis as the sample size was extremely small.

The study population represents a convenience sample of adults who were predominantly white British from 3 surgeries in Lewes. Therefore additional studies are needed to represent other diabetes populations as the intervention may have shown some effect. It might be interesting to recruit people with diabetes who have mild depression as the TGT intervention has shown to alleviate depressive symptoms. The prevalence of depression in people with diabetes is high and this can have a negative impact on diabetes management ^[91, 114].

5.7 Conclusion

The novelty of this randomised control study was evident in that it was the first to investigate a PA intervention (TGT) in a diabetes population and investigate outcomes such as HbA1c, self-care practices and quality of life. The study found that the TGT exercise did not affect PA scores over 6 months. In addition, no differences were found between the PA intervention and control groups in diabetes related measures.

This study was also able to analyse the relationship between PA and diabetes related-outcomes by following the sample population longitudinally and found that PA was only predictive of diabetes satisfaction up to six months. More investigation into the design of PA interventions is needed for people with diabetes.

In summary, this study has investigated the relationship between PA and health outcomes and the impact of a PA intervention. The results generated throughout this thesis will now be discussed in chapter 6 collectively with particular focus on the novel contributions and the future directions.

Chapter Six: General Discussion

The research conducted in this thesis fills a gap in existing knowledge because, despite there being a growing body of literature to suggest that PA is associated with better health outcomes in a number of chronic conditions ^[2, 9], there are no studies that have investigated a PA intervention in people with diabetes.

The original aims of this thesis were to test the stress-buffering hypothesis of PA using an experimental design, to test the association between PA and health outcomes in people living with diabetes, and to test the effectiveness of a simple intervention to improve PA in people with diabetes. This thesis contributes to the existing literature in three main ways:

- i. by testing the stress-buffering hypothesis using a experimental manipulation of PA
- ii. by investigating the association between PA and health-outcomes in people with diabetes
- iii. by investigating the efficacy of a PA intervention in both diabetes and non-diabetes populations on subjective and objective health outcomes

This chapter will now conclude as follows. It will summarise the main findings from each study and then it will discuss (i) the methodological limitations of the studies; (ii) the efficacy of PA interventions; (iii) the stress-buffering model of PA; (iv) the role of PA in people with diabetes; and finally (v) the implications and future directions of this research.

6.1 Summary of Main Findings

6.1.1 Impact of the TGT intervention on reactions to stress (Chapter 3)

The TGT intervention maintained PA levels after one week compared to the control group where they significantly decreased. The stress manipulation did elicit a stress response at visit one and visit two. No changes were observed in DBP/HR reactivity and DBP/HR recovery between the two visits. Differences were observed however in SBP reactivity over the two visits, but were not dependent on the PA intervention. SBP recovery was slower for individuals in the PA intervention group following the one week interval. No changes were found in how individuals perceived the stressfulness of the tasks between the two visits.

6.1.2 The relationship between PA and diabetes health outcomes (Chapter 4)

No direct association was found between PA and HbA1c. However, when analysed further, 'following a healthy diet', was found to moderate the relationship between PA and HbA1c such that PA predicted HbA1c in participants who reported not following a healthy diet but did not in people who did. Higher levels of PA were associated with lower levels of HbA1c in participants who reported not following a healthy diet. Additionally, individuals higher in PA were twice as likely to adhere to a healthy diet independent of exercise, avoiding high fat foods and instrumental coping. This relationship, however, was not independent of NA. Individuals who adhered to a healthy diet and avoided high fat foods had lower HbA1c. A significant relationship between PA and diabetes quality of life was found such that individuals higher in PA had better DQOL satisfaction and fewer diabetes related worries. Hierarchical regression analysis showed that the relationship between PA and DQOL satisfaction reached near significance independent of type of diabetes, age, BMI, marital status, NA, perceived stress, depression and smoking status, instrumental coping, attending support groups, DQOL diabetes worries and DQOL impact. PA levels moderated the relationship between perceived stress and DQOL impact.

6.1.3 Impact of a PA intervention in people with Diabetes (Chapter 5)

The PA intervention did not affect PA levels in participants with diabetes. There were no significant interaction effects of time and PA on diabetes related outcome measures indicating that the pattern of change in diabetes related outcome measures was the same for both the control group and the intervention group. In combining the sample population, PA predicted DQOL satisfaction up to 6 months after controlling for baseline DQOL satisfaction and NA. No link was found between PA, healthy diet and HbA1c.

6.2 Methodological Limitations

There are a number of limitations that need to be considered when interpreting the findings of these studies. Firstly, in Chapter 5, the actual sample size that was recruited at baseline for each group was 20. Post hoc power analysis showed that with an alpha set to .05 and 20 participants in each group, this study had 80% power to detect an effect size of $d = .91$. In contrast, Chapter 3 was adequately powered; however it still failed to detect an effect of the TGT intervention. In Chapter 4, the a priori sample size calculations specified a required sample size of 191. Post hoc power analysis showed that with an alpha set to .05 and with 147 participants who completed the questionnaire, this study had 80% power to detect an effect size of $d = .23$. For two of the diabetes related factors (HbA1c ($n = 87$) and DQOL social worries ($n = 57$)), this study had 80% power to detect an effect size of $d = .29$ and $d = .35$.

Recruitment was voluntary in all of the studies and this might have had some bearing on the type of person that would have participated. Participants that voluntarily take part in studies tend to be more motivated and interested in the study itself ^[3] which might explain why we saw high levels of PA in all of our studies.

The studies reported in Chapters 3 and 5 did not measure whether individuals completed the intervention tasks for the week. This was intentional, partly to avoid a Hawthorne effect where the study participants change their behaviour simply because they think that someone is watching them ^[86], and partly to mimic what might occur in primary

care setting where it would be difficult to follow up patients advised to follow a simple intervention. Additionally, knowledge that the note-books were to be collected may have increased attrition to the task or the study. The downside of this is that we cannot say for certain whether participants did complete the TGT intervention or not. However, individuals were asked whether everything was ok in completing the written tasks and in response, none of the participants reported having any problems.

Our studies utilised self-report questionnaires to measure behavioural and psychosocial factors as well as some physiological factors. Self-report measures can be criticised for being open to bias. To overcome this, only questionnaires that had demonstrated reliability and validity were used. We also tried to address this issue by measuring objective markers such as HbA1c which is known to correlate with better diabetes management. By introducing these measures, it meant that participants were asked to visit their local surgery thus increasing participant burden which might also explain the small sample size recruited in Chapter 5. We used the PANAS to measure PA independently from NA. Although this questionnaire has been criticised for memory recall and the influence of current mood state ^[9], the participant burden of other methods to measure PA such as Ecological Momentary Assessment (EMA) and Positive Emotional Style (PES) may impede the research. Furthermore, it cannot measure both PA and NA at the same time and therefore if we had used any of these methods we would have had to use another instrument to measure NA thus increasing participant burden.

Although it was our intention to investigate a causal link between PA and health outcomes, the PA intervention used in Chapters 3 and 5 did not increase PA. Nevertheless, we were still able to investigate two clear groups as opposed to performing a median split to compare high and low PA in Chapter 3 and in Chapter 5; we were able to investigate the effects of PA longitudinally in people with diabetes.

In Chapter 5, we recruited people from one specific area which meant recruitment was restricted to a sub population. As a consequence, we were unable to explore the effect of the intervention in a diverse population with diabetes.

6.3 Efficacy of Positive Affect Interventions

Chapters 3 and 5 provided novel contributions to the current literature through investigation of a PA intervention on diabetes related measures (HbA1c, self-care practices and quality of life) and also on cardiovascular measures (reactivity and recovery). Previous research has suggested that such interventions are beneficial in increasing well-being [3, 57, 58] and that well-being is linked to better health [2, 50]. Whilst there has been minimal research in demonstrating this link, no studies have been conducted in a diabetes population.

The findings from our studies suggest that a simple intervention administered alone was not effective in increasing PA. This contradicts previous research which has shown the same intervention to increase happiness and decrease depression for up to six months [57]. One explanation for this is that the high levels of PA seen in the samples for Chapters 3 and 5 may have dampened the efficacy of the TGT intervention. Therefore, as opposed to the results of the studies showing that TGT intervention is not effective in increasing PA, the results might indicate a “ceiling effect” where the scores are so high on the scale that there is little room for improvement. This would suggest that the TGT intervention may still be beneficial for individuals lower in PA.

Indeed, the TGT intervention was originally first tested in people who were mildly depressed [57] and significant improvements were found in levels of happiness and depression. Based on a ratio calculation, as the maximum score for the PANAS is 5 and for the Steen Happiness Scale (SHI) is 10, our study samples exhibited higher levels of PA (6.6) at baseline compared to the Seligman et al study where participants scored on average, 5.6 at baseline. In addition, Sin and Lyumbursky found in a meta-analysis of 4235 participants that people who were depressed experienced more increases in well-being and reductions in depression compared to people who were not depressed. They discuss this in relation to a possible “floor effect” where depressed people have more to gain from the intervention.

We used the PANAS to measure changes in PA and NA whereas; Seligman et al used the SHI to measure changes in happiness. The SHI is extremely sensitive to changes in happiness and this is highly probable because this questionnaire measures happiness

using a scale that ranges from extreme sadness to neutral to extreme happiness ^[14]. The PANAS however uses a ‘not at all’ to ‘extreme’ response format which is another reason to why we may have not seen an immediate effect.

An alternative explanation for the lack of effect found of the intervention is that the demographic of the samples used for the current studies differed in some important ways from the samples used in published studies finding an effect. For instance, Sin and Lyumbursky report that the benefits of positive interventions correlate with age such that older individuals are more likely to benefit more from PA interventions compared to the younger population. Thus we would expect the intervention to be less beneficial in a sample with a young mean age. However, the PA intervention did not affect our diabetes population who had a mean age of 65 years.

PA interventions promote positive feelings and behaviours, rather than directly focusing on the negative consequences. Interventions designed to increase PA have been associated with both physiological and psychological health measures ^[3, 60, 61, 63]. Individuals can vary in strengths, interests and preferences and therefore we must also appreciate that individuals might find certain interventions more effective than others and therefore more work is needed to see if PA interventions more generally can be effective on health outcomes.

6.4 The stress-buffering model

One of the original aims of this thesis was to test the stress-buffering model of PA ^[2]. According to the model, people with higher levels of PA respond better to stress and thus do not experience the negative health consequences that have been linked to stress ^[2]. Our studies extended previous research in two ways. Firstly, by testing the effect of a PA intervention on reactions to stress; and secondly, by testing the model in a diabetes population.

The results reported in Chapter 3, showed that following the intervention, participants who had been assigned to the TGT intervention had significantly higher levels of PA than those assigned to the control condition. Despite this, no significant differences

were observed between the groups in their reactivity to the stress task. This does not provide support for the stress-buffering model and contradicts other research which has shown people higher in PA to react better to stressful tasks [20, 24, 39, 42, 46, 48, 49]. These contradictions in findings may be due to variations in the measurements of PA or the tasks used to elicit stress. Steptoe et al found that EMA-derived measures of PA were associated with lower BP reactivity and more rapid recovery following a stress-task but PANAS-derived scores were not [46]. EMA-derived measures provide multiple measures of affect that are derived within or between days [9].

In chapter 4, we found that high levels of PA dampened the effect of perceived stress on diabetes quality of life impact. This subscale addressed questions such as “pain associated with treatment” “feeling physically ill” and general restrictions to daily life. A poor diabetes impact quality of life score might lead to poorer adherence to treatments which could potentially increase the risk of developing complications. We found that in people who had PA levels greater than 3, the relationship between stress and quality of life was less strong. This is interesting because the mean participants PA levels in all of the other studies were greater than 3 and therefore this might be a reason why we did not find a link between PA and certain health outcomes.

Overall, our studies failed to provide support for the stress-buffering model but this may be due to individuals participating in our studies having high levels of PA. Another explanation might be that in response to stress (Chapter 3), individuals perceived the tasks as a challenge as opposed to a threat. The broaden and build theory suggests that positive emotions such as joy and excitement have the ability to broaden a person’s thinking and as a result this would build resources such as positive psychosocial factors to overcome challenges [187]. The slower recovery found in SBP for people in the TGT group might suggest that it was because they had higher PA and therefore, reacting to the stressor as a challenge even though they were in the recovery period. It is possible that the slower recovery might be because of other factors, however if this was the case, then perceived stress scores at the end of the study could have possibly been higher.

6.5 Positive Affect and Diabetes Mellitus

The studies reported in Chapters 4 and 5 were among the first to investigate the relationship between PA and (i) HbA1c (ii) self-care practices and (iii) quality of life in people with diabetes. Furthermore, they contribute to existing knowledge by investigating the relationship between PA and (i) HbA1c and healthy diet (ii) DQOL satisfaction and (iii) diabetes related worries using a longitudinal study design in people with diabetes.

The main findings presented in Chapter 4 were not replicated in Chapter 5. The only exception was DQOL satisfaction where we found that PA reached near significance in predicting diabetes quality of life satisfaction in the cross-sectional study (Chapter 4) and predicted DQOL satisfaction up to 6 months in the longitudinal study (Chapter 5).

Studies have reported that individuals with diabetes have lower quality of life compared to the general population. Testa et al found that increases of HbA1c greater than 1% was linked to a decrease in quality of life ^[206]. Poor quality of life can lead to lack of engagement towards self-care practices which can then impact the management of the condition. Diabetes quality of life satisfaction was measured using the DQOL instrument and addressed issues such as satisfaction to sleep, flexibility, time spent exercising, social relationships and life in general. All of these items indicate how satisfied the individual is in managing their condition. The findings here support previous research that has demonstrated a link between PA and health related quality of life in other chronic conditions ^[207].

No association was found between PA and HbA1c in the present studies. This contradicts previous research that has established a link between the two in non-diabetic women ^[132]. As mentioned, throughout this discussion, PA levels were high among the participants for our studies compared to other published literature. Additionally HbA1c levels were relatively low in the diabetes samples and therefore the restricted variability in PA levels and HbA1c levels may explain the lack of relationship found between the two.

Tsenkova et al reported that the sample recruited for their study had HbA1c levels of 5.34% at baseline and found that PA was a significant predictor of lower HbA1c over two years ^[132]. In comparison, as expected, our samples mean HbA1c was higher (Chapter 5 = 7.32%), however we found no association between PA and HbA1c over time. Furthermore, Tsenkova et al also investigated coping strategies and found that PA moderated the relationship between problem focused coping strategies and HbA1c. However, our study (Chapter 4) showed no associations between coping style, PA and HbA1c. Generally, problem focused coping strategies have been linked with better adjustment and lower distress in people with diabetes ^[166, 184]. We discussed in our studies that PA showed no relationship with HbA1c because our samples had good glycemic control at baseline. However, Tsenkova et al ^[132], also report low levels of HbA1c in their sample and do report an association with PA. Factors that are more diabetes specific might impede HbA1c in people with diabetes such as type of diabetes, duration and treatment and medication regime. Indeed ‘following a healthy diet’ was found to moderate the PA/HbA1c relationship.

One final explanation for the lack of relationship found in a diabetes population is that the strength of the association between PA and health is less strong in diseased populations ^[30]. While previous literature has shown a link between PA and health ^[2], some studies suggest that the link may be stronger in healthy populations than diseased ones ^[30].

6.6 Implications and Future Research

Research has shown that PA can be beneficial in predicting better health outcomes ^[2, 9], however, many of these studies have investigated the relationship using both cross-sectional and longitudinal study designs. Pressman and Cohen proposed two theoretical models ^[2] linking PA to health (see Figures 1.1 and 1.2). Although, these models suggest a causal pathway, many studies fail to incorporate an experimental methodology. This thesis contributed to existing knowledge by attempting to design studies that could determine a causal link between PA and health outcomes in people with diabetes. The findings highlight that the link between PA and health outcomes

might not be seen in people who already exhibit high levels of PA. Based on this, our studies were unable to demonstrate causality, however future studies could potentially use our study design on different study populations incorporating a more extensive PA intervention. Furthermore, because of the high levels of PA seen in all of our studies, future studies should consider incorporating a screening questionnaire that assesses individuals PA scores and anyone above a certain affect level be excluded.

We did not measure compliance to the PA intervention; however, it would be beneficial to know whether participants actually completed the exercises, while allowing them to feel like they are not being judged. A possible solution might be to instruct individuals to complete the tasks online. An investigator can then monitor if they have completed the task without access to the written content.

Both of our diabetes studies were underpowered. To address the issue of recruitment, future studies should consider increasing the catchment area. For instance, by expanding the recruitment area, it will not only increase the sample population but more importantly it might increase the diversity of people that participate which unfortunately is where this study came short of.

Both of the diabetes studies were advertised to people with type 1 or type 2 diabetes. The prognosis and management of type 1 and type 2 diabetes differ and therefore future studies might want to consider only recruiting people with either type 1 or type 2 diabetes.

Chapters 3 and 5 used a PA intervention that was simple, cost effective and easy to implement. Diabetes is a chronic condition that involves a complex treatment regime and therefore the objective was to use a PA intervention that does not add to the burden of the condition. However, the results of that study highlighted that the PA intervention might need to be tested in diabetics with low PA or that it might need to be more specifically tailored. For instance, Charlson et al designed a PA intervention that was based on quantitative and qualitative methodologies^[59]. The methodology incorporated both self affirmation and positive affect and this showed favourable effects in people with a chronic condition^[59]. It would be interesting to recruit people with diabetes and follow Charlson et al methodology^[59].

Chapters 3 and 5 excluded people who had a psychological disorder that was mood related. This was intentional, firstly because we did not want medication or psychological treatments influencing the results and secondly we wanted to investigate the effects of the intervention first, on people with diabetes without depression. This thesis has demonstrated that the intervention might not be effective in people with high PA. We did not anticipate seeing such high levels of PA, partly because in comparison to previous literature PA scores were much lower and partly because diabetes is a chronic condition, so although people might not have a psychological disorder, we assumed that their affect would be lower. Therefore based on these reasons we hypothesised that an intervention might have an effect on PA scores. There is evidence to suggest that the TGT intervention does alleviate depressive symptoms and therefore it will be interesting to extend this research by investigating a diabetes population that is depressed. Studies that have investigated diabetics with depression have shown to have significantly higher levels of HbA1c ($> 8\%$)^[204, 205] which would address the issue of recruiting people who already have good glycaemic control.

Although not inevitable, the onset of diabetes complications is not foreseen at the start and individuals are more likely to develop complications as the condition progresses, therefore quality of life might worsen as the duration increases. Our studies found that PA is predictive of DQOL satisfaction up to six months and therefore future studies might want to investigate patients who have diabetes complications and see whether PA buffers the relationship between quality of life and complications. People who have developed complications are more likely to have lower quality of life but if PA buffers this relationship, it can potentially reduce cost as people higher in PA should be more satisfied with their diabetes and therefore are more likely to physically feel better and motivated to look after themselves compared to people who have low PA.

Chapter 3 used a laboratory stressor to elicit a stress response in healthy participants. Goetsch et al investigated blood glucose levels in responses to laboratory stressors in people with diabetes^[208]. This study recruited 22 individuals with diabetes and 9 people without diabetes. The results of this study found significant increases in blood glucose levels in response to stress compared to people without diabetes, however this study did not measure mood and in particular PA. With growing evidence suggesting

that PA is linked to biological measures in response to stress, future studies might want to investigate whether PA dampens the effect of stress on blood glucose levels in people with diabetes.

The Positive Affect and Negative Affect Schedule (PANAS) is a widely used instrument and it was used in this thesis to measure PA independently from NA. The method in which PA is measured as well as the independence of PA and NA has come under some scrutiny (see section 2.1.1), however the PA intervention used in this thesis supported that PA and NA are independent using the PANAS. For instance, in Chapter 3, we were able to conclude that the PA intervention affected PA scores but not NA scores after the one week interval (see figures 3.2 and 3.3). It is important that the current literature does investigate the PA independently from NA as it highlights and provides a strong basis that PA is not the bipolar opposite but an independent dimension in predicting favourable health.

6.7 Conclusion

The objective of this research was to contribute to the existing literature by investigating the role of PA in people with diabetes. The randomised control studies that were implemented in this thesis were amongst the first to use an intervention designed to increase PA and investigate the impact on health outcomes such as HbA1c, self-care practices, quality of life and CV reactivity and recovery.

The results of this thesis found that the TGT intervention might not be as effective in people with high PA and therefore to test efficacy of the TGT intervention on health outcomes further, people who exhibit lower levels of PA or who exhibit depressive symptoms should be recruited.

The results also showed that PA might be linked to better diabetes-related outcomes (healthy eating and diabetes quality of life) but not to CV reactivity and recovery. The relatively high levels of PA seen in volunteers participating in these studies may have influenced the results.

The role of PA in health outcomes is an interesting area of research that is evolving. However, as much of the literature is based on studies that are cross-sectional or prospective in design, a shift towards the set up of experimental study designs, as demonstrated in this thesis, needs to be implemented to investigate the causal link between PA and health outcomes.

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Appendices

Appendix A: Ethical Approval Letter and Supporting Documents for Chapter 3



Participant Identification Number: _____

Consent Form

Name of Research Study: An Investigation in Positive Psychology and Cardiovascular Function

Name of Researcher: Meenal Patel

Please initial/tick box

I confirm that I have read and understood the information provided, have had the opportunity to ask questions and have had these answered satisfactorily

I understand that I will be invited to the University of Brighton at the beginning of the study and again after one week. At each visit I understand that the research student or her supervisors will measure my blood pressure, heart rate, weight and height.

I understand that I will have to complete a written exercise for 7 days

I understand that I will be asked to complete specific tasks during my visit.

I understand that I will have to answer various questionnaires about mood state.

I agree to the use of anonymous data in reports and publications

I understand that if I wish not to continue with this study, I am free to withdraw at any time using the contact details provided below; no reason for this decision will be requested. I can request for my data to be destroyed, however once the study has finished and personal details are no longer required and therefore have been destroyed, I understand that I will not be able to withdraw my data from the study

I agree to take part in the study

Participants Name

Date

Signature

Researchers Name

Date

Signature

When completed, photocopy will be given to participant; hard copy for researcher file.

Appendix B: Ethical Approval Letter and Supporting Documents for Chapter 4



pabs.ethics@bton.ac.uk

8th September 2010

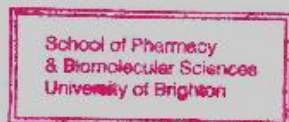
PABSREC APPLICATION 0938

Project title: "You and Your Diabetes Online Study"

Investigator name(s): Meenal Patel

Name of Supervisor (s): Dr Sian Williams and Dr Moira Harrison

The School Ethics Committee has approved the above application.



Yours sincerely

A handwritten signature in black ink, appearing to read "Anne Jackson".

Dr Anne Jackson

Chair, School of Pharmacy and Biomolecular Sciences Research Ethics Committee.

pp

Table 6.1 Correlational matrix of main results

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	
1. PA (n = 138)	-																									
2. NA (n = 137)	-.22**	-																								
3. PSS (n = 146)	-.43**	.69**	-																							
4. Active Coping (n = 145)	.19*	.01	-.04	-																						
5. Instrumental Coping (n = 145)	.23**	.08	-.01	.63**	-																					
6. Total Complications (n = 145)	.01	.01	-.04	.19*	.02	-																				
7. HbA1c (n = 87)	-.10	-.13	-.03	-.01	-.20	-.04	-																			
8. Healthy Diet (n = 147)	.23**	-.12	-.13	.15	.21**	.02	-.29**	-																		
9. Specific Diet (n = 147)	.09	.05	-.02	.19*	.26**	.07	-.30**	.42**	-																	
10. Exercise (n = 147)	.06	.08	.00	.29**	.15	-.06	-.12	.23**	.26**	-																
11. Glucose testing (n = 147)	.11	-.03	.02	.1	.18*	.08	.17	.03	.07	.27**	-															
12. Feet checks (n = 147)	.08	.07	.05	.06	.11	-.01	-.07	.14	.07	.04	-.04	-														
13. Smoking (n = 128)	.09	-.12	-.21*	.02	.13	.05	.01	.05	.14	.04	.08	.13	-													
14. DQOL satisfaction (n = 147)	.37**	-.56**	-.53**	.07	.19*	-.10	-.07	.15	.14	.05	-.03	.03	.19*	-												
15. DQOL Impact (n = 145)	.10	-.46**	-.34**	-.10	.12	-.19*	-.08	.07	.05	-.002	-.19*	-.05	.03	.54**	-											
16. DQOL Social Worries (n = 127)	.16	-.63**	-.62**	.001	-.08	-.11	-.06	.16	.07	-.10	-.21	.23	.20	.45**	.54**	-										
17. DQOL Diabetes worries (n = 57)	.18*	-.46**	-.42**	-.04	-.01	-.19*	-.13	.09	-.03	.01	-.25**	-.02	.13	.60**	.66**	.59**	-									
18. BMI (n = 132)	-.14	.11	.20*	-.07	-.14	.06	-.13	-.13	.07	-.19*	-.19*	.12	-.11	.42**	-.05	.19	-.11	-								
19. Marital status (n = 144)	-.25**	.25**	.25**	.002	-.10	.01	-.05	-.05	-.05	.03	-.24**	.04	-.11	-.29**	-.09	-.51**	-.09	.09	-							
20. Depression diagnosis (n = 137)	.09	-.36**	-.38**	-.09	-.09	-.12	.05	-.03	-.10	.03	-.04	.02	.14	-.19*	.20*	.44**	.16	.17	.15	-						
21. Alcohol (n = 110)	-.13	-.10	-.10	-.07	-.09	-.04	.24	-.12	-.30**	-.01	.05	.03	.01	.18*	-.08	-.05	-.06	-.23*	-.05	.17	-					
22. Type of diabetes (n = 144)	-.06	-.01	.08	.04	-.08	-.07	-.28**	.11	.12	-.14	-.54**	.13	-.02	-.11*	.21*	.25	.24**	.30**	.01	.17	-.08	-				
23. Education Course (N/Y) (n = 131)	-.07	.19*	.22*	.14	.12	-.04	-.14	-.12	.02	.01	-.08	.10	.02	-.05	-.06	-.05	-.04	.14	.08	.11	.08	.10	-			
24. Attend support group (N/Y) (n = 131)	.11	-.19	-.14	.28**	.20*	.21*	.06	.07	.15	.09	.13	.04	.10	.30**	.28**	.25	.23*	-.08	-.18*	-.05	-.07	.08	.22*	-		
25. Gender (F/M) (n = 141)	.04	-.22*	-.22**	-.07	-.05	.05	.18	-.18*	-.18	-.04	-.02	.02	-.06	.08	-.09	.19	.01	-.18*	-.04	.17*	-.13	-.16	-.12	-.17	-	
26. Age (n = 140)	.12	-.31**	-.32**	.12	-.004	.32**	-.08	.10	.07	-.08	-.21*	.10	.17	.38**	.38**	.61**	.41**	-.04	-.13	.02	.38**	.42**	.09	.52**	-.03	

Note r/ρ = Figures here represent either the r or ρ statistic as some of the data was not normally distributed. ** $p < .001$ * $p < .05$. n = number of participants

Thank you for showing an interest in this study. If you decide to complete this survey you can be automatically put into a draw for a chance to win an IPOD touch.

This survey will take approximately 20 minutes to complete and it is designed to measure how you feel about your diabetes. It also includes some general questions about yourself and your diabetes care. Your answers will not be judged in any way or affect your care. You can miss out any questions that you do not wish to answer. All information about you will be anonymous and will be handled in confidence and will be kept in a secure place.

If you feel that when completing the questionnaire you no longer would like to take part then please press "Exit this survey" which is on the right hand corner of each page. In doing this, your answers will not be used for this study.

I would like to thank you for your time and hope that you are still interested in taking part.

Best Wishes

Meenal Patel

1. What type of diabetes do you have

- Type 1 diabetes
- Type 2 diabetes
- Gestational diabetes

2. How many years ago were you diagnosed with diabetes

- 0-2 2-5 5-10 10-20 20-30 30+

3. What treatment are you currently taking to control your diabetes

- Diet and Exercise
- Oral Medication
- Insulin
- Oral Medication and Insulin

4. Are you currently taking medication prescribed by a doctor to lower your blood pressure?

- Yes
- No

5. Are you currently taking medication prescribed by a doctor to lower your cholesterol?

- Yes
- No

6. Are you currently taking a daily low dose of Aspirin (75mg)

- Yes
- No

7. Your doctor probably takes a blood sample from you to measure your HbA1C. This test gives you and your doctor an indication on how well you are controlling your diabetes.

If you know or can find out your most recent HbA1c result please write it below.

8. Please can you list all medication/insulin you are currently taking.

Please tell us the name, dosage and frequency (eg Metformin, 500mg, 2xdaily)

Name of Medication	
Dosage	
Frequency	
Name of Medication	
Dosage	
Frequency	
Name of Medication	
Dosage	
Frequency	
Name of Medication	
Dosage	
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Name of Medication	
Dosage	
Frequency	
Name of Medication	
Dosage	
Frequency	
Name of Medication	
Dosage	
Frequency	
Name of Medication	
Dosage	
Frequency	
Name of Medication	
Dosage	
Frequency	
Name of Medication	
Dosage	
Frequency	

Frequency

1. Have you ever had any of the following conditions?

- Heart Disease
- Diabetic ketoacidosis
- Cancer
- Angina
- Eye Trouble (cataracts)
- Osteoporosis
- Heart Attack
- Any other Eye problems
- Asthma and respiratory diseases
- Stroke
- Thyroid Dysfunction
- Arthritis
- Congestive Heart Failure
- Nerve damage
- HIV
- Hypertension
- Amputation from foot disease
- Back pain
- Hypercholesterolemia (high cholesterol)
- Hypoglycaemia (low blood sugar)
- Alzheimer's disease
- Kidney Disease
- Erectile dysfunction

Other Medical Conditions (please specify)

2. Mental Health

	Yes	No	NA
Have you been diagnosed with depression	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If you answered yes - are you taking medication for depression	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If you answered yes - please can you write the name of the medication	<input type="text"/>		

1. The questions below ask you about your diabetes self-care activities during your last 7 consecutive days you were not sick.

How many of the last SEVEN DAYS did you

	0	1	2	3	4	5	6	7
follow a healthy eating plan?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
eat five or more servings of fruit and vegetables?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
test your blood sugar?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
test your blood sugar the number of times recommended by your health care provider?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
eat high fat foods such as red meat or full fat dairy products?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
check your feet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
inspect the inside of your shoes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. On average, over the past month, how many DAYS PER WEEK

	0	1	2	3	4	5	6	7
have you followed your eating plan?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Have you smoked a cigarette - even one puff during the past SEVEN DAYS?

- Yes
- No






4. If yes, how many cigarettes did you smoke on an average day? Number of cigarettes

5. Do you ever drink alcohol?

- No – Please go to question 6
- Yes – please complete the additional questions below

6. How often do you have a drink that contains alcohol?

- Monthly or less
- 2 to 4 times per month
- 2 to 3 times per week
- 4+ times per week

				
Pint of regular beer/lager/cider = 2 units	Alco pop or can of lager = 1.5 units	Glass of wine (175ml) = 2 units	Single measure of spirits = 1 unit	Bottle of wine = 9 units

7. How many UNITS of alcohol do you drink on a typical day when you are drinking?

1 to 2
 3 to 4
 5 to 6
 7 to 8
 9 to 10
 11+

8. The scale consists of a number of words that describe different feelings and emotions. Read each word and then click the appropriate answer next to that word. Indicate to what extent you felt this way in general. Use the following scale to record your answers.

	Very slightly or not at all	A little	Moderately	Quite a bit	Extremely
Interested	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Distressed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Excited	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Upset	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strong	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Guilty	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Scared	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hostile	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Enthusiastic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Proud	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Irritable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Alert	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ashamed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Inspired	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nervous	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Determined	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Attentive	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Jittery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Active	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Afraid	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

9. Please read each statement carefully. Please indicate how satisfied or dissatisfied you currently are with the aspect of your life described in the statement. There are no right or wrong answers to these questions. We are interested in your opinion.

How satisfied are you with

	Very Satisfied	Moderately Satisfied	Neither	Moderately dissatisfied	Very dissatisfied
the amount of time it takes to manage you diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the amount of time you spend getting checkups?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the amount of time it takes to determine your sugar levels?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your current treatment?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the flexibility you have in your diet?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the burden your diabetes is placing on your family?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the knowledge about your diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your sleep?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your social relationships and friendships?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your sex life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your work, school, and house hold activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the appearance of your body?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
the time you spend exercising?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your leisure time?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
life in general?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. How often do you

	Never	Very Seldom	Sometimes	Often	All of the Time
feel pain associated with the treatment of your diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
embarrassed by having to deal with your diabetes in public?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
feel physically ill?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
feel good about yourself?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
feel restricted by your diet?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
feel that because of your diabetes you go to the toilet more than others?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
feel teased because you have diabetes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
have low blood sugar?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
have a bad night's sleep?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
find your diabetes limiting your social relationships and friendships?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
miss work, school, or household duties because of your diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
find yourself explaining what it means to have diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
that your diabetes interrupts your leisure-time activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
tell others about your diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
find that you eat something you rather shouldn't rather than tell someone you have diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
hide from others that you are having an insulin reaction?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

11. How often does your diabetes

	Never	Very Seldom	Sometimes	Often	All of the Time
interfere with your family life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
interfere with your sex life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
keep you from driving a car or using a machine? (e.g., a type writer)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
interfere with your career?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

12. Please indicate how often the following events happen to you. Please select the option that best describes your feelings. If the question is not relevant to you, select "does not apply"

How often do you worry about whether you will

	Never	Very Seldom	Sometimes	All the time	Does not apply
get married?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
have children?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
not get a job you want?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
be denied insurance?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
be able to complete your education?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
miss work?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
be able to take a vacation or a trip?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
pass out?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
get complications from your diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

13. How often do you worry

	Never	Very Seldom	Sometimes	All the time	Does not apply
that your body looks differently because you have diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
about whether someone will not go out with you because you have diabetes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

14. The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate by selecting how often you felt or thought a certain way.

In the last month, how often have you

	Never	Almost Never	Sometimes	Fairly Often	Very Often
been upset because of something that happened unexpectedly?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
felt that you were unable to control the important things in your life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
felt nervous and "stressed"?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
felt confident about your ability to handle your personal problems?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
felt that things were going your way?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
found that you could not cope with all the things that you had to do?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
been able to control irritations in your life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
felt that you were on top of things?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
been angered because of things that were outside of your control?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
felt difficulties were piling up so high that you could not overcome them?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

15. Please indicate how you usually deal with the statements described below

	I usually don't do this at all	I usually only do this sometimes	I usually do this fairly often	I usually do this alot
I concentrate my efforts on doing something about my diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I take action to try and make my diabetes better.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I try to get advice or help from other people about what to do about my diabetes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I receive help and advice about my diabetes from other people.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

16. Have you attended an NHS educational programme (for example DESMOND)?

Yes

No

17. Do you attend any support groups on a regular basis

Yes

No

We would really appreciate it if you could please answer the following questions. All data will be strictly confidential.

1. Please complete the following

City/Town:

Country:

2. Gender

Male

Female

3. What is your age (years)

4. What is your height (feet/inches OR cm)

feet inches cm

Height

5. What is your weight (stones/pounds OR kg)

stones pounds kg

Weight

6. Are you currently

married civil partnership

separated

widowed

single

divorced

cohabitating

7. What educational qualifications do you have? Please tick all that apply

GCSEs / O-levels

A-levels

Degree

Postgraduate qualification

No qualifications

Other (please specify)

8. Is your home

- Owned - with a mortgage to pay
- Owned – with no mortgage to pay
- Rented from council
- Rented from private landlord

Other (please specify)

9. Ethnic Origin

- | | | |
|--|---|--|
| <input type="checkbox"/> White | <input type="checkbox"/> Other mixed background | <input type="checkbox"/> African |
| <input type="checkbox"/> White British | <input type="checkbox"/> Asian or Asian British | <input type="checkbox"/> Other Black background |
| <input type="checkbox"/> Irish | <input type="checkbox"/> Indian | <input type="checkbox"/> All Black groups |
| <input type="checkbox"/> Other White background | <input type="checkbox"/> Pakistani | <input type="checkbox"/> Chinese or Other Ethnic Group |
| <input type="checkbox"/> All white groups | <input type="checkbox"/> Bangladeshi | <input type="checkbox"/> Chinese |
| <input type="checkbox"/> Mixed | <input type="checkbox"/> Other Asian background | <input type="checkbox"/> Other ethnic group |
| <input type="checkbox"/> White and Black Caribbean | <input type="checkbox"/> All Asian groups | <input type="checkbox"/> All Chinese or Other Groups |
| <input type="checkbox"/> White and Black African | <input type="checkbox"/> Black of Black British | <input type="checkbox"/> All Ethnic Groups |
| <input type="checkbox"/> White and Asian | <input type="checkbox"/> Caribbean | |

Thank you for completing this online questionnaire. To show our appreciation you have a chance to win an IPOD touch. For more details please see below.

Thank you for your time

Best Wishes

Meenal

1. If you would like to be entered into this draw, please can you give us either your email address or telephone number so we can contact you if you win.

Please note that this information will be stored separately from the responses you have made in this questionnaire.

Email Address:

Phone Number:

Appendix C: Ethical Approval Letter and Supporting Documents for Chapter 5

NHS
National Research Ethics Service
Brighton East Research Ethics Committee
 NHS Brighton & Hove
 1st Floor, Prestamex House
 171-173 Preston Road
 Brighton
 East Sussex
 BN1 6AG
 Telephone: 01273 545373
 Facsimile: 01273 545372

25 June 2009

Miss Meenal Raj Patel
 MPhil/PhD Student
 University of Brighton
 PABS University of Brighton
 C801 Cockcroft Building, Lewes Road
 Brighton
 BN2 4BJ

Dear Miss Patel

Study Title: An investigation of a positive psychology intervention in people living with diabetes
REC reference number: 09/H1107/51
Protocol number: 2.0

Thank you for your letter of 18 June 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

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

Confirmation of ethical opinion

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

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

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

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

This Research Ethics Committee is an advisory committee to South East Coast Strategic Health Authority
 The National Research Ethics Service (NRES) represents the NRES Directorate within
 the National Patient Safety Agency and Research Ethics Committees in England

Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

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

Approved documents

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

Document	Version	Date
Participant Consent Form	3.0	25 June 2009
Participant Information Sheet	3.0	25 June 2009
Covering Letter		17 March 2009
CV of Dr Williams		17 March 2009
Investigator CV		16 March 2009
Letter to Doctors	1.0	16 March 2009
Participant invitation letter to University	1.0	
Evidence of indemnity		04 June 2008
Letter from Sponsor		16 March 2009
Participant end of study letter	1.0	16 March 2009
Participant instruction letter for questionnaire	1.0	16 March 2009
Profile of Mood state	1.0	16 March 2009
Diabetes - Quality of Life	1.0	16 March 2009
Centre for epidemiological studies - Depression scale	1.0	16 March 2009
Positive psychology and diabetes	1.0	16 March 2009
Poster	1.0	16 March 2009
You and your diabetes questionnaire	1.0	16 March 2009
Letter from Professor Andrew Church		16 March 2009
Application		17 June 2009
Protocol	2.0	16 May 2009
Presentation to participants	2.0	16 May 2009
Controlled letter to participants	2.0	16 May 2009
Invitation letter to participants	2.0	16 May 2009
Intervention letter to participants	2.0	16 May 2009
Subjective Well-being	2.0	16 May 2009
The summary of diabetes self care activities	2.0	28 April 2009
Response to Request for Further Information		18 June 2009

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

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

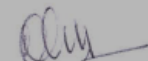
- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H1107/51**Please quote this number on all correspondence**

Yours sincerely



Dr Paul Seddon
Chair

Email: nischinth.cherodian@bhcpcct.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: Miss Hilary Ougham
University of Brighton, Registry
Mithras House, Moulsecoomb,
Brighton
BN2 4AT

NHS Brighton and Hove



Sussex NHS Research Consortium

Research Consortium Office
Worthing Hospital
Lyndhurst Road
Worthing
West Sussex
BN11 2DH

Tel: 01903 285027
Fax: 01903 209884
www.sxrc.nhs.uk

Miss Meenal Patel
MPhil/PhD Student
University of Brighton
PABS University of Brighton
C801 Cockcroft Building
Lewes Road
Brighton
BN2 4GJ

27/08/2009

Dear Miss Patel,

Our ID: 1245/NOCI/2009

TITLE: An investigation of a positive psychology intervention in people living with diabetes.

Thank you for your application to the Sussex NHS Research Consortium for research governance approval of the above named study.

I am pleased to inform you that the study has been approved, and so may proceed. This approval is valid in the following Organisations:

- Brighton & Hove City tPCT

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

- NHS R&D Form (submission code: 12832/53193/14/90)
- SSI Form (submission code: 12832/53377/6/267/21223/147530)
- Protocol, version 2.0 (dated 16/05/2009)
- Depression Scale, version 1.0 (dated 16/03/2009)
- Diabetes Quality of Life, version 1.0 (dated 16/03/2009)
- Subjective Well-being, version 2.0 (dated 16/05/2009)
- The Summary of Diabetes Self Care Activities, version 2.0 (dated 28/04/2009)
- You and Your Diabetes Questionnaire, version 1.0 (dated 16/03/2009)
- Leaflet, version 1.0 (dated 16/03/2009)
- Poster, version 1.0 (dated 16/03/2009)
- Intervention Letter for Participants, version 2.0 (dated 16/05/2009)
- Controlled Letter for Participants, version 2.0 (dated 16/05/2009)
- Participant Information Sheet, Version 3.0 (dated 25/06/2009)
- Participant Consent Form, version 3.0 (dated 25/06/2009)
- Invitation Letter to Participants, version 2.0 (dated 16/05/2009)
- Participant Invitation Letter to University, version 1.0 (dated 16/03/2009)
- Participant End of Study Letter, version 1.0 (dated 16/03/2009)
- Presentation to Participants, version 2.0 (dated 16/05/2009)
- Letter to Doctors, version 1.0 (dated 16/03/2009)
- Indemnity certificate (unsigned, dated 17/07/2009)
- CV for Meenal Raj Patel (signed and dated 30/07/2009)
- Confidentiality agreement between researcher and Stanford Medical Centre (signed and dated 10/06/2009)



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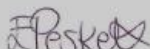
- Confidentiality agreement between researcher and Charter Medical Centre (signed and dated 22/06/2009)
- Confidentiality agreement between researcher and The Haven Practice (signed and dated 25/06/2009)
- Confidentiality agreement between researcher and St Peter's Medical Centre (signed and dated 29/06/2009)
- Confidentiality agreement between researcher and Ardingly Court Surgery (signed and dated 02/07/2009)
- Sponsor letter (signed and dated 16/03/2009)
- University of Brighton Ethical Approval (signed and dated 16/03/2009)
- Brighton East REC provisional opinion letter (signed and dated 15/04/2009)
- Brighton East REC approval letter (signed and dated 25/06/2009)
- Brighton East REC acknowledgement of non-substantial amendment (signed and dated 17/08/2009)

Your research governance approval is valid providing you comply with the conditions set out below:

1. You commence your research within one year of the date of this letter. If you do not begin your work within this time, you will be required to resubmit your application.
2. You notify the Consortium Office should you deviate or make changes to the approved documents.
3. You alert the Consortium Office by contacting me, if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction.
4. You complete and return the standard annual self-report study monitoring form when requested to do so at the end of each financial year. Failure to do this will result in the suspension of research governance approval.
5. You comply fully with the Department of Health Research Governance Framework, and in particular that you ensure that you are aware of and fully discharge your responsibilities in respect to Data Protection, Health and Safety, financial probity, ethics and scientific quality. You should refer in particular to Sections 3.5 and 3.6 of the Research Governance Framework.
6. You ensure that all information regarding patients or staff remains secure and strictly confidential at all times. You ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice, Data Protection Act and Human Rights Act. Unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

Good luck with your work.

Yours sincerely,



Miss Emma Peskett
Research Governance Officer

Email: emma.peskett@wsht.nhs.uk
Tel: 01903 285222 Ext 4781
Fax: 01903 209884



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Miss Meenal Patel
MPhil/PhD Student
University of Brighton
PABS University of Brighton
C801 Cockcroft Building
Lewes Road
Brighton
BN2 4GJ

23/06/2010

Dear Miss Patel,

Our ID: 1245/NOCI/2009

TITLE: An investigation of a positive psychology intervention in people living with diabetes.

Further to the initial study approval letter on 9th January 2010, a substantial amendment has been received for research governance review and approval.

I am pleased to inform you that the substantial amendment has been approved, and so may proceed. This approval is valid in the following Organisations:

- **NHS Brighton and Hove**
- **NHS West Sussex**
- **NHS Hastings and Rother**
- **NHS East Sussex Downs and Weald**

The final list of substantial amendment documents reviewed and approved is as follows:

- Notice of Substantial amendment form (amendment 3) (unsigned and undated, received 21/06/2010)
- Brighton East REC amendment approval letter (signed and dated 07/06/2010)
- Protocol (version 3, dated 10/05/2010)
- Participant Information Sheet (version 6, dated 03/06/2010)
- Consent Form (version 3, dated 10/05/2010)
- Leaflet (version 3, dated 10/05/2010)

Your research governance approval is valid providing you comply with the conditions set out below:

1. You commence your research within one year of the date of this letter. If you do not begin your work within this time, you will be required to resubmit your application.
2. You notify the Consortium Office should you deviate or make changes to the approved documents.
3. You alert the Consortium Office by contacting me, if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction.
4. You complete and return the standard annual self-report study monitoring form when requested to do so at the end of each financial year. Failure to do this will result in the suspension of research governance approval.
5. You comply fully with the Department of Health Research Governance Framework, and in



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particular that you ensure that you are aware of and fully discharge your responsibilities in respect to Data Protection, Health and Safety, financial probity, ethics and scientific quality. You should refer in particular to Sections 3.5 and 3.6 of the Research Governance Framework.

6. You ensure that all information regarding patients or staff remains secure and strictly confidential at all times. You ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice, Data Protection Act and Human Rights Act. Unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

Good luck with your work.

Yours sincerely,



Mrs Helen Vaughan
Senior Research Governance Officer

Email: helen.vaughan@wash.nhs.uk
Tel: 01903 285222 x 4190
Fax: 01903 209884



Participant Identification Number: _____

Consent Form

Name of Project: The Investigation of Positive Psychology in Diabetes

Name of Researcher: Meenal Patel

Please initial box

I confirm that I have read and understood the information sheet provided, have had the opportunity to ask questions and have had these answered satisfactorily

I understand that I will be invited to the University of Brighton at the beginning of the study and then at 3 months and 6 months. At each visit I understand that the research student or her supervisors will measure my blood pressure, weight and height. I also understand that at each visit I will give a finger prick samples to measure HbA1c.

I understand that relevant sections of my medical notes and data collected during the study may be looked at by the research student and her supervisors from the University of Brighton. Also the regulatory authorities and the NHS trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

I understand that I will have to answer various questionnaires about mood state in particular happiness, quality of life and behaviour.

I agree to the use of data and anonymous quotes in reports and publications

I understand that if I wish not to continue with this study, I am free to withdraw at any time using the contact details provided below; no reason for this decision will be requested. I can request for my data to be destroyed.

I agree to take part in the study described

Participant's Name

Date

Signature

Researcher's Name

Date

Signature

When completed, one copy for participant; one copy for researcher file.

Appendix D: Presentation of Research

EXTERNAL

Poster Presentation: Investigating the impact of a positive affect intervention on cardiovascular responses to acute laboratory stress (March 14th 2013).

Diabetes UK Professional Conference 2013: *The Future of Diabetes: Putting Evidence into Practice*. Manchester Central Convention Complex, Manchester, 13th - 15th March 2013

Poster Presentation: Investigating the relationship between positive affect and health outcomes in people living with diabetes (March 8th 2012).

Diabetes UK Professional Conference 2012: *Diabetes: Overcoming Hurdles, Achieving Success*. Scottish Exhibition and Conference Centre (SECC), Glasgow, 7th - 9th March 2012

Poster presentation: Is Positive Affect related to Health Outcomes in People Living with Diabetes? (September 16th 2011).

British Psychological Society, Division of Health Psychology Annual Conference & Silver Jubilee. Southampton University, 14-16th September 2011.

INTERNAL

Presentation: Diabetes and Health Outcomes: The Role of Positive Affect (25th June 2012)

University of Brighton Doctoral College: The 1st Faculty of Science and Engineering Post- Graduate Research Student Conference. *The Impact of Your Research*, 25th – 26th June 2012.

Presentation: Positive Psychology and Diabetes (23rd April 2010)

Spring Festival of Social Sciences and Humanities, University of Brighton, Hastings Campus (23rd April 2010).

OTHER

Although these were not conferences (i.e. no abstracts were required) – the work was still presented

Presentation: Diabetes Module: Research presented to University of Brighton, final year pharmacy students (28th March 2011)

Presentation: Burgess Hill and District Diabetes Support Group (24th Feb 2010).

Poster: University of Brighton Researchers' Poster Competition (27th Dec 2009)

ATTENDANCE ONLY

UK Society for Behavioural Medicine 7th Annual Scientific Meeting: *Motivating, enabling and prompting behaviour change for health*. University of Sterling, 13th -14th December 2011.

Diabetes UK Professional Conference 2011: *One step ahead: meeting future challenges in diabetes*. International Convention Centre (ICC) London ExCeL, 30th March – 1st April 2011

Diabetes UK Professional Conference 2010: *Diabetes: Challenges in all ages*. Arena and Convention Centre (ACC) Liverpool, 3rd - 9th March 2010