Development and evaluation of an ACT-based lifestyle education intervention for patients with pre-diabetes: A randomised controlled trial

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Abstract

Type 2 diabetes is a potentially debilitating health condition, and rising prevalence rates of both diabetes and pre-diabetes (the precursor to diabetes) globally and in New Zealand has made prevention an important research focus. Early research indicated dramatic reductions in modifiable diabetes risks factors through the provision of lifestyle education interventions for those with pre-diabetes. However, the time and resource intensive nature of these interventions presented challenges for their implementation, and studies employing briefer more pragmatic interventions produced less compelling results. Incorporating a psychological component into lifestyle education interventions has been highlighted as a possible avenue for enhancing outcomes. This thesis describes the development/adaptation of two intervention approaches for patients with pre-diabetes; lifestyle education alone and lifestyle education combined with Acceptance and Commitment Therapy (ACT). The goal of the ACT/Education approach was to connect participants' lifestyle goals to personally meaningful values, and equip them with skills to deal with difficult emotions that can function as barriers to goal attainment. A randomised controlled design was used to compare the effectiveness of these approaches with the provision of standard medical care. Results indicated the presence of significant cumulative intervention effects over time for HbA1c, BMI, waist circumference, saturated fat intake, life satisfaction, anxiety, and pre-diabetes knowledge; and education alone was more effective than standard care for reducing total cholesterol and waist circumference. However, results indicated that incorporating an ACT approach was no more beneficial than education alone or standard care across any of the outcome measures. Limitations related to statistical power, participant characteristics and methodology makes definitive

interpretations of these results difficult. Addressing these limitations in future research may produce more meaningful outcomes.

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Finally, to my research participants, I am forever grateful for the time and energy you committed to this study, and I hope this research will contribute, in some way, to the development of more effective diabetes prevention initiatives in New Zealand.

Ethical approval for this research was obtained from the Health and Disability Ethics Committee, Central region, reference 14/NTA/126

Table of Contents

List of Figures

List of Tables

Appendices

CHAPTER 1. Introduction

Type 2 (T2) diabetes mellitus is a potentially debilitating long-term health condition that comes with substantial physical, psychological, and economic costs. Rising prevalence rates of both diabetes and pre-diabetes within New Zealand (Coppell et al., 2013)and globally (Guariguata et al., 2013) has made diabetes prevention a central focus of international health research. A number of randomised controlled trials (RCTs), across the USA, Europe, and Asia (Kosaka, Noda, & Kuzuya, 2005; Lindstrom et al., 2003; Pan et al., 1997; The Diabetes Prevention Program Research Group, 2002), have provided consistent evidence that the risk of developing diabetes can be substantially reduced by the provision of lifestyle interventions for those identified as being pre-diabetic. These interventions targeted modifiable risk factors, such as diet, weight, and physical activity, which are demonstrated to play a key role in the development and progression of diabetes.

The problem, however, has arisen in attempting to translate findings obtained from these large-scale diabetes prevention trials into routine clinical practice (Cardona-Morrell, Rychetnik, Morrell, Espinel, & Bauman, 2010). Despite their demonstrated effectiveness, the time and resource intensive nature of these interventions has made them challenging to implement in real-life primary and community health care settings (Cardona-Morrell et al., 2010; Gray et al., 2012).

Difficulty translating knowledge obtained from early diabetes prevention trials to real life settings has led researchers to develop and evaluate brief, structured interventions that are more feasible for implementation in routine practice (Cardona-Morrell et al., 2010; Laatikainen et al., 2007). While research conducted thus far examining the efficacy of these interventions has reported significant changes in some key diabetes risk factors, notably, results have been diluted in comparison to those

obtained from earlier trials (Cardona-Morrell et al., 2010). These findings have highlighted the importance of continuing to explore ways of improving current intervention approaches for patients with pre-diabetes.

Incorporating a psychological intervention component into lifestyle education protocols has been suggested as one method of enhancing outcomes (Greaves et al., 2008; Lakerveld et al., 2013). Psychological distress has been found to be a predictor of the development of both diabetes and pre-diabetes (Tsai et al., 2012) and has been demonstrated to impact on patients' participation in lifestyle change interventions (Kyrios et al., 2009) (Laatikainen et al., 2007).

Despite these findings, only a handful of studies have explicitly looked at the benefits of incorporating psychological treatment approaches into pre-diabetes lifestyle interventions. The few that have, appear to have integrated a motivational interviewing (MI) approach, and results have been mixed (Lakerveld et al., 2013; Morton et al., 2014)**.** A larger number of studies have explored the benefits of psychological interventions for patients with an existing diagnosis of diabetes. The majority of these have focused on the provision of traditional cognitive behavioural approaches (CBT) (Sperry, 2009). Despite its popularity, the applicability of CBT for clients with physical health conditions, like diabetes, has been questioned (Vowles and McCracken, 2008), with critics suggesting some of the core assumptions of traditional CBT may not apply to patients with diabetes and other long-term health conditions (Gregg, Callaghan, Hayes, & Glenn-Lawson, 2007). Indeed, reviews of the effectiveness of traditional CBT approaches for patients with diabetes have produced mixed results, with some research suggesting CBTs benefits are limited to psychological variables and may not produce physiological or metabolic change (Elliott, 2012).

These findings have highlighted the need to explore alternative psychological approaches that may be of greater benefit to patients with pre-diabetes. Acceptance and Commitment Therapy (ACT) is a third wave cognitive behavioural therapy, which has emerged within a functional contextual framework and addresses some of the criticisms aimed at traditional CBT (Hayes, 2004). An emerging body of research has produced promising results using this approach with patients with a variety of chronic health conditions, including diabetes (Gregg et al., 2007), even when delivered in a very brief format.

Thus far, no research has been conducted exploring the benefits of ACT for patients with pre-diabetes. However, given that the lifestyle recommendations for patients with pre-diabetes are similar to recommendations for clients with diabetes (Ministry of Health, 2013) and other long-term health conditions, it seems likely that incorporating ACT into a pre-diabetes lifestyle education programme could enhance its effectiveness.

The present study sought to explore the above hypothesis by developing two brief work-shop-based lifestyle education approaches for people with pre-diabetes: one that provided lifestyle education only, and a second that incorporated lifestyle education with an ACT intervention. The effectiveness of these interventions was then compared with a standard medical care approach.

This research is the first to explore the benefits of incorporating an ACT therapeutic component into a diabetes prevention intervention. The research methods used addressed many of the flaws of previous ACT research in the health domain by employing a more robust research design, extending the range of variables under investigation, and considering the temporal stability of changes across these variables.

The following chapters of this thesis provide a rationale for the present research, describe the methodology and results, and provide possible interpretations of findings. Chapter 2 begins by exploring why diabetes prevention is a topic of current relevance both internationally and in New Zealand, and identifies the main risk factors involved in the development and progression of pre-diabetes and diabetes. Chapter 3 summarises the current state of the research, including a discussion of its limitations and application to real-world settings. Chapters 4 to 7 look at the benefits of incorporating a psychological intervention component to existing pre-diabetes lifestyle education interventions, and ACT is introduced as a potentially useful adjunct to these interventions. Chapters 8 and 9 then describe the present study, including the aims, research questions and hypotheses, and outline the intervention development processes, and chapters 10 and 11 delineate the research methodology and provide a rationale for the methods of data analysis. Finally, chapters 12 and 13 explore results in relation to the research questions and hypotheses, then interpret these in light of previous research findings. Chapter 13 also acknowledges the limitations of the present study and suggests potential avenues for overcoming these in future research.

CHAPTER 2: Pre-diabetes and Diabetes: Cause for Concern?

This chapter provides a rationale for the present research by exploring why diabetes and pre-diabetes have become conditions of concern for health professionals and researchers. It provides descriptions of the classification and diagnosis of diabetes and pre-diabetes, summarises prevalence data globally and within New Zealand, explores physical, psychological and economic costs associated with these conditions, and identifies risk factors implicated in the progression from pre-diabetes to diabetes.

2.1 Diabetes and Pre-diabetes: Classification and Diagnosis

Diabetes mellitus is an umbrella term used to describe a group of chronic metabolic conditions and can be categorised into type 1 or type 2 diabetes. Hyperglycaemia, defined as elevated blood glucose levels, is a symptom of both type 1 and type 2 diabetes and is caused by the body's inability to produce or effectively use insulin, a hormone involved in blood glucose regulation that allows movement of glucose from the bloodstream to the cells of the body where it is needed (American Diabetes Association, 2011). Type 1 diabetes, sometimes referred to as juvenile onset diabetes, accounts for 5 to 10% of diabetes cases (Centers for Disease Control and Prevention, 2005). It often has a rapid onset, and it is caused by failure of cells in the pancreas to produce enough insulin (American Diabetes Association, 2011). A more substantial proportion of diabetes cases (approximately 90 percent) are classified as type 2 diabetes (Centers for Disease Control and Prevention, 2005), also known as non-insulin dependent diabetes or adult-onset diabetes (American Diabetes Association, 2011). With type 2 diabetes, onset tends to be more gradual. Initially there is a reduction in the sensitivity of the body to normal levels of insulin, which it compensates for by increasing the amount of insulin released by the pancreas into the bloodstream. While this is initially effective in preventing hyperglycaemia, over time the pancreas becomes

fatigued and defective, resulting in reduced insulin production and leading to hyperglycaemia (American Diabetes Association, 2011).

In the late nineties, it was accepted by the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus that there is a third category of people who have glucose levels outside the normal range but do not meet diagnostic criteria for type 2 diabetes (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 1997). These individuals are classified as having pre-diabetes; in the health literature, this is also referred to as intermediate glycaemia, dysglycaemia, borderline diabetes, or impaired glucose tolerance (American Diabetes Association, 2011).

People are categorised as having pre-diabetes or type 2 diabetes based on results obtained from venous blood samples analysed to determine blood glucose concentrations. Internationally, the classification of diabetes and pre-diabetes varies slightly. According to the American Diabetes Association's diagnostic and classification criteria, individuals defined as pre-diabetic have "impaired fasting glucose (IFG) [fasting plasma glucose (FPG) levels 100 mg/dl (5.6 mmol/l) to 125 mg/dl (6.9 mmol)], or impaired glucose tolerance (IGT) [2-h values in the oral glucose test (OGTT) of 140 mg/dl (7.8 mmol/l) to 199 mg/dl (11.0 mmol/l)." However, in most countries, including New Zealand, IFG is defined as having a fasting glucose of 110 and 125 mg/dl, and this is consistent with the World Health Organisation criteria (Venkat Narayan & Williamson, 2009).

Diabetes and pre-diabetes can also be diagnosed on the basis of Haemoglobin A1c (HbA1c). HbA1c is a measure of the level of glucose in the bloodstream over 120 days (American Diabetes Association, 2011). The New Zealand Society for the Study of Diabetes (2011) now recommends that both diabetes and pre-diabetes be diagnosed on this basis, rather than glucose based criteria. This approach is also endorsed by the

World Health Organisation (World Health Organization, 2011)**.** The rationale is that blood glucose levels can be quite variable, especially for the OGTT test (New Zealand Society for the Study of Diabetes, 2011). In New Zealand, individuals with HbA1c results between 41 and 49 mmol/mol (fasting glucose 6.1 to 6.9 mmol/mol) meet criteria for pre-diabetes, and those with an HbA1c of 50 mmol/mol or greater meet criteria for type 2 diabetes (or fasting blood glucose greater than 7.0 mmol/l or random glucose greater than 11.1 mmol) (New Zealand Society for the Study of Diabetes, 2011).

2.2 Prevalence

The prevalence of diabetes, both within New Zealand and globally, is increasing at an alarming rate. There was estimated to be 108 million cases of diabetes worldwide in 2008 (NCD Risk Factor Collaboration, 2016). This estimate had risen to 371 million by 2012 (Guariguata, 2012) and 415 million by 2015 (International Diabetes Federation, 2017). It is projected that these numbers will continue to rise in the future, with global estimates predicting 642 million people will meet criteria for diabetes by 2040 (International Diabetes Federation, 2017)

New Zealand statistics for both diabetes and pre-diabetes are consistent with international trends. Results from the most recent 2015/16 New Zealand Health Survey (Ministry of Health, 2017a) found that 6.5 per cent of the population over the age of 25 were diagnosed with type 2 diabetes, with the highest prevalence found for Māori (9.1%), Asian (7.9%) and Pacific people (14.5%). Recent statistics were not available to determine current pre-diabetes prevalence rates in New Zealand. However, the 2008/09 New Zealand Adult Nutrition Survey (Coppell et al., 2013), which looked at prevalence rates for diabetes and pre-diabetes based on blood samples obtained from 4,721 New

Zealanders over the age of 15, found that 25.5% of the sample met criteria for pre-diabetes. The prevalence was 30.4% for Māori and 29.8% for Pacific peoples.

The high prevalence of pre-diabetes amongst participants in the Adult Nutrition Survey led the authors to predict that rates of diabetes in New Zealand are likely to continue to rise in the future (Coppell et al., 2013). Indeed, international research suggests the risk of someone with pre-diabetes going on to develop type 2 diabetes is at least 10 times greater than for those with HbA1c levels within the normal range (Edelman, Olsen, Dudley, Harris, & Oddone, 2004; Pradhan, Rifai, Buring, & Ridker, 2007; Sato et al., 2009; Shimazaki, Kadowaki, Ohyama, Ohe, & Kubota, 2007). Approximately 5 to 10 percent of people with pre-diabetes develop diabetes over the course of a year (Forouhi, Luan, Hennings, & Wareham, 2007), and the American Diabetes Association has estimated that around 70 percent of people with pre-diabetes will go on to develop diabetes during their lifetime (Tabak, Herder, Rathmann, Brunner, & Kivimaki, 2012).

2.3 The Cost of Diabetes

The rising prevalence of pre-diabetes and diabetes both internationally and within New Zealand is concerning because when diabetes is not effectively managed, it comes with substantial physical, psychological, and economic costs.

2.3.1 Physical costs.

The symptoms of uncontrolled diabetes, defined as either higher or lower than optimal blood glucose levels, can be both acute and chronic (Fiagbe et al., 2017). Acute symptoms of hyperglycaemia (elevated blood glucose levels) can include weight loss, blurred vision, polyuria (excessive production of urine), polydipsia (excessive thirst), and polyphagia (increased appetite) (American Diabetes Association). Hyperglycaemia can even be fatal if ketoacidosis (extremely high levels of ketones and blood sugars,

resulting in the blood becoming acidic) occurs (American Diabetes Association, 2011; Diabetes New Zealand, 2017). Acute symptoms of hypoglycaemia (low blood glucose levels) include blurred vision, irregular or rapid heartbeat, fatigue, headache, shakes, sweating, and even seizure or coma resulting in death (American Diabetes Association, 2017; Diabetes New Zealand, 2017).

The secondary/long-term complications of uncontrolled diabetes are perhaps the most debilitating. Potential secondary complications include: retinopathy (damage to the retina) leading to visual disturbance or blindness; renal dysfunction or failure; peripheral neuropathy (potentially resulting in chronic pain, foot ulcers, and limb amputation); autonomic neuropathy (associated with gastrointestinal and genitourinary symptoms); sexual dysfunction; and cardiovascular conditions (American Diabetes Association, 2017; Diabetes New Zealand, 2017). Research suggests diabetes is the leading cause of non-injury related blindness, kidney failure and lower limb amputation, and the risk of both micro and macro vascular complications is related to glycaemic control (Inzucchi et al., 2012; Stratton et al., 2006).

Cardiovascular complications of diabetes are of particular concern for health professionals because they are associated with a heightened risk of mortality. The risk of atherosclerotic disease, peripheral vascular disease, and stroke are significantly higher for people with diabetes when compared with those without (American Diabetes Association, 2011; Dasari, Oza-Frank, & Venkat Narayan, 2008). There is also evidence that those with glucose levels in the pre-diabetes range are more likely to have elevated CVD risk markers, such as hypertension and hyperlipidemia, and have an increased incidence of cardiovascular disease (CVD) and CVD related mortality (Barr et al., 2007).

2.3.2 Psychological costs.

The psychological burden of diabetes is well documented, with higher rates of mental health difficulties, such as anxiety (Tsai et al., 2012) and depression (Knol et al., 2007; Lustman & Clouse, 2007; Renn, Feliciano, & Segal, 2011; Rotella & Mannuci, 2013), observed in this population**.** Around 40% of individuals with diabetes exhibit elevated symptoms of anxiety (Grigsby & Anderson, 2002), and estimates of depression range between 20 and 30 % (Tsujii, Hayashino, & Ishii, 2012b). Diabetes with comorbid depression has also been associated with the increased use of medical services (Simon et al., 2007) and a heightened risk of mortality. A 2013 meta-analysis found that patients with type 2 diabetes and comorbid depression had a 46% greater risk of mortality when compared with patients without comorbid depression (van Dooren, Nefs, Schram, Verhey, & Denollet, 2013). People with diabetes may also experience diabetes-specific distress. Diabetes-specific distress has been differentiated from depression, and is defined as distress related to "disease management, support, emotional burden, and access to care." Diabetes distress has been associated with poor glucose control (Sekhar et al., 2013) and elevated HbA1c (Tsujii, Hayashino, & Ishii, 2012).

Research looking at the relationship between pre-diabetes and psychological functioning is more sparse. Research by Tsai (2012) found patients with pre-diabetes exhibited higher levels of a variety of psychiatric symptoms, including somatization, obsession, interpersonal sensitivity, depression, anxiety and hostility. They also found that patients who reported depressive symptoms had a 20 percent greater risk of meeting criteria for pre-diabetes (Tsai et al., 2012). This finding is consistent with the results of a recent meta-analysis exploring the relationship between depression and pre-diabetes. The authors of this research concluded that rates of depression were "moderately"

increased for patients with pre-diabetes (Chen et al., 2016). Qualitative studies exploring individuals experiences/perceptions of being classified as pre-diabetic have also highlighted the anxiety and uncertainty that can accompany this label (Andersson, Ekman, Lindblad, & Friberg, 2008; Troughton, Skinner, Robertson, Khunti, & Kamlesh, 2008). Core themes identified by Anderson and colleagues included distress associated with "seeing possibilities in an uncertain future," and "facing obstacles and loss of liberty." (Andersson et al., 2008, p. 187).

It is unclear whether psychological symptoms associated with diabetes and pre-diabetes are a consequence of the metabolic and physiological changes and complications that occur with diabetes and pre-diabetes, or whether the biochemical and behavioural changes that occur with anxiety and depression lead to changes in metabolic activity (Renn et al., 2011). One hypothesis is that the increased activation of the hypothalamic-pituitary-adrenal (HPA) axis and increased cortisol production that can occur with depression and anxiety increases insulin resistance, while efforts to regulate emotions influence motivation and perceived ability to effectively manage their pre-diabetes/diabetes, leading to poor glycaemic control. Indeed, a significant association has been found between poor glycaemic control and decreased adherence to diabetes management recommendations related to diet, medication adherence, and physical activity (Sekhar et al., 2013). Laboratory studies have also shown that even exposure to acute social stress (a 5-minute free speech task) can significantly affect glucose concentrations (Faulenbach et al., 2011). These studies highlight the interface between psychological and physical well-being.

2.3.3 Mortality, morbidity, and health expenditure.

Diabetes is associated with high rates of mortality and morbidity, and comes with substantial cost to the health system. In 2015, diabetes was found to be a

contributing factor in 1.5 million deaths globally (GBD 2015 Mortality and Causes of Death Collaborators, 2016). Treatment of the physical and psychological effects of diabetes also has a considerable impact on health expenditure. The global cost of diabetes to the health system is expected to exceed USD 490 billion by 2030, twelve percent of total health expenditure (Zhang et al., 2010). This figure would likely be inflated if people with pre-diabetes were included in the data, as impaired glucose tolerance (IGT) has also been associated with an increased risk of mortality (Younis et al., 2017).

2.4 Risk Factors for Developing Diabetes

Risk factors associated with the progression of pre-diabetes to diabetes are both physiological and behavioural, modifiable and fixed. Non-modifiable risk factors include age, gender, ethnicity, and family history of diabetes. Potentially modifiable risk factors include weight, BMI and waist circumference. These are also influenced by modifiable lifestyle factors such as diet, physical activity and tobacco consumption.

2.4.1 Non-modifiable risk factors.

2.4.1.1 Age.

Studies evaluating the predictors of developing diabetes over 10 years have found the risk to be greatest for people over the age of 45 (Marinho, Vasconcelos, Alencar, Almeida, & Damasceno, 2013). Statistics from the 2015/16 New Zealand Health Survey highlight the association between age and diabetes, indicating that 13.1 % of the population between the ages of 65 and 74 met criteria for type 2 diabetes compared with 0.5 % of the population between the ages of 25 and 34 (Ministry of Health, 2017a). Trends are similar for those with pre-diabetes. The 2008/09 Adult Nutrition Survey found 45.1 % of individuals between the age of 65 and 74 met criteria

for pre-diabetes. In contrast, only 15.8% of individuals between the age of 25-34 met criteria for pre-diabetes (Coppell et al., 2013).

2.4.1.2 Ethnicity.

Minority populations have a higher chance of developing diabetes. As mentioned previously, the 2015/16 New Zealand Health Survey (Ministry of Health, 2017a) and the Adult Nutrition Survey (Coppell et al., 2013) reported higher rates of pre-diabetes for Māori, Asian and Pacific peoples when compared with those who identified as NZ/European. The higher prevalence of diabetes amongst minority populations has been attributed to a variety of factors, including lifestyle changes associated with westernisation, lower socio-economic status, reduced access to health care services, and familial/genetic factors (Fletcher, Gulanick, & Lamendola, 2002).

2.4.1.3 Family history.

It is well established that there is a genetic component to type 2 diabetes (Marinho et al., 2013). Research suggests children with a single parent with diabetes have a 3.5 fold increased risk of developing diabetes over their life span when compared with children who do not have a parent with diabetes. There is six-fold increased risk for children with two biological parents with diabetes (Meigs, Cupples, & Wilson, 2000).

2.4.1.4 Gender.

Most studies have indicated that men have a higher risk of developing diabetes than women (Marinho et al., 2013). New Zealand statistics suggest that 7.0% of men meet diagnostic criteria for diabetes, compared with 5.9% of women (Ministry of Health, 2017a). International statistics indicate the prevalence of risk lies between 1.1 and 15.7% for women and 1.6 and 24.9% for men (Schmid, Vollenweider, Waiber, & Marques-Vidal, 2011)

2.4.2 Modifiable risk factors.

Although not all of the risk factors for the development of diabetes are within the individual's control, research suggests potentially modifiable factors play a substantial role. The US Nurse's Health Study (NHS), which began in 1976, and the NHS II, which commenced in 1986, are prospective cohort studies that have followed over 200,000 participants and collected a variety of health-related information. These studies have provided valuable data pertaining to genetic, behavioural and metabolic risk factors involved in the development of type 2 diabetes, and helped inform diabetes prevention initiatives (Ley et al., 2016. A recent narrative review of the NHS publications between 1976 and 2016 suggested that over 90 percent of diabetes cases could be prevented if individuals adopted a healthy eating programme, reduced their body mass index (BMI) to within the normal range, adhered to physical activity guidelines of exercising for at least 30 minutes per day, and abstained from smoking (Ley et al., 2016).

2.4.2.1 Diet and physical activity.

There is a good deal of evidence to suggest that dietary intake and physical activity levels play an important role in development of diabetes. The increased incidence of diabetes internationally has been largely attributed to societal changes in diet characterised by increased consumption of certain fats and low-quality carbohydrates; decreased consumption of dietary fibre, fruits, and vegetables; and an increasingly sedentary lifestyle (Ley et al., 2016).

The role of fat consumption in diabetes risk is much debated. Early research indicated a diet high in total fat was a risk factor, as it was hypothesised to contribute to insulin resistance and obesity, but not all studies have supported this hypothesis. Ley and colleagues (2016) review of the NHS studies failed to find a relationship between

total fat intake and diabetes risk, although they did find that diets high in plant-based oils and unsaturated fats (rather than animal fats or trans fatty acids) were associated with reduced risk.

Diets low in fibre and high in refined carbohydrates have also been found to increase the risk of developing diabetes. While diets high in fibre that included carbohydrates with a low glycaemic index or load (an indication of how quickly the body can digest the food and convert it to glucose) were associated with reduced risk (Ley et al., 2016). Consistent with this research, high sugar intake in both food and beverages has been associated with metabolic changes that can lead to the development of diabetes (Ley et al., 2016; MacDonald, 2016). A recent review of the literature exploring the relationship between sugar intake and diabetes reported "a clear dose-response link between fructose intake and metabolic change." This was particularly the case when a high sugar diet was accompanied by "excess energy intake" (i.e., a calorie/kilojoule intake that exceeds the body's energy expenditure) (MacDonald, 2016, p. 17). With regards to general dietary considerations, the NHS studies found that a diet that included high intake of vegetables, fruits, nuts, legumes, whole grains, and unsaturated fats, and low in sugary beverages, red or processed meats, trans-fats and sodium was associated with decreased risk of diabetes (Alam, 2009).

Physical activity levels have also been found to play a role in the development of diabetes. High levels of sedentary behaviour (i.e., time spent in front of the TV) is associated with an increased risk, while regular exercise of moderate to high intensity (including brisk walking, muscle strengthening, yoga, and resistance training) is associated with reduced diabetes risk, even when controlling for BMI (Fletcher, Gulanick & Lamendola, 2002).

2.4.2.2 Weight, BMI and waist circumference.

Because of its relationship to dietary intake and physical activity levels, both weight and BMI, especially when accompanied by central adiposity (calculated using waist circumference or waist-hip ratio), have been identified as key diabetes risk factors. (Chia, Wong, Liu, & Toh, 2017; Fletcher et al., 2002; Marinho et al., 2013). Ley's review of the NHS studies found that high body fat was the greatest risk factor, and risk increased with rising body fat. Their review also indicated that central adiposity and duration of obesity were significant predictors of risk, with risk increasing by approximately 14% for every two years of obesity (Ley et al., 2016). BMI has also been found to be a predictor of progression from pre-diabetes to type 2 diabetes. A retrospective cohort study, which looked at predictors of the development of diabetes over a 5 year period with newly diagnosed patients with impaired fasting glucose, found that having a BMI of 27.5 kg/m^2 or more was a significant risk factor for the development of both diabetes and cardiovascular events (AMI and stroke) (Chia et al., 2017). New Zealand statistics also highlight the relationship between pre-diabetes, diabetes and body weight. The 2008-2009 Adult Nutrition Survey found that 14.2 % of participants whose bodyweight was within the obese category met criteria for diabetes, compared with only 2.5% of those whose weight was within the normal range. Similarly, 32.2 % of those in the obese body weight category met criteria for pre-diabetes, and only 19.5% of those in the normal weight range (Coppell et al., 2013).

2.4.2.3 Smoking.

The greater the number of tobacco cigarettes smoked, the higher the risk of diabetes. A recent review of the literature exploring the relationship between cigarette smoking and diabetes concluded that patients with diabetes who smoke also have an increased risk of developing macrovascular complications, such as cardiovascular

disease (Zhu, Pan, Sheng, Chen, & Pan, 2017). The risk of both diabetes and cardiovascular disease decreases following smoking cessation, although some level of risk remains as much as 20 years after quitting (Ley et al., 2016).

2.5 Summary

The prevalence of diabetes and pre-diabetes within New Zealand and internationally is increasing rapidly. Rising prevalence rates are of concern due to the substantial physical and psychological costs associated with diabetes. Although not all of the risk factors involved in the progression from pre-diabetes to diabetes are amenable to change, research suggests adopting a healthy lifestyle, focused on reducing potentially modifiable physiological risk factors, may decrease the chances of developing diabetes. These results highlight the importance of developing and implementing lifestyle-based interventions for those identified as pre-diabetic.

Chapter 3: Lifestyle Interventions to Reduce Diabetes Risk

Literature reviews found no New Zealand based randomised controlled trials (RCTS) exploring the benefits of lifestyle education interventions for reducing diabetes incidence or risk. However, there have been several large scale randomised trials (RCTS) conducted across Europe, the USA and China. These studies have highlighted the potential benefits of such interventions for reducing the risk of progression from pre-diabetes to type 2 diabetes. This chapter will summarise the findings of key international studies and discuss their limitations concerning their application to real life settings.

3.1 Key Studies

3.1.1 The Finnish Diabetes Prevention Study and the European Diabetes Prevention Studies.

The Finnish Diabetes Prevention Study (DPS) (Lindstrom et al., 2003) was the first European randomised controlled trial to investigate the effectiveness of lifestyle interventions for those with impaired glucose tolerance and is considered a key study in the diabetes prevention literature. The DPS was initiated by the National Public Health Institute, and data was collected across multiple centres (Helsinki, Kuopio, Tuku, Tampere, Oulu), with 522 adults participating. Inclusion in the study required participants to be middle-aged (40 to 64 years), have a BMI greater than 25, and have elevated oral glucose tolerance (as defined by World Health Organisation criteria).

On recruitment to the DPS, participants were randomly assigned to either standard medical care or a lifestyle intervention condition. Participants in the lifestyle intervention condition attended seven (30 to 60 min) individual consultation sessions (delivered by a nutritionist at varying intervals) during the first year of the intervention, and then further sessions at three-month intervals thereafter. Intervention goals focused

on modifiable diabetes risk factors and included weight reduction (> 5%), increased physical activity (at least 30 min daily), reduced consumption of dietary fat (especially saturated fat), and increased fibre intake. Research medical practitioners reinforced information provided in individual sessions at annual visits. In addition to individual sessions, participants were invited to attend optional group sessions. These included guest lectures on topics pertinent to the prevention of diabetes, cooking classes and supermarket visits (Lindstrom et al., 2003).

Results of the Finnish DPS demonstrated the potential for lifestyle interventions to have a positive impact on behavioural and metabolic risk factors implicated in the development of diabetes, and to reduce the overall incidence of diabetes. With regards to behavioural change, self-reported physical activity levels increased substantially for those in the lifestyle intervention. At years one and three of data collection, the proportion of sedentary participants differed significantly between lifestyle intervention and standard care conditions (30% versus 14% at year 1, and 29% versus 17% at year 3)(Lindstrom et al., 2003). Similar changes were reported for diet, with significant decreases in fat consumption and increased fibre consumption found for those in the intervention condition when compared with participants in the standard care condition (Lindstrom et al., 2003).

The validity of changes in self-reported physical activity and dietary intake for DPS participants was reinforced by results obtained from more objective measures of behaviour change. The mean weight reduction for participants in the intervention group was substantially greater at year one than it was for those in the control group (4.5 kg and 1.0 kgs, respectively), and those in the intervention condition more frequently achieved weight-loss goals. Forty six percent of intervention participants achieved their weight loss goal at year one, compared with only 14% of control participants

(Lindstrom et al., 2003). Significant decreases in fasting plasma glucose, HBA1c, total serum cholesterol – to HDL cholesterol ratio, and serum triglycerides were also found for intervention participants when compared with control participants (Lindstrom et al., 2003).

The clinical significance of changes in metabolic and lifestyle risk factors for participants in the intervention arm of the DPS was exemplified by an overall reduction in diabetes risk. Three years after commencing the intervention, the overall risk of developing diabetes had decreased by 58% for those in the intervention group, and only 9% of those in the intervention group had developed diabetes compared with 20% of control participants ($P = 0.0001$) (Lindstrom et al., 2003). This result was moderated by success in achieving lifestyle goals set during the intervention (Lindstrom, Absetz, Hemio, Peltomaki, & Peltonen, 2010).

The ability to generalise results obtained from the Finnish DPP to other European populations has since been established. A pooled analysis of data from European Diabetes Prevention Studies (EDIPS), collected across three trial cohorts (the SLIM study in Maastricht, the EDIPS in Newcastle and the DPS in Finland), indicated that collectively the incidence of diabetes was 57% lower for the lifestyle intervention group than the control group. With regards to weight loss management, 38% of the intervention groups attained their intervention goal (weight reduction of at least 5%) at 1-year follow-up, and at year three follow-up 28% of the total sample had maintained this reduction. In comparison, only 14% of control participants achieved their weight loss goal at year one, and only 5% at year three (Penn et al., 2013).

3.1.2 The US Diabetes Prevention Programme.

The US Diabetes Prevention Programme (DPP) is another well-known large scale RCT that investigated the benefits of a lifestyle change intervention for obese

adults (BMI greater than 24), with impaired glucose tolerance and elevated fasting glucose concentrations, across 27 centres in the US (The Diabetes Prevention Program Research Group, 2002). This research extended European studies by comparing the effectiveness of lifestyle intervention with pharmacological intervention, metformin (an oral medication that can help to lower blood glucose levels). A sample of 3234 participants were randomly assigned to either placebo, metformin, or lifestyle modification conditions. The lifestyle intervention aimed to support participants to reduce their weight (by at least 7%) and increase their physical activity (to at least 150 minutes per week). Participants had 16 individual sessions focused on providing them with education about diet, exercise, and basic behaviour modification. Following this, participants also had the option of attending follow-up individual and group sessions to help them maintain positive lifestyle changes.

Results obtained from the DPP were similar to those reported by the Finnish DPS, with a 58% overall reduction in diabetes risk found for those in the lifestyle condition, compared with a 31% reduction for those in the metformin condition (The Diabetes Prevention Program Research Group, 2002). With regards to glycaemic control, mean fasting plasma glucose values decreased to similar levels in the first year across both metformin and lifestyle intervention conditions, but increased for the placebo group. However, the lifestyle intervention was found to have a more substantial positive impact on HbA1c results than Metformin. These results were moderated by changes in lifestyle. By the end of the 24 week intervention, 50 per cent of participants in the lifestyle condition had achieved weight loss of at least 7%, and 74% had achieved their physical activity goal of 150 minutes per week. Moreover, participants in the lifestyle condition exhibited a more substantial decrease in their weight and reported increased leisure time activity when compared with those in either placebo or metformin

conditions. The average weight loss in the lifestyle intervention was even greater than that reported in the Finnish study (5.6kgs for the lifestyle intervention, compared to 0.1 and 2.1 kgs in placebo and metformin conditions, respectively). Follow-up publications have also reported that the lifestyle intervention was more effective for reducing cardiovascular disease risk factors (i.e., triglycerides and blood pressure) when compared with placebo and metformin conditions. At 3 years post intervention, rates of hypertension had increased for those in placebo and metformin conditions but remained stable for those in the lifestyle intervention condition (The Diabetes Prevention Program Research Group, 2005).

3.1.3 The Da Quing study.

The Da Quing study (Kosaka et al., 2005) was conducted with an Asian population and was the first RCT to explore the effects of diet and exercise alone compared with diet and exercise combined. Adults over the age of 25, with impaired glucose tolerance, were randomly assigned to one of four intervention groups: diet, exercise, diet and exercise combined, or standard medical care (control condition). Interventions were provided over a 6-year period and consisted of both individual and group sessions. Results demonstrated that those in the combined lifestyle intervention had a 51% reduced incidence of diabetes (compared with control participants) at the end of the intervention period, although no significant differences in incidence rates were found between the three active intervention groups. In contrast to previous research, the Da Quing study did not find any significant differences in dietary intake between intervention and control participants; although, at 6-year follow-up physical activity levels were significantly higher than baseline activity levels for both the exercise alone and diet and exercise (combined) intervention groups. No information is reported for glycaemic control.

3.1.4 Long-term follow-up.

Extended follow-up of key international studies indicates that the effects of lifestyle interventions can be sustained in the long-term. Follow-up of the Finnish Diabetes Prevention research found that after a median follow-up period of 7 years (median of 4 years active intervention and 3 years post-intervention follow-up), the incidence of type 2 diabetes was 4.3 and (Li et al., 2008) 7.4 per 100 person-years in the intervention and control groups, respectively. This equates to a 43% reduction in the relative risk of developing diabetes. This risk reduction was found to be moderated by the achievement of intervention goals pertaining to weight loss, increased fibre intake, decreased consumption of saturated fat, and increased physical activity (Lindstrom et al., 2006). At 13 years of total follow-up (a median of 9 years following discontinuation of the intervention), the relative risk reduction had only decreased slightly to 38% (Lindstrom et al., 2013). These findings are consistent with those obtained from other large-scale RCTs. The Da Quing Diabetes Prevention Study reported a 43% reduction in diabetes incidence over a 20 year period (Li et al., 2008), and the US Diabetes Prevention Program reported a 34% reduction in diabetes incidence for the lifestyle intervention group over 10 years (Diabetes Prevention Research Group, 2009).

3.2 Limitations of Early Research

Despite promising results from early diabetes prevention studies, the ability to translate findings from large scale RCTs into real-world primary care settings has been questioned due to their intensive nature (Davies et al., 2016; Sumamo Schellenberg, Dryden, Vandermeer, Ha, & Korownyk, 2013). Most of the RCTs conducted thus far have relied on a combination of individual and group interventions and were implemented over a lengthy period of time. For example, the median number of sessions attended by participants in the Finnish DPS study was 20 (over 3 years), and

participants in the DPP study attended 16 individual intervention sessions in the first year, with a further 8 follow-up sessions and phone consultations along with the option of exercise classes.

The duration of the interventions used in the early lifestyle intervention programs, and the investment of time and personnel required, has raised questions about the feasibility of implementing interventions like these in real-world primary health care settings, which are often operating under strict financial and time constraints with limited personnel (Gilis-Januszewska et al., 2011). These concerns have led researchers to look at developing and evaluating more cost-effective, brief, structured intervention approaches that are less intensive, more economically and practically viable, and can be realistically implemented in real world settings (Simmons, Unwin, & Griffin, 2010).

3.3 Applying Diabetes Prevention Lifestyle Interventions in 'Real Life' Settings

In an effort to develop interventions that can be implemented in real life settings, several studies have attempted to adapt the approaches implemented in early RCTs into more brief, structured intervention protocols that can be easily integrated into primary/community care settings. The Good Aging in Lahti Region (GOAL) study (Absetz et al., 2007) is one such example. The GOAL study adapted the Finnish DPS protocol into a brief six session (9 hour) group-based intervention that replicated the objectives of the DPS, with a focus on improving diet, increasing physical activity, decreasing weight and reducing physiological risk factors for diabetes.

The authors of the GOAL study reported significant differences in the attainment of key lifestyle objectives when baseline results were compared with results at 1-year follow-up. Results showed that 20% of participants achieved four or more lifestyle goals. Significant decreases were also reported for diastolic blood pressure (4.0 for men), weight (1.5 kgs, men), BMI (0.5, men), and waist circumference (1.2 cm for

women, 2.3 cm for men), although for several of the clinical outcome measures results only reached significance for men; the reason for this is unclear (Absetz et al., 2007). Notably, results were also somewhat diluted in comparison to those reported by the DPS; the DPS reported a 4.5 kg weight loss for those in the lifestyle intervention condition. Although, importantly, follow-up analyses for the GOAL study revealed significant reductions in weight, BMI and total cholesterol at 3 years, indicating that despite changes being small they were maintained over time (Absetz, Oldenburg, Hankonen, Valve, & Heinonen, 2009).

The GOAL program has also been implemented in the Greater Green Triangle Region in Australia. Again, participants were provided 6 (90 minute) sessions over 8 months, but this time, results were more promising (Laatikainen et al., 2007). Statistically significant reductions in waist circumference (-3.16 cm), weight (-2.38 kg), LDL cholesterol (-0.16) and total cholesterol (-0.21) were already evident 3 months after the intervention commenced, and at 12 months a significant mean reduction was found across all clinical outcome measures, aside from systolic blood pressure. Mean waist circumference reduced by 4.17 cms, weight dropped by 2.52 kgs and fasting glucose decreased by 0.14 mmol/l. Significant mean decreases were also reported for total cholesterol (0.29mmol/l, LDL cholesterol (0.25 mmol/l), triglycerides (0.15 mmol/l) and diastolic blood pressure (2.14 mmHg). Based on waist circumference results, it was estimated that the overall diabetes risk reduction was 40 percent, and based on weight reduction results the overall risk reduction was estimated at 23 percent (Laatikainen et al., 2007).

The above results lend some credence to the possibility of adapting protocols from clinical trials that implemented time-intensive interventions into brief protocols that can be effectively integrated into primary care settings. Although, the validity of

these results is somewhat limited by their repeated measure design and high attrition rates. The absence of control or standard medical care conditions means it remains unclear whether results were due to the intervention or other extraneous factors. Also, although the investment of time and personnel was substantially less than what was required of participants in the earlier diabetes prevention trials (i.e., The DPS and DPP), the time investment for participation was still quite high (six – 90 minute sessions) (Absetz et al., 2009; Laatikainen et al., 2007). This continues to raise issues related to participant access and attrition. Indeed, only 43 percent of participants in the Greater Green Triangle program completed all six sessions. Time constraints, problems with transport, petrol costs, literacy issues and health conditions were provided as reasons for failing to complete the intervention (Laatikainen et al., 2007). Surprisingly, this attrition rate was higher than for the lengthier DPS study, which reported 8% attrition (Tuomilehto et al., 2001).

Reducing barriers to attending pre-diabetes interventions and lowering attrition are essential considerations when developing interventions targeting diabetes prevention. Because consumers of these programs have yet to progress to a chronic illness state, a large proportion are still engaged in full-time employment or have other responsibilities and obligations that can function as barriers to attending even moderate length interventions (Absetz et al., 2007). What remains unclear, is how to create lifestyle intervention approaches that are intensive enough to reduce diabetes risk, yet still economically and clinically feasible and accessible for the majority of people with pre-diabetes.

A few studies have attempted to minimise financial and time barriers associated with attending diabetes prevention interventions by developing and investigating the benefits of very brief structured approaches; however, thus far, results have been mixed.

A 2014 Canadian study, which explored the benefits of a single three hour pre-diabetes lifestyle education session targeting diet and physical activity (Weir et al., 2014), reported general trends toward improvements in self-reported dietary intake and physical activity, but results failed to reach significance. A more recent RCT, the UK "Let's Prevent Diabetes" study, produced more encouraging results (Gray et al., 2012). This study adapted an empirically validated lifestyle education intervention initially developed for people with newly diagnosed diabetes (The DESMOND programme) (Davies et al., 2008). The intervention was delivered in a group format, over six hours, with participants attending either a single full day session or two half day sessions. They were also provided 3 monthly phone support and a 3 hour booster session at 12 months. Consistent with previous more intensive trials (DPP and DPS), the overarching goal of the intervention was to increase diabetes/pre-diabetes knowledge and healthy lifestyle behaviours, and to decrease diabetes risk factors related to body weight; calorie, fat and fibre intake; and physical activity (Gray et al., 2012). Participants in the intervention condition were compared with those in a standard care condition who received written information about risk factors involved in the development of diabetes and healthy lifestyle changes they could make to reduce their risk. The authors reported **s**ignificant improvements in HbA1c and LDL cholesterol at 12 months post-intervention, along with reduced sedentary time and increased physical activity (step count) over a 3 years. They also reported a 26% reduction in diabetes risk, although this result did not reach significance (Gray, Troughton, Khunti, & Davies, 2017).

3.4 Summary and Limitations

Results of key international RCTs have provided convincing evidence that the risk of development or progression to type 2 diabetes can be reduced by up to 60 percent by providing those identified as pre-diabetic with lifestyle interventions that

target modifiable risk factors (Diabetes Prevention Research Group, 2009; Lindstrom et al., 2010). Despite these encouraging findings, the problem lies in attempting to translate findings obtained from large-scale diabetes prevention RCTs, like the DPP and DPS, into interventions that are cost-effective, low resource and pragmatic. While the results of some studies suggest brief, structured interventions can reduce diabetes risk, findings have been mixed and somewhat diluted when compared with results from the early RCTs. These results highlight the need for additional research into ways of improving current intervention approaches.

Chapter 4: Incorporating Psychological Intervention Components into Lifestyle Education Interventions

Incorporating psychological components into lifestyle education interventions, which focus on increasing patients' motivation for behaviour change and equips them with tools to manage the psychological/emotional barriers to change, has been suggested as one method of improving outcomes for people with physical health conditions (Harvey, 2015). This chapter will: 1) review research looking at the psychological barriers and motivators to lifestyle change; and 2) discuss the findings of diabetes prevention studies that have included a psychological intervention component, along with exploration of their strengths and limitations.

4.1 Psychological Barriers and Motivators of Behaviour Change

The importance of psychological factors in initiating and maintaining healthy lifestyle change was highlighted in a follow-up study conducted with Finnish DPS participants (Korkiakangas, Taanila, & Keinanen-Kiukaanniemi, 2011). This research used a qualitative approach to explore motivators to engaging in physical exercise. They found that exercise was, in part, motivated by participants' desire to be fit and healthy but was also connected to other valued life domains. These included building social connections, maintaining mental health and well-being, being outdoors and enjoying nature, and maintaining independence. This research suggests providing interventions that increase participants' psychological connection to their values behind improving their health may be an important for maintaining motivation for change.

There is a dearth of research looking at barriers to healthy lifestyle change for people at risk of diabetes. However, Everson-Hock and colleagues (2013) review of lifestyle intervention studies amongst this population reported that barriers were varied and included: social norms and preferences (i.e., individuals who labelled unhealthy

foods as “treats” and healthy foods as “boring or unsatisfying”), stress, the perception of being “stuck in a rut,” embarrassment about their condition, boredom, lack of confidence (i.e., with cooking or physical activities), health related attitudes (participants who valued their health were more likely to benefit), and perceived inability to influence their health.

As mentioned previously, psychological distress, anxiety and depression have also been found to impact on motivation to make adaptive lifestyle changes, and there is a good deal of research demonstrating that difficulty regulating these emotions impacts on health management behaviour for people with diabetes (Yap, Tam, Muniyandy, & Kadirvelu, 2015). Although there is less available literature specific to people at risk of diabetes, there is evidence to suggest psychological distress and depressed mood impact on participation in/or completion of lifestyle intervention programs. For example, an Australian study which investigated the characteristics of participants who completed a lifestyle intervention versus those who did not, found that non-completers exhibited higher baseline levels of psychological distress (assessed using the Kessler and Hospital Anxiety and Depression Scale) than completers (Laatikainen et al., 2007). Similar findings were reported by Kyrios and colleagues who found that “depressed or negative mood states” had a detrimental impact on participation in lifestyle change interventions (Kyrios et al., 2009). Review of the literature found no research exploring anxiety as a predictor of outcomes for patients at risk of diabetes**.** However, research has identified anxiety it as a significant predictor of self-management behaviour for patient with diabetes (Yap et al., 2015). As the authors of this research noted, motivation to engage in recommended lifestyle changes tends to decrease when anxiety is experienced as overwhelming.

The above findings suggest that diabetes prevention interventions should not solely focus on the physical health benefits of change, but also: 1) consider participants' personal values behind improving their health; 2) provide them with tools/strategies to negotiate unhelpful beliefs, attitudes and perceptions that can function as barriers to improving their health; and 3) assist them to find adaptive ways of dealing with uncomfortable emotions that will invariably arise in the pursuit of their goals.

4.2 Psychological Interventions for People at Risk of Diabetes

Several studies have incorporated psychological components into their lifestyle interventions, but only a few have explicitly explored the impact of these additions. Motivational interviewing (MI) appears to be the approach most frequently incorporated in lifestyle education interventions. MI is a "person-centred method of guiding to elicit and strengthen personal motivation for change"(Miller & Rollnick, 2009, p. 25} that was initially developed for use in the addiction field (Morton et al., 2014).

While there is a robust body of evidence demonstrating MI's efficacy in the area of addiction (Dunn, Deroo, & Rivara, 2001), the evidence for its effectiveness in primary physical health care settings is less compelling. A meta-analysis of MI studies targeting physical activity, dietary behaviour, and alcohol consumption, found that only 50% of the studies analysed (n= 18) reported statistically significant behaviour change for those in the MI intervention condition (Morton et al., 2014). Twenty-two of the studies included in the meta-analysis reported physical activity outcomes, yet only eleven of these found MI produced positive change. Similarly, of the nine studies that included measures of dietary change, only three reported beneficial effects of MI.

MI studies specific to diabetes prevention have also produced mixed results. For example, research by Greaves and colleagues (Greaves et al., 2008) found an MI approach to be significantly more effective than information brochures for supporting

patients at risk of developing diabetes (operationalised as having a BMI >28) to attain pre-defined weight loss goals (24% for the intervention group, versus 7% for the control group). However, no significant differences between the groups were found for the attainment of physical activity goals.

One of the reasons MI studies in the health domain may have produced such mixed results is because this approach focuses on initiating, rather than maintaining, behaviour change. While MI focuses on increasing patients' desire and intention to change (i.e., potentially moving them from the contemplative to action stages of change), it does not provide them with specific tools/strategies to negotiate the psychological/emotional barriers that can arise when making these changes. According to the trans-theoretical model of behaviour change, motivation is not fixed. Once an individual has reached the action or maintenance stages of change, over the course of time there is still potential for them to revert to pre-contemplative and contemplative stages of change (Miller & Rollnick, 2009). Indeed, there is a good deal of research illustrating that motivation can oscillate quickly and is affected by a variety of internal and external factors including mood, stress, time, and work/family demands (Everson-Hock et al., 2013).

When developing interventions for patients with pre-diabetes, the goal is to support them to make sustainable behaviour changes. Over time, they will inevitably experience unhelpful or distressing cognitions and feelings that can decrease their intrinsic motivation to change. Unless they have been equipped with effective psychological strategies to manage fluctuations in motivation, they may revert to contemplative or pre-contemplative stages of change. While MI may be useful for increasing patients' initial motivation to change, it does not provide them with specific

tools to maintain these changes over time. This may explain the variable results found when examining pre-diabetes interventions that incorporated an MI approach.

4.3 Psychological Interventions for People with Diabetes

Although only a few studies have explored the benefits of incorporating a psychological component into pre-diabetes lifestyle education interventions, the benefits of psychological approaches for people with diabetes has been more widely investigated. Perusal of the psychological intervention literature for patients with an existing diagnosis of diabetes indicates that a large proportion of the interventions currently being used with this population are based on a traditional cognitive behavioural therapy (CBT) approach.

CBT is commonly perceived to be the treatment of choice for people with diabetes due to its demonstrated effectiveness in the treatment of mental health difficulties that are frequently co-morbid with diabetes (i.e., anxiety and depression; Sperry 2009) and function as barriers to behaviour change. Traditional CBT views psychological distress as, in part, a product of dysfunctional, unrealistic or irrational cognitions (Gaudino, 2008). Consequently, CBTemploys strategies, such as verbal modification and behavioural experiments, to help patients control, alter or eliminate these thoughts in order to reduce their distress, improve self-management of their condition and enhance their quality of life (Gregg et al., 2007). While it is important to note that CBT incorporates a wide range of principles and techniques that are not limited to modification of irrational cognitions, this is often a key component of traditional CBT approaches.

Despite its popularity, the usefulness of the cognitive components of traditional CBT for patients with chronic conditions, like diabetes, has been questioned (Vowles and McCracken, 2008). As critics point out, the assumption that distress is the product of unrealistic or irrational thinking may be problematic for patients with diabetes/pre-

diabetes, as their distressing cognitions are often realistic and may even be adaptive (Gregg et al., 2007) (i.e., “if I don’t better control my diabetes, I may not be around to see my grandchildren”). Eliminating or controlling distress associated with their condition is also likely to be a challenging task, as whenever a person with diabetes/pre-diabetes attempts to alter their eating or physical activity a psychological connection is made to the potentially debilitating consequences of their condition (i.e., loss of vision, amputations). If the patient is taught to avoid, alter, or eliminate distressing thoughts or feelings about their condition, this could lead them to also avoid making important lifestyle changes that are essential to maintaining their health (Gregg et al., 2007).

Indeed, reviews of the effectiveness of traditional CBT approaches for patients with diabetes have produced mixed results. A comprehensive review of the literature by Elliot (2011) concluded that CBT had some impact on psychological variables, such as depression and anxiety, but no statistically significant effect on glycaemic control. These results suggest that although traditional CBT may reduce distress, these reductions do not necessarily translate into behavioural or metabolic change. These findings highlight the need to explore alternative psychological approaches that may be of greater benefit to patients with pre-diabetes.

Chapter 5: Acceptance and Commitment Therapy – An Alternative to Traditional Approaches

Acceptance and Commitment Therapy (ACT) is a third wave cognitive behavioural therapy developed by Hayes, Strosahl and Wilson (Hayes, Strosahl, Bunting, Twohig, & Wilson, 2004b) that addresses some of the criticisms aimed at traditional CBT. ACT's key therapeutic principles provide an interesting additional dimension to traditional CBT approaches, which arguably makes it more "realistic" alternative for patients with pre-diabetes. This chapter explores the central tenets of ACT; looks at how it differs from traditional cognitive behavioural approaches; provides a brief discussion of ACT's theoretical roots in functional contextualism and relational frame theory (RFT); looks at ACT's conceptualisation of problematic psychological processes that function as barriers to healthy living; and describes the ACT therapeutic model that has emerged from this.

5.1 Central tenets of ACT

ACT refutes the assumption that internal experiences need to be controlled or eliminated for patients to maintain "good" psychological health (Hayes, 2004). Rather than teaching patients to alter or control their thoughts, ACT focuses on teaching patients mindfulness skills to help them remain present focused, accept uncomfortable or distressing feelings, and defuse (step back) from unhelpful thoughts so that they no longer function as barriers to attaining their goals. ACT also helps patients connect their day-to-day goals to personally meaningful life values (related to work, whanau, relationships, etc.) as a way of motivating and inspiring them to make sustainable life changes. Individuals are encouraged to set concrete behavioural goals connected to these values, even while experiencing uncomfortable or painful emotions (Harris, 2009).

While there are some similarities between traditional CBT and ACT, there are also key differences, with ACT focusing on alternative behaviour change processes than traditional CBT (Graham, Gouick, Ferreira, & Gillanders, 2016). ACT questions the Western cultural perspective that happiness or feeling good are the defining features of good psychological health. Instead, ACT views emotional distress as a normal part of being human (Hayes, Follette, & Linehan, 2004a). Rather than seeking to reduce patients' experience of uncomfortable feelings, ACT aims to increase the patient's ability to undertake adaptive and meaningful activity in the presence of these feelings. Additionally, rather than teaching patients to control, eliminate, adjust or change unhelpful cognitions (e.g., replace negative or dysfunctional cognitions with more adaptive ones), ACT focuses on modifying the way people interact with their thoughts so that they have less functional impact (Harris, 2009) .

5.2 Functional Contextualism and Relational Frame Theory: The Building Blocks of ACT

ACT has emerged from a philosophy of science known as functional contextualism (Hayes, Strosahl, & Wilson, 2012). Functional contextualism posits that behaviour is shaped and influenced by a person's social and physical environment. These contexts give behaviour meaning, and attempting to change a person's behaviour without consideration of these contexts is seen as fruitless (Boone, Mundy, Stahl, & Genrich, 2015).

Consider two patients walking into their first research assessment to take part in a diabetes prevention trial. For these two individuals even though the behaviour they are engaging in is identical, their diverging historical, social, and cultural contexts mean the function of the behaviour is different. For example, if participant one grew up in a family that valued increasing their knowledge and giving back to the community, these

values provide a context to the act of walking. Taking part in the research increases their personal knowledge about what it means to have pre-diabetes, while also giving back to the community through their involvement in applied research. Walking is not just about reaching a destination, but also moving in the direction of these values. For the second research participant, the act of walking may serve an entirely different function. Perhaps they grew up in an environment that placed a strong emphasis on family responsibility and caring for others. For them, the act of walking has the function of fulfilling these responsibilities and being available to care for their whanau. Although for these two individuals the behaviour is the same, the function of that behaviour is very different (Boone et al., 2015).

Because functional contextualism assumes that behaviour is shaped by context, truth is also viewed as "contextual and pragmatic, rather than absolute" (Boone et al., 2015, p. 645). Truth is not a property inherent to a belief or idea; what is defined as true or false is effected by a variety of contingencies, including language and cultural and family beliefs. As such, a therapist operating from a functional contextual paradigm would not be concerned about the 'truth' of a patient's beliefs, but rather which belief is worthwhile engaging with in the pursuit of their goals (Hayes, 2004). A pragmatic truth criterion is adopted; which means that instead of asking patients to examine the evidence that supports or refutes their beliefs (a strategy commonly employed by traditional CBT therapists), a patient might be asked to consider the function or "workability" of engaging with or avoiding certain cognitions. Functional contextualism does not deny the existence of 'absolute truths'; it merely questions the function of focusing attention on where the true reality lies and shifts the focus to what works best for the patient (Boone et al., 2015).

5.2.1 Relational frame theory.

Functional contextualism builds on basic principles of operant and classical conditioning and incorporates a newer theory of learning, relational frame theory (RFT), which explains the role of language in learnt behaviour (Boone et al., 2015). RFT is a complex theory, and a comprehensive exploration is beyond the scope of this thesis. Put simply, RFT explains how humans "learn to relate to stimuli in their environment based on social and cultural conventions, rather than simply the physical characteristics of the stimuli" (Boone, p. 64). Research shows that animals can be taught to differentiate between two objects, such as a dining table and a coffee table, based on their physical characteristics (i.e., the dining table is "bigger" than the coffee table). However, a fundamental way in which humans differ from animals is their ability to differentiate between objects based on social conventions rather than merely physical attributes. For example, a human when shown a $1 coin and a 50-cent coin and asked which piece is "bigger", may point to the 1-dollar coin. This is a decision based on social conventions that dictate that a dollar coin is "bigger" (in value) even though it is of comparable size to the 50-cent coin. In addition, unlike animals, humans can see the word used to describe an object written on paper, or even the sound of those letters articulated, and relate to them in an equivalent way as they would to the object itself (Boone et al., 2015). For example, walking in the woods and seeing a sign with the word 'bear' on it or hearing someone say "bear" can produce a similar emotional response to physically encountering a bear (Blackledge, Moran, & Ellis, 2009b).

RFT posits that these relational processes are socially derived and have been learnt and shaped through operant processes (Hayes, Barnes-Holmes, & Roche, 2001). As Blackledge and Hayes (Blackledge & Hayes, 2001) point out, from birth, the process of conditioning children to learn the relations between symbols, situations, images,

sounds, events and objects begins, and hence words and physical situations begin to function interchangeably. These processes are useful and adaptive to the extent that they allow humans to communicate and interact at a level beyond that of non-human animals. However, these processes also have implications for one's ability to avoid or prevent aversive and distressing experiences. While animals can learn to avoid aversive experiences, such as pain, simply by staying away from situations that have previously produced pain, for humans, the task of avoiding pain is not as simple. This is because human's language capacities mean they have learnt to respond to the words that have been socially assigned to interpret or describe a particular experience as if those words are the experience (Blackledge & Hayes, 2001).

This "bi-directionality" of function (Hayes, 2004, p. 648) between language and its referents has implications for health practices across the spectrum of clinical and medical presentations, including diabetes and pre-diabetes. For example, a person with pre-diabetes who attends a consumer presentation where someone describes the "horrific" complications they are experiencing as a result of their diabetes may notice emotional distress showing up in response to this verbal description, even though they have no personal experience of these complications. The verbal description alone is enough to trigger these emotions because the person's evaluative connotations connected to the words used by the presenter (i.e., complications and horrific) allow them to experience distress vicariously.

There is now a robust body of evidence supporting the central tenets of functional contextualism (Blackledge, Ciarrochi, & Deane, 2009a). ACT has been developed based on this theory and research, with a view to developing practical therapeutic tools to change the way people relate to their internal and external experiences. Functional contextualism and RCT suggest that problematic psychological

processes that are construed as barriers to healthy living are a consequence of socially and verbally constructed processes. Therefore, the central goal of the ACT therapist is to disrupt these rigid psychological processes and teach patients more flexible and adaptive ways of interacting with their "verbal/cognitive networks that establish relations among stimuli, rules and behaviour"(Zhang et al., 2018, p. 3). In doing so, they also increase their patients' ability to engage in activities and pursuits that are personally meaningful and help them create a life that is rich and satisfying. (Hayes, 2004).

5.3 The ACT Model

5.3.1 Psychological inflexibility.

ACT does not define internal experiences (i.e., thoughts, feelings and physical sensations) as positive or negative; it suggests that uncomfortable and unpleasant inner experiences are a normal part of being human. However, ACT does contend that these essentially normal experiences can lead to suffering when the psychological processes used to deal with them are applied inflexibly or indiscriminately without recognition and awareness of their potential consequences (Hayes, Luoma, Bond, Masuda, & Lillis, 2006).

ACT posits that because of genetic and evolutionary processes, humans are programmed, where possible, to avoid or escape threat and danger. When confronted with danger, their focus automatically narrows, and their attention is consumed with identifying avenues of avoiding and escaping the perceived threat. In situations where people are in physical danger, this is usually an adaptive response. However, as discussed, humans' language capacities and their ability to derive socially constructed meaning from words have the consequence that they can perceive danger and experience distress in situations where there is no actual physical threat (Boone et al.,

2015). This escape response becomes problematic when it becomes a person's pre-dominant way of responding to painful internal or external experiences, and starts to interfere with their quality of life and ability to make healthy lifestyle decisions (Hayes, Strosahl, & Wilson, 1999).

5.3.2 Experiential avoidance and cognitive fusion.

Experiential avoidance and cognitive fusion are two key aspects of psychological inflexibility. Experiential avoidance is the term used to define attempts to "avoid, control or suppress internal experiences, such as thoughts and feelings, as well as the circumstances that give rise to them" (Boone et al., 2015). Examples of experiential avoidance include behavioural avoidance strategies designed to suppress or control internal discomfort, such as drug and alcohol use and avoidance of feared objects, events or situations, as well as internal methods of control (i.e., thought stopping) (Blackledge & Hayes, 2001). For instance, when a person newly diagnosed with pre-diabetes attempts to control the anxiety they are experiencing on being assigned this label by overindulging in alcohol, cancelling their next GP appointment, and turning down the opportunity to attend pre-diabetes education classes, these are all examples of experiential avoidance.

Experiential avoidance can be problematic in several ways: First, there is a good deal of evidence to suggest that attempts to suppress thoughts and feelings can have paradoxical effects. Indeed, research on the effects of thought suppression, pioneered by Wegner's classic "white bear" experiments (where participants were asked to suppress thoughts of white bears), suggests suppression can result in patients experiencing thoughts more frequently, intrusively and intensely (Abramowitz, Tolin, & Street, 2001). Second, avoidance of health-related activities as a way of managing uncomfortable feelings is likely to have a negative impact on health and ultimately

increase the chance of fears coming to fruition (i.e., cancelling GP appointments or failing to monitor blood glucose levels may ultimately lead to a deterioration in health). Third, as life becomes increasingly consumed with avoiding discomfort, one's ability to focus attention on other meaningful aspects of life decreases (i.e., spending time with whanau, building a career, attending to spiritual growth). A by-product of this can be a general decline in emotional functioning and quality of life (Blackledge & Hayes, 2001).

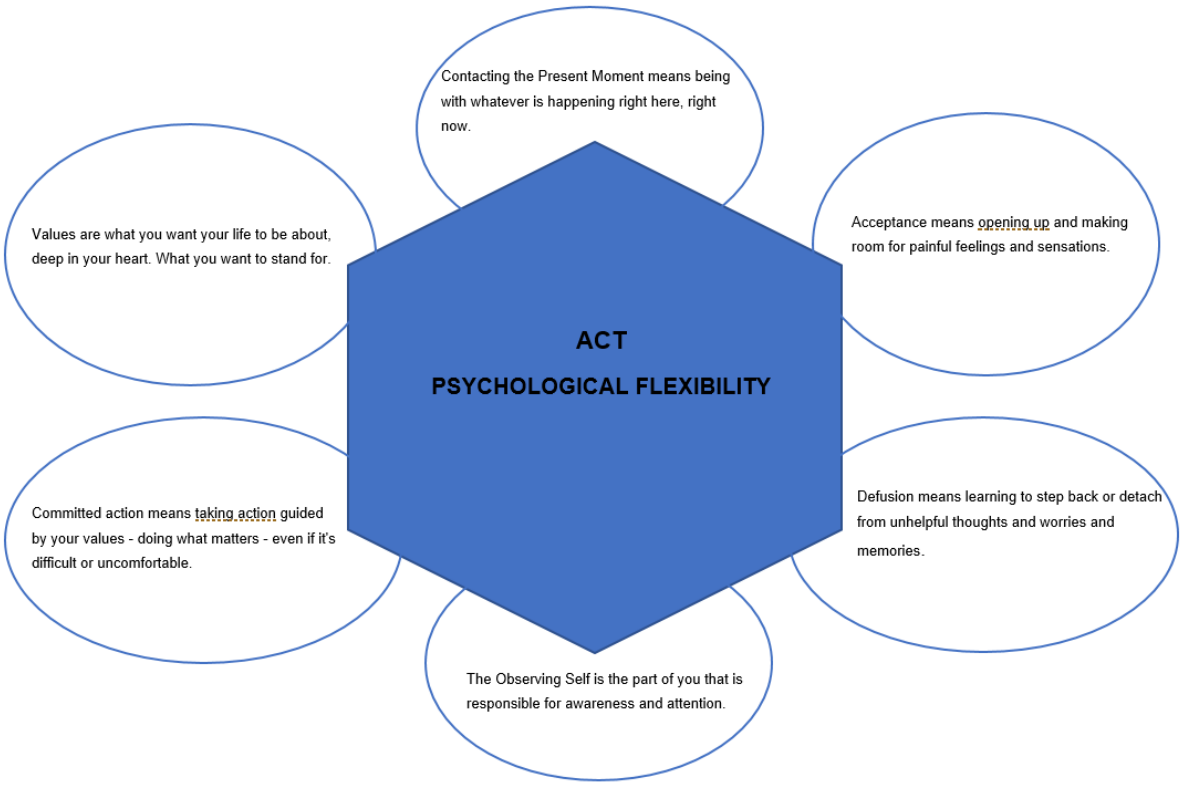
Another key feature of psychological inflexibility is cognitive fusion. Cognitive fusion refers to "over identifying with the mind, allowing our capacity for meaning making, which is essential in most contexts, to have undue influence over our behaviour."(Boone et al., 2015) An example of fusion would be someone with diabetes ruminating on thoughts about the potential long-term implications of having elevated blood glucose levels (i.e., will I lose my sight or my limbs").

Like experiential avoidance, fusion is a normal cognitive process, and within an ACT framework is not defined as inherently positive or negative (Harris, 2009). The ACT therapist is more interested in exploring its function; how workable or unworkable is it for the patient to fuse with certain thoughts. If connecting with these thoughts leads them to take actions to improve their health (i.e., exercising more regularly), fusion could be considered adaptive. Conversely, if the patient responds to these thoughts by spending countless hours searching online resources seeking information about the dire complications associated with diabetes, their anxiety might increase, and the capacity to focus their attention on taking behavioural steps to improve their health may decrease. In this situation, cognitive fusion would be considered maladaptive.

5.3.3 The Hexaflex: Building psychological flexibility.

As shown in Figure 1, the ACT therapeutic model, known as the Hexaflex, focuses on decreasing the dominance of experiential avoidance, cognitive fusion and other forms of psychological inflexibility as methods of responding to distress, and increasing patients psychological flexibility (Harris, 2009). From an ACT perspective, psychological flexibility refers to "the ability to contact the present moment more fully as a conscious human being, and to either change or persist when doing so serves valued ends" (Hayes et al., 2004b, p. 5). Psychological flexibility includes six core interrelated processes: Values, committed action, defusion, self as context, acceptance and contact with the present moment. These are described below, along with their potential application for patients with pre-diabetes.

Figure 1**:** The Hexaflex Model (Lombard, 2018)



5.3.3.1 Values and committed action.

Rather than focusing attention on avoiding or controlling discomfort or rigid preoccupation with cognitions, ACT focuses on assisting patients to create a life that provides them with a sense of meaning, purpose and vitality (Blackledge et al., 2009a). It achieves this by helping them clarify and articulate their values, and commit to day-to-day actions that are aligned with these values. From an ACT perspective, values are defined as "verbally construed, global, desired life consequences" (Hayes et al., 1999, p. 206). They can be differentiated from goals in that they are not defined by specific actions but are qualities of ongoing action or guidelines for interacting with the world (Harris, 2009). Examples of values might include being authentic, respectful, loving or curious. Values are not under aversive control; instead, the focus is on engaging in life in a way that provides lasting and stable reinforcement (Blackledge & Barnes-Holmes, 2009). Because what is defined as reinforcing varies across individuals and contexts, a core focus of therapy is to help patients clarify and connect with their own personally meaningful values. This is achieved using a variety of experiential activities, such as asking the patient to visualise important celebrations and consider what they would like their loved ones to say about what was important to them in life and how they behaved on an ongoing basis (Harris, 2009).

Once the patient has clarified their values, ACT assists patients to commit to specific actions designed to move them in the direction of those values (Edelman et al., 2004). These might be small steps, such as reading about diet changes they can make to reduce their HbA1c, or larger goals, such as attending the gym. These goals are directly connected to the patient's articulated values, and these values are used to motivate and inspire them to stay on track (Harris, 2009). For example, if a patient identifies being connected with whanau as an important value, their therapist might explore with them

how being physically active allows them to stay engaged with their children and grandchildren.

5.3.3.2 Cognitive defusion.

Cognitive defusion is the alternative to fusion. It is the act of looking at one's thoughts rather than from them. Cognitive defusion is a process that involves noticing and observing the process of thinking, and instead of allowing thoughts to automatically dictate actions, allowing them to influence action only when doing so moves the patient in valued directions (Boone et al., 2015).

Consider the patient who values connection with whanau and has set a goal of attending the gym regularly. In the pursuit of this goal, uncomfortable or unhelpful thoughts (i.e., "I'm too tired to get there today) will inevitably arise. If the patient fuses with such thoughts and allows them to dictate their behaviour, these thoughts will function as barriers to attending the gym. However, if the patient is taught skills to assist them to simply notice and observe when these thoughts arise, without automatically identifying with or reacting to them, it is possible for them to make choices that are different to what their mind dictates. Unlike traditional CBT, the focus is not on examining the "truth" of the thoughts or changing their content; instead, the focus is on the workability of thought engagement. ACT uses a variety of techniques to assist patients to defuse from unhelpful/unworkable thoughts. These include labelling thoughts as stories, imagining thoughts as passengers on a bus they are driving, or undermining the literal meaning of words through language deconstruction exercises (i.e., the rapid repetition of key words or singing their thoughts).

5.3.3.3 Self as context.

Self as context is a process closely related to defusion and refers to the ability to flexibly hold "multiple perspectives on the self and experience" (Boone et al., 2015, p.

649). The idea of an observing self is central to this process. The observer self is a way of relating to experience where one can differentiate the thoughts from the self that holds those thoughts (Hayes et al., 2006). As with the other mindfulness processes, self as context is introduced to the patient as a new way of interacting with thoughts that serves to undermine their literal value and highlights the potential for valued action even in the face of uncomfortable internal experiences (Harris, 2009).

5.3.3.4 Acceptance.

Acceptance is introduced within an ACT framework as an alternative to experiential avoidance (Hayes et al., 2006). Acceptance has been defined as a "stance of non-judgemental awareness and actively embracing the experience of thoughts, feelings, and bodily sensations as they occur" (Hayes & Strosahl, 2004, p. 7). It should be distinguished from tolerance, resignation or abandonment. It is the act of allowing internal experiences to be, without struggling with or attempting to control them (Hayes et al., 2006).

Importantly, ACT does not suggest that acceptance of distress is an appropriate response in every context. Consistent with the overarching goal of psychological flexibility, acceptance is indicated as an alternative to experiential avoidance when avoidance has been identified as an obstacle to moving toward values (Blackledge & Barnes-Holmes, 2009). For example, if a patient's efforts to avoid distress at being told they meet criteria for prediabetes results in failure to attend GP appointments, they may be encouraged to accept and create space for these feelings if doing so allows them to take active steps to improve their health.

5.3.3.5 Contact with the present moment.

Contacting the present moment involves focused and deliberate attention to the current experience. This includes attending to thoughts, feelings and sensory

experiences (Boone et al., 2015). In ACT therapy, contact with the present moment is facilitated using exercises that encourage the patient to notice and attend to specific aspects of their experience (i.e., noticing their breathing). Contact with the present moment has been described as the “antithesis” to rumination on the conceptualised past or future (Boone et al., 2015, p. 650). This is because assisting patients to make deliberate contact with direct experience allows them to identify the discrepancies between language and experience, and therefore undermines their literal belief in their thoughts as valid descriptors of reality (Blackledge & Barnes-Holmes, 2009). For example, a patient who frequently ruminates about past regrets regarding lifestyle factors (i.e., smoking) that may have contributed to their health issues or fuses with worries about how their health might deteriorate in the future, might be taught strategies to bring their mind back into the present moment. By facilitating present moment focus, the therapist assists patients to consider actions they can take in the here and now to improve their health and stay connected to their values.

5.4 Summary

Traditional cognitive behavioural approaches have viewed psychological distress and maladaptive behaviours as a product of unrealistic or irrational cognition, and hence seeks to teach patients strategies to assist them to challenge, alter, control or de-amplify these thoughts (Gregg et al., 2007). This perspective has been criticised by some, who have argued that for patients’ with chronic health conditions these thoughts and feelings may be adaptive and attempts to eliminate them could have negative health consequences (Gregg et al., 2007). In contrast, ACT views uncomfortable or distressing cognitions as a normal part of the human experience. Therefore, rather than seeking to control them, ACT teaches patients new ways of interacting with them so that they no

longer function as barriers to participating in life in a healthy and meaningful way (Hayes et al., 2004b).

ACT's theoretical roots lie within Functional Contextualism and Relational Frame Theory. These theories illustrate how a person's social and physical environment shapes their behaviour (Hayes et al., 2006). A pragmatic truth criterion is adopted, which focuses on examining the workability of engaging with certain beliefs or cognitions, rather than examining the evidence supporting or refuting them (Boone et al., 2015). Relational frame theory also explains the role of language in behaviour, (Blackledge et al., 2009b) and highlights how humans' capacity for language impacts on their ability to avoid or prevent aversive or distressing internal experiences, and can lead them to learn to respond to words/thoughts as though they are the experience itself (Boone et al., 2015).

Based on the above theories, ACT seeks to disrupt rigid, maladaptive, psychological processes and change the way people relate to language and their internal and external experiences. It does this by assisting patients to develop mindfulness skills focused on: 1) increasing their willingness to accept and create space for uncomfortable internal experiences (i.e., thoughts, feelings, body sensations); 2) enhancing their ability to be present with all aspects of the here and now experience; 3) assisting them to develop multiple perspectives on the nature of one's self and their experience; and 4) teaching them to step back from cognitions that, when fused with, serve to move them away from their identified goals. The patient's purpose (or why) for learning these skills is connected to personally meaningful values. These values function as the patients compass, and serve as a source of inspiration and motivation to commit to initiating and maintaining healthy and adaptive behaviour change (Harris, 2009).

Chapter 6: Examining the Evidence: The Benefits of ACT for Patients with Long-Term Health Conditions

Evidence is steadily growing that supports the efficacy of ACT for patient with long-term health conditions, with research conducted across a diverse range of health conditions, including obesity (Berman, Boutelle, & Crow, 2009; Forman, Butryn, Hoffman, & Herbert, 2009; Lillis, Hayes, Bunting, & Masudo, 2009), chronic pain (McCracken, MacKichan, & Eccleston, 2007)**,** cancer (Feros, Lane, Ciarrochi, & Blackledge, 2013; Hawkes, Pakenham, Chambers, Patrao, & Courneya, 2014; Rost, Wilson, Buchanan, Hildebrandt, & Mutch, 2012), cardiac disease (Goodwin, Forman, Herbert, Butryn, & Ledley, 2012), epilepsy (Lundgren, Dahl, Melin, & Kies, 2006), multiple sclerosis (Nordin & Rorsman, 2012; Sheppard, Forsyth, Hickling, & Bianchi, 2010), and diabetes (Gregg et al., 2007) producing promising results. Many of these studies indicate an ACT based approach can be beneficial for: 1) promoting healthy lifestyle change and reducing physiological risk factors associated with long-term health issues, 2) improving emotional functioning and distress tolerance, 3) enhancing quality of life and 4) increasing psychological flexibility. This chapter provides a summary of the ACT research findings within the health domain for adults, followed by a more explicit focus on research with patients diagnosed with diabetes.

6.1 Distress and Emotional Functioning

Although reducing patients' emotional distress is not the primary goal of ACT, research indicates reduced distress, increased distress tolerance and improved emotional functioning are often by-products of using this approach. Research by Feros and colleagues (Feros et al., 2013), which explored the effectiveness of an ACT based intervention for cancer patients, reported significant decreases in self-reported distress, along with symptoms of depression, anxiety and stress, when pre-intervention results

were compared with results at post intervention and 3 month follow-up. Equally promising results were found using ACT with obese *patients* and those with chronic pain. A European study with patients experiencing chronic disabling pain reported reduced distress, depression and anxiety following an ACT intervention, and these results were stable at 3 month follow-up (McCracken et al., 2007). Additionally, research exploring the benefits of a 6 hour ACT intervention for obese patients reported significantly greater reductions in self-reported distress (d = .92, large effect) and objective distress tolerance (as assessed using a breath holding task) (d = .89, large effect) when those in the ACT condition were compared with those in a wait list condition (Lillis et al., 2009).

There is also emerging evidence that ACT compares favourably to other active intervention approaches. A 2012 study that compared the effectiveness of ACT and cognitive therapy for women with ovarian cancer, reported significantly greater reductions in distress for participants in the ACT condition. Again, this effect size was in the large range (d = 1.28) (Rost et al., 2012).

While several studies have reported improvements in emotional functioning and distress tolerance following an ACT intervention, a few studies have produced less conclusive results (Hawkes et al., 2014). Research exploring the effectiveness of a phone based ACT intervention for colorectal cancer survivors found both ACT and treatment as usual (TAU) groups showed significant improvements in distress at six and twelve-month follow-up but the difference between ACT and TAU groups did not reach significance. The authors suggested that the absence of a significant difference between the groups might be related to the fact that the intervention did not focus specifically on distress but rather lifestyle change behaviours (i.e., diet and physical activity) (Hawkes et al., 2014). It is also possible that the use of a phone-based intervention, as opposed to a face-to-face intervention, was a factor. Similarly, research by Nordin and Rorsman (2012), which

compared an ACT intervention with relaxation training for patients with multiple sclerosis, found no significant difference between the groups on measures of distress at 3 month follow-up. However, the interpretation of these results is limited by this study's small sample size, which affected the researchers' ability to detect significant small to medium size effects (Graham et al., 2016).

6.2 Lifestyle Change and Physiological Markers of Condition Management

The benefits of ACT for promoting healthy lifestyle changes and reducing physiological markers of illness development or progression has also been demonstrated. A pilot study investigating the benefits of a 4 session group-based intervention for patients with cardiac illness, reported positive and significant improvements in diet, weight and BMI between pre and post intervention (Goodwin et al., 2012). Dietary change was assessed based on calorie, fat and sodium intake, and large effect sizes were found across all three measures (d = 1.03, 1.15 and 1.63). Effect sizes for weight and BMI were smaller but still significant (d = 0.13 and 0.11).

Although the results of the above studies appear promising, the external validity of these findings is limited by the absence of a control condition, meaning we cannot be sure these changes would not have occurred in the absence of any intervention. However, two RCTs in cancer and obesity have produced similarly favourable results. Lillis and colleagues (Lillis et al., 2009) research with obese individuals participating in a weight loss program, which included a wait list control, found significantly greater improvements in BMI (d = .68) at 3 months post-intervention for those in the ACT condition. A mean percentage weight loss of 1.5% was found for those in the ACT condition, while a 3% weight gain was reported for those in the wait list condition. Similarly, Hawkes and colleagues (Hawkes et al., 2014) research with patients with colorectal cancer reported significantly greater changes in diet and weight (d = 0.20 -

0.23) when ACT was compared with TAU (defined as provision of written education materials focused on cancer risk reduction), and these changes were largely maintained 12 months post-intervention. Notably, no significant changes in physical activity were found for the ACT group at initial follow-up, but significant improvements were reported at 12 months post-intervention. This finding highlights the importance of conducting research that includes extended follow-up.

6.3 Quality and Satisfaction with Life

Improving patients' quality of life (QOL) and assisting them to create a life with meaning and purpose is one of the central tenets of ACT. Research in the areas of obesity, cancer, paediatric pain and multiple sclerosis have indicated participants experienced improved QOL following an ACT intervention, with several reporting effect sizes in the moderate to large range (Graham et al., 2016). For example, Feros' (2013) research with cancer patients found significant and positive improvements in QOL between pre and post-intervention and three month follow-up (d =.50); Lillis and colleagues (Lillis et al., 2009) research with obese individuals reported significant and large improvements in QOL for those in the ACT condition when compared with a wait list control (d = 1.14 a large effect); and an ACT intervention for patients with whip lash related chronic pain reported significantly larger post-intervention improvements in life satisfaction for participants in the ACT condition compared with those in a wait list control condition (d = 2.13). This latter effect remained stable and within the large range at 4 month follow-up (d = 1.24) (Wicksell, Olsson, & Hayes, 2010). Changes in QOL have even been reported using very brief ACT protocols. A study evaluating the benefits of ACT for patients with multiple sclerosis reported a significant positive effect on QOL following a single session intervention (d =0.24) (Sheppard et al., 2010).

Although the majority of studies have reported benefits of ACT for life satisfaction and QOL, a few have produced mixed results. Hawkes' research with colorectal cancer survivors reported significant differences between ACT and TAU groups in cancer-specific QOL (physical well-being) at 6 and 12 month follow-up, but no difference between the groups in other domains of QOL, with both groups exhibiting comparable improvements over time (Hawkes et al., 2014). Similarly, a 2008 RCT, which compared 12 hour ACT and yoga interventions for patients with drug refractory epilepsy, found significantly greater improvements at 6 and 12 month follow-up in QOL (as measured by the WHOQOL-Bref) for those in the ACT condition compared with those in a yoga condition (Lundgren, Dahl, Yardi, & Melin, 2008b). However, the yoga group reported significantly greater improvements in satisfaction with life. The authors attributed this to the fact that the WHOQOL-Bref has more specific questions about barriers and challenges to QOL, which is more consistent with the focus of ACT (Lundgren et al., 2008b).

6.4 Psychological Flexibility

The primary goal of ACT is to increase patients' psychological flexibility, and several studies have explored changes in psychological flexibility as a result of an ACT approach, along with looking at the extent which these changes mediate outcomes on other dependent measures. These studies have generally used adapted versions of a popular ACT process measure, the Acceptance and Avoidance Questionnaire (AAQ) (Hayes et al., 2004c).

Research with obese patients (Lillis et al., 2009) and patients affected by cancer (Feros et al., 2013; Hawkes et al., 2014) reported significant increases in psychological flexibility as a result of ACT interventions. Lillis' (2009) research with obese patients indicated significant increases in psychological flexibility in comparison with participants

in a wait list condition, and Hawkes (Hawkes et al., 2014) research with cancer patients indicated significant differences in comparison to a TAU group.

Three studies were also found that suggested psychological flexibility mediated the benefits of ACT on other psychological and physiological outcome measures. Wicksell and colleagues (Wicksell et al., 2010) found psychological flexibility mediated the impact of the ACT intervention on self-reports of pain related disability; Lillis and colleagues (Lillis et al., 2009) found mediating effects on measures of quality of life, weight related stigma and distress tolerance; and Feros and co-authors (Feros et al., 2013) reported that psychological flexibility predicted outcomes on measures of distress, mood and quality of life. Research with patients with MS failed to find significant improvements in psychological flexibility between ACT and a relaxation groups, but, as noted previously, this study was limited by its small sample size (Sheppard et al., 2010).

6.5 Summary

Research within the health domain suggests an ACT approach may have benefit for patients with a variety of physical health issues. Encouraging results have been found across a wide range of variables including emotional functioning and distress tolerance, self-report and physiological indicators of lifestyle change and condition management, and quality and satisfaction with life. Consistent with the core goal of ACT, there is also evidence that these interventions increase psychological flexibility, with several studies finding changes in psychological flexibility mediated changes on other outcome variables. Although a few studies produced mixed results or failed to demonstrate the benefits of ACT in comparison to active treatment or control conditions, these outcomes can be partially explained by methodological factors such as the mode of intervention, sample size, intervention focus and intervention goals.

Given the promising results obtained across a broad range of health condition studies, of which several targeted physiological factors that are also associated with the development and progression of diabetes (i.e., diet, weight, and BMI), it seems likely that an ACT approach could also be a useful adjunct to lifestyle education interventions for patients with pre-diabetes and type 2 diabetes. Moreover, ACT's ability to produce clinically and statistically significant changes when delivered in relatively brief group or workshop based format addresses limitations of early diabetes prevention studies, which were time and personnel intensive.

Chapter 7: ACT for the Management and Prevention of Type 2 Diabetes

Three published studies were found exploring the benefits of ACT for patients with diabetes; however, only one of these studies was published at the time the present research commenced. No studies were found that looked at the benefits of ACT for patients with pre-diabetes. Studies in the diabetes domain were all RCTs that compared ACT combined with diabetes education, with diabetes education alone. One study also included a standard medical care control condition. The first two studies provide promising evidence for the benefits of ACT for diabetes (Gregg et al., 2007; Shayeghian, Hassanabadi, Aguilar-Vafaie, Amiri, & Besharat, 2016), but outcomes from a 3rd study (Whitehead et al., 2016) were less convincing. This chapter will (1) review the diabetes research, and (2) consider the potential benefits of ACT for patients with prediabetes.

7.1 ACT and Diabetes

Gregg and colleagues published the first study exploring the benefits of an ACT-based intervention for adults with type 2 diabetes (Gregg et al., 2007). Their research looked at the effectiveness of ACT for self-reported diabetes management and glycaemic control amongst patients recruited from a community health centre in the United States. Participants were randomly assigned to one of two treatment conditions; education alone or education plus ACT, with participants in both conditions attending a one day, seven hour, workshop. Those in the education workshop were presented with information about diabetes self-management (i.e., glucose monitoring), what it means to have diabetes, management of diabetes complications, and lifestyle changes they could make to improve their diabetes management and reduce their risk of illness progression. The ACT/education intervention incorporated the same elements as the education intervention, in an abbreviated form (approximately 4 hours duration). This intervention

also included an ACT component, which provided information and experiential exercises designed to teach participants mindfulness processes. These mindfulness processes were introduced to (1) assist participants in dealing with difficult cognitions and feelings related to having diabetes, and (2) allow them to explore and connect with values underlying effective diabetes management, and encourage them to commit to actions aligned with these values (Gregg et al., 2007).

Gregg's (Gregg et al., 2007) research produced promising evidence of the benefits of ACT for improving diabetes self-management. At 3 months post-intervention, participants who attended the ACT/Education workshop were significantly more likely to be in good diabetic control (as indicated by HbA1c venous blood results) than participants who attended the education only workshop (η_p^2 .08). They reported significantly better diabetes self-management and greater psychological flexibility. Importantly, no difference between the groups was found for diabetes understanding and knowledge, suggesting that abbreviating the education component of the intervention did not compromise participants' learning. Mediation effects were also reported for diabetes self-management and psychological flexibility; results demonstrated that increased self-reported acceptance and diabetes self-management mediated changes in HbA1c (Gregg et al., 2007).

Although Gregg's (Gregg et al., 2007) study provided promising evidence for the benefits of integrating an ACT component to diabetes education interventions, it had several limitations: (1) it only included a three month follow-up period, making it difficult to establish the temporal stability of changes; (2) it included a limited range of outcome measures (HbA1c, diabetes self management and understanding, and psychological flexibility), and (3) it did not include a standard care control condition, making it difficult

to establish whether either the ACT/ED or ED Only interventions were more effective than the usual care provided to patients.

Gregg's (Gregg et al., 2007) research has also been criticised for "overselling" its results. O'Donohue and colleagues (O'Donohue, Snipes and Soto, 2016) claim that several outcomes reported in Gregg's original dissertation were not reported in subsequent journal publications. Alleged omissions included failure to disclose that no statistically significant differences in Hba1c were found between ACT/ED and ED Only interventions over time, and failure to report the results of several process measures, such as the White Bear Inventory (a measure of experiential avoidance).

O'Donohue (O'Donohue et al., 2016) also highlighted a number of methodological shortcomings of Gregg's research (Gregg et al., 2007). These included the fact that the intervention facilitators were not blind to the intervention conditions, failure to report the facilitators therapeutic allegiance, the absence of robust psychometric data for the ACT process measure used (AADQ), and the use of a very basic measure of self-management behaviour that did not account for the quality or duration of these behaviours.

Gregg and Hayes (2016) responded to O'Donohue and colleagues' (O'Donohue et al., 2016) critique by stating that their assertions were largely based on "misunderstandings" of the data and failure to recognise that improved data analysis methods had been employed since the original dissertation was completed. Gregg and Hayes (2016) dispute the claim that negative HbA1c results reported in her dissertation were not referenced in journal publications. They point out that following initial analyses a "superior" method of statistical analysis was used that accounted for variance between the groups in baseline results (ANCOVA) (Gregg and Hayes, 2016, p.28) and a non-significant trend and small effect was found in favour of ACT/ED over ED Only. Gregg

and Hayes (2016) further assert that the number of participants in good HbA1c control at 3 month follow-up was indeed significant. While they acknowledge that this would not be the case if controlling for "experimental-wise alpha," they also point out that this is advised against by "modern statisticians."

In response to O'Donohue's (O'Donohue et al., 2016) criticism that non-significant results of certain process measures were not reported, Gregg and Hayes (2016) point out that these were not primary or targeted process measures. They also point out that it is common to include minor measures when completing a dissertation, but not feasible to include all of these measures when writing publications. With regards to methodological criticisms, Gregg and Hayes (2016) acknowledge these limitations, but accurately point out that these were clearly explicated in the journal publication, along with a clear rationale as to why these decisions were made.

Since commencing the present research, two further studies have been published evaluating the benefits of ACT for adults with diabetes. The first was conducted in Tehran (Iran), and used the ACT protocol developed by Gregg (Gregg et al., 2007) but in a more intensive 10 session group intervention. Again, participants were randomly assigned to ACT/education or education only conditions, and outcomes focused on change in HbA1c, self-reported diabetes management and acceptance (Shayeghian et al., 2016). Results were similar to those reported by Gregg (Gregg et al., 2007). Participants who attended the ACT intervention were found to have significantly lower HbA1c (η_p^2 .25), and reported higher levels of acceptance (η_p^2 .44) and diabetes self-care (η_p^2 .22) at post-intervention than those in the education only group. These results remained stable at 3-month follow-up (Shayeghian et al., 2016).

A second RCT, conducted in New Zealand and published in 2016, produced less conclusive results. Whitehead and colleagues evaluated the benefits of a 6.5 hour nurse

led ACT/education intervention in comparison to education only (Whitehead et al., 2016). Unlike Gregg and colleagues study (Gregg et al., 2007), this study incorporated a usual medical care control condition (routine care through the participants' GP Practice), and an outcome measure of emotional functioning; the Hospital Anxiety and Depression Scale (HADS). Results of this study showed a reduction in HbA1c at 6 months post-intervention for both Education and ACT/Education groups, with 56 % of the Education group improving their HbA1c, 51% of the ACT/Education group, and only 24% in the control group. However, analyses only demonstrated a significant difference between the Education Only group and the Usual Care group. The difference between the ACT/Education and Usual Care groups did not reach significance. There were also no significant differences found between the three intervention conditions for acceptance, anxiety, depression, and understanding of diabetes (Whitehead et al., 2016).

Whitehead and co-authors (Whitehead et al., 2016) suggested that their divergent results could be attributed to differences in the mean years since participants received their diabetes diagnosis. In Gregg's (Gregg et al., 2007) study, the mean years since diagnosis was 5.3 and in Whitehead's study the mean years since diagnosis was 10.03 years. It was suggested that the period of time that had elapsed since diagnosis could affect participants' ability to adjust personal values and attitudes related to their condition. It could be that over time people become more fused with unhelpful cognitions regarding the meaning of diabetes and their ability to make behavioural changes to improve their health. Also, Gregg's (Gregg et al., 2007) study only included a 3 month follow-up, whereas Whitehead and colleagues (Whitehead et al., 2016) research reported 6 month follow-up. It is possible that in the absence of booster sessions, the benefits of the intervention decreased over time.

The lack of change across the psychological variables included in Whitehead and colleagues' study might also be attributed to floor effects. Notably, participants in all three groups had mean scores on the HADS that were within the normal range at pre-treatment. This was the case across both anxiety and depression scales and meant there was minimal room for improvement.

Cultural differences could further explain differences in outcomes across the three diabetes studies. Gregg and colleagues study was conducted in the United States (Gregg et al., 2007), Shayeghian's in Iran (Shayeghian et al., 2016), and Whitehead's in New Zealand (Whitehead et al., 2016). While Shayeghian's research demonstrates that ACT has some cross-cultural efficacy, it is possible that certain skills/constructs introduced as part of this approach may not effectively translate to a New Zealand context.

7.1.1 Summary

The above research, although somewhat mixed, suggests ACT could be an effective adjunct to lifestyle education approaches for patients with diabetes. Outcomes indicate ACT when combined with diabetes education can produce changes in self-reported diabetes management and physiological indicators of disease progression (HbA1c). Moreover, the finding by Gregg and colleagues (Gregg et al., 2007) that changes in acceptance mediated changes on these variables, suggests ACT processes were an active ingredient in these outcomes.

In two of the studies reviewed, ACT combined with education was found to be significantly more effective than an alternative active intervention that solely targeted lifestyle education. A third study failed to corroborate these findings; this could be attributed to the follow-up period, time since diagnosis, or cultural factors. While further research is still needed to establish the extent to which these results can be generalised, particularly to a New Zealand population, the potential benefits of ACT for helping

patients with diabetes improve their self-management and reduce physiological indicators of illness progression certainly warrants further research attention.

If ACT is found to be of benefit for diabetes management, it is conceivable that it may also have benefits for diabetes prevention, given that the modifiable risk factors involved in both the development and progression of type 2 diabetes are the same. Rather than solely targeting ACT/lifestyle education interventions at the level of illness management, it makes sense to also target prevention focused care. As discussed previously, providing prevention focused interventions for patients at risk of diabetes has potential to not only benefit the individuals involved but also significantly reduce pressure on a health system which is struggling to meet the demands of a rapidly exploding diabetes population. It would, therefore, make sense to explore the addition of ACT to lifestyle education interventions for people with pre-diabetes, with a view to addressing psychological and motivational factors that function as barriers to healthy lifestyle change.

7.2 ACT and Pre-diabetes

ACT's focus on increasing patients' psychological flexibility makes it a plausible addition to existing pre-diabetes lifestyle education interventions. As previous research has demonstrated (Everson-Hock et al., 2013), patients who value their health are more motivated to make lifestyle changes to improve their health. ACT seeks to enhance patients' willingness to change by assisting them to explore and connect with their personal values, and then uses this knowledge to move them from pre-contemplative or contemplative stages of behaviour change to action and maintenance (Prochaska & DiClemente, 1983). Rather than motivating patients to change by highlighting the negative consequences of developing diabetes, a message that is often highlighted in diabetes prevention campaigns and can promote fear and avoidance, the focus is on

connecting health to other valued domains of life that have personal and long-term significance (e.g., being active with whanau, maintaining independence). ACT also teaches patients' mindfulness skills to help them negotiate the many and varied psychological barriers that inevitably arise in the pursuit of their lifestyle goals, and, in doing so, provides them with tools to maintain long-term change, even when their intrinsic motivation to persist is low (Harris, 2009).

Chapter 8: The Present Study

The present study sought to explore whether incorporating an ACT component into a brief structured workshop-based pre-diabetes lifestyle education intervention would enhance its effectiveness. This chapter 1) outlines limitations of previous research and addresses how the present study attended to these, 2) highlights innovative aspects of the study and how it contributes to the literature, and 3) provides the research aims, questions and hypotheses.

8.1 Overcoming Limitations of Existing Research

When embarking on new research, it is worthwhile considering the limitations of previous research in order to create a robust methodology that produces valid and reliable results. A recent review of research examining the effectiveness of ACT for people with long-term health conditions highlighted some of the limitations of existing research in the health domain and provided recommendations for improving future research. (Graham et al., 2016). This review concluded that although ACT based interventions produced a variety of improved outcomes, only a small proportion of studies used RCT designs, sample sizes were often small, and the follow-up duration limited. The absence of RCT designs is problematic because without a control condition we cannot be sure whether results are due to the intervention, factors unrelated to the therapy (e.g., a spontaneous improvement over time), or placebo effects. Similarly, small sample sizes create issues with statistical power, due to an inverse relationship between sample size and statistical power, while the absence of extended follow-up post-intervention means we cannot be sure of the temporal stability of outcomes (Graham et al., 2016).

Graham and colleagues' review (Graham et al., 2016) provided several recommendations for improving the methodology of future research. These recommendations included: 1) conducting a priori power calculations to establish the

sample size required, 2) using RCT designs that incorporate both active and standard care or wait list control conditions, 3) ensuring active control interventions are of similar length and intensity to the experimental control, and 4) incorporating extended follow-up periods.

The methodological limitations discussed by Graham were largely consistent with my general review of the ACT research in the health domain. Notably, many of these limitations were addressed in the diabetes-specific studies. All three of the ACT/diabetes studies used RCT designs and conducted a priori power analyses to determine the required sample size. They also all incorporated an active control intervention (education only) that was of the same length as the experimental intervention. However, two of the studies (Gregg et al., 2007; Shayeghian et al., 2016) only included a brief (3 month) follow-up period and did not include a standard care control condition. Whitehead and colleagues (2016) study was the only one that included a standard care control condition and extended the follow-up period from 3 months to 6 months. While the inclusion of a third standard care intervention arm inevitably increases the sample size needed, it is important because in the absence of a standard care condition we cannot be sure whether either of the active interventions was more effective than usual care. This is important information when considering which interventions are economically feasible and worthwhile implementing on a large scale. Extended follow-up is also important for providing information about the ability of the intervention to produce sustainable changes, and identifying if, and when, additional supports or interventions should be offered to patients.

8.2 Innovative Aspects of the Research

The present study is the first conducted within New Zealand or internationally exploring the benefits of incorporating an ACT approach into a lifestyle education

protocol for patients with pre-diabetes. This study sought to build on Gregg and colleagues (Gregg et al., 2007) research with diabetes patients by adapting the ACT component of their protocol to make it appropriate for patients with pre-diabetes. The research addressed limitations of Gregg's research by: (1) including both education only and standard medical care control conditions; (2) incorporating both 3 and 6 month follow-up assessments to establish the temporal stability of changes on dependent measures; and (3) incorporating additional outcome measures that research in other domains of health have been found to benefit from an ACT approach; these included measures of emotional functioning and quality/satisfaction with life, along with more intensive assessment of self-reported lifestyle change and physiological markers of diabetes and diabetes-related complications.

8.3 Research Aims

This study aimed to:

1. Develop two brief, structured, manualised group intervention approaches for patients with pre-diabetes: Pre-diabetes education only (ED Only), and pre-diabetes education plus ACT (ACT/ED).
2. Compare the effectiveness of the two interventions, on dependent measures of lifestyle self-management, physiological indicators of pre-diabetes management, quality of life, and emotional functioning, with the provision of standard medical care.
3. Establish the temporal stability of changes by collecting data at 3 and 6 months post-intervention.
4. Explore whether changes in lifestyle self-management, physiological indicators of pre-diabetes management, quality of life, and emotional

functioning were mediated by changes in pre-diabetes knowledge/understanding.

5. Explore whether changes in key ACT therapeutic processes (psychological flexibility) mediated changes in lifestyle self-management, physiological indicators of pre-diabetes management, quality of life, and emotional functioning for those in the ACT/ED condition.

8.4 Research Questions

1. What impact does combining a pre-diabetes lifestyle education intervention with an ACT based intervention have on pre-diabetes patients' self-reported engagement in lifestyle change recommendations (physical activity, diet, and smoking) and physiological indicators of lifestyle change (HbA1c, lipids, weight, BMI and waist circumference)? Does ACT/ED have added benefits over ED Only or Standard Care?
2. What impact does combining a pre-diabetes lifestyle education intervention with an ACT intervention have on pre-diabetes patients' self-reported quality of life and emotional functioning? Does ACT/ED have added benefits over ED Only or Standard Care?
3. What are the mechanisms of change for those in the ACT/ED intervention? If changes in self-reported lifestyle management and physical indicators of lifestyle management occur for those in the ACT/ED condition, are these changes mediated by changes in acceptance and action. Are changes in these variables for either ACT/ED or ED only intervention groups mediated by changes in pre-diabetes knowledge?

8.5 Hypotheses

Based on my review of the pre-diabetes intervention literature and research on the benefits of ACT for patients with chronic health issues, including type 2 diabetes, the following predictions were made:

1. When the results of the three interventions (ACT/ED, ED Only and Standard Care) are combined, results will show statistically and clinically significant improvements over time on physiological indicators of pre-diabetes management (HbA1c, lipids, weight, waist circumference and BMI) and self-report measures of lifestyle change (diet, exercise, smoking).
2. ACT/ED and ED only will have a greater impact on self-report measures of lifestyle change (diet, exercise, smoking) and physiological indicators of pre-diabetes management (HBAIC, lipids, weight, waist circumference, BMI,) than Standard Care.
3. ACT/ED will have a greater impact on self-report measures of lifestyle change (diet, exercise, smoking) and physiological indicators of pre-diabetes management (HBAIC, lipids, weight, waist circumference, BMI,) than ED Only.

8.5.1 Secondary hypotheses.

1. ACT/ED and ED Only interventions will produce improvements in participants' quality of life at 3 and 6 month follow-up.
2. ACT/ED and ED Only will have a larger effect on participants' quality of life than Standard Care.
3. ACT/ED will have a greater effect on participants' quality of life than ED Only.
4. ACT/ED will result in reductions in anxiety, depression and distress tolerance.
5. ACT/ED will result in greater reductions in anxiety, depression and distress tolerance than either ED Only or Standard Care

6. ACT/ED will result in improvements in self-reported acceptance and action
7. ACT/ED will result in greater increases in acceptance and action than ED Only or Standard Care.
8. ACT/ED and ED Only groups will exhibit comparable levels of pre-diabetes knowledge, and their knowledge would be greater than those in the Standard Care condition.

8.5.2 Mediation hypotheses

1) For those in the ACT/ED group, improvements on self-report and physiological indicators of lifestyle change will be mediated by increases in acceptance and action.
2) For those in ACT/ED and ED Only conditions, improvements in self-reported lifestyle change and physiological indicators of pre-diabetes management will be mediated by changes in pre-diabetes knowledge.

Chapter 9: The Interventions

Three modes of intervention were developed and implemented during the course of this study: Standard Care, ED Only, and ACT/ED. This chapter provides a rationale for the use of manualised intervention approaches and outlines the content and development of the ED Only and ACT/ED interventions, including the cultural, medical, clinical and consumer consultation processes and adaptations

9.1 Rationale for the Use of Manualised Interventions

Research suggests there are advantages and disadvantages of using manualised interventions. A review of the literature by Dobson and Shaw (1988) suggested the disadvantages of manualised intervention include reduced flexibility to tailor interventions to individual patient needs, decreased ability to assess and evaluate the impact of therapist variables (i.e., creativity and empathy) on outcomes, and an emphasis on treatment fidelity over process. In contrast, they cite the advantages of manualised approaches as increased internal validity, the ability to establish the differential effectiveness of interventions, the increased ability to control for extraneous treatment variables (i.e., type and amount of intervention training), enhanced replicability, ease of training, and ability to identify the effective therapy components. More recent reviews of clinicians' perspectives of manualised interventions found that the majority of clinicians perceived intervention manuals as a useful tool for keeping therapy on course (Forbat, Black, & Dulgar, 2015), and practitioners who used treatment manuals were more likely to apply empirically validated interventions (Waller, Stringer, & Meyer, 2012).

Because it was a priority to develop an intervention that can be delivered by health practitioners from varied professions (i.e., nurses, dieticians and physical activity coordinators), ease of training, replicability and treatment fidelity were priorities. For

these reasons, a decision was made to create intervention manuals that gave clear guidelines for the content and delivery of interventions.

9.2 Intervention Mode

The ED Only and ACT/ED interventions were designed to be delivered in a brief, manualised, workshop format, based around a power-point presentation. Both of the interventions were 4.5 hours duration and delivered across two morning sessions held on consecutive weeks. The first session was 2 hours and the second was 2.5 hours, with a 15-minute refreshment break scheduled midway.

9.3 The Manuals

The intervention manuals provided workshop facilitators with the following: 1) a background and rationale for the intervention approach; 2) an outline of the intervention components, intended mode of delivery, desirable facilitator characteristics, cultural considerations, session materials, session overviews, learning goals and key messages; 3) example dialogue and interactive exercises to be used alongside a power point presentation.

9.3.1 Lifestyle education manual.

Facilitators were given a manual/guide to direct their delivery of the interventions. The lifestyle education manual provided an intervention approach that integrated education about what it means to have pre-diabetes with information about specific lifestyle changes participants could make to reduce their risk of developing type 2 diabetes. The intervention incorporated a variety of interactive activities to enhance learning, and participants were given practical tools to assist them with these changes (Appendix A).

Session 1 covered the following topics:

1. Overview of session 1

2. What is pre-diabetes?
3. Understanding HbA1c
4. Where does glucose come from?
5. Understanding the glycaemic index
6. How the body absorbs glucose, and the role of insulin in pre-diabetes/diabetes
7. Type 2 diabetes – why the worry?
8. Risk factors for developing pre-diabetes/type 2 diabetes.

Session 2 covered the following topics:

1. Review of session 1 and overview of session 2
2. What is healthy eating, and where do I start?
3. Adjusting the scales – the importance of maintaining a healthy weight
4. Quick tips for healthy eating and weight loss
5. Getting active
6. What else can I do to reduce my risk?
7. Tracking your progress
8. Summary/wrap-up

A PowerPoint presentation accompanied the facilitator manual. The presentation was adapted from an existing pre-diabetes workshop developed by Kauri Health, reviewed and updated by Manawatu/Horowhenua Diabetes Trust, and endorsed by Dr Helen Snell (Nurse Practitioner at MidCentral Health). The PowerPoint was based on pre-diabetes advice/guidelines for the lifestyle management of pre-diabetes published by the New Zealand Ministry of Health (2013). This PowerPoint was previously used by the Diabetes Trust in workshops for consumers with pre-diabetes.

The Manawatu Diabetes Trust conducted a repeated measures pilot study in 2013 to evaluate the effectiveness of the original intervention for reducing the risk of type 2 diabetes amongst patients with pre-diabetes. This study produced promising results. They found a marked improvement in pre-diabetes knowledge, with an average increase of 24.2%. They also found a statistically significant change in HbA1c, HDL and cholesterol/HDL ratio over the 12-month evaluation period. Of the 30 participants who attended the intervention and gave follow-up venous blood samples, 73 % decreased their HbA1c (by between 1.0 and 7.0 mmol/mol), and 79% improved their cholesterol/HDL ratio (by 1 to 1.1 mmol/mol). Notably, this was a repeated measures design that did not have a control condition, which means a variety of extraneous factors could have impacted on the results (i.e., we cannot be sure the education sessions alone were responsible for the changes). Also, there were no baseline blood samples collected. For the purpose of data analysis, the patient's most recent HbA1c result (obtained from medical record) was treated as the baseline result. For several participants, these samples were collected more than 3 months prior to the intervention commencing, meaning changes in outcome variables could have occurred before receiving any intervention. Despite these limitations, the findings of this study suggested further development and evaluation of the program could be worthwhile; consequently, a decision was made to use this intervention as the basis for the lifestyle education intervention used in the present study.

The original PowerPoint developed by Kauri Health was designed to be presented in a 1.5 to 2-hour workshop. For the present study, the workshop was expanded to fit within a two session 4.5-hour workshop. The duration was adjusted in collaboration with Diabetes Trust to allow incorporation of more specific information about lifestyle changes participants could make to reduce their diabetes risk, along with

additional exercises to illustrate the ideas and principles discussed. Incorporating this information made the intervention more consistent with the content of existing empirically validated interventions, such as the US Diabetes Prevention Program (The Diabetes Prevention Program Research Group, 2002).

Exercises adapted from the Diabetes Prevention Program (DPP) included exercises designed to encourage participants to consider what 'healthy eating' means, and assist them to calculate their weight loss goals and identify the calorie, fat and carbohydrate content of their food. A section on the importance of tracking their progress was also incorporated, and participants were provided with specific tools, such as a physical activity diary, food diary and weight record to assist them with this. The decision to incorporate this information was based on research indicating that monitoring body weight, physical activity and food consumption increases the likelihood of achieving and maintaining behaviour change and weight loss (Akers, Cornett, Savla, Davy, & Davy, 2012).

9.3.2 ACT/Education manual.

Session 1 of the ACT/ED manual included all the lifestyle education material provided in the ED Only manual. Session 2 covered the same topics as session 1, just in an abbreviated form. It also included two additional topics, which explored psychological and motivational factors that can influence health behaviour (Appendix B).

Session 2 covered the following topics:

1. What is healthy eating, and where do we start?
2. Adjusting the scales – the importance of maintaining a healthy weight.
3. Quick tips for healthy eating and weight loss.
4. Getting active.

5. What else can I do to reduce my risk?
6. Tracking your progress.
7. Time to take action: Creating values-based goals.
8. Dealing with barriers to lifestyle change.
9. Summary/Wrap-up.

The first 30 minutes of the session was spent on topics 1 to 6, and approximately 2 hours on topics 7 to 9. The psychological intervention component of the manual was based on a brief ACT approach. The goal was to assist participants to connect with and explore their personal values behind improving their health, and then use this knowledge to motivate and inspire them to make healthy changes to their lifestyle. The intervention also sought to facilitate development of adaptive skills for dealing with uncomfortable/unhelpful cognitions and feelings related to having pre-diabetes, to prevent these from functioning as barriers to lifestyle change. For example, participants were introduced to basic mindfulness skills, such as acceptance and defusion, as a way of dealing with difficult or painful thoughts and feelings related to pre-diabetes/diabetes. These skills were illustrated through metaphor and experiential exercises.

The content of the ACT component of the manual was adapted from the Acceptance and Commitment Therapy Manual for Diabetes Self-Management developed by Gregg (Gregg et al., 2007). The wording of the exercises was adjusted to make them more appropriate for patients with pre-diabetes and to fit within the time constraints of the workshop. The PowerPoint that accompanied this workshop was the same as the power point adapted for the lifestyle education intervention, with additional slides incorporated to illustrate the ACT processes introduced.

9.4 Group Guides and Hand-outs.

Group guides were created to facilitate participants' learning during and following the workshop. The group guides contained all of the PowerPoint slides shown during the workshops, the key messages presented by the facilitators, and the handouts and exercises used (Appendices C and D).

Additionally, at the start of the first workshop, all participants were given an information pack containing seven pamphlets created by Diabetes New Zealand (Appendix E). These were the same pamphlets given to participants in the Standard Care condition. The pamphlets provided information about risk factors and complications of type 2 diabetes, what it means to have pre-diabetes, and lifestyle changes (pertaining to diet and physical activity) that could be made to reduce their risk of developing type 2 diabetes and diabetes related complications (i.e., cardiovascular disease).

During the workshop, all participants also received a Diabetes New Zealand portion size plate, a wallet-sized food label reading card, a calorie and fat counter (Borushek, 2014), and carbohydrate counting cards. These tools were designed to facilitate ongoing learning post-intervention (Appendix F).

9.5 Standard Care Intervention

Participants assigned to this condition did not attend a workshop. At the end of their first assessment session (explained later in this chapter), they were given the brochures outlined above, which provided them with information about what it means to have pre-diabetes and diabetes, along with lifestyle changes they could make to reduce their risk of developing type 2 diabetes in the future. Throughout the study, they continued to receive standard medical care/follow-up through their GP Practice in line

with guidelines for pre-diabetes management provided by the Ministry of Health (Ministry of Health, 2013)

9.6 Consultation Process

9.6.1 Cultural consultation.

Both ED Only and ACT/ED manuals highlighted the importance of being mindful and respectful of the cultural beliefs and experiences of the other workshop attendees. Cultural consultation was sought to ensure the manuals were sensitive to the needs of Māori.

Cultural consultation was provided by Dr Hukarere Valentine (Ngati Kahunguna descent). Dr Valentine is a Senior Clinical Psychologist with the Massey Health Conditions Psychology Services. She has extensive therapeutic experience with patients diagnosed with type 2 diabetes, and she provides cultural consultation for graduate psychology students and clinicians working within the Massey University Psychology team. Dr Valentine reviewed the initial draft and final version of both the intervention manuals, and she provided feedback on process and content adaptations that could be made to increase the interventions sensitivity to and relevance for Māori. Two key changes were made to the manual following this consultation process:

1. Mihimihi, a process of introductions where people share about themselves, was included at the start of the first session. McClintock and colleagues highlight the importance of incorporating indigenous approaches, like mihimihi, in health research as a way of fostering respect and positive interactions between the tangata whenua (research participants) and the manuhiri (researchers/workshop facilitators) (McClintock, Mellsop, & Moeke-Maxwell, 2010). The mihimihi is about building connections between research participants and facilitators and can be useful for clarifying the research purposes. A mihimihi process can also

increase the likelihood participants will complete the research and facilitates a sense of partnership between researchers and participants (Boynton, Wood, & Greenhalgh, 2004).

In the present study, the mihimihi process began with facilitator introductions, including their name, where they were originally from/iwi connections (if applicable), work background, how they became involved in facilitating pre-diabetes interventions, their role in facilitating the sessions (to assist participants to find out more about what having pre-diabetes means, and day to day changes they can make to their lifestyle to reduce their risk of developing type 2 diabetes in the future) and their favourite food. Following facilitator introductions, participants were asked to introduce themselves. The mihimihi process was slightly different for ACT/ED and ED Only participants. Participants in both groups were asked to provide the information outlined above. In addition, those in the ACT/ED condition were asked to briefly describe two things that were most important in their life. The question aimed to encourage them to start connecting with their personal life values. These values were further explored during the second session as a way of motivating participants to commit to behavioural changes.

2. Each session was opened and closed with a whakatauki (a Māori proverb). Participants were invited to start the session with their own whakatauki, however the manual provided an example of a whakatauki that could be used by the facilitator if this invitation was declined. The whakatuaki used during the first session was “Puraho maku. Kei ngaure o mahi.” The English translation was “in order to catch fish you must first place your basket in the water.” This whakatuaki was considered relevant to the goals of the interventions because it captures the

importance of being willing to take steps outside one's comfort zone in the interest of creating life change. The whakatauki examples provided were consistent across both interventions.

9.6.2 Consumer consultation.

Two pre-diabetes consumers, one of Māori descent and one of Pākehā descent, reviewed the final draft of the facilitator guides. They were asked to provide informal verbal feedback on their ability to understand the information provided and the perceived usefulness of the intervention for supporting lifestyle change to decrease their diabetes risk. The feedback they provided was largely positive. Comments included "I wish someone had given me this feedback when I was first told I was at risk of diabetes" and "everyone needs to know this stuff." Suggestions were made about some minor wording changes that could be made to enhance understanding, and these changes were incorporated in the final version of the manual.

9.6.3 Medical and clinical consultation.

Medical/clinical consultation was provided by Dr Helen Snell. Dr Snell is a Nurse Practitioner with the Diabetes Lifestyle Centre at Palmerston North Hospital, and she has extensive clinical and research experience with patients diagnosed with type 2 diabetes. Dr Snell reviewed the initial and final drafts of the ACT/ED and ED Only manuals to ensure the medical information provided was accurate and consistent with New Zealand Ministry of Health practice guidelines. Again, some minor wording changes were made as a result of this feedback. For example, the term pre-diabetic was replaced with people with pre-diabetes.

The initial draft of the ED Only manual was also reviewed by Tracy McNeur (Clinical Nurse Specialist and author of the original education presentation from which the PowerPoint for this study was adapted) and Jackie Thompson (Clinical Nurse

Specialist from Diabetes Trust, who facilitated the original workshops). Based on their feedback, minor wording changes were made to enhance participants' understanding of the concepts presented. Tracy and Jacqui were also able to provide ideas of tools participants could be given to support their learning. For example, to illustrate and enhance recollection of portion size guidelines provided by Diabetes New Zealand, it was suggested that participants were given paper plates visually depicting the guidelines.

The dietary education components of both facilitator and group guides were reviewed by Kristen White, a registered Senior Dietitian with the Diabetes Trust. The purpose of this review was to ensure that the dietary information provided was consistent with current research and the Ministry of Health Guidelines. Minor changes were made to the manual as a result of this consultation. For example, the initial draft of the facilitator guide used calories to define the energy value of food. However, Kristen pointed out that in New Zealand, some food packaging only displays kilojoules. Consequently, a decision was made to define the energy value of both calories and kilojoules and use these terms concurrently during the workshops.

Throughout this research, consultation was provided by a pre-diabetes working group established by the MidCentral District Health Board (DHB). This group was made up a variety of health professionals with expertise in pre-diabetes/diabetes prevention and management, including Dietitians, General Practitioners (GPs), Nurse Practitioners, Clinical Nurse Specialists, Physical Activity Coordinators, and Pharmacists. The purpose of this group was to define pathways to enhance the care of patients with pre-diabetes, with an overarching goal of diabetes prevention. This working group provided informal advice about ways of recruiting participants to the study, as well as the content and process of intervention delivery.

The ACT component of the ACT/ED manual was reviewed by a Senior Clinical Psychologist, Dr Amber Barry. Dr Barry has extensive clinical experience in the use of ACT with patients with long-term health difficulties, including type 2 diabetes, and she has conducted workshops and presentations on the use of ACT with patients affected by long-term health conditions. Dr Barry reviewed the initial draft of the ACT/ED manual and provided feedback regarding adaptations that could be made to the ACT protocol used by Gregg and colleagues (Gregg et al., 2007) to ensure it was consistent with current clinical research and practice and appropriate for patients with pre-diabetes. Based on Dr Barry's feedback, an ACT metaphor known as the "chessboard," which illustrates the ACT process of "self as context," was left out of the manual. This concept is arguably the most challenging ACT process to understand, and the clinical experience of Dr Barry and the researcher suggested it was too complex to effectively illustrate in the context of a brief workshop.

A second exercise, the eulogy, that was included in Gregg's (Gregg et al., 2007) study was replaced with an alternative exercise, the "birthday speech." These exercises highlight the same ACT processes and are designed to assist people to connect with personal life values and use these values as an impetus for making adaptive behavioural changes. However, Dr Barry expressed concern that the eulogy exercise might promote morbid associations and trigger a fear response when used in group situations**.** She suggested the birthday speech as an appropriate alternative. This exercise is endorsed by advanced ACT practitioners and educators, such as Dr Russ Harris (Harris, 2009), and has been used in previous ACT research.

Chapter 10: Methods

This chapter explains the methods used to compare and evaluate the intervention approaches. It outlines the research design, the methods used to determine the sample size, inclusion and exclusion criteria, recruitment processes, participant demographics, group assignment, ethical considerations, and selected outcome measures. Finally, it details the intervention and assessment phases from pre-intervention to 6 month follow-up.

10.1 Design

This was a randomised, controlled trial with repeated measures. Participants were randomly assigned to one of three conditions: ACT/ED, ED Only, or Standard Care. Those in the ACT/ED and ED Only conditions received a total of 4.5 hours of intervention, delivered over 2 sessions and held on consecutive weeks. Those in the Standard Care condition did not attend workshops but were given written information about what it means to have prediabetes and diabetes. All 3 groups continued to receive standard care through their GP throughout the study. Four assessment phases were conducted, baseline, post intervention, 3 month follow-up and 6 month follow-up. See Table 1 for a description of the three intervention groups and their purposes, along with the assessment types and timing.

Table 1

Intervention Modes and Purposes, and Assessment Type/Timing

Intervention	Mode	Purpose	Assessment (Type/Timing)
ACT/ED	Two workshops held on consecutive weeks. Brochures on pre-diabetes/diabetes. Standard care through their GP.	To provide information about what it means to have pre-diabetes/diabetes and lifestyle changes to reduce the risk of developing diabetes. Psychological strategies to deal with uncomfortable/unhelpful thoughts and feelings that can function as barriers to adaptive lifestyle change.	Pre-assessment (1 week prior to attending the workshop) Post-assessment (directly following the 2nd workshop) 3 month follow-up 6 month follow-up
ED Only	Two workshops held on consecutive weeks. Brochures on pre-diabetes/diabetes. Standard care through their GP.	To provide information about what it means to have pre-diabetes/diabetes and lifestyle changes to reduce the risk of developing diabetes	Pre-assessment Post-assessment 3 month follow-up 6 month follow-up
Standard Care	Brochures on pre-diabetes/diabetes Standard care through their GP	To provide information about what it means to have pre-diabetes/diabetes, and lifestyle changes to reduce the risk of developing diabetes	Pre-assessment 3 month follow-up 6 month follow-up

10.2 Analysis of Sample Size

A priori power analysis using G* 3.1.2 software (Erdfelder, Faul, & Buchner, 1996) was conducted to determine recruitment targets. It was calculated that a sample size of 158 (53 per condition) would be required to detect an effect size of 0.50 (Cohen's *f*), with 80% power at a 5% significance level; this is considered a medium effect size. Based on previous research exploring the impact of an ACT/Lifestyle Education intervention on diabetes self-management, effect sizes in the medium range were expected (Gregg et al., 2007). Gregg and colleagues reported a significant moderate effect, F 91,78) = 7.14, p = .009, η_p^2 = .08, for ACT/ED over Education Only in the achievement of diabetic control (defined as HbA1c < 60)(Gregg et al., 2007). Based on this finding and allowing for a attrition rate of approximately 20%, as seen in the Finnish Diabetes Prevention Study (Lindstrom et al., 2003), the intention was to recruit 189 participants for the present study (63 per intervention).

10.3 Inclusion Criteria

Inclusion criteria required that patients were:

1. Over the age of 18
2. Fluent in spoken and written English
3. Had a formal classification of pre-diabetes from a medical professional.

The prediabetes inclusion criteria were based on World Health Organisation (WHO) criteria for pre-diabetes classification. This requires patients to have an impaired fasting glucose (IFG between 6.1 and 6.9 mmol-1 inclusive) and an impaired glucose tolerance (IGT 2 hour postprandial glucose concentration between 7.8 and 11 mmol), and/or an HbA1c between 41 and 49.

10.4 Exclusion Criteria

Patients were ineligible to participate in the study if they:

1. Were cognitively impaired.

2. At risk of harm to/from themselves or others (i.e., suicidal/homicidal ideation).

3. Had a comorbid medical diagnosis or condition that was terminal and likely to be fatal within one year.

4. Were already participating in a formal pre-diabetes lifestyle education intervention.

5. Were receiving psychiatric or psychological intervention at the time of recruitment or had a severe psychiatric disorder (e.g., schizophrenia).

6. Met criteria for type 2 diabetes. Again, this was based on WHO criteria (i.e., IFG greater than or equal to 7mmol/l, and/or 2-hour plasma glucose of greater than or equal to 11.1 mmol/l and/or HbA1c of 50 mmol/l or greater).

These inclusion and exclusion criteria were put in place to reduce the potential for confounds that could impact on the reliability and validity of the research (e.g., difficulty comprehending English could impact on the benefits participants received from the intervention). These criteria were also put in place to reduce risk. For example, the decision to exclude participants with safety/risk issues was made because the interventions were not designed to address these issues. Including participants with safety/risk issues also had the potential to compromise the learning of other participants.

10.5 Recruitment

10.5.1 Recruitment consultation.

Before commencing the research, the lead researcher consulted with the District Health Boards Pre-diabetes Working Group, the Manawatu Diabetes Trust and five

local GP practices to establish whether it was realistic to recruit a sample of 190 from the Palmerston North region. The practices consulted all indicated they had at least 100 patients who met criteria for pre-diabetes, and the Manawatu Diabetes Trust said they were approached frequently by Practice Nurses requesting interventions for patients with pre-diabetes. The consensus was that this sample size could be easily recruited from within the Palmerston North area. This feedback was consistent with New Zealand statistics indicating that approximately 25% of the population meet criteria for pre-diabetes (Coppell et al., 2013). Based on these statistics and my consultation with health professionals, the recruitment goal for the present study seemed realistic and attainable.

10.5.2 Recruitment processes.

All GP practices in Palmerston North and Feilding were approached to participate in the study. Practices that expressed interest in referring to the study were informed that the purpose of the research was to find out "which types of lifestyle intervention approaches were most effective for helping patients with pre-diabetes make lifestyle changes to reduce their risk of developing type 2 diabetes." They were not provided information about the content of the interventions or the research hypotheses. Additionally, potential referrers were given an information sheet which explained the expectations of participation in the study and the inclusion and exclusion criteria (Appendix G).

Thirteen of the GP Practices approached agreed to take part in the study; however, referrals were only received from eight practices. GPs and Practice Nurses were asked to provide patients who met inclusion criteria with an invitation to participate in the study. The invitation provided a broad outline of the purpose of the research and expectations of participation (Appendix H). If patients expressed interest in being involved, they were asked if they were willing to be referred to the study. Their

health professional then completed a referral form and mailed or faxed this to the researcher (Appendix I).

On receipt of the referral form, the researcher contacted the potential participant by phone and gave them further information about the purpose of the research and participation requirements. They were also given the opportunity to ask questions or raise concerns. Potential participants were given limited information about the interventions. They were told that they could be assigned to one of three interventions for people with pre-diabetes, but they were not informed of the intervention content, goals or research hypotheses.

If, after speaking with the researcher, the potential participant expressed interest in taking part in the study they were sent an information sheet and consent form for further consideration (Appendix J). They were then phoned a week after this information was sent and asked if they would still like to take part in the study. Those who agreed to take part were required to complete a participant consent form. This could be either mailed back to the researcher before the first assessment or brought to their initial assessment session.

10.5.3 Recruitment methods.

Recruitment methods included speaking at local practice nurse forums, meetings and presentations with the local Primary Health Organisation, meetings with GP Practices (along with fortnightly follow-up phone calls and email reminders), and posters and flyers in GP Practice waiting areas.

Despite the above recruitment methods, 6 months after recruitment commenced only 60 participants had agreed to take part in the study. In an effort to generate additional referrals, a decision was made to accept self-referrals to the study. Media releases were created for local newspapers, including The Manawatu Standard, The

Tribune, Massey News, MidCentral Health and Primary Health Organisation Newsletters (Appendix K). Invitations to participate in the research were also placed in community facilities such as local gyms, supermarkets, pharmacies, and hospital notice boards, and social media posts were placed on Instagram and Facebook.

The recruitment zone was also extended to Dannevirke. Dannevirke is within the MidCentral region but was not previously considered due to its distance from Palmerston North (approximately 50 minutes). However, given the low referral rate, a decision was made to approach a large GP Practice in Dannevirke. This Practice agreed to refer to the study and sent a mass mail-out of participant invitations to 400 patients who met criteria for pre-diabetes. This mail-out generated 15 referrals. Despite substantial investment of time and energy, after 12 months of recruitment and failure to generate more than a trickle of new referrals, a decision was made to cease recruitment.

10.6 Participant Population

A total of 98 patients were either referred or self-referred to the study. Of these patients, 87 took part in at least one assessment session, 84 completed the study, and 83 provided data suitable for analysis.

Of the 98 patients referred, 2 participants were excluded from participation because following referral to the study they received blood test results indicating they met criteria for type 2 diabetes. Additionally, 9 potential participants declined to take part when provided further information by the researcher about the requirements of participation. Seven of these participants declined to participate due to the time requirements and difficulty fitting workshops around work and family commitments. The other 2 participants cited personal situations that had occurred since the time of referral, which prevented them from taking part.

Of the 87 participants who attended an initial assessment session, 3 did not complete the study: 1 participant passed away shortly after participating in the workshop, another relocated cities following the workshop, and a third was diagnosed with a terminal illness prior to their 3 month follow-up. One participant completed the study but a decision was made not to exclude their data from the analysis because their HbA1c result at pre-assessment was well below the pre-diabetes range (HbA1c = 33).

10.7 Participant Demographics

The age of those who completed the study ranged from 30 to 84; the mean age was 66.6. Males outnumbered females, with 45 males participating and 38 females**.** Table 2 shows the demographic characteristics of the sample. Of the sample, 89% identified as New Zealand European and 6% as Māori. Other ethnic populations represented included Cook Island Māori, Chinese, and Malay. Most participants (96%) reported that English was their first language.

With regards to education, employment and marital status, the majority of participants had at least a secondary level qualification (70.2%) and 22% were university graduates. A large proportion of the sample indicated they were retired (52 %), with only 27.4% in full time employment, and most endorsed their relationship status as married (63.1%).

Table 2

Demographic Variables

Intervention Sample Characteristic	ACT/ED (*n* =28)	ED Only (*n* = 28)	Standard Care (*n* = 27)	Overall (*n* = 83)
Age (mean, years)	67.71	68.14	63.85	66.6
Gender (% female)	45.8	50.0	40.7	45.8
Gender (% male)	54.2	50.0	59.3	54.2
Ethnicity (%)				
NZ European	89.3	89.3	88.9	89.2
Māori	7.1	7.1	3.7	6.0
Cook Island Māori	3.6	0.0	0.0	1.2
Chinese	0.0	0.0	3.7	1.2
Malay	0.0	0.0	3.7	1.2
Other	0.0	3.6	0.0	1.2
Marital status (%)				
Single	7.1	7.1	7.4	7.2
Married	71.4	57.1	63.0	63.9
Defacto	0.0	10.7	7.4	6.0
Separated	0.0	3.6	3.7	2.4
Divorced	7.1	7.1	11.1	8.4
Widowed	14.3	14.3	7.4	12.0
Education (%)				
Primary	0.0	3.6	3.7	2.4
Secondary	64.3	71.4	74.1	69.9
University graduate	25.0	21.4	22.2	22.9
Post-graduate	10.7	3.6	0.0	4.8
Employment (%)				
Full-time employment	32.1	14.3	33.3	26.5
Part-time employment	10.7	21.4	22.2	18.1
Unemployed/looking for work	3.6	0.0	0.0	1.2

Retired	53.6	60.7	44.4	53.0
Unable to work due to disability	0.0	3.6	0.0	1.2
First language				
English				96.4
Danish				1.2
Malay				2.4

Note. ACT = Acceptance and Commitment Therapy. ED Only = Education Only.

As shown in Table 3, a high proportion of participants had comorbid medical conditions (78.6%). This information was based on a health status questionnaire completed by their GP. Data for 8 participants were missing due to unreturned questionnaires. Available data showed that the mean number of comorbid diagnoses was 2.28 (SD = 1.35), and 29.8% of those had a cardiovascular condition (note, hypertension and hyperlipidaemia were not included in this category).

With regards to medication use, 78% of the sample was taking prescription medication at the time of referral to the study. Data were missing for 8 participants. Table 3 shows the proportion of participants on various categories of medication, as identified by their GP.

Information about the mental health status of patients collected via the GP questionnaire indicated that 4 participants (4.8%) had a psychiatric history. Three of those participants had a history of depression and 1 a history of anxiety. Data was missing for 8 participants.

Information collected from GPs regarding the year of pre-diabetes diagnosis indicated that the date of diagnosis ranged from 1995 to 2016 (median = 2014). Information obtained from medical records on the patient's most recent HbA1c

diagnosis showed the mean HbA1c before entering the study was 42.2. HbA1c history was unavailable for 12 participant.

Table 3

Health Demographics

Characteristic	ACT/ED (*n*= 28)	Education (*n* = 28)	Standard (*n* =27)	Overall (*n* =83)
First identified as pre-diabetic (median, year)	2014	2014	2014	2014
Existing medical conditions (%)	88.0	80.0	92.0	86.7
Number of comorbid medical conditions (M)	2.38	1.95	2.52	2.28
Cardiovascular Conditions	76.9	47.4	26.1	45.5
Medications				87.8
Statins	58.3	54.2	40.9	51.4
Steroidal meds	8.3	12.5	9.1	10.0
Diabetes meds	0.0	4.2	31.8	11.4
Antidepressants	12.5	25.0	22.7	20.0
Antipsychotics	0	0	4.5	1.4
Hypertensives	66.7	50.0	59.1	58.6
Diuretics	8.3	12.5	4.5	8.6
Bronchodilators	12.5	12.5	27.3	17.1
Most recent HbA1c prior to entering the study (M)	42.68	41.84	42.18	42.23
Psychiatric History (%)	0.0	8.0	8.0	5.3
Depression	0	7.1	3.7	10.8

Anxiety	0	3.6	0	3.6

Note. Valid percentage was used to account for missing data. M = mean. % = percentage. *N* = number of participants

10.8 Group Assignment

Once participants had agreed to take part in the study, they were randomly assigned to intervention conditions using Graph Pad random number generator software (2015). Participants were then contacted via phone and booked in to attend assessment and (if applicable) intervention sessions**.** Participants were blind to the intervention group to which they were assigned and were not given information about the nature/content of the other intervention groups. There were 28 participants in the ACT/ED condition, 28 in the ED Only condition, and 27 in the Standard Care condition. Those in the Standard Care condition were asked to attend 3 assessment sessions held at 3 monthly intervals and were told that at the end of the first assessment session they would be provided information about what it means to have pre-diabetes and ways of reducing their risk of going on to develop type 2 diabetes. They were also told they would be required to have a venous blood sample taken to determine their current diabetes risk, and this needed to be completed during the week following their assessment. They were told they would be given a Medlab form when they attended their assessment session.

Those in the ACT and ACT/ED conditions were given identical information about assessment requirements. However, in addition to attending 3 assessment sessions and having blood samples taken, those in the ED Only and ACT/ED conditions were asked to attend two workshops (held on consecutive weeks), commencing the week following their initial assessment. They were told these workshops were designed to provide them information about what it means to have pre-diabetes and ways of reducing their risk of developing type 2 diabetes.

10.9 Ethical Issues

This research was approved by the Health and Disability Ethics Committee (Reference 14/NTA/126) and registered with the Australia New Zealand Clinical Trials Registry. Below are the key ethical issues that were considered when designing this research.

10.9.1 Optimising benefits.

A key ethical consideration when embarking on this research was the possibility that some participants (depending on the intervention condition to which they were assigned) might receive a more effective intervention than others. To manage this risk, a decision was made that if one intervention condition were found to be significantly more effective than others, patients who participated in the alternative interventions would be offered that intervention upon research completion.

10.9.2 Reducing risk.

To minimise the risk of physical harm to participants, throughout the course of the research all participants continued to receive standard medical follow-up through their GP practice (in accordance with guidelines provided for prediabetes management by the Ministry of Health (2013). Every participant's GP was informed of their participation in the study; a GP information sheet, along with a health history questionnaire, was sent prior to their first research assessment session. Medlab sent all blood test results collected during the study to the participant's GP. Permission to provide the GP with this information was included in the participant consent form, and provision of consent was a participation requirement. Participants were also mailed a copy of their blood test results and encouraged to contact their GP or Practice Nurse if

they had concerns or required clarification about the interpretation or health implications of their results.

No formal safety monitoring arrangements were put in place to minimise psychological harm. Although participation in the ED Only or ACT/ED condition involved discussion of topics that could potentially bring up uncomfortable and distressing emotions for participants, the facilitation of emotional expression is a psychological process encouraged, rather than avoided, within an ACT approach. Moreover, both ED Only and ACT/ED groups were facilitated by a registered Dietitian and Senior Clinical Psychologist who both had experience running group interventions, had skills in effectively dealing with difficulties that can arise in these contexts, and were aware of appropriate referral avenues should participants exhibit signs of psychological distress. As mentioned previously, clinical and medical supervision was also sought throughout the study, providing an additional safeguard to ensure group facilitators appropriately dealt with emotional or medical concerns. If any of the interventions were found to have adverse effects on participants, as determined through assessment results, the plan was to discuss this with appropriate clinical, medical or research consultants and determine an appropriate course of action.

10.9.3 Confidentiality.

The primary investigator was the only person with access to health information obtained during the study (aside from venous blood results, which were collected and analysed by Medlab). Medlab staff were not given information about the purpose of the research. The researcher administered all other outcome measures, and this information was stored in a locked filing cabinet.

Key coding was used to separate personally identifiable data from substantive data. An arbitrary code/ number was assigned to each data/identifier pair before splitting

them. Identifying data was then stored on a password protected computer at the Massey Psychology Clinic. If there were concerns about the physical or emotional safety of a participant (based on the results of questionnaires or physiological results), identifying data could be accessed by the primary researcher and the participant contacted. This situation did not arise during the study.

10.9.4 Potential conflicts of interest.

The primary researcher was employed as a Clinical Psychologist for the Massey University Health Conditions Psychology Service, which provides psychological support for patients with long-term health conditions, including type 2 diabetes. Although patients with pre-diabetes do not meet criteria for this service, if they were to go on and develop type 2 diabetes, they could potentially be referred there. The plan was that if research participants presented to this service, they would be offered the option of seeing another clinician.

10.9.5 Participant reimbursement.

Participants received a $15 petrol voucher after attending each of the three assessment sessions (pre, 3 month and 6 month) to reimburse them for travel costs. No reimbursement was provided for workshop attendance.

10.10 Outcome Measures

The outcome variables were physiological indicators of pre-diabetes management, HbA1c, lipids, weight, body mass index and waist circumference; self-report measures of lifestyle change pertaining to dietary intake, physical activity; measures of quality/satisfaction of life, and measures of emotional functioning. Changes in key ACT therapeutic processes (acceptance and action) were also assessed, and a brief measure of treatment satisfaction was included to establish whether there were differences between ED Only and ACT/ED conditions in this regard. Finally, pre-diabetes

knowledge/understanding was assessed to determine whether changes in primary outcomes were related to changes in pre-diabetes knowledge.

The measures listed below were chosen because they have sound psychometric properties. They also provided internationally comparable data due to being used in previous diabetes and/or pre-diabetes research.

10.10.1 Physical indicators of pre-diabetes management.

HbA1c, lipids, BMI, weight, and waist circumference were physical outcome measures. Research indicates these are key indicators of diabetes risk/management (New Zealand Health and Disability Strategy, 2003). The methods of assessing the above variables followed guidelines provided by the Ministry of Health (2013).

10.10.1.1 HbA1c.

HbA1c was assessed via venous blood samples, which were drawn and analysed by an accredited local laboratory, Medlab. Participants were given a referral form and asked to attend one of several Medlab facilities in the MidCentral region where a trained Phlebotomist took venous blood samples. Blood results were mailed directly to the researcher by Medlab, then mailed by the researcher to participants.

New Zealand Ministry of Health recommendations for classification of pre-diabetes were used, which define people with pre-diabetes as having an HbA1c between 41 and 49 mmol/mol. An HbA1c of 50 or greater was defined as type 2 diabetes, and an HbA1c equal to or less than 40 was defined as within the normal range (Ministry of Health, 2013. It should be noted that these cut-offs are somewhat arbitrary. Although the relationship between HbA1c and microvascular changes tends to occur when HbA1c is greater than 40 (Florkowski, 2013), there is some research to suggest the risk of cardiovascular events can increase with HbA1c levels as low as 31 mmol/mol (Khaw et al., 2004).

HbA1c provides an indication of chronic glycaemia. This should be differentiated from current glycaemia, which can be affected by factors such as the food the participant has recently consumed. In contrast, HbA1c gives an indication of glycaemia over the 8 to 12 week life span of the red blood cells, by measuring the number of glucose molecules attached to haemoglobin (Little & Sacks, 2009). Recent blood glucose levels most strongly influence HbA1c. Approximately 50 percent of an HbA1c value is established in the month before testing; a further 25% is established in the month prior (Florkowski, 2013).

There is some debate as to whether HbA1c is the most accurate measure for diagnosing diabetes or pre-diabetes metabolic states, with some research indicating it lacks the sensitivity of oral glucose tolerance testing (Pajunen et al., 2010). However, HbA1c is now accepted by the World Health Organisation (World Health Organization, 2011), the American Diabetes Association (American Diabetes Association, 2011), and The New Zealand Ministry of Health (Ministry of Health, 2013) as a reliable and valid method of assessment, and it is the method recommended by the New Zealand Society for the Study of Diabetes (2012) for diagnosing both diabetes and pre-diabetes. With regards to the ability of HbA1c to predict clinical outcomes, research indicates it is as good at predicting microvascular changes and outcomes (i.e., retinopathy) as fasting or 2-hour plasma glucose testing (Colagiuri et al., 2011).

HbA1c is also more time effective, and convenient for the patient than traditional methods of diagnosis, such as oral glucose or fasting plasma glucose testing, as it does not require fasting or dietary change and only one blood sample is required (Florkowski, 2013). In contrast, OGTT requires overnight fasting and a specified diet for the three days before testing. OGTT is also poorly tolerated by a significant proportion of patients, resulting in low compliance rates and additional testing. In the

present study, these were important methodological considerations as these factors can impact on participant recruitment and retention (Florkowski, 2013).

10.10.1.2 Body weight and body mass index (BMI).

Obesity-related chronic inflammation has been identified as a key risk factor for the development of insulin resistance (Bhattacharya & Mukherjee, 2016). Having a BMI greater than 30 is an individual risk factor for the development of type 2 diabetes (Ministry of Health, 2012). BMI is a measure of the ratio of body fat to weight. BMI was calculated using the participants' height and weight. The formula used was the participant's weight in kilograms divided by their height in metres squared.

Body weight was assessed using Weight Watchers calibrated bioelectrical impedance scales. Patients were requested to wear light, loose clothing and remove their shoes before being weighed. Weight was recorded in kilograms to the nearest 0.1 kg.

Height was measured using a Seca 213 portable stadiometer on a firm even floor. Participants were requested to remove their shoes and stand up straight with their head facing straight ahead and their heels, shoulders and buttocks contacting the back of the stadiometer. Measurements were taken to the nearest millimetre.

For the purpose of analysis and interpretation, New Zealand Primary Care Guidelines for the categorisation of BMI were used (Ministry of Health, 2012)**:** Normal = 18.5 to 24.9 kg/m^2, overweight = 25.0-29.9 kg/m^2, obese = 30 kg/m^2 or greater.

10.10.1.3 Waist circumference.

Waist circumference was assessed because a waist circumference equal to or greater than 100 for men and 90 for women has been found to be risk factor for the development of type 2 diabetes (Ministry of Health, 2012). Waist circumference was measured using a Seca tape measure. Measurements were taken while the participant

was standing up straight and attired in light clothing. The measurement was taken between the rib and iliac crest to the closest 0.1 cm.

10.10.1.4 Lipids.

Lipids were included as a measure of physiological change because prospective research indicates dyslipidaemia is a risk factor in the development of type two diabetes and diabetes-related complications (Song et al., 2016; Wilson et al., 2007). Associations have been found between a variety of lipid measures and diabetes risk. High triglycerides, total cholesterol, and LDL cholesterol have been associated with up to 6 times greater risk of type 2 diabetes (Song et al., 2016) and low HDL has been associated with an increased risk of vascular diseases. Lipid results have been frequently used in previous research as markers of diabetes and cardiovascular risk (Ridker, Rifai, Cook, Bradwin, & Buring, 2017; Tajima et al., 2014).

In the present study, venous blood samples were taken by a trained phlebotomist and analysed in a certified Med Lab facility. A full lipid profile was obtained; total cholesterol, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C) and triglycerides. Total cholesterol refers to all of the cholesterol in the lipoprotein particles. LDL cholesterol refers to the amount of cholesterol in the LDL particles. This is often referred to as “bad’ cholesterol because it deposits cholesterol along the blood vessel walls and is associated with an increased risk of atherosclerosis. Levels of LDL-C are obtained from the results of total cholesterol, HDL- C and triglycerides. HDL cholesterol refers to the amount of cholesterol in the HDL particles. It is often referred to as “good” cholesterol because it helps clear the LDL cholesterol and delivers them to the liver to excrete. Finally, triglycerides are a measure of all of the triglycerides contained in the lipoprotein particles; the majority of

which are very low density lipo-proteins (American Association for Clinical Chemistry, 2017).

When analysing lipid results, the following Ministry of Health Guidelines (Ministry of Health, 2012) were used to identify participants at increased cardiovascular risk. Levels below, or in the case of HDL-C, greater than these were classified within the normal range.

1. Total cholesterol greater than 4.0 mmol/L
2. LDL cholesterol greater than 2.0 mmol/L
3. HDL cholesterol less than 1.0 mmol/L
4. Triglycerides greater than 1.7 mmol/L

10.10.2 Lifestyle behaviours.

Three lifestyle behaviours were assessed: dietary intake, physical activity, and smoking.

10.10.2.1 The Dietary Instrument for Nutrition Education (DINE) (Roe, Strong, Whiteside, Neil, & Mant, 1994).

The DINE was used to assess fat and fibre intake. The DINE assesses the dietary intake of 19 food groups that are frequently consumed in western cultures and provides overall scores for fat (broken down into saturated and unsaturated fat) and fibre intake. A score is assigned to each food group based on the nutritional content of an average portion size and how often it is consumed. Participants can be categorised according to high, medium and low levels of fibre and fat consumption (Little & Margetts, 1996).

The DINE was chosen because it has been previously used as an assessment tool in studies exploring the impact of lifestyle interventions with participants with impaired glucose regulation (Troughton et al., 2015) and would, therefore, provide comparable

data. The other advantage is that it is a brief, clinician-administered, structured questionnaire, which can be administered by health professionals without specialist nutrition knowledge or training. The DINE takes around 10 minutes to administer and score, and research indicates it has reasonable concurrent validity. For example, when the DINE method was compared with results from a 4-day diet recall, Pearson correlation coefficients were reported at 0.51 for total fat, 0.57 for saturated fat, 0.43 for polyunsaturated fat, and 0.46 for fibre intake. Exact categorisation agreement was 53% for fats and 52% for fibre intake. These results were better than the psychometric properties of other brief self-report measures of dietary intake (Roe et al., 1994).

The disadvantage of the DINE is that it only assesses fat and fibre intake. Ideally, it would have been useful also to assess carbohydrate intake, as this was a target of the intervention. However, I was unable to find a brief assessment that covered all three dietary domains, and obtaining this information would have required time-consuming methods of assessment, such as total food recall. Given, that this was one of many measures (and a secondary outcome measure) a decision was made to use the DINE.

For the present study, the wording of the DINE was slightly changed on certain questions to make it appropriate for New Zealand participants. For example, the DINE refers to semi-skimmed milk as red striped top, whereas in New Zealand semi-skimmed milk is blue top, hence this item was changed for the purpose of this study. These changes were made in consultation with a dietician, Kirsten White.

10.10.2.2 Short Form International Physical Activity Questionnaire (SF-IPAQ).

The self-administered short form of the SF-IPAQ was used to assess physical activity levels. The SF-IPAQ was developed by an international consensus group who aimed to construct a measure that was internationally relevant for monitoring physical

activity across cultures (Craig et al., 2003). The SF-IPAQ consists of 9 items. Instructions request participants to report the number of days during the previous week they spent engaged in vigorous, moderate or walking activities, and the amount of time 'usually' spent engaged in that activity on one of those days. Participants are also asked about the amount of time spent sitting or lying down as a measure of sedentary behaviour.

The SF-IPAQ has adequate psychometric properties that are at least equivalent to other self-report physical activity measures (Craig et al., 2003). Psychometric data collected across 12 countries indicate it has sufficient reliability (Spearman p = 0.76), concurrent validity (pooled p = 0.58, when compared with similar self-report measures), and criterion validity (p =0.30, established by comparing SF-IPAQ data with data from a Computer Science Accelerometer) (Craig et al., 2003).

Although the SF-IPAQ was originally developed for use with adults between the ages of 18 and 65, several studies have used it to assess activity levels for older adults (Deng et al., 2008; Forsen et al., 2010). Deng and colleagues (2008) reported good test re-test reliability (intra-class coefficient = 0.81 – 0.89) and criterion validity (Pearsons *r* = 0.58), with a moderately strong relationship found between the walking domain of the IPAQ and pedometer-assessed steps. The SF-IPAQ has also been previously used in research with people with type 2 diabetes (Nolan, Raynor, Berry, & May, 2016) and research exploring the benefits of ACT based interventions for cardiac patients (Goodwin et al., 2012)

Results of the SF-IPAQ were processed according to guidelines provided by the IPAQ authors (Guidelines for the data processing and analysis of the International Physical Activity Questionnaire, 2005). Data was collated and an estimated MET (Metabolic Equivalent of Task) was assigned to each activity. The following MET values were used for walking = 3.3 METS, moderate physical activity = 4.0 METS, and vigorous

physical activity = 8.0 METS. Continuous scores for each of these activities were calculated with SPSS using the formula below:

Walking MET-minutes/week = 3.3* walking minutes*walking days

Moderate MET-minutes/week = 4.0* moderate-intensity activity minutes *moderate days

Vigorous MET-minutes/week = 8.0 *vigorous-intensity activity minutes *vigorous-intensity days

Total physical activity MET-minutes/week = sum of walking+moderate+vigorous MET-minutes/week scores (IPAQ Research Committee, 2005).

Participants can be categorised into low, moderate or high levels of physical activity based on their MET activity. High activity is defined as "at least one hour per day or more, of at least moderate intensity activity above the basal level of physical activity" (IPAQ Research Committee, 2005, p. 4) Moderate activity is defined as "a level of activity equivalent to half an hour of at least moderate intensity physical activity on most days" (IPAQ Research Committee, 2005, p. 5). This is consistent with the New Zealand Ministry of Health recommendations for physical activity (Ministry of Health, 2015). Low activity is defined as anything below moderate activity.

10.10.3 Quality and satisfaction with life.

10.10.3.1 Satisfaction with Life Scale (SWLS) {Diener, 1985 #212.

The SWLS was developed as a brief measure of general/global satisfaction with life. It consists of five statements (e.g., "The conditions of my life are excellent"), which participants rate their level of agreement/disagreement with on a 7 point Likert type scale (1 = strongly disagree, 7 = strongly agree). Scores can range from 5 to 35, with higher scores indicating greater levels of life satisfaction. Scores in the range of 5 to 9 represent extreme dissatisfaction, and scores between 31 and 35 indicate extreme satisfaction. A score of 20 is considered neutral, suggesting the participants are "equally" satisfied and dissatisfied with their life {Diener, 1985 #55}.

A review of the SWLS by Pavot and Diener (1993) reported that it has good convergent validity when compared with other measures of life satisfaction (both self-report and clinician/interviewer ratings), and adequate discriminant validity when compared with alternative clinical measures of emotional functioning (i.e., the Beck Depression Inventory). It has also been demonstrated to be sensitive to changes in life circumstances and therapeutic change, as demonstrated by its use in clinical trials (Pavot & Diener, 1993).

The SWSL has been used in several studies evaluating the benefits of physical health care initiatives (Pavot & Diener, 2008), and as an outcome measure with an older New Zealand based sample (Good, 2008). It has also been used in research exploring the effectiveness of an acceptance-based intervention with patients with long-term health problems (Cederberg, Cernvall, Dahl, von Essen, & Ljungman, 2016).

The SWLS has consistently demonstrated good internal consistency across a variety of studies conducted with diverse populations. Pavot and Diener's review of the literature (1993) reported coefficient alphas ranging between 0.79 and 0.89 across a range of patient groups. This is considered a good level of internal consistency (Pallant, 2007). A recent intervention study, which examined the influence of ACT processes (psychological flexibility) for people with physical health conditions (Graham et al., 2016), reported a Cronbach alpha coefficient of .88. Similarly, a New Zealand based study focused on an older population reported a Cronbach's alpha of 0.84 (Good, 2008). This study also found the SWLS to be "highly correlated" with the World Health Organisation Quality of Life –Bref global scale. In the present study, the Cronbach's alpha coefficient was .83.

With regards to normative data, research indicates that participants with physical health conditions generally report lower levels of life satisfaction than healthy

participants. Pavot & Diener (2008) reported mean scores ranging from 16.1 to 25.6 across 8 health-related samples. Although, notably, the mean reported for a sample of French Canadian participants with type 2 diabetes was 24.9 (SD was not available). This is the same mean score reported for a healthy sample of Australian adults, suggesting life satisfaction may not be markedly lower for individuals with type 2 diabetes than it is for healthy individuals.

10.10.3.2 The WHOQOL-BREF- Australian Version (Murphy, Herrman, Hawthorne, Pinzone, & Evert, 2000).

The WHOQOL-Bref is a self-report measure designed to assess perceptions of health-related quality of life. The original WHOQOL-100 (from which the WHOQOL-Bref was created) was developed with input from 14 countries and is hence considered to have good cross-cultural validity (Power, Bullinger, Harper, & Group, 1999). However, the original version was lengthy to complete, hence, researchers often prefer to use the shortened version (Krageloh et al., 2012). This was an important consideration in the present study, as multiple measures were administered.

The WHOQOL-Bref is composed of 26 items that were taken from the original WHOQOL-100 questionnaire. The WHOQOL-Bref produces 4 domain scores, which measure quality of life across physical, psychological, social and environmental domains. Items 1 and 2 of the WHOQOL are scored separately. These questions refer to the participant's overall satisfaction with their health and overall perception of their quality of life. The higher the score, the higher the perceived quality or satisfaction with life (World Health Organisation Quality of Life Group, 1998).

The WHOQOL-Bref has excellent psychometric properties, and these have been established with a New Zealand population using the Australian version (Krageloh et al., 2012). Krageloh and colleagues (2012) reported a Cronbach's alpha of 0.91 for the

overall scale, and Cronbach alpha's of 0.80, 0.82, 0.71, and 0.81 for physical, psychological, social, and environmental scales, respectively. Criterion validity was also good, with individual scales assessing overall satisfaction with health and quality of life (items 1 and 2) found to correlate significantly with the other items of the WHOQOL-Bref ($p < 0.01$). Internal consistency was also good in the present study, with Cronbach's alpha's of 0.86, 0.76, 0.74, and 0.84 found for physical, psychological, social and environmental scales, and Cronbach's alpha of 0.92 found for the overall scale.

10.11.4 Emotional Functioning.

Measures of emotional functioning were used to assess symptoms of anxiety, depression and distress tolerance. The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) was used to assess changes in anxiety and depression, and the Distress Tolerance Scale (DTS) (Simons & Gaher, 2005) and Breath Holding Task were used to assess the ability to tolerate uncomfortable or distressing situations.

10.11.4.1 Anxiety and Depression.

The HADS is a brief, 14 item, self-report measure that was designed to identify symptoms of anxiety and depression for non-psychiatric patients. Participants rate their response to a series of statements (i.e., "I feel tense or wound up") on a 4 point Likert scale ranging from 0 to 3. Seven of the 14 items assess anxiety symptoms and 7 assess depressive symptoms. Participants are asked to respond to these questions based on how they have been feeling over the past week. According to HADS guidelines for scoring/interpretation, scores on the anxiety and depression scales (respectively) ranging between 0 and 7 are defined as normal; scores between 8 and 10 indicate mild symptoms, 11-14 moderate symptoms and 15-21 severe symptoms. (Zigmond & Snaith, 1983).

The HADS was chosen for use in the present study because it is often considered more appropriate for patients with chronic physical health conditions than other measures

of anxiety and depression, such as the Beck Depression Inventory and The Beck Anxiety inventory. Unlike these measures, the HADS items do not include somatic symptoms of anxiety and depression (i.e., dizziness and fatigue). These symptoms can mimic symptoms of chronic health conditions, including those related to diabetes and cardiovascular issues, resulting in a falsely inflated score (Bjelland, Dahl, Haug, & Neckelmann, 2002).

The HADS has been found to possess good psychometric properties and to be reliable in detecting anxiety/depression amongst patients in medical settings (Zigmond & Snaith, 1983). A review of the psychometric properties of the HADS demonstrated that the anxiety and depression factors are distinguishable, and concurrent validity is solid with positive correlations reported between the HADS and similar measures of emotional functioning, such as the Beck Depression Inventory (range = .61 to .83) and the General Health Questionnaire (.50 and .66) (Bjelland et al., 2002). This review also found the HADS to have good sensitivities and specificities (around 0.80) across both anxiety and depression sub-scales (Bjelland et al., 2002).

In addition, the HADS has been found to demonstrate good internal consistency, with Cronbach's alphas reported ranging between .68 and .93 (mean = .83) across a variety of population groups (Bjelland et al., 2002). A New Zealand based study of older adults reported an alpha of 0.84 for the anxiety scale, and 0.75 for the depression subscale (Roberts, Fletcher, & Merrick, 2014). In the present study, Cronbach's alpha on the depression scale was a little lower (0.73) than Cronbach's alpha for the anxiety scale (.86). This is still considered a good level of internal consistency (Pallant, 2007). The HADS has been previously used in international studies exploring the impact of structured lifestyle education interventions on diabetes risk (Yates et al, 2012).

10.11.4.2 Distress Tolerance.

The DTS (Simons & Gaher, 2005) and a Breath Holding Task were used to assess participants ability to tolerate distress**.**

The DTS is a 15 item self-report measure, which assesses participants' perceived ability to tolerate negative emotional experiences. Written instructions direct participants to rate their level of agreement/disagreement with a series of statements that refer to their beliefs about feeling distressed or upset (i.e., "I can't handle feeling distressed or upset"). Ratings are made on 5 point Likert type scales, ranging from 1 (strongly disagree) to 5 (strongly agree) (Simons & Gaher, 2005b).

A four-factor structure has been identified for the DTS (Simons & Gaher, 2005). These factors refer to an individual's tolerance, appraisal, regulation, and absorption of distress. Higher scores indicate greater distress tolerance skills. Research by Simon and Gaher (2005) with a student population, indicated this measure has good internal consistency, along with good discriminant, convergent and criterion validity. Similar results have since been found with more mature samples (Hsin Hsu, Collins, & Marlatt, 2013). Hsin Hsu and colleagues (2013) reported a Cronbach's alpha of .95. They also reported good convergent validity with the Five Factor Mindfulness Questionnaire (FFMQ), with positive correlations found for the DTS and all of the FFMQ sub-scales. In the present study, the 15 item version of the DTQ showed good internal consistency, with a Cronbach alpha coefficient of .89.

A breath holding task was also used as a behavioural measure of distress tolerance. This task involved requesting the participant to hold their breath for as long as possible while being timed with a stopwatch. This procedure is then repeated following a 5 minute rest period. The maximum breath holding duration is documented as the distress tolerance score.

Breath holding tasks have been used in previous research examining lifestyle change (i.e., smoking cessation) (Leyro, Zvolensky, & Bernstein, 2010), and in research evaluating the effectiveness of ACT-based intervention with individuals with chronic health issues (Lillis et al., 2009).

10.11.5 Psychological flexibility.

Psychological inflexibility and experiential avoidance were assessed using the Acceptance and Action Pre-diabetes Questionnaire, AAPDQ; a 10 item self-report measure (Appendix L).

Acceptance and Action Questionnaires are frequently used in ACT research (Lundgren, Dahl, & Hayes, 2008a). The original measure, the AAQ-I, was developed by Hayes and colleagues (Hayes et al., 2004d) and has been successfully modified for use with patients with a variety of health conditions by altering the wording of the items to make them more specific to the health condition of interest**.** The Acceptance and Action Diabetes Questionnaire (AADQ) (Gregg et al., 2007) and the Acceptance and Action Epilepsy Questionnaire (AAEQ; Lundgren et al., 2008a) are two examples of its use in health research.

The AAPDQ is a modified version of the AADQ, which was developed by Gregg (Gregg et al., 2007) to assess levels of experiential avoidance for patients with type 2 diabetes. Gregg and colleagues found the AADQ had excellent internal consistency (Cronbach alpha = .94) when used with patients with type 2 diabetes from a low socio-economic community.

For the present study, this measure was adapted to make it suitable for use with patients with pre-diabetes. For example, question 1 of the AADQ required participants to respond to the statement “I try to avoid reminders of my diabetes.” On the AAPDQ, this was changed to “I try to avoid reminders that I am at increased risk of developing

diabetes". Question 10 ("I avoid thinking about what diabetes can do to me") of the AADQ was not included in the AAPDQ. This item was removed following clinical consultation, as it was not considered relevant for people with pre-diabetes. Two versions of the AAPDQ were initially created with slightly different wording. The first explicitly referred to pre-diabetes, the second referred to participants' risk of developing type 2 diabetes. Both these measures were trialled with 3 pre-diabetes consumers to ensure they were easily comprehensible. Based on their feedback, a decision was made to use the second version of the scale. In the present study, the Cronbach alpha was .75. This is still considered an acceptable level of internal consistency (Pallant, 2007).

Like the AADQ, the AAPDQ was designed to assess participants' acceptance of thoughts related to their risk of developing type 2 diabetes, and the extent to which these thoughts function as barriers to valued action. For example, participants are asked to rate their level of agreement with statements like "I don't exercise regularly because it reminds me that I am at risk of developing diabetes." Ratings are made on a 7 point Likert type scale ranging from "never true to always true."

10.11.6 Diabetes knowledge.

Diabetes knowledge/understanding was assessed using a 10 item pre-diabetes knowledge test (Appendix M). This test was adapted from the Michigan Diabetes Research and Training Centre's Brief Diabetes Knowledge Test (Diabetes Research and Training Center, 1998) by the Manawatu Diabetes Trust. It has been previously used by Diabetes Trust to evaluate participants' retention of the information presented during their pre-diabetes education workshops.

The original Michigan Knowledge Test consisted of 14 items designed to assess the level of diabetes knowledge/understanding of people with type 2 diabetes who are non-insulin dependent (Diabetes Research and Training Center, 1998). Ten of these items

made up the diabetes knowledge test used in this study. These items were selected because they matched the content of the lifestyle education component of the interventions. These items assessed participants' basic understanding of what it means to have diabetes and adaptive lifestyle changes that can be made to reduce the risk of developing diabetes and diabetes-related complications. This measure did not assess their understanding of the psychological concepts and processes introduced during the ACT intervention.

10.11.7 Socio-demographic and health information.

Socio-demographic data were collected using a questionnaire designed specifically for this study (Appendix N). Demographic information collected included age, ethnicity, gender, marital status, education and work status. Health demographics were also collected using a GP questionnaire (Appendix O). Information was obtained regarding the year of pre-diabetes diagnosis, current medications, and co-morbid medical and psychiatric conditions (depression and anxiety).

10.11.8 Treatment credibility/satisfaction.

Intervention acceptability/credibility was assessed using a brief Participant Satisfaction Questionnaire (Appendix P). This required participants to rate on 5 point Likert scales how effective and helpful they found the treatment, their overall level of satisfaction with the intervention, and whether they would recommend the intervention to a friend. Scales ranged from 1 (not at all effective/helpful/satisfied) to 5 (very effective/helpful/satisfied). These scales have been used in previous ACT-based research (Forman et al., 2009) Qualitative information was also obtained to establish what participants found most and least helpful about the intervention, how they thought the intervention might affect their lives, and whether there was anything that could have been done to improve the intervention.

10.11.8 Treatment fidelity.

The use of a treatment manual, which specified the duration and timing of the intervention components and provided sample dialogue to assist facilitators with information delivery, was intended to increase treatment fidelity and consistency. In addition, the primary researcher was a co-facilitator of the workshops, which allowed her to monitor the dietician's consistency with and adherence to the manual.

As suggested by Ost (2008), the intention when designing the study was to video record all intervention sessions, then randomly select twenty percent of these sessions to be viewed by an independent rater blind to the research purposes/ hypotheses. This independent party would then rate the facilitators for their degree of adherence to the manual. Unfortunately, due to equipment failure during two of the workshops and subsequent recruitment issues, this measure of fidelity was not used.

10.12 Procedures

10.12.1 Assessment and workshop facilitation.

The ED Only and ACT/ED groups were facilitated by the lead researcher, Sarah Malthus, a female senior Clinical Psychologist, and Kirsten White, a female senior Dietitian with the Manawatu Diabetes Trust. At the time of intervention delivery, Sarah had 8 years of clinical experience working with patients affected by long-term physical health conditions. Throughout the course of the study she was employed by the Massey University Long-term Health Conditions Service; a psychology service that provides assessment and therapeutic support for adults with a variety of long-term health conditions, including diabetes and cardiovascular disease. In addition, prior to embarking on this research, she had attended advanced training opportunities focused on the use of ACT with patients with long-term health conditions, including the 2013 Australia/New Zealand ACT Conference and the 2013 World Contextual Psychology

Conference, and had been using this approach therapeutically with patients with type 2 diabetes.

The dietician, Kirsten, had extensive experience working with patients with pre-diabetes and type 2 diabetes. Her role with the Diabetes Trust involved delivering both individual and group-based nutrition interventions, designed to decrease participants' risk of diabetes or diabetes-related complications. Kirsten was also employed as a part-time lecturer in nutrition by the University of Victoria and had extensive knowledge of the empirical literature looking at the relationship between diet and physical health.

The presentation format was consistent across all workshops. Both Sarah and Kirsten presented background information about what it means to have pre-diabetes and risk factors for developing pre-diabetes. Kristen presented all material and activities related to dietary change, while Sarah presented information regarding the importance of physical activity along with the psychological component of the ACT/Education workshop.

10.12.2 Workshop and assessment location, timing, and size.

Due to the researcher being unable to access a single venue that was available for the scheduled workshop dates and times, the workshops were held at two venues; Wharerata Conference Facilities at Massey University and The Bank of New Zealand Conference Facilities located in central Palmerston North. In total, 5 ACT/ED workshops were held, and 4 ED Only workshops. Four of these workshops were held at the Wharerata Conference facilities on the Massey University campus, and 5 were held at the BNZ Conference facilities, Palmerston North. All of the workshops were held on a week day in the morning. Seven of the workshops commenced at 9.30 am, and 2 were delayed until 10 am to allow travel time for those attending from Dannevirke.

The original intention was to have 10 to 12 participants in each workshop; however, the referral rate was slower than expected. Consequently, in the interest of retaining participants, a decision was made to run smaller groups. Group sizes ranged from 5 to 11.

Baseline and post-assessment sessions were held individually in two locations. The majority of participants were seen at the Massey Psychology Clinic in the therapy rooms, aside from Dannevirke based participants who were seen at the Barraud Street Health Centre in the clinical rooms.

Participants in the Standard Care condition attended baseline and post assessment sessions, but they did not attend the workshops

10.12.3 Assessment phases.

There were four assessment phases: baseline, post-intervention, 3 month and 6 month follow-up. Participants in the ACT/ED and ED Only conditions participated in all 4 assessment sessions. Those in the Standard Care condition attended baseline and 3 and 6 month follow-up assessments. They did not complete the post-intervention assessment because this was focused on assessing participants' knowledge/understanding of information presented during the workshop, and their satisfaction with the intervention. This assessment was not relevant for those in the Standard Care condition because they did not attend the workshops.

For participants in ACT/ED and ED Only conditions, their baseline assessment was scheduled one week prior to attending their first workshop. For participants in the Standard Care condition, their baseline assessment was scheduled three months prior to their first follow-up session.

10.12.3.1 Phase 1: Baseline.

During this phase:

1. The GP Questionnaire was sent to each participant's GP. This was sent the week prior to participants attending their baseline assessment
2. Participants attended their pre-intervention assessment at the Massey Psychology Clinic and completed the measures listed below in the following order:

    Socio-demographic questionnaire

    Pre-diabetes Knowledge Test

    DINE

    AAPDQ

    Health Care/Status Questionnaire

    SWLS

    DTS

    HADS

    WHOQOL-Bref

    SF-IPAQ

At the start of the session, participants were thanked for participating in the study, and the information provided in the participant information sheet was reiterated. Participants were then told they would be asked to complete a series of questionnaires designed to help the researcher understand their physical and emotional well-being, which would take approximately 50 minutes. Measurements of waist, height, and waist circumference would then be taken, and they would be asked to participate in a brief breath holding activity. All participants were provided with their physical measurement results during this session, but they were not provided feedback about the results

obtained from psychometric measures. If participants asked about these results, they were told they could access them from the researcher once the study was complete.

The Socio-demographic Questionnaire and the Pre-diabetes Knowledge Test were completed first with the researcher present to prevent participants from accessing correct responses via smartphones or similar methods. The researcher then administered the DINE. The researcher left the room while the participant completed the remaining questionnaires. On re-entering the room, the researcher asked the participant if they had any questions then checked the questionnaires to ensure they were complete.

3. The researcher then took measurements of the participant's height, weight, and waist circumference and completed the breath holding task.
4. Before leaving, participants were given a blood test referral form, which they were requested to take to a local Medlab facility and have blood drawn. They were told that the purpose of this test was to establish their diabetes and cardiovascular risk.

10.12.3.2 Phase 2: Post-intervention.

Directly following the workshop, participants in the ACT/ED and ED Only conditions were given the Pre-diabetes Knowledge Test to complete. This test was completed with the researcher present and participants were instructed not to discuss their responses with fellow workshop attendees. They were also given the Participant Satisfaction Questionnaire to take home and complete. They were requested to complete this individually and return it to the researcher via post within a week. A freepost envelope was provided.

10.12.3.3 Phase 3: Follow-up.

Three and 6 months after attending the workshop, or for Standard Care participants after attending their baseline assessment, participants attended follow-up assessment sessions. Aside from the socio-demographic questionnaire, participants

completed the same questionnaires, measurements, and activities they did at baseline. The same instructions and researcher processes and procedures were used during these sessions. Following the session, participants were given a Medlab form and requested to have blood samples taken within the following week.

Chapter 11: Data Analysis

All numerical data were analysed using SPSS (version 24) for Windows. A series of mixed between-within subjects analyses of variance (ANOVA) were conducted to compare the effectiveness of the 3 interventions (Standard Care, ED Only, ACT/ED) over time on the dependent variables. This chapter provides a rationale for using mixed ANOVAs, explores the assumptions underlying this approach, and provides a rationale for the effect size and post hoc statistics used.

11.1 Rationale for Mixed ANOVA Approach

A mixed ANOVA approach was considered appropriate because it allowed for control of pre-existing variations between the intervention groups on dependent measures and combined between subjects variables (intervention condition) and within subjects variables (time) in a single analysis (Pallant, 2007). Mixed ANOVAs are recommended when between and within subjects approaches are combined in a single study because they provide information about: (1) whether there were main effects of the interventions on the dependent variables over time, and (2) whether changes on dependent measures differed between the three intervention groups (Pallant, 2007). For example, was there a significant change in HbA1c results across the three assessment periods (main effect), and did changes in HbA1c over time significantly differ for the three intervention groups (interaction effect)?

Although mixed ANOVA allows for analysis of both main and interaction effects, its use can be problematic in studies involving a large number of dependent variables. This is because conducting multiple ANOVAs using the same data set increases the risk of committing a type 1 error (i.e., rejecting the null hypothesis when it is correct) (Pallant, 2007). Consequently, the use of mixed multivariate analyses of variance (MANOVA), the multivariate version of ANOVA, was considered.

Mixed MANOVA includes multiple variables in a single analysis, essentially creating a new dependent variable that is a “linear combination” of these dependent variables (Tabachnick & Fidell, 2013, p. 245). This new variable is then analysed using the traditional mixed ANOVA procedure. The main benefit of MANOVA is that multiple analyses are not required, consequently, the risk of type 1 error is reduced (Tabachnick & Fidell, 2013). However, although MANOVA controls for the increased risk of type 1 error, it is only more powerful than ANOVA in certain conditions. Because MANOVA essentially creates a new variable that is a combination of multiple dependent variables it is difficult to interpret the effects of the interventions on individual dependent variables, meaning important results can be obscured (Tabachnick & Fidell, 2013). For this reason, several authors suggest multivariate analyses should only be used when there is a clear relationship between variables and a robust conceptual rationale for combined analysis (Pallant, 2007; Stevens, 2009; Tabachnick & Fidell, 2013).

In the present study, I was concerned about combining sets of variables for two reasons. First, this was the only randomised controlled study evaluating the effectiveness of pre-diabetes interventions in New Zealand, therefore, it could not be assumed that relationships amongst variables that had been found in international studies would apply to a New Zealand population. Second, although there was some theoretical and empirical evidence to indicate relationships between certain dependent variables under consideration, not all studies have demonstrated this pattern. Because the relationships among many of the dependent variables included in the present study were unclear, the rationale for combining sets of variables in a MANOVA was not strong.

Additionally, MANOVA has assumptions over and above those required for ANOVA in order to retain power. Violation of those assumptions can have more detrimental effects than violation of ANOVA assumptions (Tabachnick & Fidell, 2013). For example, MANOVA is particularly sensitive to multivariate outliers (scores/results that diverge from the majority), linearity (a linear relationship between dependent variables), and the absence of multicollinearity (high correlations between dependent variables) and singularity (Pallant, 2007). In the present study, these assumptions were violated for multiple variables, which would likely have impacted on the power of the test to detect effects. For the above reasons, a decision was made to conduct multiple mixed ANOVAs and control for the risk of type 1 error using alternative methods of statistical adjustment. These are described later in this chapter.

11.2 Assumptions of Mixed ANOVA

Before analysing the data, the key assumptions underlying the use of all parametric tests were evaluated, along with those specific to mixed ANOVA.

11.2.1 Independence of observations.

A key assumption of parametric tests is that participant measurements and observations are independently assessed and not influenced or impacted by the observations or responses of others (Pallant, 2007). In the present study, this assumption was controlled for by (a) collecting pre-intervention, 3 and 6 month follow-up data individually; and (b) using standardised instructions for the administration of questionnaires and collection of physical measures of behaviour change (i.e., waist circumference). The only data that was collected in a group context was the post-intervention version of the pre-diabetes knowledge test. This questionnaire was completed at the end of the second group intervention session. As discussed previously, to ensure individual participant responses were not influenced by others in the group, all

participants were asked to complete the measures individually and to refrain from discussing their responses with other group members.

11.2.2 Random sampling.

A second general assumption of parametric testing is that data are derived from a random sample (Pallant, 2007). This assumption was violated to some extent, as potential participants were required to meet criteria for pre-diabetes and those with a psychiatric history or cognitive impairment were ineligible to participate.

Although the sample from which participants were recruited was not completely random, Tabachnick and Fidell (2013) acknowledge that true random sampling in the context of social sciences research is difficult. They suggest this assumption can be considered fulfilled if participants have been recruited from the same population and randomly assigned to the various levels of the independent variable; this was the case in the present study. All participants were patients with pre-diabetes who resided in the MidCentral region and were randomly assigned to the 3 intervention conditions. This assumption was therefore considered to be sufficiently met for the purpose of parametric analysis.

11.2.3 Normal distribution.

Parametric tests are most powerful if scores on the dependent variable are normally distributed (Pallant, 2007). A mix of visual observation and data analysis techniques were used to assess this assumption. Techniques used included; visual analysis of histogram and box plot graphs to explore the shape of the distribution and detect outliers, along with calculation of skewness and kurtosis values and the Kolmogorov-Smirnov statistic. When outliers were detected, mean scores were compared with 5% trimmed means, as suggested by Pallant (2007), to establish the impact of extreme outliers.

11.2.3.1 Kolmogoriv Smirnov test.

This calculates "the level of significance for the differences from the normal distribution" (Hair, Black, Babin, Anderson, & Tatham, 2006, p. 82). Non-significant results (>.05) indicate a normal distribution (Pallant, 2007). In the present study the assumption of normality was violated for the following variables: HbA1c (pre, 3 month and 6 month), weight (6 months), life satisfaction (pre, 3 month, 6 month), and DTS (pre and 6 months).

11.2.3.2 Histograms, skewness and kurtosis values.

To assess the type and magnitude of the normality deviations, the distribution of each group was explored using histograms along with skewness and kurtosis values. Positive skew (this refers to scores merging to the left of the graph; Pallant, 2007) was observed for HbA1c (pre) and weight (3 months). AAPDQ (3 and 6 months) DTS (3 and 6 months) HADS (3 and 6 months). Negative skew (scores merging to the right of the graph; Pallant, 2007) was observed for life satisfaction (pre, 3 months, and 6 months). Positive kurtosis was observed for: HbA1c (3 and 6 months)

11.2.3.3 Box plots.

Observation of box plots suggested that in many cases the abnormal distribution was contributed to by the presence of outliers. These are defined by SPSS as extreme scores "that extend more than 1.5 box lengths from the edge of the box" (Pallant, 2007). Outliers were detected across most dependent variables. When outliers were detected, raw scores were compared with the original data/questionnaires to ensure the responses were valid, and no errors were identified.

Mean values were also compared with 5% trimmed means. These were calculated by removing the top and bottom 5 percent of scores and then recalculating the mean. Comparison of original and trimmed mean values illustrated that these

outliers were generally having a negligible impact on the mean. One extreme score was detected for the pre-intervention HbA1c. This score was well below the pre-diabetes threshold and was having a clinically meaningful impact on the group mean. Consequently, a decision was to remove this participant's data from all analyses. The rationale being that the intervention was designed to target individuals with pre-diabetes and this participant's pre-intervention result was well below the pre-diabetes range. Other scores were retained that were also within the normal range but closer to the pre-diabetes cut-off (HbA1c results > 36). These data were included in the analyses because research suggests individuals with HbA1c results in this range may have an increased risk of cardiovascular disease (Khaw et al., 2004).

In sum, although violations of normality were detected across several dependent variables, violations of the nature/type described above have been found to have minimal impact on type 1 and type 2 error, and the impact of non-normal distribution decreases as the magnitude of the sample increases (Pallant, 2007). Tabachnick and Fidell (2013) advise that in moderate to large samples (i.e., 30 or more participants) violations of normality have limited impact on the significance or power of the parametric test. The one exception to this rule is platykurtosis (flattened distribution) (Stevens, 1996). Platykurtosis was not observed for any of the dependent variables.

11.2.4 Homogeneity of variances.

Parametric tests assume that samples have been derived from populations where the variances are the same (Pallant, 2007). As advised by Pallant (2007), the Levene test was used to test this assumption, with *p* values greater than .05 indicating the assumption had been met. The Levene test was considered more appropriate than alternative tests (i.e., Bartlett's and Cochran's) because it is less influenced by abnormal distribution of scores on the dependent variable (Pallant, 2007).

Results of the Levene test indicated the homogeneity assumption was satisfied across most dependent variables, as indicated by *p* values greater than .05. Violations were found for life satisfaction (3 months), total cholesterol (3 and 6 months), and the IPAQ (total MHET minutes pre, 3 and 6 months) indicating unequal variances. These violations were relatively small, and several authors point out that most parametric tests (including mixed ANOVA) are relatively insensitive to such violations when intervention groups are of similar sizes (Pallant, 2007; Stevens, 2009; Tabachnick & Fidell, 2013); consequently, a decision was made to continue to run mixed ANOVA analyses for these groups.

11.2.5 Sphericity.

The assumption of sphericity requires that the variances of the differences in scores between the intervention conditions are equal. For example, when the differences between each pair of scores for the various intervention conditions are calculated, these differences should have equal variances (Pallant, 2007). This assumption was tested using Mauchly's Test of Sphericity, which was calculated as part of the SPSS output. The assumption was considered violated if the result was significant ($p = <.05$). This assumption was violated for many of the variables (sphericity is commonly violated), hence a decision was made to report the multivariate statistics provided by SPSS in the mixed ANOVA output. These statistics do not have an underlying assumption of sphericity (Pallant, 2007)

11.2.6 Homogeneity of intercorrelations.

This assumption is specific to mixed ANOVAS. Mixed ANOVA is most powerful when the distribution pattern of inter-correlations between the various levels of the between subjects factor (intervention condition) are similar. This assumption was assessed using Box's M statistic. A conservative alpha of .001 was set, as suggested by

Pallant (2007), and the assumption was considered violated if the result was significant. The only variables that violated this assumption were BMI (>30), weight, and IPAQ (moderate, vigorous and total activity) scores. Consideration was given to using an alternative test to establish significance, however, the differences in means between these groups was quite small, and of questionable clinical significance, and as Pallant (2007) points out there is no robust non-parametric alternative to mixed ANOVA.

11.3 Missing Data

Prior to data analysis, all data were screened to detect missing values. A small amount of data was missing across all variables, but there was no identifiable pattern. Missing values were managed using the exclude cases pairwise" option on SPSS. This meant a participant's data was only excluded if the data was necessary for analysis of that particular dependent variable; their data was not excluded from all analyses. Pallant (2007) recommends dealing with data in this way unless there is a strong rationale for replacing missing values.

11.4 Managing Type 1 Error

As mentioned previously, conducting multiple ANOVAs with the same data set can increase the risk of committing a type 1 error (rejecting the null hypothesis when it is correct). Tabachnick and Fidell (2013) suggest one way of reducing this risk is to conduct a Bonferroni adjustment. This involves dividing the alpha (.05) by the number of dependent variables.

When distinct families/groups of variables are used, a family-wise error rate can be adopted for each group. Separate Bonferroni adjustments are then calculated for each of these groups of variables. If certain variables within a particular group are considered more important than others, they can be assigned more "liberal alphas" (Tabachnick &

Fidell, 2013, p. 349). This is appropriate providing the combined alphas for all of the variables within the group are no greater than .05.

In the present study, dependent variables were categorised into the variable families listed below. These were grouped on the basis of research indicating strong relationships between scores on these variables.

HbA1c

Lipids

Weight and BMI,

Waist Circumference

Distress Tolerance Scale (DTS) and breath holding task

ACT Processes (AAQ)

Physical Activity (total activity, walking, moderate activity, vigorous activity and sedentary activity)

Dietary Intake (DINE saturated fat, unsaturated fat and fibre scores)

Intervention Satisfaction (scores on the four PSQ scales)

A family-wise alpha of .05 was set for each of these variable groups, and the alpha was divided by the number of ANOVAs conducted for each group.

11.5 Post-hoc Testing

When significant main or interaction effects were found, post-hoc comparisons were conducted to establish the location of differences. A decision was made to use post hoc comparisons rather than planned comparisons. This decision was based on Pallant's (2007) advice that planned comparisons should be used with caution when multiple comparisons are involved because they do not control for the already inflated risk of type 1 error. In contrast, post hoc comparisons reduce the risk of Type 1 error by adopting "more stringent" criteria for significance (Pallant, 2007, p. 207).

A Bonferroni procedure was chosen as the method of post-hoc analysis. This procedure is recommended by several authors when running analyses where multiple statistical tests are performed concurrently, as is the case with mixed ANOVA (Stevens, 2009; Tabachnick & Fidell, 2013). The Bonferroni procedure is slightly less powerful than other post hoc methods of analysis, but it has the advantage of controlling for type 1 error.

11.6 The Variables

11.6.1 HbA1c.

Pre, three and six month post-intervention results for HbA1c provided data for 2 dependent variables. Two separate mixed ANOVAs were conducted to establish if there was a main effect of the interventions over time and whether there was an interaction between intervention type and time, and alpha was set at .025. The first analysis included HbA1c data for all participants, and the second analysis only included data for participants with an HbA1c greater than 40 (criteria for prediabetes; Ministry of Health, 2013). A decision was made to analyse this data separately because a substantial proportion of participants had dropped to within the normal HbA1c range by the time they attended their first intervention session, and it was hypothesised that those with a result in the normal range might exhibit smaller decreases in HbA1c due to floor effects.

11.6.2 Lipids.

Lipid results provided data for five dependent variables. Four mixed ANOVAs were conducted to establish changes over time and the interaction between time and intervention for trigylcerides, LDL, HDL and total cholesterol. Data was also extracted and analysed separately for participants with cholesterol greater than 4.0 (criteria for high cholesterol; Ministry of Health, 2012). The alpha set for each of these variables was .01.

11.6.3 Physical measurements.

Data were analysed for 5 dependent variables, which represented changes in waist circumference, weight and BMI across time and intervention. Data were extracted and analysed separately for those with a BMI greater than 29 (criteria for obesity; Ministry of Health, 2017b). Alpha was set at .025.

11.6.4 Pre-diabetes knowledge.

Overall scores on the pre-diabetes knowledge test at pre-intervention and 3 and 6 month follow-up provided data for one mixed ANOVA. Alpha was set at .05

11.6.5 Self-report indicators of lifestyle change.

11.6.5.1 Physical activity.

Five mixed ANOVAs were conducted to establish changes across time and intervention for total MET minutes per week for walking, moderate activity, vigorous activity, total activity and sedentary time. Alpha was set at .01

11.6.5.2 Dietary intake.

The results of the DINE yielded separate scores for fibre, fat and unsaturated fat scales. Three ANOVAs were conducted to establish whether there were main effects for time or interactions between time and intervention for total scores on these scales. Alpha was set at .016.

11.6.6 Distress tolerance.

Overall scores on the DTS and breath holding task provided data for two dependent variables. Separate ANOVAs were conducted for each of these and alpha was set at .025.

11.6.7 Anxiety and depression.

Results on the anxiety and depression subscales of the HADS were analysed separately. Alpha was set at .025.

11.6.8 Quality of life.

Participants responses on the WHOQOL-Bref produced 4 domain scores pertaining to participants physical, psychological, social, and environmental quality of life, along with two individual item scores pertaining to participants overall perception of their health and quality of life. In the interest of providing comparable results for interpretation, and based on guidelines for analysis of the WHOQOL-Bref (Murphy et al., 2000), raw scale scores were transformed to a 0 to 100 scale using the following formula:

$$[\text{Transformed Scale} = \frac{(\text{actual raw score} - \text{lowest possible raw score})}{\text{Possible raw score range}} \times 100]$$

These transformed scores provided data for six dependent variables and separate mixed ANOVAs were conducted for each of these. Alpha was set at .008

11.6.9 Satisfaction with life.

Participant's responses to the 6 items of the SWLS were summed to produce total scores for each of the assessment periods. Two mixed ANOVAs were then conducted to establish whether the mean scores across the 3 groups differed across time and intervention; alpha was set at .025.

11.6.10 Acceptance and action.

Participants overall scores on the AAPDQ at pre-intervention and 3 and 6 month follow-up provided data for one dependent variable and alpha .05

11.6.11 Intervention satisfaction.

Total scores on the four scales of the Participant Satisfaction Questionnaire (effectiveness, helpfulness, satisfaction and recommendation) collected at post-intervention for participants in the ED Only and ACT/ED groups provided data for 4 independent samples t tests. T tests were used because there was no repeated measures

factor and only two levels of the between subjects factor. Pallant (2007) suggests t tests are the most appropriate form of parametric testing in this situation. T tests have the same underlying assumptions as those required for ANOVA. Alpha was set at .025 for these variables.

11.7 Effect Sizes

The importance of providing effect size statistics alongside significance values is well-established (Pallant, 2007; Stevens, 2009; Tabachnick & Fidell, 2013). Significance testing is often seen as the gold standard of statistical analysis to determine the effectiveness of clinical interventions, and non-significant results are frequently interpreted as confirmation of the null hypothesis that there is no difference between intervention groups. However, with small to moderate sample sizes, this assumption can be problematic, because insignificant results may be due to inadequate power.

In the present study, it was important to be aware of the potential impact of insufficient power on ANOVA results because recruitment issues meant that the studies sample was smaller than intended. An a priori power analysis indicated a sample of 158 would provide sufficient power (>.80) to detect medium effects. However, the present sample was substantially smaller than this (N= 83), meaning the tests only had the power to attach significance to relatively large effects. Consequently, it was deemed important to calculate effect sizes to assess both the validity of the analysis and the potential practical and clinical utility of the results.

The effect size statistic, partial eta squared (η_p^2) was calculated as part of the mixed ANOVA procedure using SPSS. Partial eta squared represents "the proportion of variance of the dependent variable that is explained by the independent variable" (Pallant, 2007, p. 208), and Tabachnick and Fidell (2013) suggest it is a more reliable indicator of effect size than the more commonly used eta squared. The following

guidelines were used to interpret partial eta squared: .01 = small, .06 = medium, .138 = large (Pallant, 2007).

When significant effects were found, further point estimations of effect size were calculated to assess the magnitude of difference between all possible pairs of means (e.g., ACT/ED and ED Only, ACT and Standard Care, Standard Care and ED Only) using Cohen's *d* effect size index (small =.20, medium = .50, and large = .80) (Cohen, 1988). Cohen's *d* represents group differences using standard deviation units. This was calculated from individual group means and standard deviations using the online cognitive flexibility calculator (Wiseheart, 2013)**.**

Chapter 12: Results

This chapter presents the results of the present research, which explored the impact of three modes of pre-diabetes lifestyle interventions, ACT/ED, ED Only and Standard Care, on dependent measures of physiological indicators of pre-diabetes management, self-reported lifestyle change, quality/satisfaction with life, emotional functioning, acceptance and action, pre-diabetes knowledge and intervention satisfaction.

For each group of dependent variables, the research hypotheses are outlined, followed by a description of trends pertaining to (a) the collective effect of the three interventions on dependent variables over time, and (b) whether these changes differed across the three intervention groups. More specific trends are then described for each of the dependent variables, along with effect size statistics and the results of parametric tests. For statistically and clinically significant effects, post-hoc comparisons and/or further point estimations of effect size are reported to demonstrate the magnitude and location of differences.

12.1 Physiological Indicators of Pre-diabetes Management: HbA1c, Lipids, Weight, BMI and Waist Circumference.

It was predicted that when the results of the three intervention groups were combined there would be significant improvements in physiological indicators of pre-diabetes management over time (i.e., when comparing pre-intervention results with those obtained at 3 and 6 month follow-up). In addition, it was predicted that when results were compared across interventions, ACT/ED and ED Only would have a significantly greater impact on physiological variables than Standard Care, and ACT/ED would have a greater impact than ED Only.

12.1.1 HbA1c: Main effect of time.

When mean results for HbA1c were collapsed across intervention conditions, there was an overall decrease of 0.65 between pre-intervention and 3 month follow up, and a greater decrease of 0.98 between pre-intervention and 6 month follow-up. At pre-intervention, the overall mean for HbA1c was 41.00. Based on Ministry of Health criteria for pre-diabetes (Ministry of Health, 2012), these results show that prior to receiving any intervention the majority of participants' HbA1c results were only just within the pre-diabetes range. By 3 and 6 month follow-up, the majority of participants' HbA1c results had dropped to within the "normal" range (< 41), meaning they no longer met criteria for pre-diabetes (see Table 4).

The above trends were found to be significant, with results of a mixed between-within subjects ANOVA indicating a statistically significant main effect for time, F (1, 75) = 7.333, p = .001, η_p^2 =.089. Post hoc pairwise comparisons carried out to establish the location of these differences, revealed a significant difference between pre-intervention and 3 month follow-up (M = .619, SE = .269, p = .024,) and pre-intervention and 6 month follow-up (M = .96, SE = .26, p = .000,) for all participants regardless of intervention group. The magnitude of these differences was small (d = 0.25 and d = .037, respectively). These results are consistent with the hypothesis that there would be a main effect of the interventions over time.

Table 4

Mean HbA1c Results Across Time and Intervention

	Intervention							
Time Period	Standard Care		ED Only		ACT/ED		Total	
	M	SD	M	SD	M	SD	M	SD
Pre-intervention	40.88	2.29	41.55	2.65	40.50	2.32	41.00	2.43
3 months	40.51	2.59	40.11	2.56	40.45	2.81	40.35	2.62
6 months	40.44	3.29	39.85	3.29	39.75	2.34	40.02	2.86

Note. N = 78 (Standard Care = 27, ED Only = 27, ACT/ED = 24). M = mean. SD = standard deviation.

12.1.2 HbA1c: Interaction between time and intervention.

To determine whether there were differences in HbA1c results between groups, mean HbA1c results were examined separately and comparisons made between interventions. A progressive downward trend was observed for all 3 interventions across the 3 assessment phases (see Table 4). Consistent with expectations, the decrease was smallest for those in the Standard Care condition, with a mean decrease in HbA1c of 0.37 between pre-intervention and 6 month follow-up. When compared with Standard Care, greater decreases were found for those in ACT/ED and ED Only conditions, but, contrary to expectations, the greatest decrease was found for those in the ED Only condition. Those in the ACT/ED condition showed a mean decrease in HbA1c of 0.75 between pre-intervention and 6 month follow-up, while the ED Only group showed a decrease of 1.7, with their mean HbA1c decreasing from 41.55 at pre-intervention to 39.85 at 6 month follow-up. Effect sizes were in the small range for those in the Standard Care and ACT/ED conditions (d = 0.18 and d = 0.32), and the moderate range for those in the ED Only condition (d = 0.66).

To assist in the clinical interpretation of findings, the percentage of participants in the pre-diabetes range was calculated for each of the intervention groups across the 3

assessment periods. Pre-intervention results indicated that 48.1 percent of those in the Standard Care condition were within the pre-diabetes range on commencing the research. This had increased slightly to 51.9% at 3 month follow-up, but reduced to 32.0 percent by 6 month follow-up.

Similar trends were found for those in the ED Only and ACT/ED conditions at 6 month follow-up, although, unlike the Standard Care group, mean decreases in Hba1c were already apparent for these groups at 3 month follow-up. For those in the ED Only condition, the percentage of participants in the pre-diabetes range decreased from 53.6 % at pre-intervention to 39.3% at 3 month follow-up and 35.7% at 6 month follow-up. Fifty percent of participants in the ACT/ED condition were in the pre-diabetes range at pre-intervention; this had reduced to 42.9% at 3 month follow-up and 35.7% at 6 month follow-up.

Despite the above trends, a mixed ANOVA showed that none of the observed differences between the intervention groups were statistically significant, F (2,75) = 1.855, p = .12, η_p^2 = .047. These results are inconsistent with the hypothesis that ACT/ED and ED Only would have a significantly greater impact on HbA1c than Standard Care, and that decreases in HbA1c would be greater for ACT/ED than for ED Only.

12.1.3 HbA1c >40: Main effect of time.

Due to concerns about floor effects, data were explored and analysed separately for participants with an HbA1c above 40. Observation of trends indicated larger changes in HbA1c for these participants over time.

As shown in Table 5, when results were collapsed across intervention conditions, there was an overall decrease of 1.59 between pre-intervention and 3 month follow up, and this change remained relatively stable at 6 month follow-up. The results

of a mixed ANOVA found a statistically significant main effect for time, F (2,38) = 13.86, p = .00, η_p^2 = .262, and pairwise comparisons revealed significant differences between pre-intervention and 3 month follow-up (MD = 1.53, SE = .33, p = .000, d = 0.79) and pre-intervention and 6 month follow-up (MD = 1.56, SE = .35, p = .000, d = 0.76). The difference between 3 and 6 month follow-up did not reach significance (MD = .028, SE = .32, p = 1.00, d = 0.01). These results were consistent with predictions.

Table 5

Mean HbA1c Results Across Time and Intervention (HbA1c > 40)

	Intervention Condition							
Time Period	Standard Care		ED Only		ACT/ED		Total	
	M	SD	M	SD	M	SD	M	SD
Pre-intervention	42.40	1.76	42.84	1.95	43.37	1.50	42.78	1.80
3 months	41.53	2.13	40.73	2.51	41.75	2.86	41.21	2.43
6 months	41.77	3.05	40.57	2.58	41.62	2.19	41.19	2.69

Note. N = 42 (Standard Care = 15, ED Only = 19, ACT/ED = 8). M = mean. SD = standard deviation. Only participants with an HbA1c > 40 were included in this analysis.

12.1.4 HbA1c >40: Interaction between time and intervention.

When only results for participants with an HbA1c greater than 40 were included in analyses comparing changes over time between the three intervention groups, the trends detected were similar to those reported previously, although effect sizes were larger. Decreases in HbA1c were smallest for those in the Standard Care condition, with a mean decrease of 0.87 (d = 0.48) between pre-intervention and 3 month follow-up. Those in the ACT/ED condition showed a mean decrease in HbA1c of 1.62 (d = 0.726) between pre-intervention and 3 month follow-up, and the ED Only group showed the greatest decrease (2.11 points, d = 0.726).

Results remained relatively stable at 6 month follow-up, with very small further decreases for those in ACT/ED and ED Only groups, while the Standard Care condition exhibited a slight increase in HbA1c (see Table 5). Despite the larger effect sizes, once again, results of a mixed ANOVA did not find these trends to be statistically significant, F (2,39) = 1.40, p = .24, η_p^2 = .067. These results are contrary to predictions, although interpretation is limited by the small and unequal group sizes, which impacts on the power of ANOVA to detect statistically significant results (Pallant, 2007).

12.1.5 Lipids: HDL and LDL cholesterol and triglycerides.

Changes over time in LDL cholesterol, HDL cholesterol and triglycerides were minimal for all three interventions, with effect sizes in the small range (Appendix Q). Results of 3 separate mixed ANOVAS found no significant main effects for time and no significant interactions between time and intervention. These results are inconsistent with expectations.

12.1.6 Lipids: Total cholesterol.

Changes in cholesterol over time were very small for all 3 intervention groups. When the results of the intervention groups were combined, changes in total cholesterol were insignificant. A significant interaction was found between intervention and time, F (2,73) = 3.74, p = .006, η_p^2 = .093. The mean total cholesterol of participants in the ED Only group decreased by 0.36 (d = 0.22) between pre-intervention and 3 month follow-up. In contrast, the total cholesterol of those in Standard Care and ACT/ED conditions increased by 0.12 (d = 0.22) and 0.13 (d = -0.18), respectively, between pre-intervention and 3 month follow-up (see Table 6). These trends are consistent with the prediction that ED Only would have benefits over Standard Care, but contrary to the expectation that ACT/ED would have benefits over ED only.

Table 6

Mean Total Cholesterol Results Across Time and Intervention

	Intervention Condition							
Time Period	Standard Care		ED Only		ACT/ED		Total	
	M	SD	M	SD	M	SD	M	SD
Pre-intervention	5.11	0.92	4.69	0.99	4.80	1.18	4.87	1.03
3 months	5.23	1.01	4.33	0.98	4.93	1.30	4.82	1.15
6 months	5.12	1.01	4.44	0.95	4.84	1.30	4.79	1.11

Note. N = 76 (Standard Care = 26, ED Only = 27, ACT/ED = 23). M = mean. SD = standard deviation.

12.1.7 Lipids: Total cholesterol >4.0.

As discussed previously, due to concerns about floor effects, data was analysed separately for participants with a total cholesterol greater than 4.0 (Ministry of Health Criteria for high cholesterol). Results showed that the interaction between time and intervention was larger than that observed when results for all participants were included in the analysis. Only small changes were found between pre-intervention and 3 month follow-up for those in the Standard Care (MD = -0.11, d = 0.23) and ACT/ED Conditions (MD = - 0.16, d = 0.2), but the mean total cholesterol for participants in the ED Only condition reduced by 0.48 (d = 0.86) between pre-intervention and 3 month follow-up (see Table 7); a large effect. Results of a mixed ANOVA indicated these differences were significant F (2,54) = 4.23, p = .003, η_p^2 = .136. Again, these results are consistent with the prediction that ED Only would have benefits over Standard Care, but contrary to the hypothesis that ACT/ED would have benefits over ED Only.

Table 7

Mean Total Cholesterol Results Across Time and Intervention (Total Cholesterol >40)

	Intervention							
	Standard Care		ED Only		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	5.46	0.63	5.10	0.79	5.39	0.82	5.31	0.75
3 months	5.57	0.78	4.62	0.91	5.55	0.98	5.23	0.98
6 months	5.47	0.76	4.72	0.92	5.46	0.99	5.20	0.94

Note. N = 57 (Standard Care = 21, ED Only = 20, ACT/ED = 16). Only participants with a cholesterol > than 4.0 were included in this analysis.

12.1.8 Weight.

Participants' overall weight loss, when results of the 3 intervention groups were combined and pre-intervention measurements were compared with follow-up results, was 2.09 kgs at 3 month follow-up (d = 0.16) and 1.8 kgs at 6 month follow-up (d = 0.16) (see Table 8). These effect sizes were in the small range and a mixed ANOVA found no significant main effect for time, F (2, 80) = 1.807, p = .168, η_p^2 = .022.

Comparison of mean changes in weight for the three intervention groups found small changes for those in the Standard Care and ED Only groups between pre-intervention and 3 and 6 month follow-up. The mean weight of participants in the Standard Care group changed minimally between pre-intervention and 3 month follow-up (0.09 kg increase , d = .007), and the mean weight of participants in the ED Only group decreased slightly (1.25 kgs, d = 0.11). The mean weight decrease for participants in the ACT/ED condition was much larger, with a decrease of 5.02 kgs at 3 month follow-up (d = 0.41). This weight loss was largely maintained at 6 month follow-up, with a 4.75 kg mean weight loss still apparent (d = 0.39) (see Table 8). Despite these

trends, effect sizes were all in the small range and differences were not significant. These results are contrary to predictions regarding the presence of significant main effects of time or interactions between time and intervention.

Table 8

Mean Weight (Kgs) Across Time and Intervention

	Intervention Condition							
	Standard Care		ED Only		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	97.69	20.44	90.80	18.48	84.66	26.12	90.97	22.32
3 months	97.78	21.13	89.55	19.25	79.64	14.26	88.88	19.64
6 months	98.47	20.92	89.48	19.12	79.91	13.76	89.17	19.47

Note. N = 83; Standard Care = 27, Education = 28, ACT/ED = 28. M = mean . SD = standard deviation.

12.1.9 BMI.

As depicted in Table 9, trends observed for BMI were similar to those found for weight. When the results of the intervention conditions were combined, there was a small drop in mean BMI between pre-intervention and 3 month follow-up (d = 0.15), and a very small further decrease at 6 month follow-up (d = 0.17). Results of a mixed ANOVA found this trend was not statistically significant, with no main effect found for time, F (2,80) = 1.988, p = .14, η_p^2 = .024.

Comparison of mean results for BMI for the three intervention groups showed similar trends to those observed for weight (see Table 9). Participants in the ED Only condition exhibited a very small decrease in BMI (less than 1 point) across the three time periods, while those in the Standard Care condition showed a slight increase when mean pre-intervention results were compared with results for 3 and 6 month follow-up. Participants in the ACT/ED condition had the largest decrease in mean BMI results,

with a decrease of 1.74 points between pre-intervention and 3 month follow-up (*d* = 0.38). The mean BMI for participants in the ACT/ED condition at pre-intervention was 31.31. This places them in the obese category according to Ministry of Health (2017b) guidelines. In contrast, their mean BMI at 3 months (31.84) placed them within the overweight range, and this result was maintained at 6 month follow-up. Despite promising trends, results of a mixed ANOVA did not demonstrate any significant interaction effects.

Table 9

Mean BMI Across Time and Intervention

	Interventions							
	Standard Care		ED Only		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	34.33	6.87	31.92	5.49	31.31	8.70	32.50	7.18
3 months	34.58	6.83	31.48	5.82	29.57	5.68	31.84	6.39
6 months	34.41	6.88	31.32	5.93	29.70	5.43	31.78	6.34

Note. N = 83, Standard Care = 27, Education = 28, ACT/ED = 28. M = mean. SD = standard deviation. All available results were included in this analysis.

12.1.10 BMI >29.

When only data for participants with a BMI of 30 or greater (criteria for obesity; Ministry of Health 2017b) were included in the analysis, results were somewhat different. Overall, when the results of the groups were combined, there was a decrease in BMI between pre-intervention and the two follow-up periods, with an overall decrease of 0.99 between pre-intervention and 6 month follow-up (see Table 10). Results of a mixed ANOVA found a significant main effect for time, F (2, 49) = 3.46, p = .035, η_p^2 = .065, although effect sizes at 3 month (d = 0.22) and 6 month (d = 0.20) follow-up were in the small range.

As shown in Table 10, different trends for BMI were observed for the three intervention groups, with those in the ACT/ED group showing the greatest decrease (3.77 points) between pre-intervention and 3 month follow-up (d = 0.28); however, results did not reach significance.

Table 10

Mean BMI Across Time and Intervention (BMI > 29)

	Interventions							
	Standard Care		ED Only		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	36.97	5.89	34.27	4.18	37.36	9.57	36.04	6.49
3 months	37.03	5.91	33.66	4.66	33.59	5.85	34.91	5.60
6 months	36.97	6.10	33.89	4.42	33.90	5.11	35.05	5.38

Note. N = 53, Standard Care = 20, Education = 20, ACT/ED = 13). M = mean. SD = standard deviation. Only results for participants with a BMI > 29 were included in this analysis.

12.1.11 Waist circumference.

Overall, when the results of the three intervention groups were combined, there was a small decrease in waist circumference at 3 month follow-up (1.89 cms), although the difference at 6 month follow-up had reduced somewhat. Results of a mixed ANOVA found the overall change in waist circumference over time was moderate and significant, F (2,79) = 6.14, p = .003, η_p^2 = .071. Post-hoc pairwise comparisons found a significant mean difference between pre-intervention and 3 month follow-up (MD = 1.87, SE = .53, p = .001, d = 0.30), but no significant difference between pre-intervention and 6 month follow-up (MD = .94, SE = .53, p = .082, d = 0.158) or between 3 and 6 month follow-up (MD = -.92, SE = .52, p = .082, d = - 0.159). These results lend some support for the hypothesis that there would be a main effect of the interventions over time.

With regards to differences between the intervention groups over time, trends were similar to those observed for BMI. For those in the Standard Care condition, there was a slight decrease in waist circumference at 3 months, but this had increased to slightly above pre-intervention measurements at 6 month follow-up, with an increase of 1.54 cms when mean pre-intervention results were compared with 6 month follow-up (see Table 11). Consistent with expectations, for participants in the ED Only condition the magnitude of the decrease in waist circumference was greater at 3 month follow-up (3.5 cms, d = 0.573) than it was for those in the Standard Care condition, although this increased again slightly at 6 month follow-up. Contrary to expectations, the decrease in waist circumference for those in the ACT/ED condition was smaller (1.75 cms at 3 month follow-up; d= 0.43), however, this change was largely maintained at 6 month follow-up. Mixed ANOVA results indicated differences between the groups in waist circumference over time were significant, F (2,80) = 3.178, p = .015, η_p^2 = .074, and the effect size moderate.

Table 11

Mean Waist Circumference Results Across Time and Intervention

	Standard Care		Education		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	108.33	17.99	99.46	16.14	93.22	10.60	100.24	16.24
3 months	107.97	18.59	95.96	15.83	91.47	10.47	98.35	16.64
6 months	109.87	17.82	96.82	15.53	91.48	10.79	99.26	16.68

Note. N = 83, Standard Care = 27, Education = 28, ACT/ED = 28. M = mean. SD = standard deviation.

12.1.12 Summary.

Regarding the combined effects of the interventions over time, results were consistent with expectations and indicated the presence of significant main effects for HbA1c, BMI (>29) and waist circumference. However, despite promising trends,

significant differences between intervention groups were only found for total cholesterol and waist circumference. The pattern of results observed for these variables was inconsistent with expectations, with the ED Only group exhibiting greater decreases than the ACT/ED group.

12.1.12 Distress Tolerance and Emotional Functioning

It was predicted that the ACT/ED intervention would produce greater reductions in anxiety, depression and distress tolerance, compared with ED Only and Standard Care.

12.2 Distress tolerance.

12.2.1 Breath holding duration.

Overall, minimal changes in breath holding duration were found between pre-intervention and 3 month follow-up (1.72 secs) and pre-intervention and 6 month follow-up (0.10 secs), and effect sizes were very small (d = 0.158 and d = 0.008, respectively). The mean breath holding duration of participants in the Standard Care condition decreased between pre-intervention and 3 month follow-up, then increased slightly at 6 month follow-up. Those in the ED Only condition exhibited a small but progressive increase in breath holding duration across the 3 time periods. Those in the ACT/ED condition decreased slightly between pre-intervention and 3 month follow-up then increased again at 6 month follow-up (see Table 12).

The above trends were not found to be significant. Results of a mixed ANOVA found no significant main effect for time, F (2,79) = 1.119, p = 329, η_p^2 = .014. There was also no significant interaction between intervention type and time F(2,79) = 1.192, p = .316, η_p^2 = .029.

Table 12

Mean Breath Holding Duration Across Intervention and Time

	Intervention							
	Standard Care		ED Only		ACT/ED		Total	
Time	M	SD	M	SD	M	SD	M	SD
Pre-intervention	37.38	22.75	34.39	21.46	38.39	17.78	36.70	20.53
3 months	33.19	18.07	35.89	21.53	35.75	17.59	34.98	18.97
6 months	34.15	21.43	36.32	17.19	39.17	19.40	36.60	19.24

Note. N =82; Standard Care = 26, ED Only = 28, ACT/ED = 28. M = mean. SD = standard deviation.

12.2.1.1 Distress Tolerance Scale (DTS).

When results of the intervention groups were combined, changes in mean DTS scores over time were very small. As shown in Table 13, there was less than 2 points difference between the overall mean score at pre-intervention and the overall mean score at either 3 or 6 month follow-up. Effect sizes were in the small range (d = 0.07 and d = 0.119, respectively).

Even when the results of the three intervention groups were examined separately, changes over time were small (less than 4 points). Scores on the DTS for all three intervention groups reflected moderate levels of distress tolerance (based on criteria for interpreting the DTS). Results of a mixed ANOVA to establish the impact of the three interventions on DTS scores over time did not find a significant main effect for time, F (2,78) = .550, p = .578, η_p^2 .007, or a significant interaction between intervention type and time, F (2,78) = .329, p = .858, η_p^2 = .008.

Table 13

Mean DTS Scores Across Time and Intervention

	Intervention							
	Standard Care		ED Only		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	40.69	11.58	41.39	15.38	38.37	9.63	40.14	12.36
3 months	38.46	11.13	40.75	15.22	40.14	12.36	39.30	12.13
6 months	39.84	2.51	40.03	13.58	37.21	12.00	39.01	11.80

Note. N =82; Standard Care = 26, ED Only = 28, ACT/ED = 26. M = mean. SD = standard deviation.

12.2.2 Hospital Anxiety and Depression Scale (HADS).

12.2.2.1 Depression Scale: Main and interaction effects.

Changes in scores on the depression subscale of the HADS over time were small, with all of the intervention groups remaining within the normal range for depressive symptoms across the three assessment periods. Depression scores decreased by less than one point (for any of the intervention groups) between pre-intervention and either 3 or 6 month follow-up (see Table 14) and effect sizes were, again, small (d = 0.064 and d = 0.165). A mixed ANOVA conducted to assess the impact of the interventions across the three time periods did not find a significant main effect for time, F (2,78) = .986, p = .375, η_p^2 = .012, and also failed to find a significant interaction between intervention type and time, F(2, 79) = .332, p = .856, η_p^2 = .008.

Table 14

Mean HADS Depression Scores Across Time and Intervention

	Intervention							
	Standard Care		ED Only		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	4.15	3.13	3.64	3.04	2.32	3.03	3.35	2.84
3 months	4.03	2.95	3.46	2.75	2.17	1.94	3.20	2.66
6 months	3.50	2.51	3.25	2.27	2.28	2.08	3.00	2.32

Note. N = 82; Standard Care = 26, ED Only = 28, ACT/ED = 28. M =mean. SD = standard deviation.

12.2.2.2 Anxiety scale: Main and interaction effects.

Overall, the mean change in HADS anxiety scores between pre-intervention and 6 month follow-up was less than 1 point (see Table 15) and the effect size (d = 0.30) was small. Results of a mixed ANOVA found this effect to be significant, F (2,79) = 4.42, p .014, η_p^2 = .053, with post hoc pairwise comparisons indicating a significant difference between pre-intervention and 6 month follow-up (MD = .754, SE = .278, p = .025, d = 0.30). No significant difference was found between pre-intervention and 3 month follow-up (MD = .583, SE = .287, p = .137, d = 0.25) or between 3 and 6 month follow-up (MD = .17, SE = .229, p = 1.00, d = 0.081). There was also no significant interaction found between intervention type and time, F (2, 79) = .882, p = .476, η_p^2 = .022, indicating the impact of the intervention over time did not differ between the intervention groups. Despite the presence of a statistically significant main effect for time, the above results appear to have limited clinical significance. Based on criteria for interpreting the HADS (Zigmond and Snaith, 1983), all of the intervention groups remained within the normal anxiety range (below 7) across the three assessment periods (See Table 15).

Table 15

Mean HADS Anxiety Scores Across Time and Intervention

	Intervention							
	Standard Care		ED Only		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	5.42	3.56	5.64	3.49	5.03	3.85	5.36	3.60
3 months	4.92	3.21	4.75	3.75	4.67	3.69	4.78	3.52
6 months	4.26	2.97	4.67	2.96	4.89	3.33	4.62	3.07

Note. N = 82; Standard Care = 26, ED Only = 28, ACT/ED = 28. M =mean. SD = standard deviation.

12.2.3 Summary.

Results for measures of emotional functioning were contrary to expectations. Although a statistically significant main effect of time was found for anxiety, this was very small and of questionable clinical significance, and no significant interactions were found between time and intervention.

12.3 Self-reported Lifestyle Change: Diet, Physical Activity and Smoking

It was predicted that when the results of the interventions were combined results would indicate statistically and clinically significant improvements over time on self-report measures of lifestyle change pertaining to diet, exercise and smoking. It was also predicted that ACT/ED and ED Only would have a greater impact on these variables than Standard Care, and ACT/ED will have a greater impact than ED Only.

12.3.1 Diet: DINE results.

12.3.1.1 Fibre and unsaturated fat.

Two mixed ANOVAS were conducted to establish the impact of the pre-diabetes interventions over time on participants' self-reported intake of unsaturated fat and fibre (based on mean scale scores on the DINE). No significant main effect was

found for time, and no significant interaction between intervention and time. Effect sizes were all in the small range (see Table 16).

Table 16

Results of mixed ANOVA test of differences between groups across time on DINE scale scores (Saturated and Unsaturated Fat, and Fibre)

	Main Effect for time				Interaction between Time and intervention			
Source	*df*	*F*	*p*	η_p^2	*df*	*F*	*p*	η_p^2
Saturated Fat	2,78	4.12	.018*	.050	2,79	1.48	.209	.036
Unsaturated Fat	2,78	.961	.385	.012	2,79	.199	.939	.005
Fibre	2,78	2.15	.119	.027	2,79	1.16	.329	.029

Note. F= Fisher's ratio. *P* = probability. *df* = degrees of freedom. η_p^2 = partial eta squared

12.3.1.2 Saturated fat.

With regards to intake of saturated fat, overall, when the results of the three intervention groups were combined, there was a progressive decrease in self-reported consumption over time (see Table 17). At 3 month follow up trends were consistent with predictions. Participants in the ACT group showed the greatest drop in saturated fat (6.39), while the ED Only group only exhibited a small decrease in intake (2.78) and the mean intake of saturated fat for those in the Standard Care Condition increased slightly (1.16). Results at 6 month follow-up were more diluted. All three groups reported reduced intake of saturated fat between pre-intervention and 6 month follow-up, however, the difference between the pre-intervention and 6 month follow-up scores for ED Only and ACT/ED was minimal (ACT/ED= 4.25, ED Only = 4.0).

Despite these trends, results of mixed ANOVA found no significant interaction between intervention type and time, $F(2, 79) = 1.487$, $p = .209$, $\eta_p^2 = .036$. However, there was a small but significant main effect found for time, $F(2, 78) = 4.128$, $p = .018$, $\eta_p^2 = .050$. Post hoc pairwise comparisons found a significant difference between

overall mean scores at pre-intervention and 6 month follow-up (MD = 3.788, SE = 1.28, p = .012, d = 0.33), but no significant difference between pre-intervention and 3 month follow-up scores (MD = 2.67, SE = 1.49, p = .23), and no significant difference between 3 and 6 month follow-up (MD = 1.11, 1.27, p = 1.00)

Table 17

Mean Scores on DINE Saturated Fat Scale Across Time and Intervention

	Intervention							
	Standard Care		ED Only		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	30.34	9.36	27.60	9.75	33.10	11.13	30.35	10.26
3 months	31.50	11.17	24.82	8.81	26.71	12.48	27.58	11.14
6 months	27.23	8.17	23.60	8.00	28.85	14.66	26.54	10.89

Note. N = 82; Standard Care = 26, ED Only = 28, ACT/ED = 28. M =mean. SD = standard deviation.

12.3.2 Physical activity: SF-IPAQ results.

As shown in Table 18, results obtained from the IPAQ indicated that, overall, total mean MHET minute activity progressively increased between pre-intervention and 6 month follow-up. Comparison of results of the three intervention groups showed that those in the ED Only group exhibited the greatest increase in MHET minute activity, with an increase of 2641 MHET minutes/week between pre-intervention and 6 month follow-up, while participants in the Standard Care condition increased their activity by 1522 MHET minutes/week. Participants in the ACT/ED condition reported the highest level of MHET minute activity at pre-intervention (M = 4172, SD = 4390), but exhibited minimal change at 3 and 6 month follow-up. According guidelines for the data processing and analysis of the IPAQ (2005), 7 or more days of any combination of walking, moderate or vigorous intensity activities accumulating at least 3000 MET-

minutes/week places participants in the high activity range. Based on this criteria, all three intervention groups were already reporting high levels of physical activity prior to intervention delivery.

With regards to activity type, overall levels of walking and moderate MET minutes activity progressively increased between pre-intervention (i.e., walking = M= 1371, SD = 1739) and 6 month follow-up (walking = M = 1782, SD 2390), while vigorous activity decreased. The magnitude of these differences was small (d = 0.14), as were the differences between groups. Sedentary activity remained relatively stable over time. Overall mean sedentary activity at pre-intervention was 320 minutes per week (SD = 145.51). This increased slightly at 3 month follow-up (M = 329.07, SD = 150.44), then decreased again at 6 month follow-up (M = 312.34, SD = 144.23). These findings were contrary to predictions.

Table 18

Mean IPAQ Total Physical Activity MET Minutes Across Time and Intervention

	Intervention							
	Standard Care		ED Only		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	3810	4653	3525	5084	4172	4390	3828	4675
3 months	3651	4418	4899	4631	4187	4105	4278	4369
6 months	5332	6326	6166	6773	4050	4313	5204	5905

Note. N = 82; Standard Care = 24, ED Only = 28, ACT/ED = 26. M = mean. SD = standard deviation. See Appendix… for MHET minute scoring protocol.

Despite the above trends, Mixed ANOVAs conducted to establish the impact of the interventions over time failed to find significant main effects for time for total MET minute activities, F (2, 74) = 2.78, p = .065, η_p^2 = .036, and the magnitude of the difference between pre-intervention and 3 month (d = 0.071) and 6 month follow-up (d

= 0.24) were small. There was also no significant interaction found between time and intervention, F (2, 75) = 1.175, p = .065, η_p^2 = .036. Separate mixed ANOVAs to assess the impact of the interventions over time for walking, moderate, vigorous and sedentary activity also found no main effect for time and no significant interaction between intervention type and time. Effect sizes were all in the small range (see Table 19).

Table 19

Results of ANOVA test of differences in IPAQ Scale scores between groups and across time: Main and Interaction Effects

	Main Effect for time				Interaction between time and intervention			
Source	*df*	*F*	*p*	η_p^2	*df*	*F*	*p*	η_p^2
Sedentary	2,77	.560	.572	.007	2,78	1.58	.18	.039
Walking	2,75	1.16	0.31	.030	2,76	.846	.498	.022
Moderate	2,77	1.32	.271	.033	2,78	1.48	.209	.037
Vigorous	2,76	1.75	0.18	.044	2,77	.98	.41	.025
Total MET minutes	2,75	2.78	.065	0.36	2,75	1.17	.32	.030

Note. F= Fisher's ratio. *P* = probability. *df* = degrees of freedom. η_p^2 = partial eta squared

12.3.3 Smoking.

Only 1 participant in each intervention condition reported smoking tobacco. This remained consistent at 3 and 6 month follow-up. Consequently, data for tobacco smoking was not analysed.

12.3.4 Summary.

Results for self-reported lifestyle change variables (diet, exercise, tobacco smoking) were inconsistent with predictions. When the results of the interventions were combined, a statistically significant reduction in the consumption of saturated fat was found, but no significant differences between the intervention groups. No main or interaction effects were found for any of the other dependent variables.

12.4 Life Satisfaction and Quality of Life

It was predicted that ACT/ED and ED only interventions would produce improvements in participants' quality of life over time, but ACT/ED and ED Only would have a larger effect on participants' quality of life than Standard Care, and ACT/ED would have a greater effect on participants' quality of life than ED Only.

12.4.1 Life Satisfaction Scale.

Overall, when the results of intervention groups were combined, scores on the Life Satisfaction Scale changed by less than 1 point between pre-intervention (M = 25.03, SD = 6.00) and 3 month (M = 25.26, SD = 6.23) or 6 month follow-up (M = 25.98, SD = 6.15). Effect sizes were in the small range (d = -0.038 and 0.188, respectively). Scores for all 3 intervention groups changed very little over time. Results for those in the Standard Care and ED Only groups changed by less than 1 point across the three time periods. Those in the ACT/ED condition showed the greatest change, with an increase of 2.18 between pre-intervention and 3 month follow-up. The results for all 3 groups reflected moderate to high levels of life satisfaction. A mixed ANOVA to establish the impact of the interventions on total mean scores on the Life Satisfaction Scale over time found the above trends were not significant. No main effect was found for time, $F(2, 78) = 1.521$, $p = .22$, $\eta_p^2 = .019$, and no interaction between intervention and time, $F(2,79) = .972$, $p = .425$, $\eta_p^2 = .024$. Effect sizes were small.

12.4.2 WHOQOL.

As shown in Table 20, results of mixed ANOVAs conducted to assess the impact of the pre-diabetes interventions on physical, psychological, social and environment domain scores, along with ratings on the quality and satisfaction with life scales, found no significant interactions between intervention type and time.

With regards to main effects for time, a significant effect was found for satisfaction with life, with a progressive increase in mean satisfaction with life scores between pre-intervention and 6 month follow-up. Post hoc pairwise comparisons found a significant difference between pre-intervention and 3 month follow-up (MD = .238, SE = .093, p = .037, d = -0.216) and between pre-intervention and 6 month follow-up (MD= .358, SE = .098, p = .001, d = -0.413). This result was inconsistent with results obtained from the Life Satisfaction Scale, although notably, the magnitude of these effects was small. The overall mean rating, when the results of the intervention groups were combined, increased from 3.12 at pre-intervention to 3.48 at post-intervention. The scale used for the life satisfaction scale of the WHOQOL ranges from 1 (very dissatisfied) to 5 (very satisfied). The above results indicate that participants continued to be "neither satisfied nor dissatisfied" with their health across the three intervention periods.

Table 20

Results of ANOVA test of differences in WHOQOL scores between groups and across time: Main and Interaction Effects

	Main effect for time				Interaction between time and intervention			
Source	*df*	*F*	*p*	η_p^2	*df*	*F*	*p*	η_p^2
Overall QOL	2,78	.812	.44	.010	2,79	1.73	.144	.042
Satisfaction with Life	2,78	7.64	.001*	.088	2,79	.427	.789	.011
Physical	2,78	.825	.440	.010	2,79	.190	.943	.005
Psychological	2,78	2.13	.121	.026	2,79	1.42	.229	.035
Social	2,78	.265	.768	.004	2,79	.134	.969	.004
Environment	2,78	.155	.856	.002	2,79	.325	.861	.008

Note. N = 82. *F*= Fisher's ratio. *P* = probability. *df* = degrees of freedom. η_p^2 partial eta squared

12.4.3 Summary.

Results for quality and satisfaction with life were inconsistent with expectations; a significant main effect of time was found for the life satisfaction scale of the WHOQOL questionnaire, however, this change was small and of questionable clinical significance. No other main or interaction effects were found for scores on the WHOQOL or the Life Satisfaction Scale.

12.4 Acceptance and Action

It was predicted that ACT/ED would result in improvements in self-reported acceptance and action, and these improvements would be greater than for those in ED Only or Standard Care conditions. It was also predicted that for those in the ACT/ED group, improvements in self-reported lifestyle change and physiological indicators of pre-diabetes management would be mediated by changes in acceptance and action.

12.5.1 AAPDQ.

Small increases in AAPDQ scores, indicating decreased acceptance, were found for all 3 intervention groups between pre-intervention and 3 month follow-up. These changes remained relatively stable at 6 month follow-up (see Table 21). A mixed ANOVA, conducted to assess the overall impact of the interventions on AAPDQ scores across the three assessment periods, found a moderate sized significant main effect for time, F (2, 76) = 7.94, p = .001, η_p^2 = .093. Post hoc pairwise comparisons found significant mean differences between pre-intervention and both 3 month follow-up (MD = 2.99, SE = .823, p = .001, d = 0.426) and 6 month follow-up (MD = 2.82, SE = .90, p = .008, d = 0.351). There was no significant interaction between intervention type and time, F(2, 77) = .433, p = .784, η_p^2 = .01, indicating no differences between the groups in acceptance and action, consequently further mediation effects were not explored.

Table 21

Mean Scores on the AAPDQ Across Time and Intervention

	Intervention							
	Standard Care		ED Only		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	48.96	6.02	51.69	7.87	51.46	8.34	50.72	7.51
3 months	51.26	6.24	54.84	6.44	55.00	5.66	53.73	6.27
6 months	50.23	7.86	55.34	7.18	55.00	7.07	53.56	7.64

Note. N = 82; Standard Care = 26, ED Only = 26, ACT/ED = 28. M = mean. SD = standard deviation

12.5.2 Summary.

Results for acceptance and action were inconsistent with predictions. When the results of the interventions were combined a significant main effect of time was found, with a small decrease in acceptance and action over time. No significant interaction between time and intervention was found,

12.6 Pre-diabetes Knowledge

It was predicted that ACT/ED and ED Only groups would exhibit comparable levels of pre-diabetes knowledge, and their knowledge would be greater than those in the Standard Care condition. It was also predicted that for those in ACT/ED and ED Only conditions, improvements in self-reported lifestyle change and physiological indicators of pre-diabetes management would be mediated by changes in pre-diabetes knowledge.

As shown in Table 22, at pre-intervention all three pre-diabetes intervention groups already exhibited reasonably high levels of pre-diabetes knowledge. Scores for both ACT/ED and ED Only groups improved by just over two points at post-intervention, with some knowledge decay evident at 3 and 6 month follow-up. Participants in the Standard Care condition showed smaller but progressive increases in

pre-diabetes knowledge between pre-intervention and 3 and 6 month follow-up. Participants in the Standard Care intervention did not attend intervention sessions, consequently, their pre-diabetes knowledge was only assessed at 3 and 6 month follow-up.

The results of a mixed ANOVA found the above differences between the groups were not significant, with no interaction found between intervention type and time , F (2, 79) = .882, p = .476, η_p^2 = .022. However, a significant main effect was found for time, F (2,78) = 19.45, p = .000, η_p^2 = .19, indicating that when the results of the groups were combined, there was a significant change in pre-diabetes knowledge. Post hoc pairwise comparisons found a significant mean difference between pre-intervention and post-intervention (MD = 2.14, SE = .20, p = .000, d = - 1.54), pre-intervention and 3 month follow-up (MD = .82, SE = .17, p = 000, d = - 0.71), and pre-intervention and 6 month follow-up (MD = .99, SE = .17, p = .000, d = - 0.69), but no significant difference between 3 and 6 month follow-up (MD -.179, SE = .165, p = .849, d = - 0.015). Mediation analyses were not completed because there were no significant differences in knowledge between the 3 intervention groups.

Table 22

Mean Pre-diabetes Knowledge Scores for Intervention Conditions over Time

	Interventions							
	Standard Care		ED Only		ACT/ED		Total	
Time Period	M	SD	M	SD	M	SD	M	SD
Pre-intervention	6.50	1.81	7.28	1.62	7.28	1.69	7.28	1.64
Post-intervention			9.46	0.92	9.39	0.87	9.42	.89
3 months	6.96	1.61	8.35	1.39	8.35	1.39	8.28	1.34
6 months	7.46	1.79	8.50	1.40	8.10	1.39	8.30	1.40

Note. N = 82; Standard Care = 26, ED Only = 28, ACT/ED = 28. M = mean. SD = standard deviation

12.7 Intervention Satisfaction

Independent samples t tests were used to assess the impact of ED Only and ACT/ED interventions on scores on the PSQ. No significant differences were found between mean scores for ACT/ED or ED Only groups in the perceived effectiveness of the intervention, t (53) = -.379, p = .706 (two tailed), d = -0.088, or mean ratings for helpfulness, t (53) = .446, d = 0.197, satisfaction with the intervention, t (53) = .677, d = -0.115, and likelihood of recommending the intervention to a friend, t (53) = .969, d = 0.027. Effect sizes were all in the small range. The scores across all 4 scales of the PSQ indicated very high levels of satisfaction with both ACT/ED and ED Only interventions (0 = not at all helpful, 5 = extremely helpful; see Table 23).

Table 23

Mean Domain Scores on Participant Satisfaction Questionnaire

	Intervention					
PSQ Scale	ED Only			ACT/ED		
	N	M	SD	N	M	SD
Effectiveness	28	4.57	0.57	27	4.62	0.56
Helpfulness	28	4.92	0.26	27	4.85	0.45
Satisfaction	28	4.60	0.49	27	4.66	0.55
Recommend	28	4.89	0.31	27	4.88	0.42

Note. N = 55. M = mean. SD =standard deviation. Scales ranged from 1 to 5 (i.e., 1 = not at all helpful, 5 = very helpful)

Chapter 13: Discussion

The present study developed/adapted two lifestyle education manuals for people with pre-diabetes. The first provided lifestyle education only, the second combined lifestyle education with a psychological intervention component based on an ACT therapeutic approach. The overarching goal of the interventions was to reduce physiological and behavioural risk factors associated with progression from pre-diabetes to type 2 diabetes. The ACT/ED intervention sought to achieve this goal by 1) increasing participants' motivation to make healthy lifestyle changes through connecting their goals to personally meaningful life values, and 2) assisting them to develop skills to negotiate psychological barriers that might arise while pursuing their goals.

Once the two intervention manuals were developed, they were trialled with patients recruited through local GP practices in the Manawatu region. Participants were randomly assigned to ACT/ED, ED Only or Standard Care conditions, and the effectiveness of the interventions were compared using dependent measures of physiological indicators of diabetes risk, self-reported lifestyle change, quality of life, emotional functioning, acceptance and action, and pre-diabetes knowledge.

This chapter explores the main results of this study in relation to the research questions, compares the findings to previous research with patients affected by type 2 diabetes and other physical health conditions, and provides possible interpretation of results. The limitations of the research methodology are also highlighted, along with recommendations for future research, and implications for clinicians, researchers and policy.

13.1 Lifestyle change and physiological indicators of diabetes risk

13.1.1 Main findings.

The first research question asked, what impact does combining a pre-diabetes lifestyle education intervention with an ACT-based intervention have on pre-diabetes patients' self-reported engagement in lifestyle change and physiological indicators of lifestyle change? Does ACT/ED have added benefits over ED Only or Standard Care? Analyses showed that cumulatively, when the results of the three interventions were combined, changes were found over time across a few of the physiological and self-report indicators of lifestyle change, but the ACT/ED intervention did not provide significantly greater benefits than ED Only or Standard Care across any of the lifestyle change variables.

More specifically, combined group results for the physiological outcomes, indicated significant decreases in participants' mean HbA1c and BMI (for those with a BMI >29) occurred between pre-assessment and 3 and 6 month follow-up, and reduced waist circumference at 3 month follow-up. The changes in waist circumference and BMI were small and of questionable clinical significance (Ministry of Health, 2017b), However, based on Ministry of Health guidelines (2013), the change in HbA1c was of potential clinical significance and indicated that at the conclusion of the study the majority of participants no longer met criteria for pre-diabetes. With regards to self-reported lifestyle change, when the results of the intervention groups were combined, a significant decrease was found in saturated fat consumption between pre-assessment and 6 month follow-up, but no significant changes in consumption of unsaturated fat or fibre, physical activity levels, or tobacco smoking. The only significant group differences were found for total cholesterol and waist circumference, and the pattern of

findings suggested the ED Only intervention produced more favourable changes in these areas than ACT/ED or Standard Care interventions.

13.1.2 Comparison with previous research.

13.1.2.1 Pre-diabetes lifestyle education research.

The present findings are consistent with outcomes from previous pre-diabetes studies, which have suggested brief intervention protocols do not produce the large reductions in diabetes risk that have been found for more intensive approaches, such as those trialled in the Finnish DPS (Lindstrom et al., 2003) and US DPP (The Diabetes Prevention Program Research Group, 2002) studies. Unlike the present study, The DPS reported significant, and relatively large, reductions in sedentary activity (30% versus 14% at year 1), along with decreases in fat and fibre consumption, plasma glucose, HbA1c, total cholesterol, HDL cholesterol, triglycerides and weight (Lindstrom et al., 2003). Similarly, the DPP reported significant changes in HbA1c, which were moderated by lifestyle change, along with weight loss and reduced CVD risk factors (The Diabetes Prevention Program Research Group, 2002, 2005).

The reductions in waist circumference and total cholesterol found in the present study for those who attended the ED Only intervention, were most aligned with those reported in previous studies that have attempted to adapt intensive intervention approaches into brief cost-effective approaches, such as the Good Aging In Lahti region study (Absetz et al., 2007) and the Australian GOAL study (Laatikainen et al., 2007). These studies both reported small reductions in waist circumference following a 9 hour group-based intervention.

Cumulatively, the present findings suggest that brief pre-diabetes education interventions can provide some additional benefit to provision of standard medical care for reducing certain physiological and behavioural risk factors associated with

progression from pre-diabetes to diabetes; however, the magnitude of these changes is likely to be small and of questionable clinical significance. This is important information for PHOs and DHBs seeking to implement diabetes prevention initiatives. When considering the utility of brief versus longer-term interventions, it may be prudent to conduct a temporal cost /benefit analysis. While brief interventions may be accessible and cost-effective in the short term, in the long-term they may be less economically sound. Their reduced effectiveness means patients attending these interventions may require more medical resources across their lifetime than those provided with longer-term input.

13.1.2.2 ACT research.

There is no previous research using an ACT approach with pre-diabetes patients against which to compare findings pertaining to the effectiveness of the ACT/ED intervention used in the present study. However, the finding that ACT/ED was no more effective than either Standard Care or ED Only is inconsistent with the findings of the two type 2 diabetes studies conducted in the US (Gregg et al., 2007) and Tehran (Shayeghian et al., 2016), which both reported their ACT/ED interventions improved diabetes control (based on HbA1c) and self- care/management. The present results are most similar to those reported in Whitehead's New Zealand-based study (Whitehead et al., 2016), which also found no significant differences in HbA1c between ACT/ED and either ED Only or Usual Care groups at 6 months post-intervention. Unlike the present study, they did find a significant difference between ED Only and Usual Care, suggesting their education intervention served to enhance patients' condition management.

None of the previous ACT studies conducted with diabetes patients included measures of lipid control or other physiological indicators of diabetes management

(BMI, waist circumference etc.), but the present results for these variables are inconsistent with previous ACT research conducted with patients with other long-term health conditions, including cardiac illness (Goodwin et al., 2012), obesity (Lillis et al., 2009) and colorectal cancer (Hawkes et al., 2014). These studies reported significant improvements in objective physical indicators of condition management, including diet, weight and BMI.

13.1.3 Interpretation of findings.

Possible explanations for why the present results diverge from those reported previously relate to methodology, sample characteristics, and cultural factors.

13.1.3.1 Methodological factors.

13.1.3.1.1 Workshop length.

Although the ACT component of the ACT/ED protocol used in the present study was adapted from Gregg and colleagues manual, the intervention was briefer than those implemented by either Gregg (Gregg et al., 2007) or Shayeghian (Shayeghian et al., 2016). Participants involved in both of these studies attended 7 hour workshops, conducted over a single day, of which approximately 3 hours was focused on ACT processes (Gregg et al., 2007; Shayeghian et al., 2016). In contrast, the present study was conducted over 2 sessions (a total of 4.5 hours intervention), held on consecutive weeks, with 2 hours of the intervention focused on ACT processes.

There were several reasons the present intervention was more consolidated than those developed previously. In Gregg's study, the groups were larger (10-24 participants), likely requiring more time for participant questions and interactions; the education component of the intervention protocol covered a more extensive range of topics, some of which had no relevance for patients with pre-diabetes; and the ACT/ED intervention included the chessboard metaphor, an exercise that was excluded from the

present study following clinical consultation (as described previously) (Gregg et al., 2007). While there was a clear rationale for the methodological differences between Gregg's interventions and those used in the present study, it is possible that these adjustments diluted the effectiveness of the interventions. Although qualitative feedback indicated high levels of satisfaction with both ACT/ED and ED Only interventions, it also indicated many participants thought a lengthier intervention might have been beneficial.

13.1.3.1.2 Massed versus spaced practice.

The decision to hold the workshop over 2 days, rather than a single day (as was the case in the previous studies), may have affected outcomes. This decision was based on principles of effective learning, which suggest spaced learning is more effective than mass, along with pragmatic factors, such as increasing patient access (Rohrer, 2015). However, this decision may have affected participants' ability to effectively integrate the lifestyle education material, which was primarily in the first session, with the ACT material, which was largely presented in the second session. In the context of a two session workshop, it may be more effective to integrate the ACT material equally across both sessions.

13.1.3.1.3 Intervention type and content

Unlike previous research by Gregg and Shayeghian (Gregg et al., 2007; Shayeghian et al., 2016), in addition to incorporating an ED Only condition as an active control group, a Standard Care condition was also included in the present study to clarify whether either of the active interventions provided additional benefit over the usual care patients received through their GP Practice. While this approach may be methodologically more robust, the difficulty with 'usual' or 'standard' care approaches when conducting clinical research is that they are rarely equivalent to the care provided

to patients who are not research participants. Although the control condition in the present study was labelled ‘Standard Care,’ participants in this condition received informative brochures; completed a series of measures that were likely to trigger thinking about their lifestyle choices, quality of life and emotional well-being; and received more regular feedback about physiological risk indicators than the standard 6 to 12 month follow-up recommended by the Ministry of Health (2016). These aspects of the ‘Standard Care” intervention make it a little different to the usual care patients receive through their GP Practice, and might explain, at least to some degree, why the predicted differences between Standard Care and the active interventions were not observed. It would appear that for patients at the lower end of the HbA1c pre-diabetes range the level of intervention provided within primary care, with the addition of some written information and regular monitoring of diabetes risk and well-being, is sufficient to produce changes across some physiological and self-report variables.

It is equally possible that involvement of the GP practices in the study improved the care they provided their patients who participated. The GP practices who took part all indicated they provided care that was consistent with New Zealand Ministry of Health (2013) advice. However, the regular visits and phone calls received by GP practices during the recruitment phase of the study, along with the feedback they received about blood results, may have prompted more diligent and effective pre-diabetes management.

13.1.3.2 Sample characteristics.

A further potential reason the ACT/ED condition did not produce the favourable results reported previously is that prior studies focused on type 2 diabetes. What this means is participants entered these studies with a much higher HbA1c than participants in the present study, thus creating more room for change. Not only were participants in

the present study in the pre-diabetes range, but pre-assessment findings indicated the mean HbA1c of the sample was only just within the pre-diabetes range, with many already dropping to within the 'normal' range between recruitment and pre-assessment. These results likely limited the potential for change. Tentative support for this theory is provided by results obtained for participants' with an HbA1c over 40, with significantly larger changes in HbA1c found over time for this group. Although the differences between the groups still failed to reach significance (unsurprising, due to the reduced sample size), trends suggested greater decreases for ACT/ED participants and ED Only participants compared with those who received Standard Care. These results suggest different outcomes may have been observed if higher cut-off criteria for HbA1c had been used. Previous research has demonstrated the impact of HbA1c cut-off scores on the effectiveness of lifestyle interventions. Sub-group analysis of data obtained from the Japan Diabetes Prevention Program found lifestyle interventions were most effective in the long-term prevention of type 2 diabetes for those with HbA1c levels within, rather than below, the pre-diabetes range. (Sakane et al., 2014).

The reason for the reduction in participants HbA1c prior to entering the intervention is unclear. It is possible that participants who volunteer to take part in a pre-diabetes study are already at the action stage of change (Prochaska & Velicer, 1997) and investing in healthier lifestyle choices. There is certainly evidence to suggest that even consenting to participate in a clinical trial can have a positive effect on HbA1c. A 2007 study, which looked at the impact on HbA1c for patients with diabetes who had been screened for eligibility to take part in diabetes studies (but were yet to receive intervention), reported a significant reduction in HbA1c over a 28 day period, despite receiving no active intervention. Notably, greater reductions were found for those who

initially had the poorest diabetes management (Gale, Beattie, Hu, Koivisto, & Tan, 2007).

13.1.3.3 Cultural factors.

As discussed, the present findings are most aligned with the only previous New Zealand based ACT research with type 2 diabetes patients (Whitehead et al., 2016).This raises questions about the cross-cultural validity of ACT and the ability to generalise findings from international research to a New Zealand context. It has been suggested that ACT's theoretical roots in functional contextualism, with its emphasis on determining the function of behaviour within a given context and the exploration of personally meaningful values, makes it an approach that can be applied across varied cultural contexts (White, Gregg, Batten, Hayes, & Kasujja, 2017); a finding supported by ACT based research with Indian (Lundgren et al., 2008b), South African (Lundgren et al., 2006), and Persian (Shayeghian et al., 2016) populations. In saying this, to date, research with a New Zealand population is limited. It may be that further exploratory research is necessary to establish ways of effectively translating and adapting ACT experiential activities and metaphors to make them more meaningful for a New Zealand population. Exploration of appropriate adaptations for Maori and Pacific peoples is particularly important, given the high rates of diabetes and pre-diabetes within these groups. Integrating tikanga, along with purakau and whakatauki, may help bring ACT concepts and processes to life for Maori patients.

13.2 Quality of Life and Emotional Functioning

13.2.1 Main findings.

The second research question asked, what impact does combining a pre-diabetes lifestyle education intervention with an ACT intervention have on participants' self-

reported quality of life and emotional functioning? Does incorporating an ACT intervention have added benefits over education alone or standard care?

Results indicated that ACT/ED did not provide any additional benefits over ED Only or Standard Care for quality of life or emotional functioning. When the results of the three interventions were combined, a small change in life satisfaction was observed over time on the WHOQOL questionnaire, and anxiety levels significantly decreased between pre-intervention and 6 month follow-up on the HADS. However, these results were of questionable clinical significance, as they indicated participants continued to be neither satisfied or dissatisfied with their quality of life and anxiety remained within the 'normal range' (Zigmond & Snaith, 1983). Moreover, the ACT/ED intervention did not provide significantly greater benefits than ED Only or Standard Care for any of the measures of emotional functioning or quality of life, and there were no compelling trends.

13.2.2 Comparison with previous research and interpretation of findings.

The finding that the ACT/ED intervention produced no significant changes in quality or satisfaction with life in comparison to Standard Care or ED Only diverges from previous research that has demonstrated the benefits of ACT for enhancing QOL for patients with obesity (Lillis et al., 2009), pain (Wicksell, Melin, Lekander, & Olsson, 2009), cancer (Feros et al., 2013), and multiple sclerosis (Sheppard et al., 2010). All of these studies reported moderate to large improvements in QOL and/or satisfaction with life following an ACT intervention. For patients with MS this occurred following a single session intervention.

The reason the present results differ from those found previously may be due to the nature of the health conditions targeted. Prior research focused on conditions with definable physical symptoms and/or complications that can function as barriers to living one's desired life. In contrast, pre-diabetes, rather than being a defined medical

condition, is a warning sign that internal physiological damage is occurring or likely to occur in the future. While there is evidence to suggest vascular changes are already occurring for those with pre-diabetes (Barr et al., 2007)**,** unlike other physical health conditions, these physiological changes are silent. In fact, there are no reliable physical symptoms to indicate a person has pre-diabetes; a venous blood sample is the only method of detection (Ministry of Health, 2012). For these reasons, the impact of pre-diabetes on QOL, particularly pertaining to physical functioning, is likely to be less substantial than for other health conditions. This explanation is at least partially supported by the present study's finding that at pre-assessment participants were neither satisfied or dissatisfied with their lives.

The finding the ACT/ED intervention did not produce changes in distress tolerance, anxiety or depression also lies in stark contrast to research using ACT based interventions with a variety of health conditions. This research has reported favourable results using ACT interventions for obesity (Lillis et al., 2009), cancer (Feros et al., 2013), and pain (McCracken et al., 2007), with one study indicating ACT produced significantly greater reductions in distress than traditional CBT (Rost et al., 2012).

The present findings are consistent with research using a phone based ACT intervention with colorectal cancer patients, which found no significant differences in distress between ACT and TAU conditions (Hawkes et al., 2014), as well as research with MS patients, which did not find significant differences in outcomes between ACT and a relaxation intervention (Nordin & Rorsman, 2012). Whitehead's study was the only diabetes study that included a measure of anxiety and depression (Whitehead et al., 2016). Like the present study, they used the HADS, and they found no significant differences between ED Only, ACT/ED and Usual Care conditions.

Once again, it seems likely that both the present results and those reported by Whitehead (Whitehead et al., 2016) can be attributed to floor effects. In both of these studies, participants' anxiety and depression scores were already within the normal range at pre-assessment, creating minimal room for improvement. If anxiety and depression scores had been higher when participants entered the study, a different pattern of results might have been observed.

The finding that participants' emotional functioning was largely within the normal range prior to receiving any intervention may also explain why greater changes in physiological and self-report indicators of lifestyle management were not found for those in the ACT/ED intervention. When addressing barriers to lifestyle change, the ACT/ED intervention primarily focused on providing participants with strategies to deal with difficult/unhelpful/uncomfortable emotions (i.e., anxiety) that can arise in the pursuit of their lifestyle goals. However, based on pre-assessment results, the majority of participants were already functioning optimally in this regard, therefore any intervention targeting these issues was unlikely to produce substantial changes.

13.3 Acceptance and action, and pre-diabetes knowledge

13.3.1 Main findings.

Research question 3 asked, what are the mechanisms of change for those in the ACT/ED intervention? If changes in self-reported lifestyle management and physical indicators of lifestyle management occur for those in the ACT/ED condition, are these changes mediated by changes in acceptance and action. Are changes in these variables for either ACT/ED or ED only intervention groups mediated by changes in pre-diabetes knowledge?

Because no significant differences between ACT/ED and either ED Only or Standard Care groups were found for self-report or physical indicators of lifestyle

management, mediation analyses were not completed for acceptance or pre-diabetes knowledge. For acceptance, when the results of the interventions were combined, a moderate increase in scores on the AAPDQ was found over time, indicating reduced acceptance and increased experiential avoidance, but no significant differences were found between the groups. For pre-diabetes knowledge, when the results of the groups were combined, there was a significant difference between pre-assessment results and 3 and 6 month follow-up results, but no differences were found between the groups.

13.3.2 Comparison with previous research and interpretation: Acceptance

The above results indicate, contrary to predictions, that the ACT/ED intervention was no more effective in promoting increased acceptance of internal experiences than ED Only or Standard Care conditions. This finding is contrary to previous research conducted in the areas of obesity (Lillis et al., 2009), cancer (Feros et al., 2013; Hawkes et al., 2014), and pain- related disability (Wicksell et al., 2010), which reported greater increases in acceptance as a result of their ACT interventions. These findings are also contrary to both Gregg (Gregg et al., 2007) and Shayeghian's (Shayeghian et al., 2016) findings, which indicated their ACT/ED group exhibited greater acceptance than their ED Only group, and Gregg's study, which further indicated that changes in acceptance mediated changes in HbA1c.

The present findings are congruent with Whitehead's diabetes research, which reported no significant difference between ACT/ED and ED Only for acceptance (Whitehead et al., 2016). They are also consistent with previous research (Sheppard et al., 2010) conducted with MS patients, which found no improvement in acceptance for patients who attended a single session ACT intervention, despite changes on other outcome variables.

It is not completely clear why the ACT/ED intervention failed to increase participants' acceptance of thoughts and feelings related to the risk of developing diabetes. The primary goal of ACT is to decrease the dominance of unworkable psychological processes, such as experiential avoidance, as strategies for responding to uncomfortable internal experiences, and increase patients' acceptance and overall psychological flexibility (Zhang et al., 2018). It is possible that participants in the present study were yet to experience the negative consequences of experiential avoidance, and, therefore, the intervention was not effective in generating sufficient willingness to accept the difficult thoughts and feelings associated with having pre-diabetes. Unlike patients with type 2 diabetes, who have likely already experienced some of the negative consequences of their condition, patients with pre-diabetes are merely faced with the prospect of developing this condition and its complications. For the patient with type 2 diabetes, avoidance of thoughts and feelings associated with their condition is likely to negatively impact on their self-management behaviour, which can have acute physical consequences (Gregg et al., 2007). For example, the patient with diabetes who avoids thinking about his condition, and consequently neglects to take his insulin, is likely to experience a negative impact of this behaviour on his blood glucose levels. This, in turn, could produce a range of distressing physical and psychological symptoms, including blurred vision, tiredness, excessive thirst, and irritability. In contrast, for the patient with pre-diabetes, avoidance of thoughts and feelings associated with their condition is unlikely to produce any acute negative physical or psychological consequences in the short-term. While they may be cognitively aware that failure to engage in healthy lifestyle behaviours has potentially negative future consequences, this risk is not imminent or definite; therefore the costs of avoidance could be perceived as too remote to warrant a shift toward acceptance. In this context, experiential avoidance

may still be seen as a workable response. Indeed, from an ACT therapeutic perspective there is no such thing as a positive or negative emotion regulation strategy. The key is to: (1) assist patients to develop psychological flexibility to enable them to consider whether their current strategies for interacting with their emotions move them toward or away from their values, and (2) if their current emotion regulation strategies are found to be unworkable, consider alternative more functional strategies they can employ (Harris, 2009). It may be that for patients in the early stages of pre-diabetes some degree of experiential avoidance is perceived as workable, and, in the absence of adverse physical symptoms, is not considered a barrier to valued living.

A further consideration when interpreting outcomes is whether the measure used to assess experiential avoidance and acceptance was measuring what it intended to. In the present study, acceptance was measured using the AAPDQ. As mentioned previously, this was adapted from the AADQ (the measure used in Gregg's study) (Gregg et al., 2007), which was previously adapted from the original AAQ, developed by Hayes (Hayes et al., 2004c). Although only minor wording changes were made to this measure to ensure the items referred to diabetes risk as opposed to type 2 diabetes, and consumer consultation was sought to determine its comprehensibility, it is important to acknowledge there were no formal validation processes for the AAPDQ. It is possible that the minor wording changes compromised the validity of the measure.

13.3.3 Comparison with previous research and interpretation: Pre-diabetes knowledge.

Previous ACT research in the diabetes domain has not included measures of diabetes knowledge. Whitehead and colleagues did include a 10 item measure of participants' understanding of diabetes management but found no significant differences between the groups (Whitehead et al., 2016). Gregg also found no significant

differences in understanding, although this was predicted as they did not include a standard care condition as a control for the active interventions (Gregg et al., 2007).

The presence of a ceiling effect may explain why ED Only and ACT/ED groups did not significantly differ in their diabetes knowledge. Pre-assessment outcomes indicated that participants already had a high level of pre-diabetes knowledge prior to receiving any intervention. Although results indicated knowledge increased for both ED Only and ACT/ED groups at post-assessment, indicating the interventions increased their pre-diabetes knowledge to some degree, there was negligible room for improvement. There was also some evidence of knowledge decay at 3 month follow-up, meaning the differences between the three interventions failed to reach significance at this time.

Greater differences between the active intervention groups and the Standard Care group may have been observed using a more in-depth measure of diabetes knowledge. The measure used in the present study was adapted from the Michigan Diabetes Research and Training Centre's Brief Diabetes Knowledge test, and had been previously used to assess outcomes for patients attending pre-diabetes education sessions provided through the Manawatu Diabetes Trust. Their analysis indicated improved diabetes knowledge (24.2% improvement) directly following the intervention, however, their participants had lower pre-assessment scores, they did not track whether improvements were maintained, and there was no standard care comparison group. These factors likely contributed to their divergent results.

13.4 Limitations and Directions for Future Research

Several of the present studies limitations, and the impact of these on the interpretation of outcomes, have already been discussed. However, there are some more general limitations pertaining to the results as a whole that still warrant consideration.

These relate to statistical power, measurement issues and treatment fidelity. This section will discuss these issues and explore options for how they, and other limitations, can be overcome in future research.

13.4.1 Statistical power.

The reliability and validity of the present findings are seriously limited by having insufficient statistical power to detect small to moderate effects, due to having a smaller than intended sample size. Statistical power refers to the probability that the statistical tests used will yield significant effects, and is impacted by factors such as ES, N and alpha (*p*) level (Cohen, 1988). Several authors have pointed out that underpowered samples are a major issue contributing to the reporting of false negative results in the literature. When a study is underpowered, this can result in the researcher failing to reject the null hypothesis even when it is correct, simply because the statistical tests used lack the power to detect the desired effects (Vadillo, Konstantinidis, & Shanks, 2016).

When developing this study the intention was to recruit 190 participants, which would have provided sufficient power to detect medium effect sizes similar to those reported in previous ACT research (Gregg et al., 2007; Shayeghian et al., 2016). Unfortunately, due to recruitment issues, only 98 patients were recruited to the study, and only 83 provided data suitable for analysis. Having a substantially smaller sample size than intended only provided sufficient power (80%) to detect large effects, and minimal power to detect small to medium size effects. This makes the interpretation of insignificant results difficult because a non-significant/null result could mean either (a) there was no effect, or (b) there was an effect but the study did not have adequate sensitivity to detect it (Gravetter & Wallnau, 2004; Vadillo et al., 2016). Trends and effect sizes were reported alongside the results of significance tests to assist in the

interpretation of findings; however, several authors point out that robust conclusion cannot be drawn on the basis of these findings (Gravetter & Wallnau, 2004).

The most effective method to increase statistical power in future research would be to recruit more participants. The reasons for the difficulty recruiting participants to the present study are not completely clear. Due to the small population of New Zealand, the participant pool is far smaller than for studies conducted in Europe, the United States and Asia. In saying that, consultation with relevant parties (i.e., Diabetes Trust and the PHO), along with prevalence statistics (Coppell et al., 2013), suggested there was a sufficient pool from which to achieve the recruitment target.

The initial plan when designing the study was to send a letter to all pre-diabetes patients in the practices that had agreed to take part inviting them to be involved in the study. With most practices indicating they had well over 100 patients who met criteria for pre-diabetes, this approach would have provided a large recruitment pool. However, consultation with local GP practices suggested several practices were not comfortable with this recruitment method. A number of practices disclosed a reluctance to refer patients they had not directly spoken with about the study, and two practices indicated that they did not routinely use the term ‘pre-diabetes’ to classify patients within the HbA1c classification criteria, due to concern that this label would heighten their anxiety.

A second identified recruitment barrier was the opportunity for patients to be referred to alternative pre-diabetes interventions that did not require the same time investment necessary for participation in the present study. At the time of recruitment, two alternative pre-diabetes intervention programs were being implemented in the Manawatu region, and both required a substantially lower time investment (1.5 hours intervention, with no pre-assessment or follow-up) than was required for the present

study (4.5 hours intervention, with additional time required for pre-assessment and follow-up). For patients engaged in full-time employment or with other responsibilities, these alternative intervention programs were likely to present a more desirable option.

Recruitment is an ongoing issue in clinical trials, and overcoming the barriers can be challenging (Ost, 2008; Vadillo et al., 2016). When conducting research with patients with physical health conditions, it requires buy in not only at a participant level but also a DHB, PHO and practitioner level. Financial support was accessed for this initiative through the local DHB, and substantial effort invested in recruitment activities, but perhaps more time and resources were required to ensure community and practice level buy in.

Difficulties associated with recruiting sufficient participant numbers to a single study has led some authors to suggest combining results derived from multiple studies using meta-analytic approaches (Tabachnick & Fidell, 2013; Vadillo et al., 2016). When the results from individual underpowered studies are combined, the ability to detect modest differences is increased. These techniques are important to consider when conducting research with emerging therapeutic approaches, as such studies often lack the funding support to access the sample sizes needed. As a recent review of ACT research in the area of chronic health (Graham et al., 2016) pointed out, underpowered samples are common with ACT research. And, despite promising outcomes using an ACT approach, the insufficient statistical power of many of the studies conducted thus far impacts on perceptions of the empirical evidence underlying the approach, and this makes interpretation of outcomes challenging.

Conversely, increasing the sample size of ACT studies, or combining results in an effort to detect significant effects, should be weighed against the potential clinical utility of the findings. Detecting a significant result does not mean that result is

clinically meaningful (Pallant, 2007). For example, the present study found that when the results of the groups were combined there was a statistically significant reduction in anxiety over time. But, as described previously, that result had questionable clinical significance, with all participants remaining within the 'normal' symptom range.

The power of future research to detect significant effects could also be increased by employing more stringent participant inclusion criteria to increase the likelihood of obtaining larger effects. In the interest of recruiting a large enough sample, inclusion criteria were kept to a minimum. Criteria simply required participants to be over the age of 18, fluent in English, and meet HbA1c criteria for pre-diabetes. No inclusion criteria were put in place based on other pre-diabetes risk factors (such as BMI) or indicators of emotional functioning. Some of the previous pre-diabetes lifestyle intervention research has incorporated more stringent inclusion criteria. For example, the Finnish DPS study limited participation to adults between the ages of 40 and 64 with a BMI greater than 25 (Lindstrom et al., 2003), and the US DPP required participants to have a BMI greater than 24 (Diabetes Prevention Program Research Group, 2005). The larger effects reported in these studies are unlikely to be solely attributable to these factors, but it is possible that the present study would have found larger effects if narrower inclusion criteria were put in place. In saying that, the effect of employing more stringent inclusion criteria on effect sizes would need to be weighed against the impact on recruitment. The more inclusion criteria in place the smaller the potential participant pool.

13.4.2 Fidelity.

There were no formal measures put in place to ensure treatment fidelity. The interventions were manualised and led by the same co-facilitators to ensure consistency in delivery, but due to equipment failure no formal fidelity measures were used. Fidelity

measures are undoubtedly important in clinical research trials to ensure that the content and style of intervention delivery adheres to the therapeutic model and protocol on which it is based (Schinckus, Van den Broucke, & Housiaux, 2014). Establishing implementation fidelity in the present study may have provided valuable information regarding why the ACT/ED and ED Only interventions were not effective, along with information about the components that need to be adapted for future success (Schinckus et al., 2014).

13.4.3 Summary

The findings and limitations of this study provide important directions and recommendations for future research.

First, replication of the study with more stringent inclusion criteria. Requiring higher cut off criteria for physiological variables like HbA1c and BMI may decrease the likelihood of obtaining floor effects and help clarify whether the interventions were just too brief to produce clinically meaningful change, or, alternatively, whether these interventions are only effective for patients with specific risk factors.

Second, replication of the research with patients exhibiting unworkable emotion regulation strategies, such as those demonstrating high levels of experiential avoidance and/or symptoms of distress, anxiety or depression. This would also provide information about the characteristics of patients most likely to benefit from ACT-based interventions, help to eliminate floor effects and provide important information to assist health practitioners with determining optimally beneficial treatment pathways.

Other methodological factors to consider in future research include looking at ways of increasing the sample size, formally validating measures like the AAPDQ, incorporating fidelity measures to ensure interventions are delivered as intended, and utilising more in-depth measures of pre-diabetes knowledge that are sensitive to change.

Attaining a sample size that will provide sufficient power to detect effects is likely to be particularly challenging when conducting research in geographical regions with a small potential population pool. Increasing the sample size may require a more intensive focus on recruitment that involves building effective collaborative partnerships with potential referrers, recruiting participants from multiple regions, and/or combining results obtained from similar research using meta-analytic techniques.

Finally, future research is recommended to establish the cultural and/or ethnic validity of ACT-based interventions for patients with pre-diabetes and diabetes. Research with ethnic groups who are disproportionately affected by diabetes, such as Maori and Pacific peoples, is particularly important, and vital if DHBs and PHOs are looking to formally implement such interventions as part of their National diabetes prevention programs.

Implications for policy and clinical practice

Implications for policy and clinical practice are made tentatively due to the methodological limitations of the present research. However, when the present results are interpreted alongside the existing pre-diabetes education literature there are some important factors that should be considered by policy developers when creating best practice guidelines for diabetes prevention.

The present results fail to lend substantial support for the effectiveness of brief pre-diabetes education approaches for reducing diabetes risk. While these interventions may be more cost effective than long-term interventions and improve patient access, their diluted effects mean they may actually increase overall costs for the health system. Moreover, the provision of formal pre-diabetes interventions may be unnecessary for a large proportion of patients at the lower end of the pre-diabetes range, with standard interventions provided through GP Practices, alongside monitoring of physiological and

behavioural risk factors and written information around diabetes risk reduction, sufficient to produce physiological and behavioural change.

It is possible that pre-diabetes patients who exhibit low motivation, anxiety, depression or other forms of emotional distress, that are functioning as barriers to healthy lifestyle change, will benefit from the provision of additional pre-diabetes education interventions. This could include a psychological adjunct that equips them with skills to deal with difficult thoughts and feelings; however, further research is needed to establish whether an ACT-based approach is the most effective form of psychological intervention for these patients.

13.5 Conclusions

This study adapted a lifestyle education intervention for people with pre-diabetes that incorporated an ACT therapeutic component, with the objective of reducing risk factors associated with progression to type 2 diabetes. The effectiveness of this approach was then compared with the provision of Education Only or Standard Medical Care through the patients' GP Practice.

When the results of the three intervention groups were combined, improvements were found over time for HbA1c, BMI, waist circumference, saturated fat intake, life satisfaction, anxiety, and pre-diabetes knowledge. However, results failed to suggest that an approach incorporating ACT therapy was more effective than education alone or standard care for patients with pre-diabetes. While education alone was found to be significantly more effective than standard care for reducing total cholesterol and waist circumference, the approach incorporating ACT therapy was not significantly more effective than education alone or standard care across any of the outcome measures.

Unfortunately, due to limitations related to statistical power, participant characteristics and methodology, definitive interpretations and conclusions cannot be

reached. It is hoped that future researchers will seek to replicate this study while addressing some of these limitations. This may involve utilising more creative recruitment methods to obtain a larger sample, adjusting the inclusion criteria, incorporating fidelity measures, validating existing measures, and tailoring the intervention for use with a New Zealand population.

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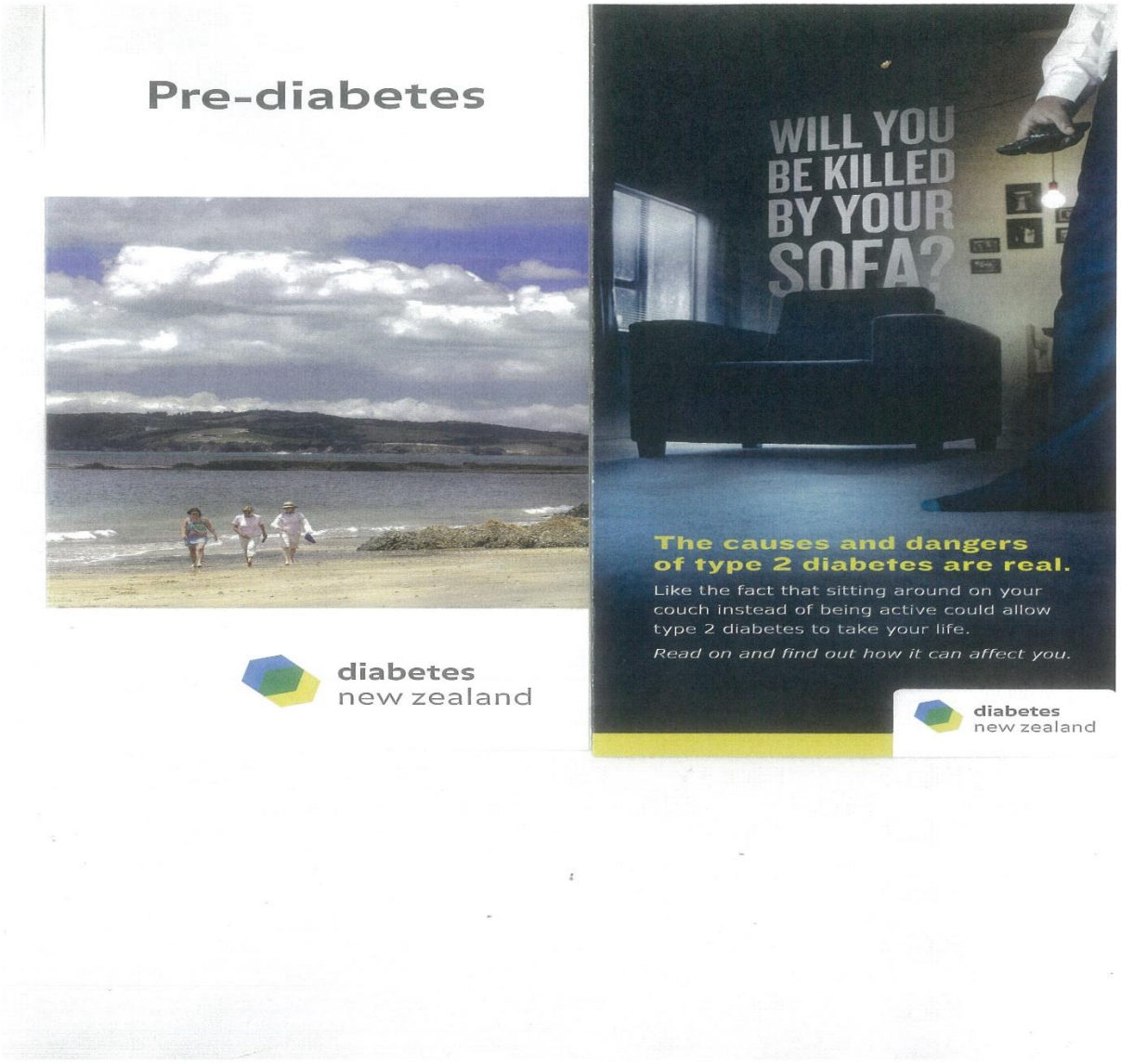
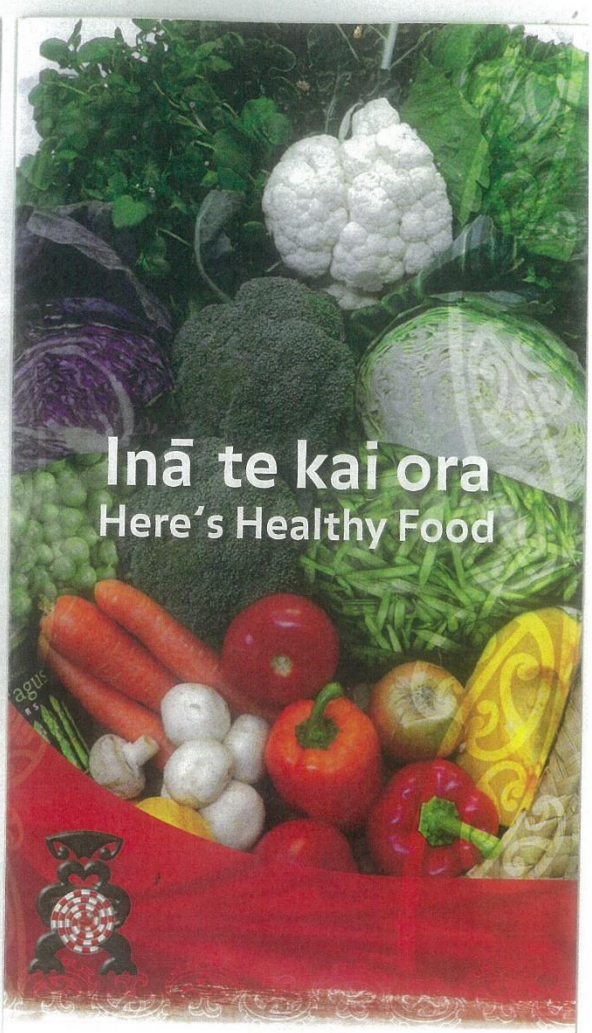
Appendices

Appendix E – Pre-diabetes Information Pack



diabetes and
physical activity

diabetes
new zealand



diabetes
new zealand

Cholesterol

Heart Foundation®

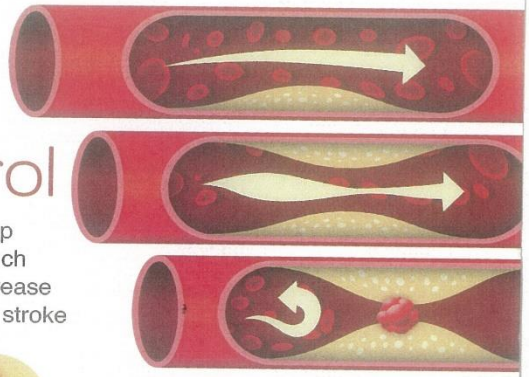
Cholesterol is a type of fat that circulates in your blood and performs a number of important functions

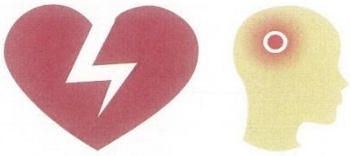
≈75% is produced by your liver

≈25% comes from what you eat

HIGH Cholesterol

Extra cholesterol can build up in your body. Having too much in your bloodstream can increase your risk of a heart attack or stroke





Cholesterol can build up and narrow your arteries

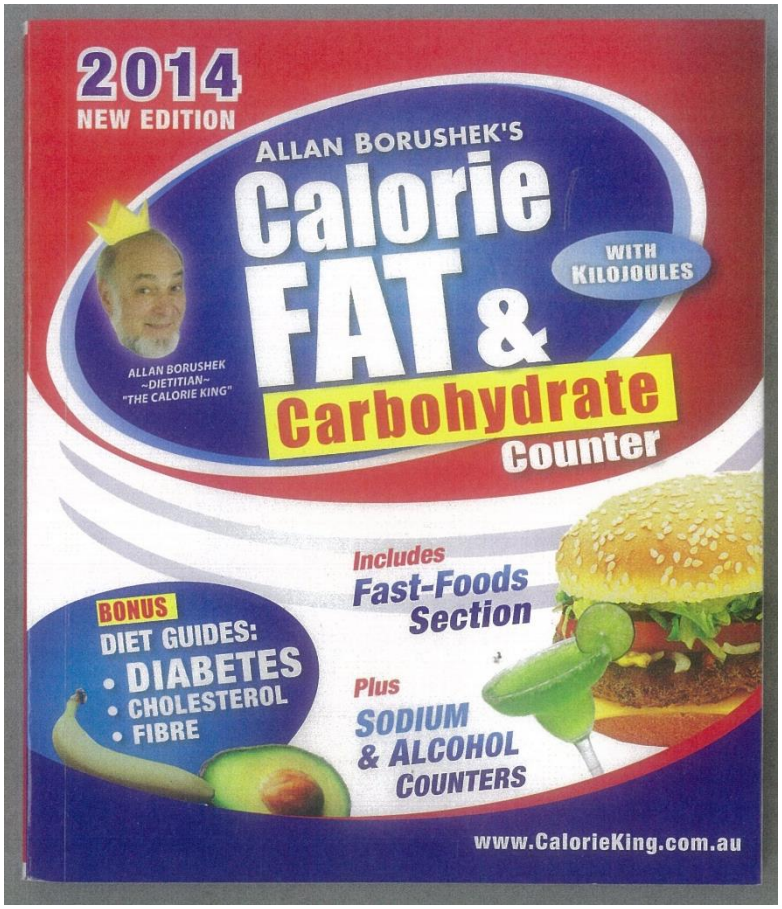
A clot in a narrowed artery can cause a heart attack or stroke

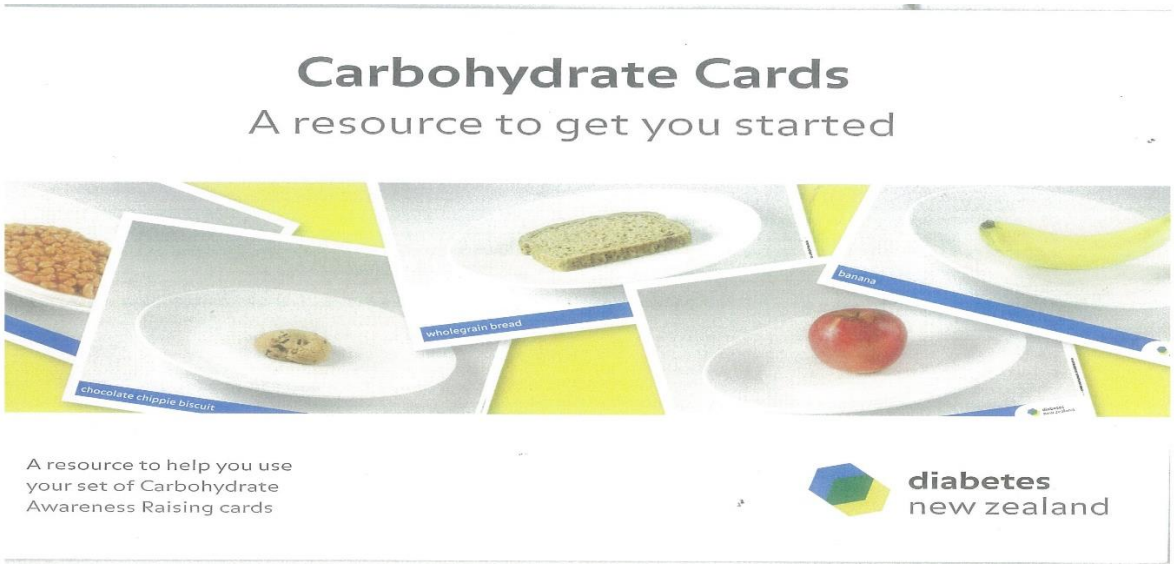
54% OF PEOPLE admitted to hospital with a heart attack have high cholesterol

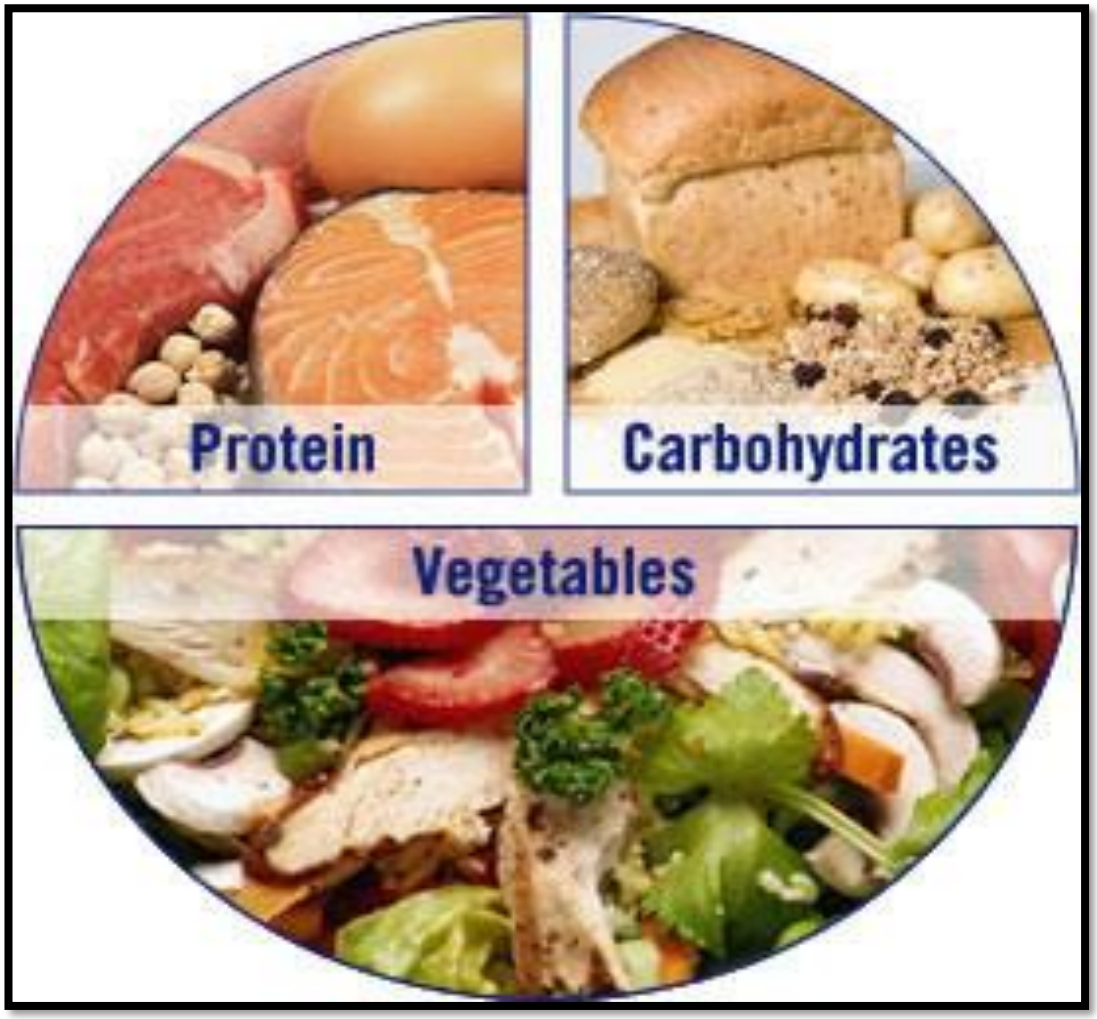
Many people are unaware they have high cholesterol. The only way to find out is to have a blood test

Cholesterol is only one of the risk factors for heart attack and stroke. Ask your health professional what your overall risk is

Appendix F – Workshop Resources







Label Reading

10 10 6 rule

Less than 10 grams of fat per 100 grams

Less than 10 grams of sugar per 100 grams

Greater than 6 grams of fibre per 100grams

Less than 450 mgs of sodium per 100 grams

Appendix G – Referrer Information Sheet

PRE-DIABETES INTERVENTION STUDY

REFERRER INFORMATION SHEET

Study title: Comparison and evaluation of lifestyle education approaches for patients with pre-diabetes.

Locality: Palmerston North **Ethics committee ref:** 14/NTA/126

Lead investigator: Sarah Malthus **Contact phone number**: [redacted]

You are invited to refer your patients to a study involving the comparison and evaluation of lifestyle education interventions for patients with pre-diabetes.

WHAT IS THE PURPOSE OF THE STUDY?

- *The purpose of this study is to find out which types of lifestyle intervention approaches are most effective for helping patients with pre-diabetes make lifestyle changes to reduce their risk of developing type 2 diabetes. Recent research indicates that rates of type 2 diabetes and pre-diabetes are increasing in New Zealand and internationally, and these rising rates are (in part) related to lifestyle factors, such as diet, weight, and physical activity. This research will provide important information for health providers about strategies/interventions that can be put in place to support patients with pre-diabetes to make lifestyle changes to reduce their risk of developing type 2 diabetes.*
- *The interventions used in this study all adhere to pre-diabetes lifestyle education recommendations provided by the New Zealand Ministry of Health (August 2014), and there is preliminary evidence to suggest that the intervention approaches included in this study can be beneficial for those with pre-diabetes*
- *Participants in this study will be randomly assigned to one of three intervention conditions. The use of random assignment decreases the likelihood that the results of the study will be influenced by factors other than the intervention.*
- *This study has been approved by the HDEC ethics committee*

WHO CAN BE REFFERED TO THE STUDY?

Patients who meet the following criteria can be referred to the study:

- *Adults over the age of 18*
- *Those who are fluent in spoken and written English*
- *Those who meet formal classification criteria for pre-diabetes. Classification is based on World Health Organisation (WHO) criteria – IFG between 6.1 and 6,9 mmol/l inclusive, and IGT (2 hour post-prandial glucose concentration between 7.8 and 11 mmol/l inclusive, and/or HbA_1c between 41 and 49 mmol/l)*

Patients who meet the following criteria are not eligible to participate:

- *Those who meet diagnostic criteria for T2 diabetes. Classification is based on World Health Organisation criteria – fasting plasma glucose of greater than or equal to 7mmol/l and/or 2 hour plasma glucose of greater than or equal to 11.1 mmol/l and/or HbA_1c of 50 mmol/l or greater.*
- *Those who have significant cognitive impairment.*
- *Those at risk of harm to/from themselves or others (i.e., suicidal/homicidal ideation).*
- *Those with a comorbid medical diagnosis/condition that is terminal and likely to be fatal within one year.*
- *Those who have or are already participating in a structured pre-diabetes lifestyle education intervention.*
- *Those with a severe psychiatric disorder.*
- *Those currently receiving psychiatric or psychological intervention*

WHAT WILL PARTICIPATION IN THE STUDY INVOLVE?

- *Patients who choose to take part in the study will be requested to attend an initial assessment session (approximately 60 minutes) where they will be given some brief questionnaires to complete These questionnaires provide us information about their diet, physical activity, emotional wellbeing, and quality of life. Measurements of their height, weight, waist circumference will also be taken at this time, and they will be provided with a blood test referral form and requested to go to a local Med-lab facility and have a blood sample taken for analysis of HbA_1c and lipids.*
- *Depending on which intervention group the patient has been assigned, they may also be requested to attend two (2 and 2.5 hour) group education sessions, which will provide them with information about what pre-diabetes is and lifestyle changes they can make to improve their prognosis.*
- *At three and six month intervals after attending these interventions, participants will be requested to attend two further assessment sessions (approximately 60 minutes in length) where they will be given follow-up questionnaires to complete and measures of height, weight, waist circumference, and BMI will again be completed. They will also be provided with follow-up blood test referral forms*

and, again, requested to have blood samples taken at a local Med-lab facility for analysis of HbA1c and lipids.

- *The total time involved in participating in this research varies from approximately 3 to 7 hours (over 6 months) depending on the intervention group to which the patient has been assigned.*
- *Blood results collected from patients during the course of this study will be forwarded to their General Practitioner. However, their GP will not be given information about the results of questionnaires.*

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

- *The risks involved in participating in this study are believed to be low. Some of the tests/questionnaires administered may include questions that are sensitive or embarrassing for some participants. If participants find any of the tests/procedures conducted as part of this research are causing them significant distress, they will be encouraged to discuss these with the lead investigator (Sarah Malthus) who is a registered Clinical Psychologist. If, for any reason, they feel unable to address these directly with the lead investigator, the participant information sheet has details of other parties who can be contacted.*
- *A possible benefit of taking part in this study is that participants will make some positive lifestyle changes that may reduce their risk of developing T2 diabetes in the future. They may also notice improvements in how they feel and their general quality of life.*
- *The wellbeing of your patients is of upmost importance, and we will take every step possible to ensure their physical and emotional well-being during the course of the study.*

WHO PAYS FOR THE STUDY?

- *Participating in this study will not cost participants anything*
- *Participants will be given three $15 petrol vouchers, after attending each of the three assessment sessions, toward reimbursement of travel costs.*

WHAT IF SOMETHING GOES WRONG?

- *If participants are injured in this study, which is unlikely, they will be eligible for compensation from ACC just as they would be if they were injured in an accident at work or at home. They will have to lodge a claim with ACC, which may take some time to assess. If their claim is accepted, they will receive funding to assist in their recovery.*

PARTICIPANT RIGHTS?

- *Participation in the study is voluntary and patients are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage*

- *Participants have the right to access information that is collected about them as part of the research at any time.*
- *Participants will be told of any new information about adverse or beneficial effects related to the study that become available during the study that may have an impact on their health*
- *Information collected as part of this study will be securely stored in a locked filing cabinet at Massey University and/or a password protected computer. Only the lead investigator will have access to identifying information (i.e., name, age, date of birth). Questionnaires and test results will be coded to ensure the privacy of their information.*

WHAT HAPPENS AFTER THE STUDY ?

- *After the study has been completed, all participants will be offered the opportunity to access the intervention that is found to be most beneficial at no cost.*
- *Study data will be securely stored in a locked filing cabinet at Massey University or in a password protected computer for a period of 10 years. Data (in a non-identifiable form) may be retained for possible future use. The lead investigator (Sarah Malthus) will be responsible for the secure storage of this information.*
- *Blood samples analysed in the course of this study will be destroyed after analysis by Med-lab staff who adhere to nationally approved protocols for the destruction of tissue samples.*

HOW CAN I REFER PATIENTS TO THIS STUDY?

- *Patients who meet inclusion criteria for the study can be given an invitation to participate. If they express interest in participating, a referral form can then be completed (with the patients consent) by their GP, Practice Nurse, or any member of the practice team using the referral form attached. This form can then be faxed to the Massey Health Conditions Service, F: 06 350 2264, or, alternatively, emailed to the lead investigator at s.malthus@massey.ac.nz.*
- *Once the referral has been received, the patient will be contacted via phone by the lead research investigator who will provide them with more information about the study and send them a Participant Information Sheet and Consent Form to read. Within a week of the participant receiving this information, the lead investigator will make further contact to answer any questions the potential participant might have and establish whether they would like to take part in the study.*
- *You will be informed via email about whether your patient has consented to participate in the research. If your patient chooses not to participate their referral information will be destroyed.*

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact Sarah Malthus (Lead Investigator, Massey University) on:

Phone: [redacted] *or 06 3505180*
Email: *s.malthus@massey.ac.nz*

Alternatively, if you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: *0800 555 050*
Fax: *0800 2 SUPPORT (0800 2787 7678)*
Email: *advocacy@hdc.org.nz*

For Maori health support please contact Dr Hukarere Valentine (Clinical Psychologist, Massey University Psychology Service) on:

Phone: 06 3505180
Email: H.Valentine@massey.ac.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: *0800 4 ETHICS*
Email: *hdecs@moh.govt.nz*

Appendix H – Invitation to Participate

MASSEY UNIVERSITY
TE KUNENGA KI PŪREHUROA
UNIVERSITY OF NEW ZEALAND

INVITATION TO PARTICIPATE IN A PRE-DIABETES

RESEARCH PROJECT

KIA ORA! YOU ARE INVITED TO PARTICIPATE IN A RESEARCH PROJECT LOOKING AT THE IMPACT OF PROVIDING BRIEF LIFESTYLE EDUCATION FOR PEOPLE WITH PRE-DIABETES.

The purpose of this research is to identify which interventions are most effective for supporting people with pre-diabetes to make changes that will reduce their risk of developing type 2 diabetes. Your participation in this research will contribute to knowledge in this area which may benefit you and your family/whanau in the future.

If you decide to participate:

- It will take a total of 3 and 7 hours of your time over 6 months.
- You may be asked to attend two brief (2 hour) intervention sessions. These will give you information about what pre-diabetes is and lifestyle changes you can make to decrease your risk of developing type 2 diabetes in the future.
- You will be asked to complete some brief questionnaires that give us information about your lifestyle, well-being, and physical health.
- You will be asked to have some blood samples taken. These give us information about your diabetes risk.

If you are interested in finding out more about taking part in this research, please speak to your GP or Practice Nurse who can complete a referral form for you. Alternatively, you can directly contact the lead researcher, Sarah Malthus, on [redacted].

Please note, referral to the researcher does not mean you have agreed to take part in the study; it just gives you the opportunity to find out more about what participation involves. Participation is voluntary. Your decision to participate/or not will not affect the health care you receive.

Thank you very much for considering this invitation

0800 MASSEY
MASSEY.AC.NZ

Endorsed by

MidCentral District Health Board
Te Pae Hauora o Ruahine o Tararua

THE ENGINE OF THE NEW NEW ZEALAND

Appendix I – Referral Form

HEALTH CONDITIONS PSYCHOLOGY SERVICE

PRE-DIABETES INTERVENTION STUDY REFERRAL FORM

REFERRER'S DETAILS

Name:

Job title/Position:

Practice:

Email address:

Phone number:

DETAILS OF THE PERSON BEING REFERRED

Name:

Gender:

Date of birth: **NHI:**

Address: **GP:**

Phone number(s):

Alternatively, attach patient ID label over this section

Please indicate if the patient meets the following criteria for participating in this study

- ❍ Is over the age of 18
- ❍ Meets criteria for pre-diabetes (HbA_1c between 41 and 49)
- ❍ Has been informed he/she meets criteria for pre-diabetes
- ❍ Has consented to being contacted by the researcher about participating in this study
- ❍ Is fluent in spoken and written English

Thank you for your referral. The lead research investigator (Sarah Malthus) will make contact with your patient within the next week.

Please fax this form to 06 350 2264 (Attention: Sarah Malthus), or email it to s.malthus@massey.ac.nz. Confirmation that the referral has been received will be sent via email within 5 working days.

Appendix J - Participant Information Sheet and Consent Form

PRE-DIABETES INTERVENTION STUDY

PARTICIPANT INFORMATION SHEET

Study title: A comparison of lifestyle interventions for people with pre-diabetes.

Locality: Palmerston North **Ethics committee ref: 14/NTA/126**

Lead investigator: Sarah Malthus **Contact phone number**: [redacted]

You have expressed interest in taking part in a study looking at the impact of providing lifestyle education for people with pre-diabetes. This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. Before you decide whether you would like to participate, you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this. The lead investigator, Sarah Malthus, will phone you in the next week to go through this information with you and answer any questions you may have.

Whether or not you take part in this study is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the health care you receive. Alternatively, if you do want to take part now, but change your mind later, you can pull out of the study at any time.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep. This document is seven pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

- *The purpose of this study is to find out the type of lifestyle interventions that are most effective for reducing people's risk of developing type 2 diabetes. Research indicates that rates of pre-diabetes and type 2 diabetes are increasing in New Zealand and world-wide. These rising rates are partly related to changes in lifestyle, such as what we eat, our weight, and how physically active we are. This study will provide information for health providers about the kinds of interventions that are most effective for helping people with pre-diabetes make lifestyle changes to reduce their risk of type 2 diabetes.*
- *The interventions used in this study are in line with pre-diabetes advice provided by the New Zealand Ministry of Health (August 2013). There is scientific evidence that these approaches can benefit people with pre-diabetes.*

- *If you choose to participate in this research you will be randomly assigned to an intervention group. This means you will not be given the choice of which intervention you receive. The use of random assignment makes it is less likely that results of the study will be affected by factors other than the intervention.*
- *This study has been approved by the HDEC ethics committee*

WHO CAN TAKE PART?

- *You have been invited to participate in this study because your GP or Practice Nurse has identified that you have pre-diabetes,*
- *To be eligible to participate in this study you must also be over the age of 18 and able to speak and write English fluently. Unfortunately, we are unable to provide interpreters.*

WHAT WILL PARTICIPATING IN THIS STUDY INVOLVE?

- *If you choose to participate in the study, you will be asked to attend an initial assessment session (approximately 60 minutes). During this session, measurements of your height, weight, and waist will be taken, and you will be given 10 short questionnaires and a 5 minute exercise to complete. You will also be given a blood test referral form, which you will be requested to take to a local Med lab facility and have a blood sample taken. The tests and questionnaires used in this research give us information about your diet, physical activity, and well-being. The purpose of the blood sample is to determine your HbA_1c and lipid levels. These results provide us with information about your diabetes risk.*
- *Depending on which intervention group you are assigned to, you may also be asked to attend two group intervention sessions. These sessions are 2 and 2.5 hours in length and will be held at a local health care facility. These sessions will give you information about pre-diabetes and the lifestyle changes you can make to reduce your risk of diabetes.*
- *Three and six months after attending your initial assessment session, you will be asked to attend follow-up assessments (approximately 60 minutes each). During these sessions you will be given further questionnaires to complete, and measures of your height, weight and waist will again be taken. You will also, again, be given blood test referral forms (for HbA1c and lipids) and asked to have blood samples taken.*
- *The total time involved in taking part in this research ranges from approximately 3 - 7 hours (over 6 months). The time required depends on which intervention group you are assigned to.*
- *If you choose to participate in the study, your GP will also be given a brief questionnaire to complete. This gives us information about when you were first identified as having pre-diabetes, whether you have any other medical conditions/diagnoses, medications you are taking, and your mental health history. This information is important for us to collect because these factors can impact on intervention outcomes.*

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

- *The risks involved with taking part in this study are believed to be low. Some of the tests/questionnaires used may include questions that are sensitive or embarrassing. If you find any of the tests/procedures used as part of this study distressing, please discuss this with the lead investigator (Sarah Malthus). If you feel unable to address this directly with the researcher, at the bottom of this form are contact details of others who can be contacted.*
- *A possible benefit of taking part in this study is that you will make some positive changes to your lifestyle. These changes could reduce your risk of developing type 2 diabetes. You may also notice an improvement in how you feel.*

WHO PAYS FOR THE STUDY?

- *Participating in this study will not cost you anything*
- *You will be given a $15 petrol voucher after attending each of the three assessment sessions to reimburse you for of travel costs.*

WHAT IF SOMETHING GOES WRONG?

- *If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home.*

WHAT ARE MY RIGHTS?

- *Taking part in this study is voluntary and you are free to decline to participate, or to withdraw from the research at any time, without experiencing any disadvantage.*
- *You have the right to access information that is collected about you as part of the study at any time.*
- *You will be told of any new information about adverse or beneficial effects related to the study that may impact on your health. Your GP will be informed of your participation in the study, and they will receive all blood test results. If abnormal HbA_1c or lipid results are detected, these will be communicated/discussed with you by your GP. Your GP will not receive the results of questionnaires collected during the study.*
- *Information collected as part of this study will be securely stored in a locked filing cabinet at Massey University and/or on a password protected computer. Only the lead investigator will have access to identifying information (i.e., name, age, date of birth). Questionnaires and test results will be given a code to ensure the privacy of your information.*

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

- *You can pull out of the study at any time. This will not affect the health care you receive.*
- *After the study has been completed, all participants will be offered the opportunity to take part in the intervention that is found to be most effective. This will not cost you anything.*
- *After the study is complete, study data will be securely stored for 10 years. Data (in a non-identifiable form) may be kept for possible future use. The lead investigator (Sarah Malthus) will be responsible for the storage of this information.*
- *Blood samples taken during the study will be destroyed (following analysis) by Medlab staff using national guidelines for discarding blood.*
- *Once the study is finished, you will be sent a written summary of the results. It is expected that these will be sent out within three months of completing the study.*

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact Sarah Malthus (Lead Investigator, Massey University).

Phone: [redacted] or 06 3505180
Email: s.malthus@massey.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: *0800 555 050*
Fax: *0800 2 SUPPORT (0800 2787 7678)*
Email: *advocacy@hdc.org.nz*

For Maori health support, please contact Dr Hukarere Valentine (Clinical Psychologist, Massey University Psychology Service) on:

Phone: 06 3505180
Email: H.Valentine@massey.ac.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: *0800 4 ETHICS*
Email: *hdecs@moh.govt.nz*

PRE-DIABETES INTERVENTION STUDY
PARTICIPANT CONSENT FORM

Please tick to indicate you consent to the following

I have read and I understand the Participant Information Sheet.	Yes ☐	No ☐
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	No ☐
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	Yes ☐	No ☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes ☐	No ☐
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.	Yes ☐	No ☐
I consent to the research staff collecting and processing my information. This includes information about my health obtained from my GP or Practice Nurse about when I was first identified as having pre-diabetes, other medical conditions/diagnoses, mental health history, and medication/substance use.	Yes ☐	No ☐
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I agree to my blood samples being collected and analysed, and I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste	Yes ☐	No ☐
I consent to my GP or current health provider being informed about my participation in the study and being provided with my blood results.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	Yes ☐	No ☐
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes ☐	No ☐

I understand the compensation provisions in case of injury during the study.	Yes ☐	No ☐
I know who to contact if I have any questions about the study in general.	Yes ☐	No ☐
I understand my responsibilities as a study participant.	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

Appendix K – Media Releases

Jennifer Little
027 453 4562
j.little@massey.ac.nz
news.massey.ac.nz

MASSEY UNIVERSITY
TE KUNENGA KI PŪREHUROA
UNIVERSITY OF NEW ZEALAND

MEDIA RELEASE

Wednesday, June 3, 2015

Evaluating interventions for diabetes prevention

Clinical Psychologist and PhD researcher, Sarah Malthus, works with people who have serious complications of diabetes, such as amputations, kidney failure, and blindness. It can be "heart-breaking" work and prompted her interest in developing and evaluating interventions for people at the pre-diabetes stage, so they can avoid these complications in the future.

Diabetes is "a potentially debilitating long-term health condition that comes with substantial physical and psycho-social cost," she said, and unless more is done at a prevention level the impact on the health system is likely to be substantial.

Ms Malthus said Type 2 diabetes is referred to as a "silent killer", because in the early stages people may not have any symptoms or symptoms are very subtle .Symptoms that can indicate a shift from pre-diabetes to type 2 diabetes include; feeling tired, increased thirst, increased urination, blurred vision, and frequent infections.

Currently, approximately 25% of New Zealanders meet criteria for pre-diabetes, which means they are at high risk for developing type 2 diabetes. "These rising rates are partly related to changes in lifestyle, such as what we eat, our weight, and how physically active we are," Ms Malthus explained.

Rising rates of both pre-diabetes and diabetes within New Zealand and globally has made diabetes prevention a central focus of health research. International research has demonstrated that the risk of developing type 2 Diabetes can be substantially reduced, by almost 60 percent, by providing lifestyle interventions for people with pre-diabetes. "This study will provide information for health providers about the kinds of interventions that are most effective for helping people with pre-diabetes make lifestyle changes to reduce their risk of diabetes," she says.

Ms Malthus is based at Massey University's Psychology Clinic in Palmerston North. She is seeking 150 people with pre-diabetes who live in the MidCentral district to take part in her intervention study. In the study, funded by the MidCentral District Health Board, participants will receive information about their condition, along with practical changes they can make to their lifestyle to reduce their risk of progressing to diabetes. Involvement requires approximately 3 to 7 hours over 6 months, says Ms Malthus.

Study participants for this project will be randomly assigned to research groups, which will be provided with different types of lifestyle intervention. The interventions developed for this study have been informed by international approaches. They are in line with pre-diabetes advice provided by the Ministry of Health, and have been developed in collaboration with the Diabetes Trust along with input from Nurse Practitioners, Dieticians, and other health professionals with extensive experience in diabetes prevention and research.

THE ENGINE OF THE NEW NEW ZEALAND

MidCentral District Health Board
Te Pae Hauora o Ruahine o Tararua

Communications Unit
PO Box 2056, Palmerston North 4440
Phone: (06) 350-8945
Facsimile: (06) 355-0480
communications@midcentraldhb.govt.nz
www.midcentraldhb.govt.nz
www.twitter.com/midcentraldhb

MEDIA RELEASE

MIDCENTRAL DISTRICT HEALTH BOARD - MEDIA RELEASE

Invitation to take part in a pre-diabetes research project

Research indicates that one in every four New Zealand adults have pre-diabetes – the condition you get before you get diabetes. However, if lifestyle changes were made the risk of these people getting diabetes could be reduced by up to 60 percent.

To see if this change is possible a research project is underway in the MidCentral District Health Board area to see what types of lifestyle education interventions are the most useful for reducing people's risk of developing type 2 diabetes.

Massey University health conditions clinical psychologist and PhD researcher Sarah Malthus is working with MDHB looking to recruit a total of 190 participants in the DHB area for the study. She already has about 60 recruits, and would like 130 more.

Sarah said this is the first randomised controlled study conducted in New Zealand that has evaluated the effectiveness of pre-diabetes education interventions. "This research is vital because prevalence rates of pre-diabetes and type 2 diabetes are rising, both in New Zealand and internationally.

"Research indicates that about 25 percent of the New Zealand adult population now meet criteria for pre-diabetes. These results are sobering because they suggest that unless more is done at the diabetes prevention level, rates of diabetes will continue to rise in the foreseeable future.

"This study will provide important information for health providers about the types of intervention that are most effective for supporting people with pre-diabetes to make lifestyle changes to reduce their risk of type 2 diabetes. Research shows that lifestyle interventions can reduce the risk of diabetes by up to 60 percent.

"They can also reduce the risk of diabetes-related complications, such as heart disease, kidney failure, amputations, and blindness.

Participants can be referred for the study by their GP or Practice Nurse, and they can self-refer, but they must be over aged 18; have a blood test result that shows they have pre-diabetes.

The total time involved in taking part in the study ranges from between three to seven hours, over six months. Volunteers may be asked to attend two brief intervention sessions. These will give participants information about what pre-diabetes is, and lifestyle changes people can make, to decrease their risk of developing type 2 diabetes in the future. People will complete questionnaires giving information about their lifestyle, well-being and physical health. Some blood samples will also be taken to give researchers information about volunteers' diabetes risk. Participants will receive a $15 petrol voucher after each assessment session to compensate for their travel costs.

People interested in volunteering can contact Sarah Malthus on [redacted].

Appendix L – AAPDQ

Acceptance and Action Pre-Diabetes Questionnaire

AAPDQ

1	2	3	4	5	6	7
never true	very seldom true	seldom true	sometimes true	frequently true	almost always true	always true

DIRECTIONS: You have been identified by your General Practitioner/Practice Nurse to meet criteria for pre-diabetes. Having pre-diabetes means you are at high risk of developing type 2 diabetes in the future. This questionnaire is designed to help us understand some of your thoughts and feelings about having pre-diabetes. Read each item below, and (using the above menu) write the **number** in the response box that best describes you**.**

	ITEMS	RESPONSE
1.	**I try to avoid reminders that I am at increased risk of developing diabetes**	
2.	**I have thoughts and feelings about my risk of developing diabetes that are distressing**	
3.	**I do not take care of my health because it reminds me that I could go on to develop diabetes**	
4.	**I eat things that I shouldn't eat when the urge to eat is overwhelming**	
5.	**When I have an upsetting feeling or thought about being at risk of diabetes, I try to get rid of that feeling or thought.**	
6.	**I avoid stress or try to get rid of it by eating what I know I shouldn't eat**	

7.	**I often deny to myself what developing diabetes could do to my body**	
8.	**I don’t exercise regularly because it reminds me that I am at risk of developing diabetes**	
9.	**I avoid thinking about the future possibility of developing diabetes**	
10.	**I avoid thinking about my risk of developing diabetes because someone I knew died from diabetes**	

Appendix M – Pre-diabetes Knowledge Test

Manawatu Horowhenua Tararua Diabetes Trust

MANAWATU HOROWHENUA & TARARUA DIABETES TRUST
BRIEF KNOWLEDGE TEST - PREDIABETES

(Adapted for use in New Zealand from the Michigan Diabetes Research & Training Center's Brief Diabetes Knowledge Test)

(POST)

1. Which of the following is the highest in carbohydrate?
   a. Baked chicken
   b. Cheese
   c. Baked potato
   d. Peanut butter

2. Glycosylated haemoglobin (haemoglobin A1c) is a test that is the measure of your average blood glucose level for the past:
   a. Day
   b. Week
   c. 8-12 weeks
   d. Unsure

3. What effect does unsweetened fruit juice have on blood glucose?
   a. Lowers it
   b. Raises it
   c. Has no effect

4. For a person in good control, what effect does exercise have on blood glucose?
   a. Lowers it
   b. Raises it
   c. Has no effect

5. Which of the following is usually **not** associated with diabetes:
   a. Vision problems
   b. Kidney problems
   c. Nerve problems
   d. Lung problems

6. Eating foods lower in fat decreases your risk for:
   a. Nerve disease
   b. Kidney Disease
   c. Heart Disease
   d. Eye Disease

7. Prediabetes means:
   a. I will get Type 2 diabetes
   b. Means I am at risk of Type 2 Diabetes
   c. I just have a 'touch' of Diabetes
   d. I will not get Type 2 diabetes

8. Exercise is good because
   a. It helps with weight control
   b. Reduces insulin resistance
   c. Helps to improve mood
   d. All of the above

9. Low GI foods are
   a. All highly processed foods
   b. Carbohydrates that are digested slowly.
   c. Carbohydrates that are digested quickly.
   d. Foods that are high in sugar

10. Risk factors for developing Type 2 diabetes are:
    a. Family history
    b. Having elevated HbA1C
    c. Being overweight
    d. Aging
    e. All of the above

Filename: Documents/Education/Healthy Living/BRIEF KNOWLEDGE TEST 2013 Prediabetes POST

Appendix N – Socio-demographic Questionnaire

Socio-Demographic Questionnaire

1. What is your gender? (circle your response) Male Female Transgender

2. What is your age? _____

3. What is the highest qualification you have obtained? (tick the appropriate box)

   - ☐ Primary school
   - ☐ Secondary school
   - ☐ University graduate
   - ☐ Post-graduate degree

4. What is your employment status? (tick the appropriate box)

   - ☐ Working full-time, 35 hours or more a week
   - ☐ Working part-time, less than 35 hours a week
   - ☐ Unemployed or laid off and looking for work
   - ☐ Unemployed and not looking for work
   - ☐ Home-maker
   - ☐ In training
   - ☐ Retired
   - ☐ Disabled; not able to work
   - ☐ Other (please specify)_____

5. What is your marital status? (tick the appropriate box)

   - ☐ Single
   - ☐ Married
   - ☐ De Facto Relationship
   - ☐ Separated
   - ☐ Divorced
   - ☐ Widowed

6. What is your first language? _____

7. What is your second language? _____

9. Which ethnic group do you belong to? (tick the box or box/s that apply to you)

- ☐ New Zealand European
- ☐ Maori
- ☐ Samoan
- ☐ Cook Island Maori
- ☐ Tongan
- ☐ Niuean
- ☐ Chinese
- ☐ Indian
- ☐ Other (such as Dutch, Japanese, Tokelauan. Please state)_____

Appendix O - GP Questionnaire

PRE-DIABETES INTERVENTION STUDY

The following patient_____ has agreed to take part in a study looking at the impact of providing brief lifestyle education interventions for patients with pre-diabetes. He/she has also consented to us obtaining the information below pertaining to their medical/mental health history (see the attached consent form). It would be greatly appreciated if you could please complete the attached health history questionnaire and return it in the self-addressed envelope provided. Thank you for taking the time to complete this questionnaire.

Warm regards

Sarah Malthus
Clinical Psychologist/Researcher
School of Psychology
Massey University
Palmerston North

Health History Questionnaire

When was the patient first identified as pre-diabetic?	Month_____ Year_____
Does the patient have any other medical conditions/diagnoses? (if yes, please state)	Yes / No
Is the patient currently taking any prescribed or non-prescribed medications/substances? (If yes, please specify or, alternatively, attach a patient medication print out)	Yes / No
Does the patient have a psychiatric history? (if yes, please specify)	Yes / No

Appendix P – Participant Satisfaction Questionnaire

Participant code_____

Participant Satisfaction Questionnaire

The following questions refer to the pre-diabetes intervention you attended. Circle the number below that best describes your thoughts/feelings about the intervention.

	Not at all effective		Moderately effective		Very effective
How effective do you think the intervention will be for helping you make lifestyle changes to reduce your risk of diabetes?	1	2	3	4	5

	Not at all helpful		Moderately helpful		Very helpful
How helpful did you find the intervention for increasing your understanding of pre-diabetes?	1	2	3	4	5

	Not at all satisfied		Moderately satisfied		Very satisfied
Overall, how satisfied are you with the intervention you received?	1	2	3	4	5

	No, definitely not		Maybe		Yes, definitely
Would you recommend this intervention to a friend with pre-diabetes?	1	2	3	4	5

Participant code_____

The questions below refer to the pre-diabetes intervention you attended. We appreciate your feedback/comments ☺

1. What (if anything) did you find most helpful?

2. What did you find least helpful?

3. How do you think intervention you received might affect your life?

4. Is there anything you think could have been done to improve the intervention? If yes, how could the intervention be improved?

Appendix Q – Cholesterol Results Tables

Table Q1

Mean Total Cholesterol Results Across Time and Intervention

	Intervention							
	Standard Care		**Education**		**ACT/ED**		**Total**	
Time Period	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**
Pre-intervention	5.11	.92	4.69	.99	4.80	1.18	4.87	1.03
3 months	5.23	1.01	4.33	.98	4.93	1.30	4.82	1.15
6 months	5.12	1.01	4.44	.95	4.84	1.30	4.79	1.11

Note. N = 76; Standard Care = 26, ED Only = 27, ACT/ED = 23. M = mean. SD = standard deviation

Table Q2

Mean LDL Cholesterol Results Across Time and Intervention

	Intervention							
	Standard Care		**Education**		**ACT/ED**		**Total**	
Time Period	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**
Pre-intervention	2.85	.644	2.44	0.78	2.54	0.94	2.61	0.80
3 months	2.87	0.83	2.22	0.79	2.66	1.07	2.57	0.93
6 months	2.76	0.69	2.29	0.73	2.60	1.04	2.55	0.84

Note. N = 76; Standard Care = 26, ED Only = 27, ACT/ED = 23. M = mean. SD = standard deviation

Table Q3

Mean Triglyceride Results Across Time and Intervention

	Intervention							
	Standard Care		**Education**		**ACT/ED**		**Total**	
Time Period	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**
Pre-intervention	2.11	0.95	2.02	1.02	1.56	0.99	1.91	1.00
3 months	2.40	1.15	1.72	0.86	1.69	0.86	1.94	1.01
6 months	2.38	1.14	1.85	0.87	1.53	0.75	1.93	0.99

Note. N = 76; Standard Care = 26, ED Only = 27, ACT/ED = 23. M = mean. SD = standard deviation

Table Q4

Mean HDL Results Across Time and Intervention

	Intervention							
	Standard Care		**Education**		**ACT/ED**		**Total**	
Time Period	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**
Pre-intervention	1.23	0.30	1.31	0.40	1.53	0.46	1.35	0.40
3 months	1.27	0.34	1.31	0.40	1.50	0.38	1.35	0.38
6 months	1.21	0.33	1.28	0.37	1.53	0.43	1.33	0.39

Note. N = 76; Standard Care = 26, ED Only = 27, ACT/ED = 23. M = mean. SD = standard deviation

Table Q5

Mixed ANOVA Results for Cholesterol

	Main Effect for time				Interaction between time and intervention			
Source	***df***	***F***	***p***	η_p^2	***df***	***F***	***p***	η_p^2
HDL	2,72	.301	.740	.004	2,73	.692	.740	.004
LDL	2,70	.496	.610	.007	2,71	1.52	.198	.041
Triglycerides	2,72	.092	.912	.001	2,73	2.35	.057	.061
Total Cholesterol	2,72	.667	.515	.009	2,73	3.74	.006*	.093

Note. F= Fisher's ratio. *P* = probability. *df* = degrees of freedom. η_p^2 = partial eta squared