An Investigation Into the Use of the Complete Health Improvement Programme (CHIP) for Reversing Type 2 Diabetes Mellitus.

A Multimethod Approach

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CERTIFICATION

Statement of Original Authorship

I declare that the work contained in this thesis has not been submitted previously for a degree or diploma at this institution, an Australian or overseas university or any other institution of higher education. To the best of my knowledge and belief, this thesis contains no material previously published or written by another person except where due reference is made.

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Statement of Copyright

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Enrolling in a PhD was a journey I never envisaged embarking on. I had a keen interest in lifestyle as a means to promote health and prevent and manage disease from early in my undergraduate studies and, over time, was drawn and led by God to pursue this course of study. It was a privilege to have the opportunity to learn while simultaneously engaging with and providing information and support to the participants in my research. I want to acknowledge each study participant for being willing to participate to the level they did in both studies. The process was often time-consuming, and they were willing to give their time and of themselves to help me. I would also like to thank the medical practices and their staff, the doctors and practice managers for assisting me in obtaining access to potential participants.

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LIST OF PUBLICATIONS AND PRESENTATIONS INCLUDED AS PART OF THIS THESIS

Publication 1 (Reproduced with kind permission of Jessica Rutt, International Rights and Licensing Manager, Nursing Standard.)

Cloete, L., Mitchell, B., & Morton, D. (2017). The role of obesity in the onset of type 2 diabetes mellitus. *Nursing Standard*, *31*(22).

The major contributor and lead for this publication was Linda Cloete. This publication provided an in-depth overview of the pathophysiology related to the development of Type 2 diabetes. The target readership was primarily nurses.

Publication 2 (Available under the Creative Commons Attribution (CC-BY) licence)

Cloete, L., Mitchell, B. G., & Morton, D. (2019). Protocol: investigating the effectiveness and cost benefit of a lifestyle intervention targeting type 2 diabetes in Australia. *BMC Endocrine Disorders*, *19*(1), 1-6.

The major contributor and lead for this publication was Linda Cloete. This publication described the originally intended study protocol for this thesis.

Publication 3 (Reproduced with kind permission of Jessica Rutt, International Rights and Licensing Manager, Nursing Standard.)

Cloete, L. (2021). Diabetes mellitus: an overview of the types, symptoms, complications, and management. *Nursing Standard.*

This publication was requested by the publisher and provided a general overview of diabetes, its potential complications and management.

Presentation 1

Cloete, L., Mitchell, B. G., & Morton, D. (2019). *Protocol: Investigating the effectiveness and cost benefit of a lifestyle intervention targeting type 2 diabetes in Australia.* [Oral and poster presentation], Australasian Society of Lifestyle Medicine Conference, 15-17 September, Manly, Sydney, Australia. (Peer reviewed presentation).

The major contributor and lead for this publication was Linda Cloete. This was a presentation of the originally intended study protocol for this thesis.

Presentation 2

Cloete, L. (2020). *Reversing type 2 diabetes mellitus. [Improving general health awareness in Cooranbong and surrounding community*]. (Peer reviewed presentation.)

This presentation was aimed at and delivered to a community group. The content included basic pathophysiology of type 2 diabetes and lifestyle strategies that were previously demonstrated to prevent, manage and possibly reverse the disease.

ABSTRACT

The incidence and prevalence of Type 2 Diabetes Mellitus (T2DM) are increasing dramatically on a global level. Other than bariatric surgery, there is no known medical cure for T2DM, however, several lifestyle modifications reverse symptoms, most frequently in conjunction with a reduction in BMI. The purpose of this thesis was to discover the effectiveness of the CHIP as an intervention for reversing T2DM, by conducting two studies. The aim of Study 1 was to assess the effectiveness of the CHIP in reversing abnormal fasting blood sugar levels in T2DM clients. The aim of Study 2 was to obtain an understanding of participants' knowledge of diabetes reversal and their experience of the CHIP and adherence to lifestyle recommendations. A multimethod approach was used. Study 1 consisted of a parallel open-label randomised control trial (RCT) where the intervention was participation in the CHIP for 12 weeks followed by nine months of monthly follow-up. The control group participated in usual diabetes care. A descriptive qualitative design supported by illustrative case studies was used in Study 2 using participants from the intervention and control groups in Study 1. The results of the RCT demonstrated positive changes in measured outcomes. Most of these improvements remained significant at 12-months. Diabetes reversal was not demonstrated. No significant change in outcomes were demonstrated in the control group. Data from Study 2 suggest that 25 percent of the study cohort did not understand diabetes reversal and most participants believed they could not achieve diabetes reversal. All participants acknowledged a degree of recidivism. The synthesis of findings suggests that adherence to lifestyle recommendations is better fostered where the relevance of change is understood and where health-care providers partner with clients to educate and manage care for improved levels of self-responsibility. Better support for clients may improve resilience, and focusing on lifestyle choices that are enjoyable and rewarding may promote long-term adherence.

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Acanthosis nigrans: A skin condition characterised by dark discoloration and thickening of the skin especially in skin folds (armpit, groin, neck). It is commonly associated with obesity, insulin resistance, hormonal irregularity, and some medication use and may also present with some types of cancer.

Atrial fibrillation: A cardiac arrhythmia characterised by a depolarisation of the atria which loops back to re-depolarise the atria. It is marked by rapid randomised contractions of the atrial myocardium, causing an irregular rapid atrial rate. It is recognisable on electrocardiogram and may lead to the formation of clots and has a high risk of stroke associated with it.

Bariatric surgery: Surgical alterations to the digestive tract for the purpose of reducing volume of food intake and subsequent weight loss. The most common types are gastric banding, gastric bypass, and sleeve gastrectomy.

Blood lipids: Fat molecules that are transported freely in the blood or bound to protein. Triglycerides is an example of a freely transported blood lipid. Most blood lipids form carrier lipoproteins that transport cholesterol. These may include Very Low-Density Lipoproteins, Low-Density Lipoproteins and High-Density Lipoproteins.

Body mass index: A calculated approximation of an individual's mass classification as being of normal mass, over- or underweight. The index is calculated by dividing a person's mass in kilograms by the square of their height in metres.

Cardiovascular disease (CVD): A collective term describing diseases affecting the heart and or blood vessels and include coronary heart disease, stroke- or cerebrovascular disease, peripheral vascular disease, rheumatic fever, congenital heart diseases, deep vein thrombosis and pulmonary embolus.

CHIP (Complete Health Intervention Programme): A lifestyle education programme of 18 sessions delivered over a period of 12 weeks with each session lasting 90 minutes. Half of each session is devoted to viewing educational material via DVD presentations. The rest of the session is taken up with group activities which include discussion groups, practical cooking, or physical exercise demonstrations. The model of learning is one which encourages

the themes of learning, experiencing, and reflecting. Educational topics include aetiology and risk factors associated with a wide variety of chronic disease, benefits of positive lifestyle changes including the optimal plant-based diet and regular physical activity, stress management, the power of positive living and the avoidance of harmful substances.

DNA methylation patterns: DNA methylation is a process whereby a methyl group is added to a DNA molecule without altering the sequence of nucleotides. Methylation has the capacity to alter the activity of a DNA segment and is involved in genetic expression.

Gestational diabetes: A condition presenting with elevated blood levels of glucose during pregnancy which typically resolves after the birth. It generally poses an increased risk for later onset type 2 diabetes mellitus.

Glucagon-like Peptide-1 receptor agonists: The glucagon-like peptide-1 receptor is a receptor protein found on beta cells of the pancreas. Glucagon-like peptide-1 is a hormone that binds to the receptor and stimulates insulin secretion. It is therefore involved in the control of blood sugar level by enhancing insulin secretion. It's presence results in decreased beta cell apoptosis and enhanced beta cell proliferation (Collins & Costello, 2022).

Glucose intolerance (impaired glucose tolerance): An inability to process glucose (Diabetes Australia, 2021). A fasting blood sugar level of 5.6 to 6.9 mmol/L or a 2-hour post glucose load blood sugar of between 7.8 and 11.0mmol/L (American Diabetes Association, 2015).

Glycaemic control: The regulation and or maintenance of fasting or 2 hour post prandial blood sugar levels below 5.6 mmol/L.

GORD: Gastro-oesophageal reflux disease (GORD) is a common condition, where acid from the stomach is regurgitated up into the oesophagus. It usually occurs because the ring muscles of the cardiac sphincter (lower oesophagus) are incompetent and is aggravated by obesity, supine posture and increased abdominal pressure.

Gout: A form of arthritis characterized by abnormally elevated levels of blood uric acid and recurring attacks of joint inflammation, deposits of hard lumps of uric acid in and around the joints, and kidney stones. The predisposition is often inherited and can be promoted by

obesity, mass gain, alcohol intake, high blood pressure, abnormal kidney function, and some medications.

Hexosamine pathway: Alternate pathway that emerges from glycolysis using fructose-6-phosphate to form glucosamine-6-phosphate. Glutamine contributes to the amino acid pool. The pathway is part of a stress response pathway that maintains protein homeostasis.

Hip replacement: Also referred to as hip arthroplasty, it involves replacing parts of the hip joint with artificial implants. The hip joint consists of a ball at the top of the femur, and a socket in the pelvis. Hip replacement surgery includes replacement of one or both parts.

Homocysteinaemia: Elevated levels of homocysteine which is an amino acid which occurs in the body as an intermediate in the metabolism of methionine and cysteine for which a variety of vitamin B is necessary. An accumulation of homocysteine is linked to risk of cardiovascular disease, neurologic disorders, and some cancers.

Hyperglycaemia: Elevated blood glucose levels - fasting above 6.9 mmol/L or a 2-hour post glucose load blood sugar above 11.0mmol/L (American Diabetes Association, 2015).

Hypertension: Diagnosed as a systolic blood pressure greater than 140mmHg and, or a diastolic pressure greater than 90 mmHg (Unger et al., 2020).

Hypoglycaemia: Low blood glucose levels – below 4mmol/L.

Insulin resistance: An impaired response of the cells to insulin (mainly liver and skeletal muscles), resulting in delayed or poor ability for glucose to enter cells and subsequent elevated levels of glucose in the blood.

Insulin signalling: Insulin signalling occurs when insulin binds to plasma membrane receptors. This initiates pathways which regulate cellular metabolic pathways.

Lifestyle modification approach: An approach to healthcare by which sustained alterations are made to long-term lifestyle habits, typically related to substance use, diet, rest and sleep, stress management, recreation, and physical activity.

Low levels of physical activity: Less than a combined 150 minutes of sustained moderate level exercise per week. In addition, exercise sessions should not be separated by more than two days at a time (Bull et al.,2020).

Mental illness: Includes a broad range of clinically diagnosable conditions that present with disorganised personality, thinking and emotions significant enough to impair normal thinking, emotional control, mood, behaviour, interpersonal interactions, or daily functioning.

Obesity: Increased level of adiposity commonly defined as a body mass index over 30kg/m2**.**

Protein kinase C: An enzyme that modifies proteins by adding phosphates to them. It plays a role in signalling reactions.

Polyol: An organic compound containing multiple hydroxyl (OH) groups.

Poly-polymerase: Poly-polymerase is an enzyme involved in synthesising long chains of nucleic acids (DNA and RNA) and are involved in several cellular processes such as DNA repair, genomic stability, and programmed cell death.

Polycystic ovary syndrome: A combined endocrine and metabolic disorder presenting in premenopausal women characterised by androgen excess and ovarian dysfunction often accompanied with multiple cysts on the ovaries in the absence of other specific diagnoses. It is frequently associated with central adiposity, insulin resistance, obesity, metabolic disorders, and cardiovascular risk factors.

Post-traumatic stress disorder: A type of anxiety disorder where symptoms are triggered by experiencing or witnessing a terrifying event. Symptoms present as flashbacks, nightmares, severe anxiety as well as uncontrollable thoughts about the event.

Pre-diabetes: An alternative term used to describe the condition of having abnormally high blood sugar levels (5.6- 6.9mmol/L) that have not yet reached the levels required for a diagnosis of Type 2 Diabetes Mellitus (T2DM).

Remission: The most recent definition to achieve consensus using the Delphi process is an HbA1c of <6.5mmol/l for at least 3 months without any ongoing pharmacotherapy, medical or surgical intervention for the specific purpose of lowering blood glucose (Rosenfeld et al., 2022; Diabetes Australia, 2021; Riddle et al., 2022;).

Reversal: Reversal is used synonymously with prolonged remission of Type 2 Diabetes Mellitus (Diabetes Australia, 2021).

Routine diabetic care: The continued full spectrum of client care planned and implemented by the clients' care team with the aim of educating, monitoring, and managing abnormal blood glucose levels as well as the monitoring for and prevention of complications of diabetes.

Sedentary lifestyle: Sedentary behaviour is defined as any waking behaviour with an energy expenditure of 1.5 metabolic equivalent task (MET) or less. This will include sitting or lying. A sedentary lifestyle is one where more than 6 hours a day are spent in sedentary behaviour (Tremblay et al., 2017).

Steroidal therapy: The use of corticosteroids to treat a medical condition. It's anti-inflammatory properties- make it useful as a treatment for inflammatory and auto-immune diseases or where suppression of the immune response is necessary as in the prevention of rejection of transplanted tissues**.**

Stroke: The damage or death of brain cells due to lack of oxygen, caused by interruption of blood flow due to a rupture or occlusion of an artery supplying blood to the brain. Common symptoms include sudden loss of consciousness, loss of speech, facial deformity and weakness, or paralysis of one side of the body.

Type 2 Diabetes Mellitus T2DM: A diagnosis of Diabetes Mellitus requires a fasting blood sugar to be greater than 7.0mmol/L, or a random blood sugar of greater than 11.1 mmol/L in conjunction with at least two symptoms of Diabetes Mellitus, or a 2 hour post glucose load (during a World Health Organization (WHO) standardised OGT test) blood sugar of greater or equal to 11.1 mmol/L. (American Diabetes Association, 2015)

LIST OF ABBREVIATIONS

Abbreviation	Explanation
ALT	Alanine aminotransferase
ATP	Adenosine triphosphate
BGL	Blood glucose level
BMI	Body mass index
CAD	Coronary artery disease
CCT	Clinical controlled trial
CHIP	Complete Health Improvement Programme
CRP	C-Reactive Protein
DHEA	Dehydroepiandrosterone
ER	Endoplasmic reticulum
FBGL	Fasting blood glucose level
GLUT4	Glucose transporter type 4 (insulin-responding glucose transporter found in adipose tissue and striated muscle)
GP	General Practitioner
HbA1c	Glycosylated (or glycated) haemoglobin
HDL	High density lipoprotein cholesterol
HIT	High intensity interval training
LDL	Low-density lipoprotein cholesterol
MI	Myocardial infarction
RCT	Randomised control trial
T2DM	Type 2 Diabetes Mellitus
WHO	World Health Organisation

CHAPTER 1: INTRODUCTION TO THE THESIS

This chapter provides an overview of the background to this thesis, highlighting the research problem and the development of the Research Questions. The significance of the study and an outline of the thesis structure is also presented.

Background to the Topic

Diabetes Mellitus, meaning 'an excessive discharge of urine sweetened with honey' (Ahmed, 2002), is a chronic disorder of carbohydrate metabolism marked by high blood glucose levels. The cause can be either due to pancreatic failure to produce insulin (Type I) or defects in insulin action (Type 2). Type 2 Diabetes Mellitus (T2DM) is becoming a disease of epidemic proportions internationally (Chen et al., 2012; World Health Organization, 2011b), while in Australia, the incidence, prevalence and burden of disease associated with diabetes are increasing.

Incidence and Burden of Disease

About 1.2 million of Australia's 23 million people (4.9%) have diabetes. Most people with diabetes in Australia (83%) are classified as having T2DM, with 12 per cent being classified as having Type 1 Diabetes Mellitus (T1DM) (Australian Bureau of Statistics, 2018). Diabetes is becoming more common (Shaw & Tanamas, 2012), with the rate of self-reported cases (based on the 2017-2018 Australian Bureau of Statistics Health Survey) increasing more than two-fold from 1.5 per cent to 4.4 per cent between 1989-90 and 2017-18. In 2017-18, diabetes was more common in men, with 5 per cent of all men and 3.8 per cent of all women affected. Those aged between 65 and 74 are three times more likely to have diabetes than those aged between 45 and 54 years (Australian Institute of Health and Welfare, 2020b). In 2017-18, 2,800 new cases of T1DM were recorded, with about half of them occurring in people younger than 18 years. In the same period, 49,800 new cases of T2DM were recorded, with most occurring in people over 40 years old. However, while T2DM is generally a disease associated with older age groups, 430 new cases were reported in children and young people between the ages of 10-24 (Australian Bureau of Statistics, 2013). In 2017–18, around one in every six females aged between 15 and 49 who gave birth in a hospital were diagnosed with gestational diabetes (16 per cent, or 43,100 females)

(Australian Institute of Health and Welfare, 2020b). Persons with gestational diabetes have an increased risk of developing T2DM in later life.

Several interrelated factors increase the risk of the onset of T2DM. However, much of the pathogenesis of the disease is associated with lifestyle, particularly the lifestyle habits associated with obesity (National Institute for Health and Care Excellence, 2017). There is no known cure for T2DM, and so the prevalence and increasing incidence make it necessary to undertake research into the prevention and potential reversal of T2DM. Several studies have indicated that adopting positive lifestyle changes can successfully prevent or delay the onset of T2DM (Englert et al., 2012; Ledikwe et al., 2007; Look AHEAD Research Group, 2013). Changes such as reducing obesity, increasing physical activity levels and consuming a largely plant-based, low-fat, low-cholesterol and high-fibre diet are effective across most population groups (Lindström et al., 2013; Ramachandran et al., 2006; Ramachandran et al., 2013; Schellenberg et al., 2013).

Management of T2DM

The current goals for optimum management of T2DM as set out by the Royal Australian College of General Practitioners (2020) include glycaemic control, risk factor reduction (tobacco, body mass index, blood lipids, hypertension, sedentary lifestyle), and regular monitoring of glucose levels and risk factors. While clients are referred to a dietician and are encouraged to be more active and to cease tobacco use, prescription medication is primarily initiated and prioritised as the mechanism to control blood glucose and manage other risk factors.

Central to the present study is an intensive lifestyle intervention initiative known as the Complete Health Improvement Programme (CHIP). CHIP is a worldwide programme designed around participant self-responsibility and self-management (Morton et al., 2013, 2014a, 2014b). It is non-prescriptive and allows for participants to select the degree to which they implement the lifestyle behaviours advocated in the programme.

Research Problem

On an international level, the rate of diabetes and associated costs are still escalating (Australian Institute of Health and Welfare, 2020b). The global prevalence of T2DM is predicted to increase from 6059 per 100 000 in 2017 to 7079 per 100 000 by 2030, and it has proved to be one of the more serious public health problems of the 21st century (Khan et al.,

2020). In Australia in 2015, T2DM was the twelfth leading cause of disease burden, an increase from thirteenth in 2003 (Australian Institute of Health and Welfare, 2020a). In 2020, diabetes was the seventh leading cause of death contributing to 16,700 deaths, 10.5 per cent of all deaths in Australia. In the same year, the condition was also the principal reason for 53,900 hospitalisations and another 1,149,000 hospitalisations where diabetes was a secondary diagnosis, equating to 11 per cent of all hospitalisations (Australian Institute of Health and Welfare, 2020b). In Australia, $2.7 billion was spent on treating diabetes in the 2015-2016 financial year, equating to 2.3 per cent of all health expenditures.

In 2019-2020, the average annual cost of diabetes to the Australian health system was $3.1 billion which was 2.2 per cent of the total healthcare cost for that period (Australian Institute of Health and Welfare, 2023). However, despite large amounts of resources being spent on diabetes education and management little improvement is evident in the incidence or prevalence of T2DM.

Purpose of the Thesis and Impact of COVID-19

The purpose of this thesis was to evaluate the effectiveness of the CHIP programme in reversing symptoms of T2DM. The initial plan was to conduct a single randomised controlled trial (RCT) addressing the questions of the effectiveness of the programme. However, due to a substantial number of medical practices being unwilling to participate, recruitment and enrolment was slow. The introduction of COVID-19 restrictions necessitated the suspension of the roll-out of the CHIP intervention and required major modifications to the overall programme of research halfway through Study 1. Furthermore, due to COVID-19 the lack of access to new potential participants and the inability to progress those who were part way through the CHIP resulted in the decision to terminate the RCT study to meet university requirements for completion. The reduced number of participants resulted in the RCT being underpowered from what was planned.

However, despite these challenges, a qualitative, second research study was developed to follow the RCT comprising the first study, with the purpose of not only assessing the effect of implementation of CHIP, but understanding participants' adherence levels, their knowledge of the concept of reversal of T2DM, and their experience of CHIP. The results and conclusions drawn from this thesis have the potential to provide information and evidence for the use of a more client-directed approach to lifestyle management.

Research Questions

Four Research Questions guide this thesis and address its overall purpose. The first two questions are answered in Study 1. To explore the second research question, two additional Research Questions were developed for Study 2.

In a diabetic population within a general practice group in the Lake Macquarie region of New South Wales, Australia:

1. When compared to a control group receiving routine diabetic care, what is the effect of implementing CHIP on changes in fasting blood sugar levels (FBSL), HbA1c, fasting lipogram with triglycerides (FLT), blood pressure (BP), abdominal girth and body mass index (BMI) in participants with previously diagnosed T2DM who participated in CHIP? (Study 1).
2. Compared to a control group receiving routine diabetic care, what adherence levels (measured through changes in dietary intake, and physical activity levels, and planned exercise) over 12 months are observed in participants with previously diagnosed T2DM who participated in CHIP? (Study 1).
3. What was the participant's knowledge of the concept of diabetes reversal? (Study 2).
4. What was the participant's experience of CHIP as an intervention for diabetes reversal? (Study 2).

Research Design

The research comprised two studies (Study 1, a randomised controlled trial (RCT), n=28; and Study 2, a qualitative case study n=16) which were utilised to address the above Research Questions.

Information from data collected as part of the RCT provided insight into the participants' ideas about diabetes reversal and factors that potentially impacted long-term adherence to CHIP recommendations, control of glucose levels and diabetes risk factors. It was therefore decided to introduce a second qualitative study.

The second study investigated the participants' knowledge and perceptions of diabetes reversal, their perceived level of adherence to lifestyle recommendations and the relationship of adherence to some of the emerging physical and psychosocial factors contributing to adherence or lack of adherence. The intervention group's experience of CHIP was also assessed. Two additional research question to this effect were therefore introduced.

Significance of the Research

This thesis addresses a gap in the CHIP research advancing knowledge in T2DM prevention and reversal. Previous RCT's using the CHIP as an intervention have evaluated the effectiveness of CHIP in reducing risk factors for chronic diseases of lifestyle (including fasting blood sugar levels) and have not specifically focused on diabetes reversal. At the commencement of the PhD study, the planned RCT was the first to be conducted worldwide. Previous CHIP studies have used fasting blood glucose (FBG) levels as a measure of glycaemic control, but recent research has provided evidence that, used on its own, FBG is not necessarily an accurate reflection of glycaemic control (Rohlfing et al., 2002). Blood sugar levels may vary substantially over 24 hours depending on the types of food consumed, level of activity and time of medication use (Bonora et al., 2001; Borg et al., 2010). FBG is also a poor predictor of glycated haemoglobin also referred to as glycosylated haemoglobin (HbA1c) and post-prandial glucose levels (Borg et al., 2010; Rohlfing et al., 2002). In the RCT (Study 1) an HbA1c was used in addition to a fasting blood glucose measurement to provide a more comprehensive approach for assessing glycaemic control.

Most other studies conducted on the use of lifestyle modification for glycaemic control involve more prescriptive interventions than the CHIP. Furthermore, none of the previous CHIP studies have investigated the participants' experience of the programme. Therefore, this study had the potential to provide information related to potential improvements to the intervention. In addition, a better understanding of the factors that potentially impact adherence to lifestyle recommendations have the potential to influence primary care practice and to inform decisions about funding T2DM initiatives on the Medical Benefits Schedule (MBS).

Overview of the Thesis

Chapter 2, Review of the Literature, provides a definition of diabetes, and its pathophysiology and associated complications are explored. The incidence and statistics relating to the burden of disease and healthcare costs are covered. A detailed description of risk factors is provided as well as the current accepted diagnostic criteria and requirements for diabetes education. Health promotion and lifestyle education, particularly lifestyle as an intervention for chronic disease management, is discussed. Finally, an explanation of the origin and evolution of the CHIP as a lifestyle medicine approach to managing diabetes and other chronic lifestyle diseases is provided. The literature review culminates with an

overview of diabetes and the management thereof (Publication 1) and a description of the pathophysiology of obesity with respect to T2DM (Publication 2) (See p. iv).

Chapter 3, Theoretical Underpinnings and Methodology, discusses positivism as a theory underpinning the RCT. The study aims, research questions and methodology, including a detailed explanation of data collection methods and ethical considerations, are provided. The chapter culminates with an overview of the methodology used for the RCT (Publication 3) (See p. iv).

Chapter 4, Study 1 Results, provides the quantitative results obtained from the RCT which comprised Study 1.

Chapter 5, Study 1 Discussion and Recommendations, provides a detailed discussion of the quantitative results obtained from the RCT, as well as recommendations for future diabetes care and research following from them.

Chapter 6, Study 2 Methodology and Methods, provides insight into the reasoning behind adding a second study to the research. The methodology, data collection and data analysis methods are provided along with the ethical considerations applied.

Chapter 7, Study 2 Results, presents the qualitative results of the research.

Chapter 8, Study 2 Case Studies, presents four case studies, to provide real-life context to the results obtained in Chapter 7.

Chapter 9, Study 2 Discussion, provides a discussion of the participants' knowledge of diabetes reversal, their experience of the CHIP and adherence to recommendations. The strengths and limitations of the study are also discussed.

Chapter 10, Conclusion to the Thesis, discusses conclusions obtained from the research, and offers recommendations for practice and future research.

Conclusion to the Chapter

An overview of the background and purpose of the study has been provided. The overview commenced with an introduction to the research questions. The significance of the study and an overview of the structure of the thesis was discussed. Finally, a brief explanation of the content of each chapter was provided. In the following chapter a relevant literature for this thesis will be discussed.

CHAPTER 2: REVIEW OF LITERATURE

In this literature review, an overview of diabetes and lifestyle management approaches to improve the outcomes of chronic diseases; expressly T2DM are provided. In the section on diabetes the incidence and burden of the disease, diagnostic criteria, pathophysiology involved in the development of T2DM, an overview of metabolic syndrome, common complications, and current management of T2DM are discussed. Lifestyle alterations as they relate to T2DM are then discussed, followed by a review of the development and application of the CHIP programme as an intervention to reverse symptoms of T2DM. The section concludes by reviewing diabetes education regarding behavioural, clinical, and psychosocial outcomes.

Diagnostic Criteria of Type 2 Diabetes Mellitus

The current blood values that determine a compromised carbohydrate metabolism diagnosis are based on the threshold at which when exceeded, complications of diabetes are likely to occur. In a study conducted by Lind et al. (2019), the primary endpoint used to determine the relationship between HbA1c levels and the risk for diabetes complications was the level at which the risk for the development of retinopathy increased. An HbA1c greater than 7 per cent resulted in increased risk of developing retinopathy. Alternatively, an HbA1c of less than 6.5 per cent increased the risk for hypoglycaemic episodes in persons with insulin-dependent diabetes (Lind et al., 2019). The fasting plasma glucose, the 2-hour post glucose load on a standardised glucose tolerance test, and the glycosylated haemoglobin HbA1c can predict the presence of retinopathy, and therefore, the blood glucose levels diagnostic of diabetes mellitus (Cardoso et al., 2017).

Currently recognised diagnostic criteria for Diabetes Mellitus are outlined in guidelines set by national and international bodies (American Diabetes Association, 2021; Petersmann et al., 2019; Sherifali et al., 2018; World Health Organization, 2020a; Colagiuri et al., 2009). These guidelines provide criteria for blood glucose levels considered normal (normoglycemic), impaired glucose tolerance (IGT) and indicative of T2DM.

Indicators for elevated levels of HbA1c, which may be used to diagnose diabetes or risk for diabetes, are also supplied. A summary of these guidelines is outlined in Table 1 *Diagnostic Criteria for Diabetes Mellitus (American Diabetes Association, 2021)*. The American Diabetes Association guidelines were used for this summary as they provide the most up to date and comprehensive synopsis of the current diagnostic criteria expressed in the

international literature. When marginally elevated, blood glucose and HbA1c levels may denote an increased risk for the development of diabetes.

Historically, FBG has been used to determine blood glucose levels at screening or interim care medical visits. However, their value as predictors of glycaemic control is questionable (Rohlfing et al., 2002), particularly in persons using insulin. Blood sugar levels may vary substantially over 24 hours depending on the types of food consumed, activity level and time of medication use (Bonora et al., 2001; Borg et al., 2010). FBG is also a poor predictor of HbA1c or post-prandial glucose levels (Borg et al., 2010; Rohlfing et al., 2002); however, using a FBG as a comparison between results achieved by patient testing can be more valuable as postprandial capillary samples can be 20-25% higher than FBG (Sacks et al., 2011). Using a FBG as a sole measure for predicting glycaemic control is also open to manipulation by the patient to gain approval or avoid perceived disapproval for poor adherence. The literature recommends using one or more additional measures to obtain a more accurate picture of long-term glycaemic control (American Diabetes Association, 2021; Sacks et al., 2011; Tay et al., 2015). HbA1c measures the degree to which glucose binds to haemoglobin in the erythrocyte. Therefore, it is a much more reliable indicator of long-term (previous 8-12 weeks) glycaemic control (Sherwani et al., 2016). HbA1c correlates strongly with the average of multiple glucose measurements taken at various periods in the day, as would occur when clients perform self-monitoring capillary glucose levels. HbA1c is easy to measure and relatively inexpensive and has become a mainstay for monitoring glycaemic control (Gupta et al., 2017). Conversely, HbA1c does not help predict hypoglycaemic events or significant short-term variability in blood sugars (American Diabetes Association, 2021).

There is evidence that ethnic and racial differences exist in that African American and Hispanic populations have higher HbA1c concentrations than Caucasians (Weykamp, 2013; Ziemer et al., 2010). Age also impacts HbA1c levels in that concentrations increase by about 0.1 per cent per decade of life due to a decrease in red blood cell count associated with increasing age (Wu et al., 2017). Despite these limitations, the diabetes research community has agreed that HbA1c remains a reliable diabetes monitoring technique (Chehregosha et al., 2019).

Table 1

Diagnostic Criteria for Diabetes Mellitus (American Diabetes Association, 2021)

Glucose tests:				
Glucose defect	FBG	2-hour PPBG	RBG	2-hour PGLBG
Normoglycemic	less than 100mg/dL (5.6mmol/L)	less than 100mg/dL (5.6mmol/L)		
Impaired glucose tolerance.	100 to 125 mg/dL (5.6-6.9mmol/L)	140 to 199 mg/dL (7.8-11.0mmol/L)		
Diabetes Mellitus	greater than 126mg/dL (7.0mmol/L),		greater than 200mg/dL (11.1 mmol/L) in the presence of at least two symptoms of Diabetes Mellitus	greater or equal to 200mg/dL (11.1 mmol/L).
HbA1c test:				
Glucose defect	HbA1c			
Non-diabetic	below 5.7%			
High risk for a diagnosis of Diabetes Mellitus	between 5.7 % and 6.4%			
Diabetic A positive diagnosis for Diabetes Mellitus	greater or equal to 6.5%			

Note. Any or a combination of any of the diagnostic tests may be used to diagnose diabetes mellitus. HbA1c - glycosylated (or glycated) haemoglobin. FBG – fasting blood glucose. PPBG – post prandial blood glucose. RBPG – random blood glucose. PGLBG – post glucose load blood glucose

Risk Factors for Type 2 Diabetes Mellitus

Risk factors for the development of T2DM can be divided into non-modifiable and modifiable risk factors.

Non-modifiable Risk Factors

Non-modifiable risk factors include age, age of menarche, gender, cultural background and socioeconomic circumstances (Lee et al., 2020). Individuals over the age of 40 years are at higher risk of developing T2DM over their younger counterparts. Persons of South Asian, Chinese, African-Caribbean, indigenous African or Pacific Islander descent who are over 25 years old have more significant risk profiles when compared to relative Caucasian population groups (National Institute for Health and Care Excellence, 2017). Aboriginal and Torres Strait Islander Australians are three to five times more likely to have diabetes than non-Indigenous Australians (Australian Institute of Health and Welfare, 2020b) and twice as likely to develop gestational diabetes (Australian Institute of & Welfare, 2010). Aboriginal and Torres Strait Islander children have twice the risk of developing T2DM than their non-Indigenous peers (Australian Institute of & Welfare, 2014). T2DM-related mortality among Aboriginal and Torres Strait Islanders is also four times that of non-indigenous Australians (Australian Institute of Health and Welfare, 2020b).

T2DM is more likely to occur when a family history of T2DM exists or when a related female has previously been diagnosed with gestational diabetes (Noctor & Dunne, 2015). Individuals with pre-existing acanthosis nigricans, cardiovascular disease, stroke, polycystic ovary syndrome, conditions requiring steroidal therapy or mental illness are at greater risk of developing T2DM (National Institute for Health and Care Excellence, 2017; Stefan et al., 2017). While some of these conditions have aspects that may be modifiable, the inherited risk remans applicable. Several genes are associated with T2DM, but very few show consistencies across various ethnic groups. The concurrence of T2DM in monozygotic twins is about 70 per cent compared to 20-30 per cent in dizygotic twins. The lifetime risk of a child developing T2DM is around 40 per cent if one parent has the condition but increases to 70 per cent if both parents are affected (Kommoju & Reddy, 2011). The genetic risk associated with eating patterns, central obesity and DNA methylation patterns results in inflammation. The inflammatory response to diet and adiposity has been suggested as being involved in the development of T2DM (Goni et al., 2014; Zhou et al., 2018b). In addition, polymorphisms in mitochondrial DNA which regulate mitochondrial function and

metabolism may be associated with the metabolic changes associated with T2DM (Fazzini et al., 2021).

Modifiable Risk Factors

The most common modifiable risk factor shown to increase the risk of T2DM is obesity (defined as a body mass index (BMI) greater than 30kg/m^2). T2DM is generally associated with some genetic predisposition to alterations in fat storage sites (Sinn et al., 2019), leading to alterations in body fat distribution. Therefore, a body mass index (BMI) greater than 25 kg/m^2 accompanied by a high percentage of abdominal fat is also an independent risk factor for T2DM. A predisposition to store fat in and around abdominal organs also explains why some persons with T2DM have a normal BMI and do not appear overweight.

Acute sleep deprivation and circadian rhythm alterations contribute to obesity through alterations in food choices and portion sizes. Lack of sleep contributes to a rise in ghrelin levels, increasing hunger and growth hormone release and initiating increased fat deposition (Morin et al., 2018; Qian et al., 2019).

Other major modifiable risk factors for T2DM are hypertension (diagnosed as a systolic blood pressure greater than 140mmHg and or diastolic pressure greater than 90 mmHg), elevated cholesterol (Wada et al., 2016) or triglyceride levels (Tirosh et al., 2008; Zhao et al., 2019).

Unhealthy dietary habits have been associated with obesity, hypertension, and lipid disorders. It is therefore not surprising that populations consuming large amounts of fruits, vegetables and whole grains in combination with small amounts of animal protein show a markedly lower incidence of T2DM when compared to populations consuming a diet characterised by a high intake of processed and red meats, fried foods, sweets, deserts and refined grains (Cao et al., 2021; Chiu et al., 2018; Lee & Park, 2017; Olfert & Wattick, 2018; Papamichou et al., 2019; Pawlak, 2017). In addition, results from population-based studies have suggested that flavonoid-rich foods, such as soy (isoflavones), tea (flavanols), cocoa (proanthocyanins) and blueberry (anthocyanidins), have a beneficial effect on the metabolism, significantly reducing the risk of developing T2DM (Hussain et al., 2020; Liu et al., 2021; Proença et al., 2020; Xu et al., 2018). An adequate intake of vitamins and minerals, enough to sustain normal blood values, particularly of magnesium and vitamin D, is

protective against developing T2DM (ELDerawi et al., 2019; Hirani et al., 2014; Lips et al., 2017; Ozcaliskan Ilkay et al., 2019; Yousefi Rad et al., 2014).

Additional modifiable risk factors include low levels of physical activity (defined as less than 150min of sustained moderate exercise per week, preferably separated by no more than two days at a time) and cigarette smoking (Maddatu et al., 2017).

The interaction between the non-modifiable and modifiable risk factors contributes toward disease development and is involved in several pathophysiological pathways.

The Role of Obesity in the Pathogenesis of T2DM

The risk factor that has the strongest association with T2DM, irrespective of genetic risk, is obesity (Schnurr et al., 2020). The relationship between the onset of insulin resistance and the presence of obesity has been observed in all ethnic groups and across the full spectrum of age, gender and body mass for decades (Abuyassin & Laher, 2015; Goff, 2019; Tricò et al., 2020). Results from large epidemiological studies indicate that the risk of T2DM and associated insulin resistance increases as the per cent of body fat increases, implying that the total body fat percentage affects insulin sensitivity. In addition, total and central (intra-abdominal) adiposity is strongly linked to insulin resistance (Caspard et al., 2018). Central adiposity is also associated with plasma glucose levels, plasma insulin, total plasma cholesterol and triglyceride concentrations, decreased plasma high-density lipoprotein (HDL) cholesterol and increased plasma low-density lipoprotein (LDL) cholesterol concentration (Barroso et al., 2017; Caspard et al., 2018; Man et al., 2016).

Insulin Resistance Associated with Obesity

Cells have several ways to detect incoming nutrients, including through direct and indirect activation of transcription factors and protein kinases. These pathways integrate with incoming hormonal signals to modulate cellular metabolism, increasing anabolic reactions during nutrient surfeit and increasing catabolic reactions in post-prandial or nutrient deficit states (Gribble & Reimann, 2019). Prolonged activation of anabolic pathways may lead to unintended pathological states that could result in insulin resistance, inflammatory responses and possibly even cell death (Schwartsburd, 2017). Various interacting factors determine an individual's physiological and biochemical response to long-term nutrient overload. For example, one individual may be obese with normal cell biochemistry relating to glucose and lipid metabolism and other vascular risk factors. In contrast, another individual may

demonstrate only minor alterations in body mass and yet present with distinctly abnormal physiology (Stefan et al., 2017). Phenotypic alterations largely determine the variance in response, as is demonstrated by the increased burden of metabolic dysfunction in Asians at a much lower BMI than in Caucasians and other ethnic groups (Hills et al., 2018).

Nutrient intake exceeding expenditure is either converted into biological precursors for catabolism or stored. Irrespective of nutrient type, excess nutrients are primarily stored as fatty acids in the form of triglycerides, a form that is quickly mobilised in times of nutrient deficit (Malone & Hansen, 2019). Whether deposition occurs in the abdominal or peripheral adipocytes is thought to be attributed mainly to environmental and genetic factors (Frank et al., 2019). A 'tipping point' is reached when decreased adipogenesis and angiogenesis occur along with adipocyte hypertrophy (Nijhawans et al., 2020). At this point, an inflammatory reaction activates the nuclear factor-kappa-B pathway resulting in the downregulation of cellular insulin signalling, increased macrophage production, and increased secretion of interleukins and tumour necrosis factor (Engin, 2017). This inflammatory process is thought to reduce the capacity for adipogenesis (Jiang et al., 2019). The subcutaneous tissue, therefore, becomes dysfunctional or inadequate as a storage source and excess energy is stored in myocytes, hepatocytes, vascular cells, and pancreatic beta cells. Fat deposits in muscle cells result in decreased glucose transporter (GLUT4) activity and therefore decreased glucose uptake. Fat storage in liver cells causes hepatic insulin resistance, decreased glucose uptake and hepatic gluconeogenesis (Chadt & Al-Hasani, 2020). The tipping point, likely to be influenced by genetic and environmental factors, may be reached at varying levels of adiposity, including non-obese states (Frayn, 2016; Nijhawans et al., 2020).

Fat accumulated from a higher calorie intake than expenditure results in "fatty-liver disease". Overfeeding for three weeks can increase the liver fat percentage by 30 per cent (Sevastianova et al., 2012). Fatty liver triggers various adaptive and non-adaptive cellular responses that contributes to the development of insulin resistance and leads to cellular dysfunction. An increase in liver fat of 30 per cent is also associated with a 30 per cent rise in serum alanine aminotransferase (ALT) levels, an enzymatic marker indicative of liver disease or damage. Both liver fat and ALT levels are reversed by a hypocaloric diet (Sevastianova et al., 2012).

The inability of the pancreatic beta cells to adapt to a reduced level of insulin sensitivity in muscle and liver cells is what precipitates the onset of T2DM (Chareyron et al., 2020). Studies conducted on persons with T2DM who have undergone significant calorie

restriction resulting in liver and pancreatic fat loss have shown marked improvement and even reversal of their T2DM. In the 1980s, Pories et al. (1992) observed that several obese individuals presented with normalisation of blood sugar levels a few days after undergoing bariatric surgery. In 90 per cent of clients, this remission lasted more than ten years. More recently, results from a study involving 148 individuals with a diagnosis of T2DM who underwent bariatric surgery demonstrated that the degree of remission of their diabetes was directly related to the degree of weight loss, with very little association between the degree of remission and duration of their T2DM prior to surgery (Dang et al., 2019; Steven et al., 2015). Although not as successful, similar results were achieved in a study of individuals who had undergone gastric banding (Li et al., 2019). In hypocaloric states, loss of body weight reduces liver and other visceral or subcutaneous fat stores (Parry & Hodson, 2017). This process also occurs with more moderate calorie restriction over an extended period, with fasting plasma glucose concentrations improving due to a decrease in liver fat content, resulting in the normalisation of hepatic insulin sensitivity (Parry & Hodson, 2017; Ross et al., 2020). Lean, glucose-tolerant offspring of parents with T2DM will exhibit moderate to severe skeletal muscle insulin resistance (Nyenwe et al., 2017). These genetically predisposed individuals progress to impaired glucose tolerance with fat accumulation. However, glucose tolerance is maintained due to a marked increase in insulin secretion. Poor insulin sensitivity initially results in the overproduction of insulin by pancreatic beta cells. Hyperinsulinemia, associated with hyperglycaemia and poor insulin sensitivity, is a possible primary cause of insulin resistance and glucose intolerance (Bergman et al., 2019; Johnson, 2021). In addition, hyperinsulinemia creates reactive hypoglycaemia which causes hunger and cravings, often for high-energy foods. These cravings often predispose to an increase in calorie consumption (Brown et al., 2017). Elevated insulin concentrations may down-regulate insulin receptors and desensitise post-receptor cellular pathways (Choubey et al., 2020; Johnson, 2021).

The Role of Hepatic Glucose Production

Liver fat content is also associated with the extent to which insulin sensitivity suppresses hepatic glucose production (Luukkonen et al., 2020; Utzschneider et al., 2019). It has been shown that decreasing the fat content of the liver results in reduced hepatic glucose production and may improve fasting blood sugar levels (Luukkonen et al., 2020). Endogenous glucose production stems from glycogenolysis (breakdown of stored glycogen) and gluconeogenesis (the creation of glucose from non-carbohydrate sources). The

contribution of these two methods of glucose production to maintain normal blood sugar levels varies according to circumstances relating to energy requirement and post-prandial timing (Hatting et al., 2018).

Hepatic insulin resistance plays an essential role in developing hyperglycaemia in T2DM due to the impaired suppression of endogenous glucose production by the liver (Samuel & Shulman, 2016). However, hepatic glucose production may be normal in lean, relatively insulin-sensitive clients with a diagnosis of T2DM (Conte et al., 2012; Trouwborst et al., 2018). Insulin will suppress hepatic glucose production and lipolysis (lipid breakdown) in peripheral tissues (Fletcher et al., 2019).

The Role of the Pancreatic Beta Cell

The inability of the pancreas to adapt to insulin resistance places an increased secretory burden on the beta-cells. In addition, obesity, pregnancy, a sedentary lifestyle and overeating are all factors that lead to weight gain and adiposity, resulting in increased insulin insensitivity and demand for insulin secretion (Hudish et al., 2019). Beta cell adiposity and increasing demand for insulin are associated with beta cell failure (Oh et al., 2018). The frequency with which beta cell failure occurs appears to be strongly related to an individual's genetic predisposition (Rojas et al., 2018).

Despite the close relationship between liver fat, skeletal muscle insulin resistance and raised liver enzymes, hepatic insulin resistance is not always related to liver adiposity (Johnson, 2021; Taylor, 2013). A required degree of genetic, ethnic or lipo-susceptibility of the metabolic organs is therefore indicated (Nyenwe et al., 2017; Stefan et al., 2017).

The Role of Other Metabolic Factors

Several other biochemical pathways affecting insulin resistance, glucose metabolism and T2DM are related to alterations in the innate immune function (Zhou et al., 2018a), circadian rhythms (Javeed & Matveyenko, 2018), mitochondrial processes (Thivolet et al., 2017) and insulin signalling (Yan et al., 2021). While the pathways and biochemistry related to these are unique, the effects are related to the three cardinal physiological abnormalities: insulin resistance, defect in insulin secretion and increased glucose production by the liver. As a result of the multiple pathogenic pathways involved in the disease process, T2DM typically presents with several metabolic and other complications.

Complications of Type 2 Diabetes Mellitus

A combination of a constellation of physiological, biochemical, clinical, and metabolic problems often co-exist in individuals with insulin resistance or T2DM. These metabolic derangements are individually and collectively associated with an increased risk of cardiovascular disease. Typically, these derangements are hypertension, obesity (particularly visceral adiposity) and atherogenic dyslipidaemia, and together are recognised as the deadly quartet, also referred to as Syndrome X or Metabolic syndrome. The recently adopted Harmonized Definition of Syndrome X or Metabolic syndrome requires that three of the following five risk factors are present: enlarged waist circumference based on population or country-specific criteria; triglycerides above 3.8 mmol/L (150 mg/dL), and HDL-C less than 1 mmol/L (40 mg/dL) in men and less than 1.2 mmol/L (50 mg/dL) in women, a systolic blood pressure greater or equal to 130 mm Hg or a diastolic blood pressure greater or equal to 85 mm Hg and fasting glucose greater than 5.5 mmol/L (100 mg/dL). Taking medication to manage hypertriglyceridemia, low HDL-C, hypertension, and hyperglycaemia is an alternative indicator (Lam & Leroith, 2019).

CVD is a major cause of death among people with T2DM. Results from a systematic review of global data revealed that CVD accounted for approximately half of all deaths in persons with T2DM studied between 2007 and 2017 (Einarson et al., 2018). The SAVOR-TIMI 53 trial attributed two-thirds of deaths to cardiovascular conditions (Cavender et al., 2016). T2DM acts synergistically with other major risk factors for cardiovascular disease (smoking, hypertension and dyslipidaemia) to increase the risk for CVD and stroke (Glovaci et al., 2019). Over 60 per cent of people with T2DM will develop cardiovascular disease, with about 40 per cent attributable to ischemic heart disease, 15 per cent to other cardiac conditions, principally congestive heart failure, and about 10 per cent from a stroke. (Low Wang et al., 2016). Women with T2DM are particularly susceptible to cardiovascular complications, presumably due to prolonged exposure to cardiovascular risk factors in the pre-diabetic stages, possibly associated with higher adiposity and the fact that females may lose the cardioprotective effect of oestrogen as a result of menopause (Muka et al., 2016; Peters & Woodward, 2018). In addition, a more significant adverse influence of diabetes on blood pressure, blood lipids and inflammation occur in women than in men (Shahwan et al., 2019; Zorena et al., 2020)

The overarching risk for CVD associated with diabetes is the risk attached to dyslipidaemias, which include hypertriglyceridemia, low plasma HDL, and elevated levels of

small, dense LDL particles (Shahwan et al., 2019) and the production of atherogenic very-low-density lipoproteins (VLDL) (Yanai, 2017). Due to the increased risk of cardiovascular disease associated with all forms of diabetes dyslipidaemia in persons with diabetes is treated as aggressively as in persons with a previous cardiac event. In addition, individuals with insulin resistance and obesity should also be aggressively treated to lower blood lipids because they are considered to be at higher risk of cardiovascular events (Shahwan et al., 2019).

The presence of hypertension and diabetes increases the risk of cardiovascular disease fourfold (Hu et al., 2007). Impaired capacity for vasodilation and alterations in blood flow are thought to provide a link to the development of hypertension in insulin-resistant individuals. The proposed mechanisms for the association between insulin resistance and hypertension include the following factors:

- insulin-induced activation of the sympathetic nervous system,
- insulin's intrinsic ability to promote sodium and water reabsorption in the kidney resulting in expanded plasma volume,
- increased peripheral resistance from vascular remodelling occurs as a consequence of endothelial changes. (Ohishi, 2018).

Hyperglycaemia-induced vascular damage is believed to be initiated through increased mitochondrial superoxide (free radical) production, which blocks glycolysis and increases flux through the hexosamine pathway. As a result, levels of transforming growth factor-β are increased. Transforming growth factor-β is responsible for tissue repair; however, when over-expressed may lead to excessive collagen deposition (Shang et al., 2017).

Nitric oxide is produced from the amino acid L-arginine and is responsible for the vasodilatory effects on the vasculature. Increased oxidative stress associated with T2DM increases the oxidation of nitrous oxide and contributes to low L-arginine levels. Low arginine levels predict the incidence of microvascular complications in T2DM (Ganz et al., 2017). Microvascular disease contributes to organ damage, resulting in cardiac failure (Roy et al., 2020), stroke, cognitive deterioration and renal failure. In addition, sensory organ damage results in vision and hearing loss, whereas peripheral micro-circulatory damage results in neuropathy and peripheral vascular disease.

The accumulation of extracellular matrix in the glomerulus is an early indication of the development of diabetic glomerulosclerosis. Several mechanisms have been implicated in this hyperglycaemia-induced condition, including activation of the polyol pathway and glucose-induced stimulation of protein kinase-C. Increased flux through the hexosamine pathway leads to overexpression of transforming growth factor-β and is, therefore at least partly responsible for glomerular dysfunction (Miranda-Díaz et al., 2016; Shang et al., 2017).

Diabetic retinopathy is one of the most common complications of diabetes resulting in progressive damage to the retina leading to vision loss of varying degrees (Wang & Lo, 2018). Diabetes is also associated with low levels of some of the protective metabolites, such as vitamin B12 and folic acid (Lei et al., 2018), leading to homocysteinaemia. Hyperglycaemia also activates protein kinase C, poly-polymerase, the polyol and hexosamine pathways, as well as stimulating several inflammatory cytokines and chemokines that contribute toward oxidative stress and pro-coagulation (Ighodaro, 2018). An increase in growth factors contributes to basal membrane thickening (Roy & Kim, 2021; Shang et al., 2017). Hyperlipidaemia is responsible for the increased circulation of fatty acids, ketone bodies and ceramides, which potentially damage the micro-circulation and neurons (Busik, 2021). The altered mitochondrial function impedes retinal cell metabolism and function (Nolan et al., 2021).

Prevention and Management of Type 2 Diabetes Mellitus

The current management of T2DM is multi-pronged. Aspects of this approach that will be discussed include lifestyle modification, diabetes education, and medication use. Lifestyle modification approaches are recommended in the initial post-diagnosis phase (Blonde et al., 2022). It is recommended that the performance of lifestyle measures, the expected clinical outcomes, general health status and quality of life of individuals utilising lifestyle measures be monitored as part of routine diabetes medical care (American Diabetes Association, 2019). Lifestyle modification is advocated with medication where necessary to obtain suitable glycaemic control.

Lifestyle Measures

Weight loss and exercise are the two most effective lifestyle measures to improve insulin sensitivity (Mendes et al., 2016). Both modalities are independently effective and can be additive when combined to improve insulin action (Leitner et al., 2017; Mendes et al.,

2016; Taylor et al., 2019). Weight loss is advocated as the primary tool in managing overweight persons with T2DM, particularly when associated with other cardiovascular risk factors (Lingvay et al., 2021; The Royal Australian College of General Practitioners, 2020). Weight loss can also delay or prevent at-risk or vulnerable individuals from developing T2DM (Knowler et al., 2002; Look AHEAD Research Group, 2013; Rydén et al., 2013). In overweight individuals, weight loss has been shown to reduce hepatic glucose production, improve insulin resistance and fasting hyperinsulinemia to improve glycaemic control (Holst et al., 2018; Lingvay et al., 2021; Perry et al., 2014). Weight loss of 5 to 10 per cent is also associated with blood pressure reduction and improved lipid profile (Look AHEAD Research Group, 2016; Wing et al., 2011). Current recommendations for weight loss are to aim for a 15 per cent reduction as a primary treatment goal. Weight loss may be achieved through lifestyle, the addition of medication (Glucagon-like Peptide-1 receptor agonists) or bariatric surgery where suitable and available (Lingvay et al., 2021).

Abdominal obesity has been correlated with insulin resistance and the risk of T2DM (Caspard et al., 2018). The link between increased abdominal fat and an increased risk of coronary heart disease has also been shown to be more closely related to visceral fat than overall obesity (Lahey & Khan, 2018). Therefore, the hip-to-waist measurement ratio has become a convenient risk assessment tool. A waist-to-hip ratio of greater than 0.9 in men or greater than 0. 8 in women is indicative of abdominal obesity (World Health Organization, 2011a) and, therefore, also of an increased potential to develop cardiovascular disease and diabetes. The Commonwealth of Australia Department of Health and aged Care (2021) regards a waist circumference greater than 94 cm in men and 80 cm in women as predictive of an increased risk of developing T2DM. A waist measurement of greater than 102cm in men and 88 cm in women is regarded as being high risk for developing T2DM (2021).

Regular exercise training has also been shown to increase insulin sensitivity (Bird & Hawley, 2017; Prior et al., 2014) and delay or prevent the onset of T2DM in those at increased risk (Colberg et al., 2010). The primary biochemical changes from exercise training include increased glucose transporters, capillary density, red glycolytic muscle fibres and mitochondrial density (Parise et al., 2020; Stanford & Goodyear, 2014).

Exercise improves insulin sensitivity in a graded dose-response association such that greater insulin sensitivity was obtained with higher-intensity exercise and greater calorie consumption per week (Dubé et al., 2012). High-intensity interval training (HIT) and moderate sustained exercise similarly effect insulin sensitivity (Ryan et al., 2020). Even

light-intensity physical activity has been shown to improve physical and psychological health, quality of life, well-being, cerebellar function and functional capability in older adults (Ehlers et al., 2018). Results from a study by Garthwaite et al. (2021) on sedentary persons with metabolic syndrome demonstrated that insulin sensitivity was improved by spending more time standing (Goldenberg et al., 2021).

Exercise recommendations for people with diabetes are to undertake at least two 20-minute sessions per week of resistance training in addition to 120-150 minutes per week of aerobic activity such as walking or swimming (Sigal et al., 2018). Using a pedometer to measure physical activity has been recommended as both practical and accurate in measuring the degree of physical activity in people with T2DM (Baskerville et al., 2017). Previous studies have indicated that pedometers provide an accurate assessment of ambulatory activities in a non-diabetic population in that pedometer readings were correlated well with aerobic capacity (maximal oxygen uptake). These results allowed a more realistic assessment of perceived everyday activity (Bassett, 2000; Bjørgaas et al., 2005). Endorsement for the use of pedometers by individuals with T2DM as an accurate assessment of physical activity was provided by the authors of the First Step Program (Tudor-Locke & Bassett, 2004).

Dietary recommendations include an individualised eating plan of nutrient-rich foods rather than calorie-rich foods. Nutritional guidelines recommend increasing the intake of high-fibre fruit and vegetables and reducing the intake of processed foods, high-fat foods, red and processed meat, and sugary foods (Diabetes UK 2018). Individualised dietary goals that account for the person's lifestyle, dietary preferences, nutritional needs, and socioeconomic circumstances are essential to promote adherence.

Medication is recommended when inadequate lifestyle therapy and glycaemic control are not achieved. Metformin is regarded as the first-line therapy unless contra-indicated or not tolerated. If a client's HbA1c remains above 7 per cent, dual therapy is instituted by adding a Sulphonylurea, Dipeptidyl peptidase-4 inhibitor, Sodium-glucose co-transporter 2 or a Glucagon-like peptide-1 receptor agonist inhibitor. Should more intensive therapy be required, an additional agent from the above list or Acarbose, a Thiazolidinedione, or Insulin may be commenced. Glucagon-like peptide-1 receptor agonist inhibitors and Sodium-glucose co-transporter-2 or Glucagon-like peptide-1 receptor agonist inhibitors with insulin are not approved by the Pharmaceutical Benefits Scheme (The Royal Australian College of General Practitioners, 2020).

Guidelines on General Practice management of T2DM recommend diabetes screening every one to five years based on scored risk. Risk scores are calculated on the cultural group, family history, history of gestational diabetes or HbA1c or blood sugar result on previous screening and co-morbid risk factors (Bell et al., 2020; The Royal Australian College of General Practitioners, 2020). In addition, diabetes care should be aligned with recommendations set out by the chronic care model. The model prescribes that diagnosed individuals interact with a multidisciplinary team to access client-centred education, community and other support tools, evidence-based treatment methods, ongoing monitoring and tertiary care (The Royal Australian College of General Practitioners, 2020).

Diabetes Education

Diabetes education has been defined as "an interactive process that facilitates and supports the individual and for the families and carers are significant social contacts to acquire and apply the knowledge, confidence, practical problem-solving and coping skills needed to manage the life of diabetes to achieve the best possible outcomes within their unique circumstances" (Eigenmann & Colagiuri, 2007). Understanding how and why people learn is fundamental in educating clients and their families in a way that will improve knowledge and foster the implementation of actions. Educational theory provides insight into how people take in information through their senses, make connections with existing knowledge and then, through a range of cognitive processes, become more self-aware, implement problem-solving strategies, and change behaviours (Thompson et al., 2021).

Therapeutic client education for diabetes is recognised as a fundamental and essential component of care since Jean-Philippe Assal introduced it as an approach to diabetes care in the 1970s (Maldonato et al., 1995). From its inception, a holistic approach was adopted, including medical, psychological, and educational components. Diabetes education in Australia is most often conducted by trained diabetic educators who may either originate from several medical or allied medical professional backgrounds or by Aboriginal healthcare workers who have undergone additional diabetes education training (King et al., 2019). Diabetes education is usually conducted individually or in small groups using face-to-face teaching methods.

Resources for diabetes education in Australia consist of a workforce of about 1,500 diabetic educators registered with the Australian Diabetes Education Association (ADEA) (Australian Diabetic Educators Association, 2021), over 70 specialist diabetes centres mostly attached to public hospitals, most private specialist diabetes centres, community nurses,

pharmacists and dieticians, as well as practice nurses and aboriginal health workers (Institute of & Welfare, 2002; Australian Diabetic Educators Association, 2021;; National Association of Diabetes Centres 2019). In addition, diabetologists, endocrinologists and general practitioners may provide limited education during consultation (King et al., 2019).

Education Theory

Four broad categories of theories have been described as relevant to education: Behaviorism, Cognitivism, Constructivism and Humanism. Behaviorism describes a collection of theories that focus on the teaching and learning of skills. While specific acquired skills, for example, blood glucose measurement, is critical in diabetes education, much deeper learning is required for lifestyle adjustment and behaviour change (Rosenstock et al., 1988). Cognitive theories explain the need to consider the cognitive processes and information required that relate to and are necessary for learning. These would include prior experiences and personal beliefs. Because humans are cognitive beings, providing information and knowledge acquisition are fundamental to promoting behaviour change (Dozois et al., 2006).

Constructivist theories, however, describe how humans engage in the learning process through several activities and strategies. It promotes group interaction, problem-solving, questioning and activity-related learning. It also reinforces the need to consider prior experience and beliefs to learn. Learning is conducted in an environment that is relevant and meaningful to a person's life experience (Packer & Goicoechea, 2000). Humanist theories provide a basis for a learner-centred approach to learning, emphasising collaboration and consultation. The learner must feel secure, respected, esteemed and empowered (Braungart et al., 2020).

Diabetes Education Outcomes

Motivational knowledge alone is regarded as insufficient to effect behaviour change. Knowledge and understanding of what is required to change and the need to comprehend the health and other life benefits of change is essential (Colagiuri et al., 2009). According to the Australian National Standards for Diabetes Education Programs (2001), the five objectives of diabetes education are to:

- enable persons with diabetes to "understand how diabetes affects their body and the implications of healthy living with diabetes";
- enable persons with diabetes to "make informed decisions and take action towards healthy living with diabetes…… within the context of their own spiritual and cultural values, socioeconomic needs and desired quality of life";
- enable persons with diabetes to "use available resources to facilitate the early identification of risk factors for diabetes complications and to minimise the impact of diabetes complications";
- make the community "aware of diabetes mellitus and the needs of individuals living with diabetes"; and
- make the community "aware of risk factors, actions that delay the onset of diabetes, and signs and symptoms of diabetes".

Individuals who have received diabetes education should ideally be able to apply their knowledge to demonstrate desirable clinical outcomes, exhibit self-determination (the ability to make informed decisions relating to one's health outcomes), self-management, and display psychological adjustment to their diagnosis. In addition, the programme or programmes through which this is achieved are likely cost-effective (Colagiuri & Eigenmann, 2009).

Indicators identified in the Australian National Consensus on Outcomes and Indicators for Diabetes Patient Education (Colagiuri & Eigenmann, 2009) are as follows:

- Knowledge
- Self-management and behaviour change
    - dietary habits
    - physical activity
    - foot care
    - adherence to medical treatment
    - self-monitoring of blood glucose
    - smoking cessation
- Clinical outcomes
    - glycaemic control (FBGL, HbA1c)
    - blood lipids
    - blood pressure
    - body mass & BMI

- Psychological adjustment and self-determination
    - well-being
    - quality of life
    - depression and anxiety
    - empowerment
    - self-efficacy
- Long-term outcomes
    - mortality
    - complications (cardiovascular, renal, retinopathy, peripheral vasculature)
- Health service utilisation
    - number and length of hospital admissions
    - primary care
    - specialist services

The effectiveness of diabetes education has primarily been measured using markers of glycaemic and metabolic control, essentially eliminating factors relating to knowledge gained or put into practice, quality of life and attitudes towards diabetes (Colagiuri et al., 2009). In recent years, the move towards person-centred education requires greater diversity in outcome measures that include associated behavioural and psychosocial change (McCay et al., 2019).

Education and Self-management for Behavioural Outcomes

Systematic reviews conducted by Deakin et al. (2005) and Norris et al. (2001) concluded that diabetes education produced significantly improved knowledge among intervention group participants compared to control group participants. Other studies confirmed these results, including the DESMOND and X-PERT programmes (Adolfsson et al., 2007; Davies et al., 2008; Deakin et al., 2006; Miller et al. 2020, Shiferaw et al., 2021).

Analysis conducted on glycaemic control and self-management behaviours (physical activity, healthy diet, foot care and blood glucose self-monitoring) where interventions engaged participant activity showed significant positive effects on these parameters. HbA1c levels were improved in participants with previously poorly controlled blood sugar, where culturally-tailored interventions or face-to-face interventions were applied in combination with follow-up telephone calls (Almutairi et al., 2020).

Results of a systematic review conducted by (Deakin et al., 2005) indicated that participating in group diabetes education increased an individual's consumption of fruit and vegetable portions in their diet and decreased their consumption of saturated fats when compared to a control group. Other study results showed similar effects but also showed that participants consumed less sugar and sucrose and spent more time engaging in physical exercise (Davies et al., 2008; Ko et al., 2007; Norris et al., 2001). Diabetes education focused on increasing fresh fruit and vegetable consumption and using farmer's market vouchers as incentives, resulting in improved purchasing behaviour and daily intake of fresh fruit. These results demonstrated that an intervention to improve knowledge and access might significantly impact food behaviours, obesity and diabetes outcomes, particularly among low-income and racially diverse communities (Weinstein et al., 2013).

Systematic reviews conducted by Norris et al. 2001, Deakin et al. (2005), and Deakin et al. (2006) indicate that diabetes education improved self-monitoring of blood glucose in the short-term but has no significant value after six months, 12 and 14 months, respectively. A RCT conducted by Korean researchers, used a self-reported questionnaire and reported improved self-monitoring at all follow-up time points (annually for four years) in the intervention group over the control group (Ko et al., 2007). The results from another systematic review indicated that self-monitoring of blood sugar levels may improve HbA1c levels and glycaemic control in persons with T2DM (Mannucci et al., 2017). Further, a systematic review and meta-analysis demonstrated that 8 to 14 blood sugar measurements per week were most likely to improve glycaemic control and weight management in clients with T2DM not yet requiring insulin (Xu et al., 2019). A further RCT was conducted where individuals in the intervention group were provided with blood glucose testing equipment and shown how to use it (Young et al., 2017). The researchers, however, appeared to need to provide information or education on goal setting or self-management of blood sugars. Compliance with testing decreased considerably during the study, and results showed that glycaemic control was no better in the intervention than in the control group. These results suggest that providing the opportunity for testing without engaging the individual in goal setting or providing purpose for the exercise is ineffective in improving glycaemic control (Young et al., 2017). Continuous glucose monitoring may be a viable option for improving long term compliance with monitoring on persons treated with insulin however the cost benefit of utilising this technology in uncomplicated insulin management has not been established. Randomised trials have indicated that glycaemic control is significantly

improved in persons with poorly controlled T2DM treated with basal and prandial insulin regimes (Beck et al., 2017; Martens et al., 2021). McCay et al (2019) in a systematic review demonstrated that behavioural and psychological assessment is just as important as clinical assessment in determining education effectiveness.

Diabetes education may also have some positive outcomes on smoking cessation. The DESMOND trial reported a 3.6 times higher rate of non-smoking in the intervention group than in the control group (Davies et al., 2008). Smoking cessation as part of a structured, general self-care diabetes education course demonstrated improved smoking behaviour (Gehlawat et al., 2019).

Diabetes Education and Clinical Outcomes

Duke et al. (2009) conducted a systematic review and meta-analysis to investigate the effect of individual diabetes education on indicators of metabolic control. Nine studies involving 1359 participants were included in the study. Six studies compared a one-on-one intervention to usual care, and another three compared one-on-one education to group education programmes. Individual education did not significantly improve HbA1c levels over a 12 to 18-month period; however, significant benefits on glycaemic control were obtained in a subgroup analysis of three studies where participant's mean baseline HbA1c was more than eight per cent. In a comparison of studies using either individual or group education as the intervention, there was no significant reported difference in glycaemic control at 12 or 18 months between those studies using individual or group educational methods.

Consistent with a review conducted in 2003 (Loveman et al., 2003), findings from a more recent review (Loveman et al., 2008) indicated that a reliable positive relationship between the effects of client education and glycaemic control could not be demonstrated despite significant differences in mean HbA1c levels between intervention and control groups. In circumstances where a positive relationship did exist between education and glycaemic control, the effects were generally small but relatively long-lasting. These inconsistent results were confirmed by another meta-analysis performed by Conn et al. (2007).

A review conducted by Deakin et al. (2005) consisted of a meta-analysis of three studies which investigated HbA1c levels at 4 to 6 months post-intervention, another seven studies which assessed HbA1c levels at 12 to 14 months post-intervention and another two studies which assessed HbA1c levels at two years post-intervention. The results showed

statistically significant reductions in HbA1c levels where participants received group-based diabetes education compared to control groups. The authors of the review concluded that diabetes education conducted in groups is effective in improving HbA1c levels.

The conclusion of another systematic review conducted in 2007 by Sigurdardottir et al. found that participants' initial HbA1c level was the single most crucial factor determining the glycaemic control obtained in response to diabetes education. When initial HbA1c levels were greater or equal to 8 per cent, the reduction achieved was 0.8 to 2.5 per cent, whereas when the initial HbA1c level was less than or equal to 7.9 per cent, the resulting alteration ranged between +0.1 to -0.7 per cent.

The Cochrane review conducted by Deakin (2005), also demonstrated that there was little evidence for diabetes education programmes impacting body mass or BMI at six months post-intervention. A further meta-analysis of four studies revealed non-significant weight loss in the intervention groups over the control groups. An additional meta-analysis of four studies evaluated BMI changes at 12 to 14 months post-intervention. The results indicated no effect. Results from a study conducted by Hörnsten et al. (2005) showed initial improvements in BMI post-intervention (12 months), while the control group remained static. However, there was no significant difference between the intervention and the control group at one-year and five-year follow-ups. Another review conducted by Norris et al. in 2001 found 13 studies that indicated a positive relationship between client education and weight loss. In most of these studies, education interventions involving regular reinforcement sessions or short follow-up periods were researched. Four of the studies had follow-up periods of more than five months. The average weight loss reported was 2 kilograms. This was confirmed in the DESMOND trial (Davies et al., 2008). While most studies demonstrated little effect of diabetes education on weight loss and BMI, education that included regular re-enforcement sessions demonstrated some effect on weight loss.

Diabetes Education, Psychological Adjustment and Self-determination

In a systematic review, Zhang and colleagues (2007) assessed the effect of various adult diabetes education interventions on health-related quality of life. The SF-36 questionnaire was used as the assessment tool. The pooled effect from five randomised controlled trials demonstrated significantly improved physical function, mental health and decreased body pain levels. Pooled results for another five interventions showed significantly improved social function, vitality, and mental health, and a decrease in limitations due to

physical problems between pre- and post-intervention data. It was concluded that although interventions can improve health-related quality of life in adults with diabetes, the magnitude of the effect varies with different interventions.

A study undertaken by Whitlock et al. (2000) indicated no significant difference in participants' responses on the SF-36 questionnaire which demonstrated the little effect of the education classes and weekly telemedicine interactions when compared to usual care. Results from a RCT (Davies et al., 2008) designed to evaluate the effectiveness of a structured group education programme and an intervention trial (Shibayama et al., 2007) designed to evaluate the effectiveness of one-on-one lifestyle counselling on quality-of-life indicated no significant differences between intervention and control groups. However, in a study conducted on 147 obese individuals (Wolf et al., 2004) using a dietician-run lifestyle programme as an intervention, seven of nine quality-of-life domains showed significant improvement ($p< 0.05$) in the participant over the control group after 12 months. Studies performed to elicit whether diabetes education is associated with improved quality of life yield inconsistent results. These inconsistent results may be attributed to the significant differences in education duration, content, and educational methods.

Group vs Individual Education

Results from systematic reviews have not shown a significant difference in HbA1c outcomes based on whether education programmes were conducted individually or in groups (Gary et al., 2003; Norris et al., 2001). Norris et al. (2001) demonstrated that group-based lifestyle interventions were more effective and positive outcomes were achieved regarding weight loss, glycaemic control, diet, and self-care behaviour. Group interventions were also more cost-effective.

A RCT designed by Trento et al. (2004) compared outcomes of group diabetes education to individual diabetes education. The study was conducted as part of a hospital-based diabetes care programme over five years. The intervention group received group education sessions three-monthly, while the control group continued with usual care consisting of one-on-one medical consultation and diabetes education sessions. The results indicated that after a five-year follow-up, diabetes knowledge, participant's problem-solving ability, and quality-of-life for the individuals engaging in group care were improved. At the end of the 5 years the control group who had received individual education and medical

consultations demonstrated waning diabetes knowledge and problem-solving ability accompanied by a deterioration in quality-of-life indicators. It was concluded that one-on-one consultation and education might not be associated with progressive improvement in knowledge, problem-solving ability, and quality-of-life perceptions. However, education delivered in a group setting with participant-centred activities may improve knowledge, glycaemic control and behaviour (Trento et al., 2004).

Peer group education has also been successful in improving clinical outcomes. The results of a systematic review of seven RCTs found no evidence that healthcare provider education was superior for knowledge, behavioural or psychological outcome measures than peer education. HbA1c was also statistically significantly lower in some peer education groups than healthcare provider-led control groups (Gatlin et al., 2017). Peer education improved the quality of life in elderly persons with diabetes, specifically in the dimensions of worries about diabetes effects, the impact of diabetes treatment, and satisfaction with diabetes treatment (Ghasemi et al., 2019).

Self-management Education

Self-management may be defined as any activity undertaken by an individual that promotes health and well-being and prevents or limits illness. Managing diabetes and preventing complications requires knowledge and extensive self-care. Individual capacity to obtain and retain required knowledge and to manage health and health behaviours are critical predictors of diabetes outcomes. Self-management education programmes are designed to therefore focus on improving the participant's capacity in these areas (American Association of Diabetes Educators, 2020). The American Association of Diabetes Educators (AADE) has developed the AADE 7 Self-Care Behaviours as a framework for diabetes education that is client-centred and promotes self-management. These behaviours include healthy eating, being active, monitoring, taking medication, problem-solving, healthy coping, and reducing risks (American Association of Diabetes Educators, 2020). This model of care combines self-management with team-based care to improve satisfaction, decrease cost, lower risks and admission rates and improve overall health. The AADE 7 Self-Care Behaviours model has been successfully used in a study where the results demonstrated improved diabetes knowledge and blood glucose control (Kolb, 2021). The National Diabetes Services Scheme (NDSS) in Australia provides access to diabetes medication and products and through the Diabetes Australia website access to support and educational materials. The Australian

Diabetes Educators Association receives funding from the NDSS to deliver services and education to professionals who are involved in educating persons with diabetes Commonwealth of Australia, Department of Health and Aged Care, 2023).

Emotional distress and depression interfere with an individual's capacity to translate health literacy or knowledge into diabetes self-care behaviours (Schinckus et al., 2018). In addition to diabetes having a positive effect on diabetes self-care, a programme may be designed to ameliorate some of the psychological and social circumstances likely to impact health behaviours. An education programme based on social cognitive theory can support participants by focusing on several skills. These skills may include adapting one's emotions, developing coping skills, promoting self-efficacy in overcoming barriers and promoting self-regulation concerning behavioural consequences (Ghoreishi et al., 2019).

Diabetes education interventions improve participant's knowledge and self-care, prevent possible complications, and improve quality of life (Inzucchi et al., 2013; Wing et al., 2011). Individuals participating in diabetes self-management education demonstrate improved physical and psychosocial outcomes (Azami et al., 2018; Kolb, 2021). Approaches to education that are participant-centred and engaging are beneficial for improving glycaemic control, self-care behaviours and quality of life (Fritzen et al., 2019; Olesen et al., 2020). Unfortunately, comprehensive therapeutic education is not necessarily readily available to all clients with T2DM due to constraints in consultation time, funding, medical reimbursement programmes and availability of skilled professionals.

Lifestyle Management Programmes

As early as the early 1950s, Keys correlated lifestyle risk factors with an increased incidence of coronary artery disease (CAD). This seminal work has become known as the Seven Countries Study (Keys et al., 1984). Further research into CAD led to establishing the currently recognised major and minor risk factors that commonly lead to the development of CAD. Lowering cholesterol by using diet, drugs or a combination of both diet and pharmacotherapy was shown to be successful in hampering, arresting or reversing atherosclerosis (Carlson & Rosenhamer, 1988; Frick et al., 1987; Rifkind, 1984) and modifying plasma lipoproteins proved to be a critical factor in altering the progression of atherosclerosis (Carlson & Rosenhamer, 1988; Rifkind, 1984). In addition, multiple risk factor reduction through alterations in lifestyle in combination with drug therapy was shown

to significantly reduce the rate of progression of atherosclerosis in coronary arteries (Multiple Risk Factor Intervention Trial Research Group, 1982).

Currently, no medical therapy addresses the primary causes of chronic diseases of lifestyle (Esselstyn, 2010; Thompson, 2020). However, lowering fasting blood sugars, total body mass, BMI and skin fold measurements decreased CAD risk (Haskell et al., 1994). Many trials incorporated some elements of lifestyle modification in their design but also included pharmacotherapy to affect changes in risk factors for CAD. By the late 1970s and early 1980s, researchers began to address some of the primary causes of hyperlipidaemia and CAD by assessing the effects that diet and other lifestyle changes may have on preventing, managing and reversing CAD (Ornish et al., 1990; Ornish et al., 1979; Ornish et al., 1983). A secondary effect of these changes was reduced blood sugars and weight loss, leading to improved insulin sensitivity and reversal of symptoms in clients previously diagnosed with T2DM. Results from these pioneering studies led to the development of several lifestyle programmes directed primarily at reversing or at least preventing further development of CAD.

The Complete Health Improvement Programme (CHIP)

The CHIP, now known as the Complete Health Improvement Programme, was a lifestyle intervention programme primarily designed to reverse CAD. At its inception, it was known as the Coronary Health Improvement Programme. Hans Diehl, having been largely influenced by the experience of Nathan Pritikin, was responsible for developing the CHIP. Nathan Pritikin, a non-medical inventor, had experimented with his deteriorating health and claimed that simple lifestyle changes involving the adoption of a plant-based diet, smoking cessation and a regular exercise routine could dramatically improve the clinical course of CAD, diabetes, gout, hypertension, arthritis and obesity (Monte & Pritikin, n.d.). Dr Hans Diehl, qualified with a Master's degree in public health and a doctorate in Health Science, displayed an interest in Public Health and joined Pritikin as an epidemiology researcher, investigating the impact of lifestyle interventions on hypertension (Morton et al., 2014a).

Residential programmes which aimed to enhance compliance with lifestyle alteration, such as those run at the Pritikin Centre, have proved successful in the short term but are costly. Patient's compliance with lifestyle adjustments after returning home and engaging in regular day-to-day activity proved difficult (McDougall J, 1995; McDougall & Thomas,

2014). Diehl, therefore, developed an affordable 30-day lifestyle programme that could be delivered in the community, allowing participants to make lifestyle changes within the boundaries of their day-to-day activities and their own environment. The first 16 sessions of the CHIP were delivered to 400 participants in Creston, British Columbia, over four weeks in 1988 (Morton et al., 2014a).

In 1997 Diehl recorded a CHIP conducted in Kalamazoo, Michigan, which provided access to the programme for presentation to a wider audience. This recorded programme was designed to be run by trained volunteers who acted as facilitators rather than using a live presentation conducted by Diehl (Morton et al., 2014a). Participants were advised to complete 30 minutes of aerobic exercise daily and to consume a plant-based high carbohydrate diet consisting of less than 15 per cent of calories from fat and less than 50mg per day of cholesterol. The diet contained low levels of protein (10-15 per cent), and less than 7 per cent of the carbohydrates consumed were made up of simple carbohydrates. Sugar consumption was restricted to less than ten teaspoons and salt to less than 5g per day. Participants were encouraged to drink 8-10 glasses of water daily (Diehl, 1998). The programme results were published in the American Journal of Cardiology (Diehl, 1998). This publication became the first of a series of over 40 publications describing the efficacy of CHIP.

In 1999 a project was launched in Rockford, Illinois, to make it the healthiest city in America. The city, with a population of 130 000, was to serve as a model for community-wide cultural transformation (Englert et al., 2004). Between 2000 and 2002, more than 1500 members of the Rockford, Illinois, area participated in a live-lecture 4-week CHIP programme (Englert et al., 2012). A subgroup of 758 participants diagnosed with pre-diabetes or T2DM was studied. Glucose levels improved between 5mg/dL and 30mg/dL in individuals who were and were not taking glycaemic control medication. In approximately 40 per cent of cases, individuals already taking medication could reduce medication use during the programme (Englert et al., 2012). Most of the research conducted on the CHIP has focused on the programme's effectiveness in reversing risk factors for CAD. However, over the years, it became evident that the indicators of and risk factors for T2DM were also significantly positively impacted. Volunteer-run programmes continue to be conducted globally with studies emanating from the USA, Canada, Australasia, Philippines, and Europe (Drozek et al., 2014; Kent et al., 2015; Morton et al., 2013; Rankin et al., 2012).

In 2012, the CHIP was renamed to reflect the continuing evidence that lifestyle modifications promoted through the programme effectively reduce the symptoms of several chronic lifestyle diseases, including depression and T2DM. The programme was adapted and expanded to extend the use of the same lifestyle principles to manage a broader scope of lifestyle conditions, including T2DM. In addition, a new set of video recordings were produced (Morton et al., 2014a).

The principles of lifestyle modification espoused in the CHIP have been shown to achieve similar results in disease modification and reversal in all populations where it is adopted (Diehl, 1998; Kent et al., 2013a; Morton et al., 2013). Data analysed from studies conducted in three major developed countries indicate very similar results, which demonstrate that irrespective of nationality or environmental influences, the CHIP is effective in reducing major symptoms associated with cardiovascular diseases and diabetes (Englert et al., 2012; Kent et al., 2013a; Morton et al., 2014b; Morton et al., 2013). The effectiveness of the CHIP is illustrated in the positive changes in both blood glucose and lipid values associated with compliance with the lifestyle changes promoted by the CHIP. The benefits included reversing diabetes symptoms and for preventing the complications associated with the metabolic syndrome and co-morbid hyperlipidaemia.

Several studies conducted on health education programmes which have focused on reducing the symptoms of diabetes using similar lifestyle principles expounded by CHIP have yielded similar reductions in BMI, blood glucose and blood lipid levels (Ledikwe et al., 2007; Look AHEAD Research Group, 2013). The Diabetes Prevention Programme Research Group have shown that the cumulative incidence of diabetes is reduced more using lifestyle interventions (34%) than using metformin (18%) or a placebo for at least ten years (Diabetes Prevention Program Research Group, 2009).

A summary of studies conducted along with relevant results to T2DM is provided in Table 2

Table 2

Summary of Results from Selected Research on CHIP.

Data	Literature – results of studies conducted on CHIP														
Author	Diehl	Aldana	Aldana		Kent	Aldana JOEM		Englert	Englert	Englert	Merrill		Morton	Morton	Drozek	Rankin
Date	1998	2002	2005		2013	2005		2004	2007	2012	2008		2013	2014	2014	2012
Location	Kalamazoo	Rockford, IL	Rockford, Illinois		USA	Rockford, Illinois		Rockford, IL	Rockford, IL	Rockford IL	Rockford, IL		Australia & NZ	Canada	Appalachia, Ohio	USA
Setting	Community	Worksite	Community		Community	Worksite			Community	Community	Community		Community	Community	Community	Community
Study design	Cohort	Cohort	RCT		Cohort	RCT		Cohort	Cohort	Cohort	RCT		Cohort	Cohort	Cohort	Cohort
			Experiment	Control		Experiment	Control				Experiment	Control				
Participant number	288	442	180	186	5046	64	79	242	1042	758	174	174	790	1003	225	5070
Mean age	54.7	52.1	50.4	50.8	57.3	46.1	45.9	54.5	54.1	ND	50.4		55.9	56.3	56	57.2
Gender																
Male	40%	32%	27%	29%	33.5%	14%	14%	32%	38%	49%	27%	29%	35%	32%	28%	33.4%
Female	60%	68%	73%	71%	66.5%	86%	86%	68	62%	51%	73%	71%	65%	68%	72%	66.6%

Table 2 (cont.)

Summary of Results from Selected Research on CHIP.

Data	Literature – results of studies conducted on CHIP															
Author	Diehl	Aldana	Aldana		Kent	Aldana JOEM		Englert	Englert	Englert	Merrill		Morton	Morton	Drozek	Rankin
Date	1998	2002	2005		2013	2005		2004	2007	2012	2008		2013	2014	2014	2012
Weight lost (%)																
Male	3.3%	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Female	3.0%	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
Combined	4.4%	ND	3.65%	0.10%	ND	3.25%	0.4%	ND	4.4%	ND	ND	ND	ND	ND	ND	3.2%
Change in BMI	3.18%	4.38%	3.70%	ND	3.2%	3.43%	0.60%	ND	3.07%	ND	ND	ND	ND	ND	ND	3.2%
Change in BGL	8.15%	5.06%	3.90%	2.40%	6.3%	4.00%	3.20%	ND	-7%	-14.40%	-3.6%	-0.6%	ND	3.1%	3.5%	6.1%
Diabetic	-18%	ND	ND	ND	ND	ND	ND	ND	ND	-35%	ND	ND	-3.8%	-7%	-4.1%%	ND

Table 2 (cont.)

Summary of Results from Selected Research on CHIP.

Data	Literature – results of studies conducted on CHIP															
Author	Diehl	Aldana	Aldana		Kent	Aldana JOEM		Englert	Englert	Englert	Merrill		Morton	Morton	Drozek	Rankin
Date	1998	2002	2005		2013	2005		2004	2007	2012	2008		2013	2014	2014	2012
Non-diabetic	-3%	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	-0.3%	ND	ND	ND
Diabetes reversed (%)	ND	ND	19%	0%	ND	35%	ND	ND	ND	31%	ND	ND	ND	ND	ND	ND
Total Cholesterol																
Male	-13.36%	ND	ND	ND	ND	ND	ND	14.2%	-16.0%	ND	ND	ND	ND	ND	ND	ND
Female	-9.5%	ND	ND	ND	ND	ND	ND	7.9%	-9.3%	ND	ND	ND	ND	ND	ND	ND
Combined	ND	-13.2%	-7.4%	ND	-11.1%	-8.02%	+5.6%	10.66 %	12.16%	ND	11.63%	ND	-0.76%	-11.3%	-10.3%	--11.0%
HDL																
Male	12.4%	ND	ND	ND	ND	ND	ND	-10.1%	ND	ND	ND	ND	ND	ND	ND	ND
Female	13.4%	ND	ND	ND	ND	ND	ND	-10.3%	ND	ND	ND	ND	ND	ND	ND	ND
Combined	ND	-13.31%	7.54%	ND	8.7%	6.77%	+9.3%	10.2%	ND	ND	11.84%	ND	-0.11%	-8.8%	-10.2%	-8.6%

Table 2 (cont.)

Summary of Results from Selected Research on CHIP.

Data	*Literature – results of studies conducted on CHIP*															
Author	*Diehl*	*Aldana*	*Aldana*		*Kent*	*Aldana JOEM*		*Englert*	*Englert*	*Englert*	*Merrill*		*Morton*	*Morton*	*Drozek*	*Rankin*
Date	*1998*	*2002*	*2005*		*2013*	*2005*		*2004*	*2007*	*2012*	*2008*		*2013*	*2014*	*2014*	*2012*
LDL																
Male	*15.9%*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*	*-15.6%*	*-18.5%*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*
Female	*11.1%*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*	*-7.9%*	*-9.3%*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*
Combined	*ND*	*-14.66%*	*-9.28%*	*ND*	*-13%*	*-9.58%*	*+5.9%*	*-11.26%*	*-13.29%*	*ND*	*-12.03%*	*ND*	*-0.6%*	*-12.9%*	*-10.3%*	*-13.0%*
Triglycerides																
Male	*-14.3%*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*	*-22.3%*	*-10.3%*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*
Female	*+3.0%*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*	*-4.6%*	*-1.9%*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*	*ND*
Combined	*-4.43*	*-9.76%*	*+0.2%*	*-15.4%*	*-7.7%*	*-2.53%*	*ND*	*-12.23%*	*-6.1%*	*ND*	*-9.27%*	*ND*	*-0.19%*	*-8.2%*	*-1.7%*	*-7.7%*

Note: RCT – Randomised control trial. ND – No data provided. BMI – Body mass index. BGL – Blood glucose level. HDL – High-density lipoprotein. LDL – low-density lipoprotein. A minus sign before a value denotes a percentage decrease. A plus sign before a value denotes a percentage increase. USA – United States of America. Trig. -Triglycerides. Exp. – Experiment. Comm – community-based.

CHIP Content and Structure

The CHIP has a structured curriculum covering information on the major risk factors for developing T2DM and information and support for a recognised lifestyle adjustment. The programme was developed using elements of established theories of learning. In keeping with cognitive theory, CHIP provides a significant amount of information pertinent to the lifestyle-disease processes and the potential health benefits to be gained by adjusting to an improved lifestyle (Rosenstock et al., 1988). The current version of the CHIP (at the time of this study and still being used in Australia) consisted of 18 sessions, with a duration of 90 minutes each. About half of each session is devoted to viewing pre-recorded video material, while interactive group discussions and activities, including food preparation and exercise demonstrations, make up the remaining time. An outline of the topics covered over the 18 sessions can be viewed in Table 3.

The first 11 sessions focus primarily on acquiring knowledge in keeping with the principles of the Health Belief Model and the Transtheoretical Model of Behaviour Change (Braungart et al., 2020). A significant portion of time is devoted to recounting the successes of previous CHIP participants. This involvement by previous participants provides a personal dimension to the programme. The fact that CHIP is conducted in group settings where participants are encouraged to participate in discussions or activities for up to half of their time together is in keeping with Bandura's Social Cognitive Theory of Learning (Rosenstock et al., 1988). These same factors are also crucial in providing a basis for the learner-centred approach as described in humanist theories.

The CHIP environment is designed so the participant is respected and empowered to learn and act on that learning (Braungart & Gramet, 2010). Participants are encouraged to be responsible for their health and learning and to make empowered choices about which lifestyle principles they wish to adopt.

Health Promotion Theory Underpinning the CHIP

The WHO defines health promotion as 'enabling people to increase control over, and improve, their health. It moves beyond a focus on individual behaviour towards a wide range of social and environmental interventions' (World Health Organization - Western Pacific, 2021). Several models have been developed to inform and guide health promotion and disease prevention programmes. The Health Belief Model focuses on a person's beliefs about

their health and conditions of ill health, predicting their confidence to respond and the resulting health-related actions (Champion & Skinner, 2008).

Table 3

Overview of Content Covered in Each CHIP Session

Session number	Topic
1	The rise of chronic disease
2	Lifestyle as medicine
3	The common denominator of chronic disease
4	The optimal lifestyle
5	Eat more, weigh less
6	Fibre, your new best friend
7	Disarming diabetes
8	The heart of the matter – heart healthy
9	Controlling blood pressure and discovering protein
10	Bone health essentials
11	Cancer prevention
12	Understanding your results and taking action
13	Become what you believe. Your DNA is not your destiny
14	Practicing forgiveness
15	Re-engineering your environment
16	Stress relieving strategies
17	Fix how you feel
18	From surviving to thriving

The Theory of Reasoned Action and the Theory of Planned Behaviour describe health behaviours as being determined by an individual's attitude to the behaviour (which is also impacted by social norms and environmental situations) and their intention to carry out a behaviour. Generally, positive attitudes and environments, and social norms and supports predict positive intentions that lead to positive behaviour changes (Montaño & Kasprzyk, 2008). Social Cognitive Theory describes the influence of the environment and

society on a person's health behaviours. Vicarious learning and social support systems are used to instil a perception of self-efficacy, positively affecting behaviour change. The most common model cited to describe behaviour change is the Transtheoretical Model, otherwise known as the Stages of Change Model. It describes a person's readiness to change behaviour as a process occurring in stages, beginning with pre-contemplation, then moving through contemplation, preparation, action, maintenance and finally termination, at which stage the person has no desire to return to previous negative behaviours (Prochaska et al., 2008).

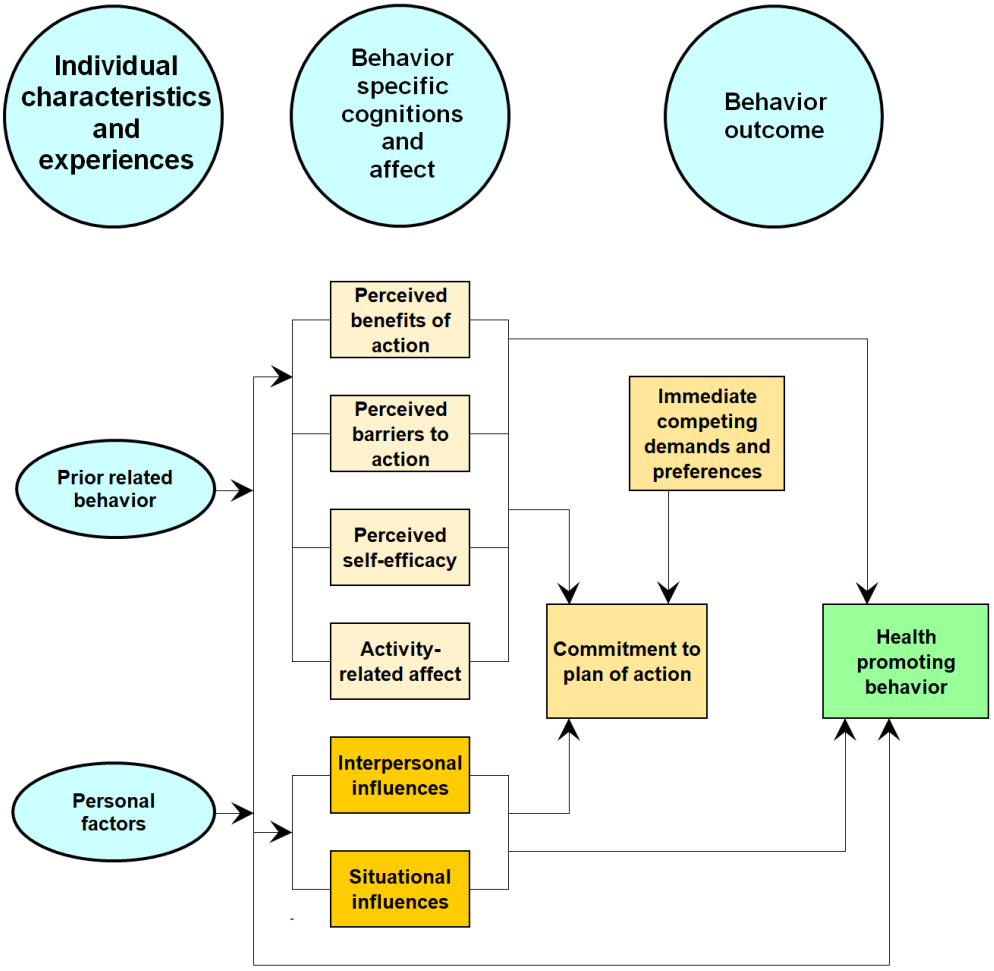
The model most accurately portraying the philosophy and process of the CHIP is the Health Promotion Model (HPM). The model was developed by Nola Pender, Professor Emeritus of Nursing at the University of Michigan, with numerous studies on health-promoting behaviours as its foundation. It was published in 1982 but was revised in 1996 to accommodate some changes in theoretical perspectives (Pender, 2010). The HPM was established as a means for nurses to comprehend the relationship between the determinants of health and the education and behavioural counselling required to promote behavioural change that would effectively improve health outcomes. It is based on a Reciprocal Interaction philosophy where humans are viewed as beings that interact reciprocally with their environment in such a way that best meets their needs. The theoretical roots include Expectancy Value Theory and Social Cognitive Theory. Expectancy Value Theory is based on the fact that individuals will perform behaviours and interactions perceived as valuable and plausible. In contrast Social Cognitive Theory determines that to alter behaviour, one must first have an alteration in thinking (Pender et al., 2011). The individual's belief about health and illness, as described in the Health Belief Model (Champion & Skinner, 2008) and their attitude and subjective norms depicted in the Theory of Reasoned Action/Planned Behaviour Model, are also reflected (Montaño & Kasprzyk, 2008) in the philosophy and process of CHIP.

The central focus of the HPM model is on eight beliefs (cognitions) which include:

- Perceived benefits of action,
- Perceived barriers to action,
- Perceived self-efficacy,
- Activity-related affect (emotions surrounding behaviour),
- Interpersonal influences (social norms, vicarious learning, and social support),
- Situational influences (compatibility with life context or environment, aesthetics),

- Commitment to the planning of action,
- Immediate competing demands and preferences (alternative behaviours that compete for a person's attention and time) (Pender et al., 2011).

Figure 1
Depiction of Health Promotion Model Adapted from Pender et al. (2011).



The Behavioural Outcome or Health Promoting Behaviour is the desired behavioural endpoint or health outcome. The assumptions on which the HPM is based reflect the perspective and behaviours of the client and the health professional. These assumptions include the following:

- Individuals seek to create living conditions through which they can express their unique human health potential.

- Individuals have the capacity for self-awareness and reflection, including the ability to assess their own competencies.
- The individual values growth and they seek to achieve an acceptable balance between change and stability.
- Individuals seek self-control concerning their behaviour.
- Individuals reciprocally interact with the environment, thus transforming and being transformed.
- Health professionals form part of the interpersonal environment and exert influence on individuals through interactions.
- Self-initiated interactions with the environment and other individuals, including health professionals is essential for health behaviour change (Pender et al., 2011).

Individual characteristics and experiences refer to factors that influence and shape health behaviours and include 'Prior related behaviours' (frequency of the same or similar behaviours in the past) and 'Personal factors' (biological, psychological, sociocultural). Therefore, previous behaviour and inherited or acquired characteristics impact a person's beliefs and actions and the emotions attached to those actions (Pender et al., 2011).

Individuals participating in CHIP will have characteristics, experiences and personal factors that will influence their readiness and ability to make behavioural changes. The mechanism through which individuals interpret their experiences which are somewhat influenced by their culture and previous experience, are also referred to by Donovan (1991) as 'interpretive structures'. In the context of health, 'interpretative structures' may be defined as how clients and society at large perceive or attach meaning to health or the absence of health. Therefore, health education performed as part of the CHIP will pass through each client's interpretative structures. Clients are generally not ignorant. Most have solid ideas or beliefs about their health or disease based on information and knowledge gleaned from various sources. Difficulty with adherence will arise where contradictions in information sources exist, when a client's ideas and beliefs do not concur with those of the medical professional they are dealing with or with the general medical ideology on a specific topic (Donovan, 1991; Donovan et al., 1989). The goal of a health education or self -management programme is, therefore, through a combination of learning experiences, to reframe or remodel a client's interpretive structures in such a way that generates an improvement in health

behaviours and increases self-efficacy. The CHIP's aim is not merely to prevent disease on the secondary or tertiary level but to provide overall access to a better quality of life.

Conclusion to the Chapter

The incidence and prevalence of T2DM are reaching epidemic proportions worldwide. It has been well-recognised for decades that obesity, particularly abdominal obesity, is a significant risk factor for the development of T2DM.

Obesity and the related accumulation of fat in body tissues play a significant role in developing insulin resistance, contributing to beta cell failure, and indirectly resulting in the overproduction of glucose in the liver. It is also well-recognised that obesity and other risk factors associated with the development of T2DM can be attributed to the Western lifestyle, which is mainly sedentary and promotes the consumption of foods high in fat, animal protein and refined carbohydrates. A diagnosis of T2DM also increases the risk for other chronic illnesses, particularly cardiovascular disease.

Lifestyle as an approach to the prevention and management of this chronic disease has been studied extensively, and guidelines for diabetes education advocate the approach as the first-line therapy option in managing T2DM (Colagiuri et al., 2009; American Diabetes Association, 2019; Blonde et al., 2022).

Several studies have been conducted on the efficacy of lifestyle as prevention and management of chronic disease; however, few relate directly to T2DM, and those that do, are mostly made up of cohort studies (Diehl, 1998; Englert et al., 2004; Englert et al., 2012; Kent et al., 2013b; Morton et al., 2014b; Rankin et al., 2012). Previous RCT studies conducted using CHIP included participants with T2DM but were not explicitly designed to study the effect of the CHIP on T2DM (Aldana et al., 2005a; Aldana et al., 2005b; Merrill & Aldana, 2009).

The current model used by most professionals involved in diabetes education has drawbacks relating to consistent efficacy and cost-effectiveness (Colagiuri et al., 2009; Conn et al., 2007; Duke et al., 2009; Loveman et al., 2003; Loveman et al., 2008). The CHIP is the only community-based and volunteer-run programme that has consistently improved fasting blood glucose levels by promoting an active, temperate lifestyle including a plant-based diet, low in fat, almost devoid of cholesterol and high in unrefined carbohydrates.

Whether the fasting glucose results in previous CHIP studies translated to better glycaemic control is debatable. Fasting blood glucose may not be an accurate predictor of

long-term glycaemic control. There is a potential need for improved accuracy in accounting for blood glucose levels throughout the 24-hour period. Most previous lifestyle studies and RCTs have focused on either exercise alone, diet alone or a combined dietary and exercise programme where the regime has been prescribed and highly structured.

Therefore, the aim of this thesis is to conduct an RCT where the education programme is self-directed, client centred, and an all-of-health lifestyle education programme. HbA1c will be used in addition to FBG to obtain a more accurate reflection of 24-hour glycaemic control. In addition, adherence to recommended lifestyle interventions and quality of life determinants will be assessed.

Publications Relating to the Chapter

Two publications were authored by the candidate from the content of this literature review. These publications contribute to the body of knowledge available to health professionals who are seeking peer reviewed information on diabetes, including the pathophysiology, potential complications and patient management. The first publication was published in 2017 and focuses on the pathophysiology associated with the development of T2DM. The second publication, published in 2021 provides a general overview of the types of diabetes, the associated risk factors, complications and management of the condition. The major contributor and lead in both publications was Linda Cloete.

Why you should read this article:

- To learn about the types of diabetes mellitus and associated presentation
- To refresh your knowledge of the complications that are associated with diabetes
- To understand the nurse's role in managing patients with diabetes

Diabetes mellitus: an overview of the types, symptoms, complications and management

Linda Cloete

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Abstract

The incidence of diabetes mellitus is rapidly increasing, and this condition often results in significant metabolic disease and severe complications. Nurses have a crucial role in monitoring, educating and supporting people with diabetes, as well as their families and significant others. This article provides an overview of the main types and common symptoms of diabetes, its acute and long-term complications and its management. It also outlines the nurse's role in diabetes care, which frequently includes assessing and empowering patients.

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Keywords

blood glucose, clinical, diabetes, diabetic foot ulcers, diabetic ketoacidosis, glycaemic control, hyperglycaemia, hypoglycaemia, insulin, type 1 diabetes, type 2 diabetes

The incidence of diabetes mellitus – particularly type 2 diabetes – is growing to epidemic proportions, contributing to the global burden of disease (World Health Organization 2016). Diabetes often results in significant metabolic disease and a range of severe complications and co-morbidities. Research has also shown that there is a link between diabetes and a variety of mental health issues, including those specific to the experience of living with diabetes such as 'diabetes distress' (Robinson et al 2018).

Nurses at all levels and in all settings will be involved in diabetes care, so it is important that they understand the pathological processes involved in diabetes, the appropriate management strategies and the support needs of patients. However, some patients have reported that nurses may lack knowledge and an understanding of diabetes (Cardwell et al 2016), and many nurses themselves have said that they lack knowledge of diabetes care, the ability to recognise, manage and prevent the common complications of diabetes, and the skills required to support patients and their families (Modic et al 2014, Jones and Ndebu 2018). This article aims to support nurses by providing an overview of the types, complications and management of diabetes.

Types of diabetes mellitus and associated symptoms

Type 1 diabetes accounts for between 5% and 10% of all cases of diabetes (Centers for Disease Control and Prevention 2021) and it is more common in younger people than in older people. The primary presentation in type 1 diabetes is a lack of insulin secretion in response to a postprandial rise in blood glucose levels. This lack of insulin secretion can result from the effects of a life event – for example illness or stress – which triggers a genetically predisposed autoimmune dysfunction of pancreatic beta cells (International Diabetes Federation 2020, World Health Organization 2021).

Type 2 diabetes accounts for ≥90% of all cases of diabetes and is a long-term condition typically seen in older adults, but it is increasingly seen in younger adults and children (Pulgaron and Delamater 2014). In type 2 diabetes, the accumulation of fat in the liver and muscle cells causes insulin resistance in those cells. Before they develop type 2 diabetes, patients first develop a degree of insulin resistance compensated for by increased pancreatic secretion of insulin. When pancreatic beta cells can no longer respond to the increasing demand

for insulin, beta-cell failure occurs (Plows et al 2018), resulting in the need for insulin supplementation.

Type 2 diabetes is generally associated with some genetic predisposition to alterations in fat storage sites, which explains why some people who have a normal body weight can still develop type 2 diabetes (Sinn et al 2019). Other non-modifiable risk factors include family history and ethnicity, with the rate of type 2 diabetes in the UK being three to five times higher among minority ethnic communities than in the white British population (Goff 2019). Several other risk factors, including obesity, disruption of the sleep cycle or circadian rhythm anomalies, and a lack of sufficient regular physical activity, can have a compounding effect on non-modifiable risk factors (Dendup et al 2018).

Gestational diabetes occurs when pregnant women develop spontaneous hyperglycaemia due to impaired glucose tolerance (Plows et al 2018). Around 80% of cases occur in women with some degree of genetically predisposed insulin resistance, which is compounded by the insulin resistance that is normal in pregnancy (Plows et al 2018, National Institute for Health and Care Excellence (NICE) 2020a). Other risk factors for gestational diabetes include all risk factors for type 2 diabetes, with the addition of low or high maternal birth weight, advanced maternal age, excessive maternal gestational weight gain, and conditions associated with insulin resistance such as polycystic ovary syndrome (Plows et al 2018, NICE 2020a). Box 1 lists the common signs and symptoms of diabetes mellitus.

Complications of diabetes mellitus

Acute complications

Hypoglycaemia is characterised by a blood glucose level of <4.0mmol/L (Joint British Diabetes Societies for Inpatient Care 2021) and it is the most common acute complication of diabetes, particularly type 1 diabetes (Ceriello et al 2019). Hypoglycaemia usually occurs as a consequence of the administration of insulin, but may also occur as a consequence of the administration of sulphonylureas, a class of medicines that are widely used in type 2 diabetes to increase pancreatic insulin secretion. Greater glycaemic variability (large changes in a person's blood glucose levels) is associated with more frequent hypoglycaemic episodes, so reducing this variability is important in preventing hypoglycaemia (Ceriello et al 2019).

Hyperglycaemia is the main cause of diabetes complications, so glycaemic control is fundamental (Nathan 2014). Hyperglycaemia is defined as a blood glucose level of >8.5mmol/L, while a blood glucose level of >10mmol/L is considered to be the threshold at which there is a significant risk of complications (Kumar et al 2010). These complications include diabetic ketoacidosis – a condition where, due to the lack of insulin, the person develops an elevated blood ketone level, which can potentially result in metabolic acidosis, coma and death (Gosmanov and Kitabchi 2018). Diabetic ketoacidosis is diagnosed if a person's blood ketone level is ≥3mmol/L, if their blood glucose level is >13.9mmol/L, or if a person has a known diagnosis of diabetes and a blood pH of <7.3 (Gosmanov and Kitabchi 2018). People with diabetes who are unwell or present with an elevated blood glucose level must be tested for blood ketones, and if this is ≥1.6mmol/L, the person requires immediate referral to their diabetes carer or team (NHS 2020).

Another potentially life-threatening complication of hyperglycaemia is hyperosmolar hyperglycaemic state, which is rare but typically seen in people with undiagnosed or suboptimally managed type 2 diabetes (Joint British Diabetes Societies Inpatient Care Group 2012). Typical signs and symptoms include excessive thirst and urination, visual disturbances and altered cognition. A person in hyperosmolar hyperglycaemic state will have a blood glucose level of >33.3mmol/L, blood ketone level of <3mmol/L, a blood pH of >7.3 and/or an osmolality of ≥320mosmol/kg (Joint British Diabetes Societies Inpatient Care Group 2012). Any person presenting with a blood glucose level of ≥22.2mmol/L requires urgent medical assessment and intervention (Joint British Diabetes Societies Inpatient Care Group 2012).

Box 1. Common signs and symptoms of diabetes mellitus

Both type 1 and type 2 diabetes
- Polyuria
- Polydipsia
- Fatigue
- Dizziness
- Mood changes
- Skin infections, itching
- Suboptimal wound healing
- Thrush
- Excessive hunger
- Headaches
- Blurred vision
- Glucose in the urine

Specific to type 1 diabetes
- Unexplained weight loss
- Abdominal pain

Specific to type 2 diabetes
- Increased weight
- Pain and/or tingling in the lower extremities
- Often there are no symptoms

Gestational diabetes
- Polyuria
- Polydipsia
- Fatigue
- Blurred vision
- Increased frequency and/or severity of nausea
- Frequent skin, bladder and vaginal infections
- Glucose in the urine

(Adapted from Atkinson et al 2014, Bandyk 2018, Plows et al 2018, International Diabetes Federation 2020)

Long-term complications

Most long-term complications of diabetes can be described as either macrovascular or microvascular in origin, with microvascular complications being more prevalent (Papatheodorou et al 2018). Macrovascular complications include cardiovascular disease, stroke and peripheral vascular disease, while microvascular complications include neuropathy, nephropathy and retinopathy.

The microvasculature has an essential role in maintaining blood pressure and providing oxygen and nutrients to tissues. Pathological changes seen in diabetes cause a thickening of the basement membrane, resulting in weak vessel

walls, reduced vessel compliance, impaired blood flow and increased permeability. This subsequently leads to reduced tissue nourishment and oxygenation (Roy and Kim 2021). Over time, the ensuing diabetic microangiopathy causes hypertension, delayed wound healing, nephropathy, retinopathy, neuropathy and several other hypoxia-related conditions.

Cardiovascular disease and stroke

Cardiovascular disease is the leading cause of death in people with diabetes (International Diabetes Federation 2020). Hyperglycaemia contributes to the plaque rupture primarily responsible for occlusive arterial disease (Papatheodorou et al 2018). Other significant risk factors for cardiovascular disease include high levels of circulating free fatty acids and triglycerides typically associated with obesity and altered glucose metabolism (Papatheodorou et al 2018).

Diabetic cardiomyopathy leading to cardiac failure is a common cardiac complication of diabetes (Jia et al 2018), as is atrial fibrillation linked to autonomic neuropathy (Karam et al 2017). Around 25% of people with diabetes develop persistent atrial fibrillation (Karam et al 2017), which increases their risk of stroke. People with diabetes have higher stroke-related morbidity and mortality and a higher incidence of post-stroke dementia than people who do not have diabetes (Bangen et al 2015).

Diabetic neuropathy and diabetic foot

Diabetic neuropathy affects around half of people with diabetes and is potentially life-threatening, since it affects both the autonomic and peripheral nervous systems.

Autonomic neuropathy commonly leads to postural hypotension, loss of sinus rhythm, resting tachycardia, painless myocardial infarction, abnormal cardiac reflexes and sudden death (Vinik et al 2018). Cardiac ischaemia as a complication of diabetes is often atypical in that it presents as general weakness, fatigue or congestive cardiac failure caused by undiagnosed myocardial infarction rather than as angina (Vinik et al 2018).

Peripheral neuropathy presents as a symmetrical polyneuropathy (motor, sensory and autonomic dysfunction), which leads to muscle atrophy and causes functional anatomical alterations such as hammertoes and subluxation or dislocation of the tarsal bones. These anatomical alterations may result in a 'rocker bottom' appearance of the foot called Charcot's foot, leading to high-pressure zones on the feet that contribute to pressure ulcers (Bandyk 2018). Muscle atrophy causes the loss of arch support and the foot becomes flatter and broader. This makes it challenging for the person to find shoes that suit their altered foot shape and pressure distribution (Bandyk 2018). A lack of sensation and proprioception predisposes the person to generalised traumatic skin injury, which is compounded by the fact that peripheral autonomic dysfunction inhibits microvascular thermoregulation and therefore generates dry, flaky skin and fissures (Coon et al 2017).

Diabetic foot is characterised by foot ulcers caused by a combination of peripheral vascular disease, peripheral artery disease and neuropathy (Costa et al 2017). Suboptimal arterial supply results in ischaemic ulcers, severe pain and possibly gangrene. Infection is a significant factor in delayed wound healing and often leads to generalised cellulitis or necrotising fasciitis (Hitam et al 2019). Diabetic foot is the main reason for non-traumatic lower limb amputation (Font-Jiménez et al 2016).

Other long-term complications of diabetes

The risk of retinopathy in diabetes increases with the severity of hypertension and hyperglycaemia (Jin et al 2018). Oxidative damage to retinal mitochondria leads to retinal cell apoptosis. Cataracts resulting from diabetes generally occur before the age of 30 years. Maculopathy is another potential cause of vision loss in people with diabetes (Stitt et al 2016).

Diabetes is the most common cause of renal impairment (Plows et al 2018). Hyperglycaemia and hypertension are common risk factors for renal impairment, with elevated low-density lipoprotein (LDL) cholesterol and triglycerides causing lipid accumulation leading to renal disease (Yuan et al 2017).

Diabetes-related gastrointestinal dysfunction and motor dysfunction are further long-term complications of diabetes and can affect glycaemic control by delaying gastric emptying (Mussa et al 2018, Ceriello et al 2019). Diabetes is also associated with gallstones, inflammatory bowel disease and *Clostridium difficile* infections, which typically present with diarrhoea symptoms and abdominal pain (Kang et al 2019) and increase the risk of faecal incontinence (Eliakim-Raz et al 2015).

Complications of gestational diabetes

Pregnant women with gestational diabetes are at risk of developing complications of diabetes during pregnancy. Gestational diabetes also increases the risk of issues with the birth and stillbirth, and can lead to health complications for the child (Plows et al 2018). In addition, the neonate is more likely to be either large or small for gestational age. Postnatal hypoglycaemia is common and can lead to brain injury if not treated appropriately. The child will be at increased

Key points

- The primary presentation in type 1 diabetes is a lack of insulin secretion in response to a postprandial rise in blood glucose levels
- In type 2 diabetes, the accumulation of fat in the liver and muscle cells causes insulin resistance in those cells
- Acute complications of diabetes include hyperglycaemia, hypoglycaemia, diabetic ketoacidosis and hyperosmolar hyperglycaemic state
- Long-term complications of diabetes include diabetic neuropathy, diabetic foot and an increased risk of stroke
- Nurses are usually involved in the assessment of patients with diabetes, as well as empowering them to manage their condition

risk of obesity in childhood and cardiovascular disease in adulthood (Plows et al 2018). For the mother, gestational diabetes and the risk of complications may continue after birth.

Management of diabetes mellitus

Glycaemic control

The priority in diabetes management is to achieve glycaemic control to prevent complications (Nathan 2014). Intensive management aiming to achieve blood glucose levels as close as possible to normoglycaemic values has been shown to reduce mortality and decrease the risk of complications (UK Prospective Diabetes Study Group 1998, Nathan 2014, Orchard et al 2015).

Fasting blood glucose levels measured by a pathology laboratory provide accurate information on blood glucose levels at the time of testing. Glycated haemoglobin ($HbA1_c$) is a measure of the haemoglobin uptake of glucose and provides an indicator of glycaemic control over a period of 2-3 months. Table 1 shows the typical values for these two glycaemic control indicators.

People with diabetes often self-monitor their blood glucose levels using capillary blood glucose measurement. Self-monitoring is particularly common in those who self-administer insulin, since it enables them to adjust their insulin doses to their needs. People taking oral hypoglycaemic agents may choose to self-monitor as a means of adjusting their diet and exercise levels to achieve improved glycaemic control (Chester et al 2018).

Insulin therapy and lifestyle management

In type 1 diabetes and some genetic types of diabetes, insulin replacement therapy is necessary and is the focus of glycaemic control. Continuous subcutaneous insulin pump therapy and real-time glucose monitoring devices, including flash sensors, may be useful and safer alternatives when glycaemic control is not regularly achieved by subcutaneous insulin injections (Hunt 2015). Lifestyle management is essential as an adjunct to insulin therapy to minimise co-morbidities and complications (Nathan 2014, NICE 2021).

In type 2 diabetes and gestational diabetes, weight management and changing suboptimal lifestyle habits are essential to achieving glycaemic control (Plows et al 2018, Strelitz et al 2019). Medicines can be prescribed to increase insulin sensitivity and glucose uptake. Supplemental insulin is prescribed in type 2 diabetes when insulin hypersecretion has led to pancreatic beta-cell failure, and in gestational diabetes if required (Plows et al 2018). Lifestyle recommendations include smoking cessation, weight management, dietary adjustments and increased daily physical activity (Strelitz et al 2019, NICE 2020b). In people with type 2 diabetes, a weight reduction of >5% of the initial body weight has been shown to improve glucose metabolism and reduce hypertension and other metabolic risk factors (Strelitz et al 2019).

Diet

Dietary recommendations for all types of diabetes include an individualised eating plan consisting of nutrient-rich foods rather than calorie-rich foods. Nutritional guidelines recommend increasing the intake of high-fibre fruit and vegetables and reducing the intake of processed foods, high-fat foods, red and processed meat, and sugary foods (Diabetes UK 2018). Individualised dietary goals that account for the person's lifestyle, dietary preferences, nutritional needs and socioeconomic circumstances are essential to promote adherence.

To avoid hypoglycaemic episodes, people with type 1 or type 2 diabetes and women with gestational diabetes who receive insulin therapy need to manage their dietary intake, in particular carbohydrates, in conjunction with insulin intake and exercise. The Dose Adjustment for Normal Eating (DAFNE) structured course can support these people to understand how to adjust their self-administered insulin dose based on their carbohydrate intake (Diabetes UK 2019). This, in addition to introducing dietary modifications gradually, can promote adherence to treatment and glycaemic control (Diabetes UK 2018).

Exercise

Diabetes is associated with a loss of muscle mass and quality of muscle fibre, leading to reduced upper and lower body strength and, in people with type 2 diabetes, a tendency to central adiposity (abdominal fat deposition) (Dahjio et al 2016). Exercise can alleviate this loss of strength and, in the case of type 2 diabetes, improve insulin sensitivity through improved muscle mitochondrial function. Other benefits of exercise include enhanced glycaemic control, reduced insulin requirements, improved blood lipid levels and improved endothelial function (Dahjio et al 2016). Even light-intensity physical movement and a reduction in sedentary lifestyle have been shown to improve physical and psychological health, quality of life, well-being, balance and functional status in older people generally (Dempsey et al 2016).

Exercise recommendations for people with diabetes are to undertake at least two 20-minute sessions per week of some sort of resistance training in addition to 120-150 minutes per week of aerobic activity such as walking or swimming (Sigal et al 2018).

Medicines

Medicines may be necessary to reduce some risk factors for complications of diabetes. Several studies have shown that blood pressure management is essential in reducing the risk of stroke in people with diabetes (UK Prospective Diabetes Study Group 1998, Royal College of Physicians Intercollegiate Working Party 2016), so antihypertensives may be required to keep an individual's blood pressure below 130/80mmHg (Passarella et al 2018).

Table 1. Typical values for glycaemic control tests

	Fasting blood glucose levels	Glycated haemoglobin ($HbA1_c$)
Normoglycaemic values	<5.6mmol/L	<6.5%
Values in diabetes mellitus	>7.0mmol/L	≥6.5%

(Adapted from American Diabetes Association 2014)

NICE (2021) guidelines recommend optimising the lipid profile of people with type 1 diabetes by using statins and/or ezetimibe, to reduce the risk of cardiovascular disease. The administration of statins and ezetimibe in combination with dietary interventions has also been shown to reduce cardiovascular risk in people with type 2 diabetes by lowering LDL cholesterol (Cannon et al 2015, Ramos et al 2018).

Role of the nurse in diabetes care

In the UK and many other countries, nurses have become increasingly involved in diabetes management, assuming responsibility for hospital and community care, being involved in screening for and managing complications, and, for some nurses, being involved in prescribing medicines (Nikitara et al 2019). For the most part, the role of the nurse is to monitor, advise and support people with diabetes, as well as to educate them on the self-management of their condition. Two of the main elements of diabetes care are assessment and empowerment.

Assessment

A comprehensive assessment of an individual's physical, psychological and social care needs must be performed before addressing any health issues (Hambling et al 2019). Table 2 shows the initial and ongoing assessments required in diabetes care. For a person newly diagnosed with diabetes, extensive assessment for potential complications and co-morbidities is required. For a person with an established diagnosis of diabetes, regular assessments are required to monitor glycaemic control and screen for complications and co-morbidities. Nurses will be involved in performing weight and blood pressure measurements, reviewing blood test results, reviewing self-monitoring records, providing wound care, making referrals, following up results, and planning interventions and follow-up visits.

Empowerment

The patient's adherence to their management plan largely depends on how empowered they feel.

Table 2. Initial and ongoing assessments required in diabetes care

Assessment	Frequency
Fasting blood glucose levels and glycated haemoglobin ($HbA1_c$)	Review blood test results at every appointment (every three to six months)
Blood lipids – low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol and triglycerides	Review blood test results at every appointment while abnormal, review annually while normal
Blood pressure	Measure at every appointment
Patient's self-monitoring records	Review at every appointment
Skin – wound care	Assess skin and manage wounds at every appointment
Weight, diet, nutrition	Assessment and counselling at every appointment, usually after an initial assessment by a dietitian or nutritionist
Physical activity, exercise	Counselling and prescription at every appointment; some patients may need to be seen by a physiotherapist or occupational therapist
Renal – serum creatinine, albuminuria and glomerular filtration rate	Annual urinalysis, or more frequently if necessary
Orthostatic hypotension, incontinence and erectile dysfunction	Annual assessment, or more frequently if necessary
Eyes – retinopathy, maculopathy and cataracts	Annual ophthalmoscopy, or more frequently if necessary
Vascular – arterial and venous insufficiency	Annual Doppler ultrasound and toe brachial index measurement, or more frequently if necessary
Dental – periodontitis	Annual assessment by a dentist or periodontist, or more frequently if necessary
Neuropathy, motor function and anatomy of the feet, pressure offloading and footwear	Annual assessment by a podiatrist, or more frequently if necessary. This is sometimes performed by a GP or a nurse practitioner
Endocrine	Patients with paediatric or resistant hyperglycaemia, frequent hypoglycaemic episodes or complicated metabolic effects need to be assessed every three to six months by an endocrinologist

(Adapted from Nikitara et al 2019, National Institute for Health and Care Excellence 2020c)

Empowering patients involves (Nikitara et al 2019):

- The collaborative development of person-centred care goals that match the person's physical, psychological and social needs.
- Access to education that will enhance the person's knowledge, skills and confidence.
- Supportive care that will encourage the person to self-manage their condition.

The role of the nurse includes fostering empowerment, which will enhance the person's adherence to their management plan and their confidence to self-manage. For people who are disabled by diabetes, nurturing support from nurses can alleviate some of the psychological burden that accompanies physical disability. The nurse's role in supporting people with diabetes also includes addressing the needs of their families and significant others (Nikitara et al 2019).

Conclusion

Diabetes is associated with a range of complications and co-morbidities. Nurses at all levels in all settings will be involved in diabetes care, so it is important that they have the knowledge and skills required to recognise, manage and prevent the common complications of diabetes, and to support patients and their families.

Essential aspects of the nurse's role in diabetes care include ensuring regular and comprehensive patient assessments, providing patient education and empowering patients to self-manage their condition.

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CPD CONTINUING PROFESSIONAL DEVELOPMENT

LONG-TERM CONDITIONS

The role of obesity in the onset of type 2 diabetes mellitus

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Abstract

The onset of type 2 diabetes mellitus is associated with various modifiable and non-modifiable risk factors, including lifestyle factors. Obesity is the principal lifestyle factor associated with an increased risk of developing type 2 diabetes. It is essential for nurses to have an understanding of the pathophysiology associated with factors that contribute to an increased risk of type 2 diabetes, particularly those associated with obesity. Nurses who have an understanding of the interaction between obesity and the onset of type 2 diabetes are better equipped to discuss the importance of weight loss and other necessary lifestyle adjustments in the prevention and management of obesity and diabetes associated with obesity, to implement evidence-based practice and to support patients to manage their health effectively.

Keywords

diabetes, diabetes mellitus, insulin resistance, obesity, pathophysiology, type 2 diabetes

Aims and intended learning outcomes

The aim of this article is to enable nurses to understand the role of obesity in the onset of type 2 diabetes mellitus. After reading this article and completing the time out activities you should be able to:

- Describe common modifiable and non-modifiable risk factors for the development of type 2 diabetes.
- Explain how obesity contributes to the following metabolic alterations associated with type 2 diabetes:
  - Resistance to the action of insulin in peripheral tissues, particularly in muscle and fat, but also in liver cells.
  - Defects in insulin secretion, particularly in response to a glucose stimulus.
  - Increase in glucose production by the liver.
- Discuss the importance of weight loss, physical activity and other lifestyle adjustments in the prevention and management of diabetes.

Relevance to The Code

Nurses are encouraged to apply the four themes of The Code: Professional Standards of Practice and Behaviour for Nurses and Midwives to their professional practice (Nursing and Midwifery Council (NMC) 2015). The themes are: Prioritise people, Practise effectively, Preserve safety, and Promote professionalism and trust. This article relates to The Code in the following ways:

- Nurses are enabled to practise effectively by improving their understanding of the link between obesity and the onset of type 2 diabetes.
- The Code states that nurses must ensure people's physical, social and psychological needs are recognised, assessed and responded to. The article equips nurses to discuss the importance of weight loss and necessary lifestyle adjustments in the prevention and management of type 2 diabetes.
- The Code indicates that nurses must focus on promoting well-being and preventing ill health. The two most

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effective measures to improve insulin sensitivity are weight loss and physical activity. Preventing obesity through the promotion of a healthy lifestyle reduces the potential for insulin resistance.

» The Code states that nurses should act in partnership with those receiving care, helping them to access relevant information and support when they need it. The article encourages nurses to reflect on local, regional and national health education programmes.

Introduction

The term diabetes mellitus is derived from diabainen, which means 'to siphon or pass through' and mellitus, which means 'sweet' (Oxford Dictionaries 2016a). It relates to the passing of 'sweetened' urine, a symptom of a chronic disorder of carbohydrate metabolism discernible by high blood glucose levels. Diabetes mellitus may be caused by failure of the pancreas to produce insulin (type 1 diabetes) or by defects in insulin action, for example defects in insulin sensitivity and the disparity between the physiological demand for insulin and pancreatic supply, which are common in type 2 diabetes and gestational diabetes (American Diabetes Association (ADA) 2016).

Incidence and burden of type 2 diabetes

The incidence of type 2 diabetes continues to rise in developed and developing countries and is predicted to pose one of the most serious public health challenges of the 21st century (Albright 2007, Chen et al 2012). It is projected that diabetes will be the seventh leading cause of death globally by 2030 (Mathers and Loncar 2006). In the UK, it is estimated that 3.3 million people (6.2% of the population) have diabetes (Diabetes UK 2016). Each year, £13.8 billion is spent in the UK on treating people with diabetes mellitus (Kanavos et al 2012). Diabetes care is estimated to account for at least 5% of UK healthcare expenditure, and up to 10% of NHS expenditure (National Institute for Health and Care Excellence (NICE) 2015a).

TIME OUT 1

Look up the prevalence statistics for type 2 diabetes in the UK (Diabetes UK 2016). What is the prevalence of this condition in your country, region or local healthcare area? Search for statistics indicating the percentage of individuals with a diagnosis of type 2 diabetes who are also overweight or obese. Is there any association between these conditions? Discuss your thoughts with a colleague.

TIME OUT 2

Reflect on the health costs associated with type 2 diabetes. What additional personal and social costs might be involved with a diagnosis of the condition? List any other potential costs.

Recognised diagnostic criteria for diabetes are outlined in ADA (2016) guidelines. The guidelines provide criteria for blood glucose levels considered normal (normoglycaemic), impaired and indicative of diabetes in relation to plasma glucose and glycated haemoglobin (HbA1c) testing (Table 1) (ADA 2016).

Risk factors for type 2 diabetes

Risk factors for the development of type 2 diabetes can be divided into two categories: non-modifiable and modifiable risk factors.

Non-modifiable risk factors

Non-modifiable risk factors include age, cultural background, family history of diabetes or a previous history of gestational diabetes. Individuals who are over 40 years old have an increased likelihood of developing type 2 diabetes compared to those under 40 years old. Individuals over the age of 25 years, who are of South Asian, Chinese, African-Caribbean, black African or Pacific Islander descent have an increased risk of developing the condition compared to Caucasians (NICE 2012). Individuals are increasingly likely to develop type 2 diabetes when there is a family history of the condition, or where a relative has previously been diagnosed with gestational diabetes (ADA 2014).

Modifiable risk factors

The principal modifiable risk factors shown to increase the risk of type 2 diabetes include:

» Obesity, defined as a body mass index (BMI) ≥30.

» A BMI ≥25 accompanied by a high

percentage of abdominal fat.

- Hypertension, diagnosed as a systolic blood pressure >140mmHg and/or a diastolic pressure >90 mmHg.
- A lack of physical activity, defined as less than a total of 150 minutes of sustained moderate exercise per week, preferably with episodes of physical activity separated by no more than two days at a time.
- Cigarette smoking and elevated cholesterol levels with a high-density lipoprotein (HDL) cholesterol level of <35mg/dL (0.90mmol/L), or a triglyceride level of greater than 250mg/dL (2.82mmol/L), are other significant modifiable risk factors (Craig and Mindell 2006, NICE 2012).

Genetic risk factors

Genetic risk factors for type 2 diabetes may be monogenic or polygenic. Monogenic risk factors for diabetes generally result from defects in the pathways that regulate insulin action in muscle, liver and fat cells, or from defects in insulin secretion in pancreatic beta cells. Monogenic defects are rare, while polygenic forms of type 2 diabetes are more common (Ahlqvist et al 2011).

The pathophysiology of polygenic forms of type 2 diabetes is complex, with genetic and environmental factors contributing to development of the condition. The presentation of the condition is also complex, involving resistance to insulin in muscle, fat and liver cells, as well as defects in the secretory function of the pancreatic beta cells associated with increased gluconeogenesis (the production of glucose from non-carbohydrate sources, mainly fats, protein and lactate) in the liver (Ahlqvist et al 2011). The term 'insulin resistance' is used to indicate the presence of an impaired biological response to exogenously administered or endogenously secreted insulin (ADA 2014).

Insulin resistance is present in most individuals predisposed to type 2 diabetes, before the onset of hyperglycaemia. Some have interpreted this to indicate that insulin resistance is the primary abnormality responsible for the development of type 2 diabetes. However, defects in beta cell function are also present in some people before the onset of type 2 diabetes, when impaired glucose tolerance is evident, and in first-degree relatives of people with type 2 diabetes who have normal plasma glucose concentrations. Therefore, although the pathogenesis of diabetes is unclear, it is evident that insulin resistance and impaired glucose tolerance are present in most individuals with the condition, often from a pre-clinical stage. There is evidence that insulin resistance is a contributing factor in the development of impaired glucose tolerance and diabetes (ADA 2014) and that insulin resistance is a predictor for the onset of type 2 diabetes (Henninger et al 2015).

TABLE 1. Blood glucose levels

	Fasting plasma glucose	2-hour post-prandial plasma glucose	Random plasma glucose	2-hour post-glucose load plasma glucose	Glycated haemoglobin (HbA1c)* test
Normoglycaemic	<100mg/dL (<5.6mmol/L)	<100mg/dL (<5.6mmol/L)			<6% (<42mmol/mol)
Impaired glucose tolerance	100-125 mg/dL (5.6- 6.9mmol/L)	140-199 mg/dL (7.8- 11.0mmol/L)			6.0-6.5% (42-48mmol/mol)
Diabetes mellitus	>126mg/dL (>7.0mmol/L)	≥200mg/dL (≥11.1mmol/L)	≥200mg/dL (>11.1mmol/L) in the presence of at least two symptoms of diabetes mellitus	≥200mg/dL (≥11.1mmol/L)	≥6.5% (48mmol/mol)

*HbA1c can be used as a diagnostic test for diabetes providing that stringent quality assurance tests are in place and assays are standardised to criteria aligned to the international reference values, and there are no conditions present which preclude its accurate measurement' (World Health Organization 2011).

(Adapted from American Diabetes Association 2016)

KEY POINT

Large epidemiological studies have indicated that the risk of type 2 diabetes, and presumably that of insulin resistance, rises as body fat content increases. This implies that the absolute amount of body fat has an effect on insulin sensitivity (Hu et al 2001, Tuomilehto et al 2001, Man et al 2016)

Obesity

Obesity is the risk factor with the strongest association with polygenic forms of type 2 diabetes. This association has been recognised for decades (Buse et al 2011). The relationship between the development of insulin resistance and the presence of obesity is found in all ethnic groups, across the full range of body weights, across all ages, and in men and women (Kodama et al 2012, Abuyassin and Laher 2015).

Large epidemiological studies have indicated that the risk of type 2 diabetes, and presumably that of insulin resistance, rises as body fat content increases. This implies that the absolute amount of body fat has an effect on insulin sensitivity (Hu et al 2001, Tuomilehto et al 2001, Man et al 2016). Total and central (intra-abdominal) adiposity are strongly linked to insulin resistance and several other metabolic variables, including plasma glucose and insulin levels, total plasma cholesterol and triglyceride concentrations and decreased plasma HDL cholesterol concentration (Appel et al 2005, Man et al 2016).

TIME OUT 3

Investigate the screening programmes for obesity and or diabetes available to your community. How could they be used or adapted to offer the best possible, and most financially viable, outcomes for population groups at risk of obesity and diabetes?

Pathophysiology

The pathogenesis of type 2 diabetes is complex. The close interaction of genetic and environmental factors contribute to the development of the condition. Typically, type 2 diabetes presents with three principal physiological abnormalities (Buse et al 2011) (Figure 1):

- Resistance to the action of insulin in peripheral tissues, particularly in muscle and fat, but also in liver cells.
- Defects in insulin secretion, particularly in response to a glucose stimulus.
- Increase in glucose production by the liver.

Other pathophysiological presentations include:

- Accelerated breakdown of fats to release fatty acids (lipolysis).
- Increased glucagon release by the pancreas (hyperglucagonaemia), leading to the increased breakdown of glycogen to form glucose.
- Increased renal tubular reabsorption of glucose.
- Alterations in the central nervous system's role in metabolic regulation, including incretin hormone deficiency and resistance (DeFronzo 2009). Incretins are responsible for stimulating a feeling of satiety and for pancreatic insulin secretion in response to eating, before blood glucose levels rise.

Physiological causes of insulin resistance

There are various ways that cells detect incoming nutrients, including direct and indirect activation of transcription factors and protein kinases. These pathways interact with incoming hormonal signals to modulate cellular metabolism, increasing anabolic reactions in times of nutrient sufficiency and increasing catabolic reactions in post-prandial or nutrient-deficit states (Buse et al 2011). Prolonged activation of anabolic pathways through overeating and lack of energy demand as a result of decreased physical activity, may lead to unintended pathological states that could result in insulin resistance, inflammatory responses and cell death.

Various interacting factors determine the individual's physiological and biochemical response to long-term nutrient overload. One individual may be obese with normal cell biochemistry in relation to glucose and lipid metabolism and other vascular risk factors, whereas another individual may present with only minor alterations in body weight and yet present with abnormal physiology (Buse et al 2011). Genetics largely determines the variance in response, as demonstrated by the increased burden of metabolic dysfunction in Asian populations at a much lower BMI than in Caucasians and other ethnic groups (Chan et al 2009).

Nutrient intake that exceeds expenditure is either converted into biological precursors for energy production, for example glucose and fatty acids, or is stored. Irrespective of the nutrient type, excess nutrients are generally stored as fatty acids in the form of triglycerides, a form that is easily mobilised in times of nutrient deficit. If the storage

capacity of adipose tissues is exceeded by increasing demand for storage, lipids and other nutrients will enter non-storage tissue such as myocytes, hepatocytes, vascular cells and pancreatic beta cells (Steven et al 2015).

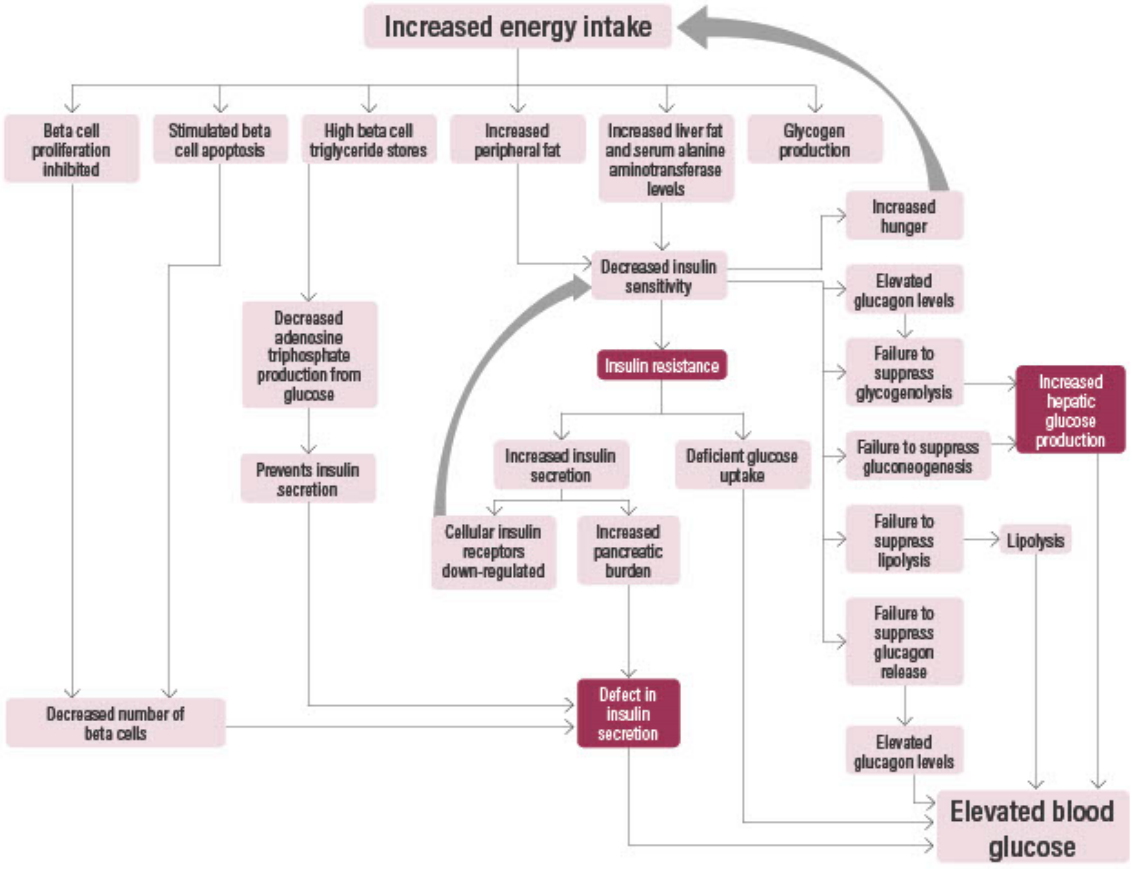
Liver fat accumulation occurs with overfeeding states, where caloric intake is greater than expenditure, resulting in 'fatty-liver'. It has been shown that overfeeding for a period of three weeks can increase liver fat by 30% (Sevastianova et al 2012). This triggers a range of adaptive and non-adaptive cellular responses that are responsible for the development of insulin resistance and lead to cellular dysfunction. An increase in liver fat of 30% is also associated with a 30% rise in serum alanine aminotransferase levels, an enzymatic marker indicative of liver disease or damage. Liver fat and serum alanine aminotransferase levels may be reversed by a hypocaloric diet (Sevastianova et al 2012).

TIME OUT 4

Read the NICE (2014) guideline on the identification, assessment and management of obesity. Are you implementing this guidance in your practice? List three improvements that could be made to your practice as a result of reading the guideline and think about how you could disseminate this information to your colleagues.

The inability of pancreatic beta cells to adapt to the reduced insulin sensitivity of muscle and liver cells precipitates the onset of type 2 diabetes (Buse et al 2011). Increased fat

Figure 1. Physiological effects of an increased energy intake on blood glucose levels



KEY POINT

Reduced insulin sensitivity initially results in hyperinsulinaemia, the overproduction of insulin by pancreatic beta cells. Hyperinsulinaemia is associated with hyperglycaemia and reduced insulin sensitivity, and has been considered a possible primary cause of insulin resistance and glucose intolerance (Marín-Juez et al 2014)

stores in the liver and in peripheral muscles contribute to insulin insensitivity (Figure 1). Studies involving individuals with type 2 diabetes who have undergone significant calorie restriction resulting in liver and pancreatic fat loss have shown marked improvement and even reversal of type 2 diabetes (Mingrone et al 2012, Steven et al 2015). Pories et al (1992) observed that patients who were obese presented with normalisation of blood glucose levels a few days after undergoing bariatric surgery. In 90% of patients, remission of diabetes lasted more than ten years following surgery. This and a further study involving 148 patients diagnosed with type 2 diabetes who underwent bariatric surgery (Steven et al 2015) demonstrated that the degree of remission of diabetes was directly related to the degree of weight loss, with little association between the degree of remission and the duration of the illness.

In another study, 73% of patients in the surgical intervention group receiving gastric banding achieved remission compared to 13% of patients in the conventional therapy group (Dixon et al 2008). In hypocaloric states, fat is mobilised from the liver before other visceral or subcutaneous stores (Colles et al 2006). This process also occurs in response to more moderate caloric restriction over an extended period of time, with fasting plasma glucose concentrations improving as a result of a decrease in liver fat content, resulting in normalisation of hepatic insulin sensitivity. However, little change is detected in muscle insulin sensitivity in response to caloric restriction, which suggests that liver insulin sensitivity is a more sensitive predictor of abnormal glucose metabolism than muscle insulin sensitivity (Petersen et al 2005, Gastaldelli et al 2007, Ravikumar et al 2008).

TIME OUT 5

How does your knowledge of obesity, particularly the accumulation of abdominal fat, affect your responsibility to provide nutrition education and weight management for at-risk individuals? How could you better fulfil this responsibility in your practice?

Reduced insulin sensitivity initially results in hyperinsulinaemia, the overproduction of insulin by pancreatic beta cells. Hyperinsulinaemia is associated with hyperglycaemia and reduced insulin sensitivity, and has been considered a possible primary cause of insulin resistance and glucose intolerance (Marín-Juez et al 2014). Hyperinsulinaemia also creates a reactive hypoglycaemia, which causes hunger and cravings, often for high-energy foods, resulting in increased caloric consumption. Elevated concentrations of insulin may down-regulate insulin receptors and desensitise post-receptor cellular pathways (Figure 1).

Del Prato et al (1994) found that physiological hyperinsulinaemia sustained for 24 hours and 72 hours in healthy individuals, specifically inhibited the ability of insulin to suppress gluconeogenesis and promoted the conversion of excess carbohydrate to fat stores. Therefore, patients with hyperinsulinemia type 2 diabetes are at increased risk of developing obesity and fatty liver, which exacerbate insensitivity to insulin and inhibit suppression of hepatic glucose production.

Hepatic glucose production

The fat content of the liver is associated with the extent to which insulin sensitivity suppresses hepatic glucose production (SeppäLä-Lindroos et al 2002). Decreasing the fat content of the liver reduces hepatic glucose production and may improve fasting blood glucose levels (Petersen et al 2005). Post-prandial glucose disposal depends on the ability of insulin to increase peripheral glucose uptake and simultaneously decrease endogenous glucose production. The kidney can contribute up to 25% of endogenous glucose production (DeFronzo et al 2012, Wilding 2014). However, the defect in type 2 diabetes is primarily associated with the regulation of glucose production in the liver. Endogenous glucose production derives from two sources: glycogenolysis (the breakdown of stored glycogen) and gluconeogenesis (Gerich 2010).

The contribution of these two methods of glucose production to maintain normal blood glucose levels varies according to circumstances relating to energy requirement and post-prandial time. Gluconeogenesis accounts for 50-96% of glucose production

under normal circumstances; this percentage increases with increased duration of fasting (Gerich 2010).

Glucose production in the liver is primarily regulated by the relative actions of glucagon and insulin; glucagon activates glucose production while insulin suppresses it (Gerich 2010). At low insulin concentrations, insulin directly suppresses about 85% of glucose production in the livers of individuals with normal glucose metabolism by inhibiting glycogenolysis. Conversely, high levels of glucagon activate glycogenolysis, resulting in increased blood glucose levels (Hall 2015). Insulin also directly suppresses gluconeogenesis.

Hepatic insulin resistance, resulting from impaired suppression of endogenous glucose production in the liver, has an important role in the development of hyperglycaemia in type 2 diabetes. The effects of gluconeogenesis are more significant than defects relating to deficient uptake of peripheral glucose (Samuel and Shulman 2016). Insulin not only functions to supress hepatic glucose production, but also suppresses lipolysis (lipid breakdown) peripherally. The resistance of adipose tissue, especially visceral fat to insulin stimulation results in increased lipolysis. Insulin also suppresses pancreatic glucagon release in healthy individuals. Therefore, glucagon levels are raised in individuals exhibiting insulin resistance, resulting in increased glycogenolysis (Samuel and Shulman 2016).

Hepatic glucose production may be at normal levels in lean individuals with a diagnosis of type 2 diabetes who are relatively insulin-sensitive, that is their beta cells are unable to cope with increased demand for insulin as a result of insulin resistance (Conte et al 2012).

Pancreatic beta cells

The incapacity of the pancreas to adapt to insulin resistance places an increased secretory burden on the beta cells of the pancreas (Figure 1). Obesity, pregnancy, a sedentary lifestyle and overeating lead to weight gain and adiposity, which may result in increasing insulin insensitivity and an increasing demand for insulin secretion. Beta cell adiposity and increasing demand for insulin are associated with beta cell failure. 'An underlying genetic predisposition appears to be a critical factor in determining the frequency with which beta cell failure occurs' (Buse et al 2011).

Chronic exposure of pancreatic beta cells to triglycerides or fatty acids decreases their ability to respond appropriately to hyperglycaemia. Beta cells import fatty acids and store excess as triglycerides. Adenosine triphosphate (ATP) is required for insulin to be secreted by beta cells. ATP is generated by glucose oxidation, the breakdown of glucose to provide energy (Hall 2015). An over-supply of fatty acids inhibits the production of ATP by glucose oxidation, a requirement for opening insulin channels and therefore insulin secretion (Zhou et al 1996). Normal insulin secretion is essential to maintain normal glucose tolerance. Abnormal insulin secretion is invariably present in patients with type 2 diabetes.

Fatty acids have also been shown to inhibit beta cell proliferation. Histological studies on the pancreas of individuals diagnosed with type 2 diabetes indicate a 20-65% reduction in beta cell mass, compared to the pancreas of healthy individuals (Meier and Bonadonna 2013). Beta cell death has been associated with other conditions related to type 2 diabetes that inhibit insulin and glucagon secretion, for example high concentrations of blood glucose, free fatty acids and cytotoxic peptides secreted by pancreatic beta cells (Cernea and Dobreanu 2013). Moreover, a high secretory demand on beta cells results in oxidative stress and misfolding of cellular proteins in the endoplasmic reticulum, which may lead to beta cell damage. Inflammatory markers, such as interleukin-1 beta (IL-1ß), have also been associated with beta cell apoptosis (Robertson and Harmon 2006, Westermark et al 2011). Beta cell loss appears to increase as the duration of experiencing type 2 diabetes increases (Rahier et al 2008).

Adipocytes function as more than storage cells. They function as regulators for the uptake and release of free fatty acids, release leptin and other hormones that indicate the energy states of the

KEY POINT

Hepatic insulin resistance, resulting from impaired suppression of endogenous glucose production in the liver, has an important role in the development of hyperglycaemia in type 2 diabetes. The effects of gluconeogenesis are more significant than defects relating to deficient uptake of peripheral glucose (Samuel and Shulman 2016)

KEY POINT

Nurses who have an understanding of the interaction between obesity and the onset of type 2 diabetes are better equipped to explain the importance of weight loss and necessary lifestyle adjustments in the prevention and optimal management of type 2 diabetes

body, and secrete various adipokines – cytokines that have hormonal, paracrine (cell-to-cell) and autocrine (same-cell) actions (Waki and Tontonoz 2007). These adipokines regulate a range of actions, including: alterations in feeding behaviour; changes in liver, muscle and adipose tissue insulin sensitivity; vascular reactivity; and progression of atherosclerosis. Adipocytes can be adversely affected by the accumulation of excess nutrients, resulting in abnormal cytokine function that leads to decreased suppression of appetite, decreased metabolic rate, and other changes in fat and glucose metabolism (Deshmane et al 2009, Karastergiou and Mohamed-Ali 2010, Lago et al 2011, Qu et al 2014).

Several factors contribute to the development of insulin resistance. Beta cell apoptosis and increased gluconeogenesis by liver cells are influenced by high energy intake, triglyceride levels, and lack of energy expenditure, which each contribute to cellular fat accumulation and are associated with obesity.

High levels of liver fat are not inevitably associated with hepatic insulin resistance, despite the close relationship between liver fat, hepatocyte insulin resistance and raised liver enzymes. This indicates a requirement for genetic, ethnic or lipo-susceptibility of the metabolic organs also to be present (Taylor 2013). The G allele of the PNPLA3 gene determines high liver fat levels that are not associated with altered glucose metabolism. Therefore, a person who is positive for this gene variant is likely to have a high liver fat content yet remain normoglycaemic, demonstrating a decreased susceptibility to insulin resistance based on liver and pancreatic fat content (He et al 2010, Lim et al 2011).

Nursing implications

Nurses who have an understanding of the interaction between obesity and the onset of type 2 diabetes are better equipped to explain the importance of weight loss and necessary lifestyle adjustments in the prevention and optimal management of type 2 diabetes. Creating opportunities to provide patient education, promote services and refer patients appropriately, may lead to families and communities being better informed, enabling them to prevent and manage type 2 diabetes. Preventing obesity through the promotion of a healthy lifestyle reduces the potential for insulin resistance. The two most effective measures to improve insulin sensitivity are weight loss and physical activity. Weight loss and physical activity are independently effective in improving insulin sensitivity; however, the benefit is enhanced significantly when they are combined.

Weight loss

Weight loss has been advocated as the first-line therapy in managing overweight patients diagnosed with type 2 diabetes, particularly for patients with additional cardiovascular risk factors. Weight loss also has an important role in preventing type 2 diabetes (Hu et al 2001, Knowler et al 2002). Weight loss in patients who are overweight has been shown to reduce hepatic glucose production and fasting hyperinsulinaemia and to improve insulin sensitivity, thereby improving glycaemic control (Kelley and Mandarino 2000). A loss of 5-10% of initial body weight is also associated with a reduction in blood pressure and an improvement in the lipid profile, contributing to the reduction in risk of cardiovascular disease associated with type 2 diabetes (Wing et al 2011).

NICE (2015a) guidelines suggest that an initial weight loss goal should be set at between 5% and 10% of body weight; however, any weight loss will translate into metabolic benefit. Where weight loss is not being achieved by recently diagnosed individuals with a BMI of greater than 35, it is recommended that they are offered an expedited assessment for bariatric surgery (NICE 2014).

Healthy eating

Dietary advice for individuals involves consuming a balanced diet that is low in fat, sugar and salt and contains a high level of fresh fruit and vegetables (Diabetes.co.uk 2017). Consuming foods that are higher in energy than is expended in physical activity will result in weight gain. Fats have the highest energy content of all

foods and are caloric-dense. Saturated fats, found mainly in animal products, coconut oil and palm oils, contribute to low density lipoprotein (LDL) cholesterol formation, therefore it is desirable to limit their consumption.

Consuming small servings of polyunsaturated and monounsaturated fats such as those found in avocado, olives, grains, nuts and seeds is important to obtain essential dietary fatty acids and fat-soluble vitamins and antioxidants. Unsaturated fats consumed in the form of whole foods are consumed in lower quantities and are less likely to raise LDL cholesterol levels than those consumed as extracted and processed oils.

Carbohydrates provide an optimum source of energy and are especially important for brain function. Good sources of carbohydrate are nutrient and fibre-dense and lower in energy. The glycaemic index represents 'the relative ability of a carbohydrate food to increase the level of glucose in the blood' (Oxford Dictionaries 2016b). Sources of carbohydrate that are high in fibre and with a low glycaemic index, such as fruit, vegetables, wholegrains and pulses, are more beneficial than refined carbohydrates, which are low in fibre and micronutrients and tend to be more calorie-dense than unrefined sources. Consuming large amounts of processed, high-fat and sweetened food is likely to result in reactive hypoglycaemia, which contributes to cravings for sweet food and overeating. A long-term effect of this is increased weight gain (Mozaffarian et al 2011).

Foods containing protein are important for tissue repair. However, animal sources of protein contain no fibre and have a higher percentage of fat than most non-animal sources of protein. Consumption of one daily serving of legumes has been shown to improve glycaemic control (Jenkins et al 2012).

Water is necessary for most body functions and is required daily to maintain adequate hydration. Water is an ideal beverage because it contains no calories. Care should be taken to restrict the intake of caloric-dense and sweetened beverages.

Physical activity

Engaging in regular physical activity has physical, psychological and social health benefits (NICE 2015b). Healthy physical activity involves including increased levels of activity in normal activities of daily living, thereby reducing sedentary lifestyle habits. It involves engaging in moderate physical activity that increases cardiovascular fitness and stamina at least three times per week, for a total of at least 150 minutes, preferably with episodes of physical activity separated by no more than two days at a time, as well and participating in activities that will improve muscle strength and flexibility (Nagi and Gallen 2010).

Health education programmes

Health education programmes, whether as a primary preventive strategy or as part of diabetes care and support, are most effective when they are patient-centred, taking into account the patient's preferences, comorbidities, current disabilities, and the potential for them to gain long-term benefit from interventions. In addition, patient education programmes should meet the cultural, linguistic, cognitive and health literacy needs in the local area (NICE 2015a). These needs should be considered in the planning phase to optimise the potential benefits.

NICE (2015a) published principles for planning and implementing diabetes education programmes that are also relevant for preventive education. These principles include:

- Providing structured, resource-effective, evidence-based education for patients, their families and carers that meets the needs of the person at the time of diagnosis, in addition to annual reinforcement of care principles.
- Ensuring education programmes have specific aims and learning objectives that meet the needs of the person.
- Ensuring education programmes are aimed at supporting the patient and their family members and carers in developing attitudes, beliefs, knowledge and skills to self-manage diabetes.
- Providing educators who are professionally trained in appropriate educational theory

KEY POINT

Health education programmes, whether as a primary preventive strategy or as part of diabetes care and support, are most effective when they are patient-centred, taking into account the patient's preferences, comorbidities, current disabilities, and the potential for them to gain long-term benefit from interventions

and the principles of diabetes care.

- Ensuring the education programme is quality-assured and regularly reviewed by competent, independent assessors and that outcomes are audited.
- Making use of group education as the preferred option, while providing alternative arrangements for patients who are unable or unwilling to participate in group programmes.
- Providing patients with appropriate resources and written material that complement the programme content.
- Ensuring the education programme meets the cultural, linguistic, cognitive and literacy needs of participants.

Nurses should be able to recognise and screen patients for potential health risks, provide appropriate health education, promote health management strategies, and refer patients to suitable health and education providers when required.

TIME OUT 6

Explore what national, regional and local health promotion programmes are available in your practice setting that address weight loss and physical activity. Obtain detailed information on three programmes to which you refer patients. Evaluate how accessible these programmes are to the general population. How often do you refer patients at risk of diabetes to appropriate resources? Can you improve the frequency and quality of your referrals?

Conclusion

Obesity, particularly abdominal obesity, is a major risk factor for the development of type 2 diabetes. A diagnosis of type 2 diabetes or obesity increases the risk of other chronic conditions, particularly cardiovascular disease. Obesity and the related accumulation of fat in body tissues have a significant role in the development of insulin resistance, contribute to beta cell failure and result indirectly in overproduction of glucose in the liver. This leads to alterations in lipid metabolism, insulin secretion and adipokine function that also contribute to the pathology of diabetes.

Nurses who have an understanding of the interaction between obesity and the onset of type 2 diabetes are better equipped to explain the importance of weight loss and other necessary lifestyle adjustments in the prevention and management of this condition.

TIME OUT 7

Nurses are encouraged to apply the four themes of The Code (NMC 2015) to their professional practice. Consider how knowledge of the relationship between obesity and type 2 diabetes relates to The Code.

TIME OUT 8

Now that you have completed the article, you might like to write a reflective account as part of your revalidation.

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Obesity and type 2 diabetes mellitus

TEST YOUR KNOWLEDGE BY COMPLETING SELF-ASSESSMENT QUESTIONNAIRE 878

1. Obesity is:

a) The principal lifestyle factor associated with an increased risk of developing type 1 diabetes

b) The principal lifestyle factor associated with an increased risk of developing type 2 diabetes

c) The principal non-modifiable factor associated with an increased risk of developing type 2 diabetes

d) The principal modifiable factor associated with an increased risk of developing type 1 diabetes

2. Which physiological process is not central to the onset of type 2 diabetes?

a) Defects in insulin secretion ☐

b) Increase in glucose production by the liver ☐

c) Increased insulin sensitivity ☐

d) Insulin resistance ☐

3. Triglycerides are not:

a) Fatty acids ☐

b) Stored preferentially in pancreatic beta cells ☐

c) Used to store excess intake of nutrients ☐

d) Stored preferentially in adipose tissue ☐

4. In a hypocaloric state, fat is preferentially mobilised from:

a) The liver ☐

b) Subcutaneous fat stores ☐

c) The heart ☐

d) The abdomen ☐

5. Hyperinsulinaemia is not:

a) A possible primary cause of insulin resistance ☐

b) A possible primary cause of glucose intolerance ☐

c) Associated with hyperglycaemia ☐

d) Known to up-regulate insulin receptors ☐

6. Endogenous glucose production derives from:

a) Gluconeogenesis only ☐

b) Glycogenolysis only ☐

c) Gluconeogenesis and glycogenolysis ☐

d) Hyperglucagonaemia and glycogenolysis ☐

7. Gluconeogenesis in the liver:

a) Accounts for 50–96% of glucose production under non-fasting conditions ☐

b) Is activated by glucagon ☐

c) Is suppressed by insulin ☐

d) All of the above ☐

8. Glycogenolysis in the liver is not:

a) Inhibited by low levels of insulin ☐

b) Activated by low levels of insulin ☐

c) Activated by high levels of glucagon ☐

d) Responsible for increased blood glucose levels ☐

9. In overweight patients diagnosed with type 2 diabetes, weight loss:

a) Has no demonstrable metabolic benefits ☐

b) Increases hepatic glucose production ☐

c) Improves insulin sensitivity ☐

d) Is advocated as a second-line therapy ☐

10. In overweight patients diagnosed with type 2 diabetes, the benefits of a 5-10% weight loss:

a) Are additive to those of exercise ☐

b) Result in improved glycaemic control ☐

c) Contribute to a reduced risk of cardiovascular disease associated with type 2 diabetes ☐

d) All of the above ☐

This self-assessment questionnaire was compiled by Beth Knight

The answers to this questionnaire will be published on 8 February

The answers to SAQ 876 on chronic heart failure: part 2, which appeared in the 11 January issue, are:

1. d 2. d 3. c 4. a 5. b 6. b 7. c 8. a 9. c 10. c

How to complete this assessment

This self-assessment questionnaire will help you to test your knowledge. It comprises ten multiple choice questions that are broadly linked to the article starting on page 59. There is one correct answer to each question.

- You can test your subject knowledge by attempting the questions before reading the article, and then go back over them to see if you would answer any differently.
- You might like to read the article before trying the questions. The correct answers will be published in Nursing Standard on 8 February.

Subscribers making use of their RCNi Portfolio can complete this and other questionnaires online and save the result automatically.

Alternatively, you can cut out this page and add it to your professional portfolio. Don't forget to record the amount of time taken to complete it.

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CHAPTER 3: STUDY 1 THEORETICAL UNDERPINNING AND METHODS

This chapter includes the theoretical underpinning based on the ontology of positivism. In addition, the aim and methods for the study are presented, including a description of the Research Questions, the study design, and specific information about the participants and study setting. The inclusion and exclusion criteria, recruitment, randomisation, and concealment processes are also discussed. A more detailed description of the primary and secondary outcome measurements, quantitative data analysis procedure and ethical considerations are also provided.

Theoretical Underpinning of Study 1

Research and theory provide the foundation for the health sciences. More specifically, theory is the framework on which nursing practice has developed. In the practice of nursing questions are developed that guide or inform research and the further development of theory (Schmidt & Brown, 2015). Therefore, when describing research, it is essential to discuss the paradigm from which the methodology was approached.

Positivism is the paradigm that has dominated most scientific research, and certainly that of medical research (Polit & Beck, 2017). Positivism originated with the French philosopher Auguste Comte when scientific discovery was growing and rapidly replacing the church as a source of knowledge. The ontology of positivism is that reality exists, and the natural law of cause and effect drives the world. The epistemological approach is that the researcher is exterior to the research subjects and is, therefore axiologically independent and unbiased. The methodological approach to positivist-based research is one where testing a hypothesis or research question is done under strict and ordered control (Polit & Beck, 2017).

Randomised controlled trials (RCT) are well supported by positivism in that *a priori* hypotheses are tested using an experimental approach where the researcher assumes the role of an external observer. Variables and measures are operationalised, and results are used to inform and advance science. Positivism focuses on identifying associations or causal relationships through quantitative study methods. The replication of findings and controlled experimentation are principles shared by positivism and RCTs (Bonell et al., 2018).

Randomised controlled trials, when correctly performed, produce knowledge by testing causal relationships between groups in response to an intervention and effect on an outcome while minimising confounding bias. A prospective study protocol guides the RCT and has strict inclusion and exclusion criteria, as well as definite, well-defined interventions

with predetermined outcome criteria and is considered the 'gold standard' for studying the safety and efficacy of new treatment modalities (Faraoni & Schaefer, 2016). Blinded and double-blinded RCTs (in which the subjects and researchers are respectively unaware of the treatment the subjects are receiving) are superior to unblinded studies. Critical analysis studies, which include practice guidelines, systematic reviews, and meta-analyses of RCTs, are regarded as the pinnacle of the hierarchy of evidence-based studies. This high-level evidence is sought by government and regulatory bodies for establishing practice recommendations and making practice-related financial decisions. An example is the process of review and consultation undertaken by the National Health and Medical Research Council (2011) during the development of the Australian Dietary Guidelines.

Aim of Study 1

The aim of this study was to assess the effectiveness of the Complete Health Improvement Programme for reversing abnormal fasting blood sugar levels in T2DM clients.

Research Questions for Study 1

Two Research Questions guided Study 1, and are re-iterated as follows. Both questions refer to a diabetic population within a general practice group in the Lake Macquarie region of New South Wales, Australia:

1. When compared to a control group receiving routine diabetic care, what is the effect of implementing CHIP on changes in fasting blood sugar levels (FBSL), HbA1c, fasting lipogram with triglycerides (FLT), blood pressure (BP), abdominal girth and body mass index (BMI) in participants with previously diagnosed T2DM who participated in CHIP?
2. Compared to a control group receiving routine diabetic care, what adherence levels (measured through changes in dietary intake, physical activity levels, and planned exercise) over 12 months are observed in participants with previously diagnosed T2DM who participated in CHIP?

Design of Study 1

A parallel open-label randomised control study design was used where the intervention was participation in the CHIP. The RCT consisted of an intervention group which received the intervention lasting 12 weeks with a further nine months of monthly follow-up in addition to usual diabetes care. The control group received usual diabetes care

only. Both groups had data collected on enrolment (initial), at 12 weeks (at the time of completion of the intervention for the intervention group) and at 12 months (after the 9-month follow-up period for the intervention group). This procedure is illustrated in Figure 2.

Setting and Participants for Study 1

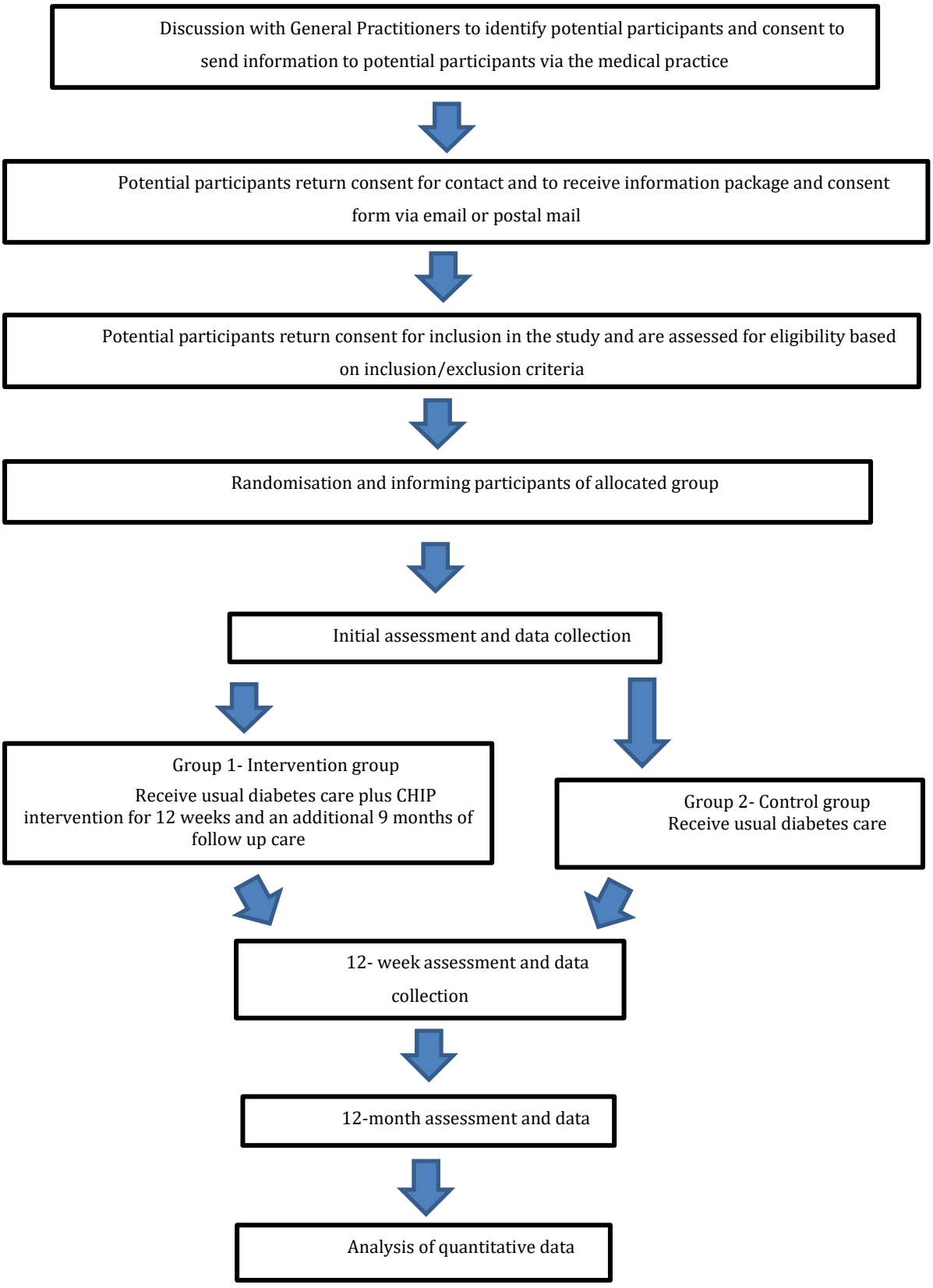
Setting

Study participants were drawn from medical practices in the Lake Macquarie region of NSW. The Lake Macquarie Local Government area lies north of the Central Coast, south of Newcastle and east of Cessnock. Major towns include Wyee, Morisset, Cooranbong, Toronto, Belmont, Cardiff, and Charlestown. The 2021 census (Australian Bureau of Statistics, 2021) population count for the area was 213,845, of which 5.5 per cent identified as Aboriginal or of Torres Island descent. Australian-born residents comprised 85.5 per cent of the group with other representative nationalities being the United Kingdom of Great Britain, New Zealand, India, South Africa, and Philippines. The median age of the population is 42 years, and the predominant social groups are young families with an average of 1.8 children per household and couples without children. Lone-person households made up 24.8 per cent of households. A language other than English is spoken in 7.2 per cent of households in the area. The mean weekly household income is $1,623. The most common medical problems recorded were a mental health disorder (12%), arthritis (11.9%), asthma (10.2%), diabetes (5.6%) and heart disease (5.5%), all of which occur at higher rates in this population group than in the state average. The area is serviced by one public and one private hospital and approximately 100 general practitioners.

The four CHIP interventions in which participants were enrolled were held within the same region at two separate community hall venues between 2018 and 2019. Initial and 3-month anthropometric measurements were taken at these venues, and 12-month measurements were taken in a private office on the Lake Macquarie campus of Avondale University. Blood samples were drawn at selected Douglass Hanly Moir Pathology

Figure 2

Summary of the Sequence from Participant Selection to Data Analysis.



Laboratories, which are accredited by the National Pathology Accreditation Advisory Council (NPAAC).

Participants

Clients diagnosed with T2DM were recruited from general practice medical centres (where practitioners had agreed to refer) in the Lake Macquarie local government area of NSW, Australia. The inclusion and exclusion criteria are discussed below. Potential participants were excluded based on the criteria below.

Inclusion Criteria

Persons over the age of 18 years with an established diagnosis of T2DM.

Exclusion Criteria

Persons would be ineligible for the study if:

a. They were aged less than 18 years.
b. The consulting medical practitioner considered that an alteration in nutrient or calorie consumption or that participating in regular moderate exercise could increase health risk which may include but may not be limited to:
    i. Persons having a history of uncontrolled hypertension with consistent resting blood pressure readings greater than 180 mmHg systolic and or greater than 110 mm Hg diastolic.
    ii. Persons with a BMI lower than 21 kg/m² and using weight-loss medication.
    iii. Persons experiencing recurrent chest pain or unstable angina.
    iv. Pregnant or lactating females, or females planning to become pregnant in the next year.
    v. Persons who had undergone angioplasty or experienced a myocardial infarction or cardiac surgery within the previous three months.
c. They had any condition that would preclude them from increasing their level of physical activity.
d. They had any physical condition or language barrier that would preclude them from understanding or safely adopting the lifestyle changes recommended by the CHIP intervention. The populations cultural and socioeconomic circumstances were diverse.

The Intervention

The Template for Intervention Description and Replication (TIDIER) (Hoffmann T, 2014) informed the details provided about the intervention. The CHIP was described in detail in the Literature Review, but for the purpose of clarity, the intervention for the RCT is described here.

The CHIP, owned and licenced by the Lifestyle Medicine Institute (2020), is a structured lifestyle programme developed to reduce the incidence and prevalence of common risk factors for chronic diseases of lifestyle. The content is delivered over 18 90-minute sessions. Half of each session consists of screening video-based educational material (obtainable from the licenced owners), which is supported by an accompanying text and workbook. The information in the video and textbook addresses all the major risk factors for developing chronic diseases associated with poor lifestyle habits. The video material and textbook also include information on self-management, the psychology of change and how to access support for making lifestyle adjustments. Each textbook chapter is designed to contain the relevant information presented, session by session. An accompanying workbook contains review and life-application questions and activities, which the participants usually complete at home. The workbook contains instructions and pages for participants to set goals for themselves and record their daily activity, either as pedometer step count or time spent doing other exercise. A third book contains a large selection of plant-based recipes that can be used to prepare healthy breakfasts, lunches, snacks, main meals, and desserts.

The first eleven sessions' content focuses primarily on acquiring knowledge of pertinent risk factors for lifestyle diseases. The following seven sessions provide information on the practicalities of making lifestyle changes and acquiring the necessary support to sustain the changes made. Table 3 contains a list of topics covered by each CHIP session. The frequency at which sessions are held is mainly left to the discretion of the team running the programme; however, CHIP designers prefer to hold three sessions per week for the first two weeks. Frequent access to participants in the first few weeks helps build rapport and provide support in the initial stages of the programme. Usually, the third and fourth weeks contain two sessions each, after which sessions are held weekly for another eight weeks.

The second part of each 90-minute session involves group discussion, questioning, active learning, and problem-solving activities. Part of the time is devoted to previous participants relaying their success stories. Cooking demonstrations and food tasting are also included in each session. An example of the schedule for a CHIP session is provided in Table

4. The schedule is flexible according to the length of the video material needing to be presented at each session.

The CHIP is a community-based and volunteer-run programme; therefore, the facilitators, cooks and presenters are mostly lay persons who have received training to conduct the sessions during a three-day course. In many situations, medical and mainly allied medical health professionals voluntarily assist in running the CHIP.

Facilities required to run the CHIP include an indoor location with access to chairs for seating and media on which the video material can be played and screened. The video material is usually provided on a USB stick. Depending on the degree to which volunteers plan for food demonstrations determines the requirement for cooking facilities. Most venues have access to a food preparation area, refrigerator and microwave. However, many programmes use insulated cooling boxes to transport ingredients, an electric hot plate to cook, and other portable equipment like blenders and utensils are transported into the facility as required. Food is usually served on disposable plates, and tasting is facilitated with disposable cutlery. Additional games, exercises and interactive activities are planned and modified at the presenter's discretion based on the participant's suitability and the location.

Table 4

Example of CHIP Session Schedule.

Time	Activity
7:00pm	Welcome and overview of previous sessions workbook questions.
7:10pm	Video presentation
7:30pm	Group discussion/game/success story
7:35pm	Q&A and stretching/exercise demonstration
7:50pm	Video presentation
8:10pm	Cooking demonstration and food tasting
8:25pm	Discussion and Q & A
8:30pm	Conclusion and workbook homework assignments

Outcome Measures

The primary outcome for Study 1 was improved glycaemic control. Secondary outcomes included improved body mass, body height, BMI, waist circumference, hip circumference, lipid profile, and blood pressure, obtained at an appointment when anthropometric measurements were conducted, and physical activity levels, dietary consumption and quality of life measurements sustained over the 12-month study period obtained by means of a survey questionnaire. The survey, which included the Active -Q, RAND-36 and the food frequency questionnaire, was mainly self-administered by participants before attending an appointment at which anthropometric measurements were conducted. The researcher reviewed each survey with the participant during the measurement appointment to clarify any misconceptions, establish consistency with responses and fill in any missing data. Three of the participants required help filling in most parts of the surveys. In these cases, the survey (except for demographic details and medical and medication history) was used as an interview questionnaire and completed by the researcher.

Primary Outcome Measure

Glycaemic Control

Glycaemic control was measured using fasting blood glucose (FBG) and HbA1c levels. The FBG was measured in milligrams per decilitre (mg/dL). The HbA1c was measured according to the International Federation of Clinical Chemistry (IFCC) guidelines in millimoles per mole (mmol/mol) and as a percentage (%) when aligned to the assay used in the Diabetes Control and Complications Trial (DCCT) (Nathan & Group, 2014). In the case of the initial FBG and HbA1c tests required on enrolment, where participants had undergone testing within the 30 days prior to enrolment, and the testing requirements were met as described, the results of those tests were used as the initial FBG and HbA1c result. Participants who had yet to undergo testing were provided with written instructions to complete at least an 8-hour fast before presenting themselves for blood sampling as Sacks et al. (2011) recommended and implemented by Douglass Hanly Moir Pathology. Participants were reminded of the fasting requirements prior to testing. At the time of testing, they were again asked whether they had and for how long they had fasted. FBG and HbA1c levels were measured using a blood sample drawn by a trained phlebotomist and analysed by Douglass Hanly Moir Pathology Laboratory, Wahroonga, Sydney. Blood tests were completed on enrolment, at 12 weeks and again at 12 months.

Secondary Outcome Measures

Body Mass

Body mass (used interchangeably with bodyweight where colloquially appropriate in this document) was measured in kilograms by the researcher on the same set of calibrated scales at each assessment time point (enrolment, 12 weeks and 12 months post-enrolment). The scale was stationed on a hard, flat surface to ensure measurement accuracy. Each person was weighed without shoes or excess clothing (coats, heavy jumpers, handbags), and individuals were asked to wear similar clothing at each weigh-in (National Nurses Nutrition Group, 2013).

Body Height

Body height was measured by the researcher in centimetres using the same measurement tool at each assessment time point (enrolment, 12 weeks and 12 months post-enrolment). Individuals' height was measured while not wearing shoes or headwear. Height was measured with the person standing against the measurement tool in a neutral spine position (erect, hands at the side and eyes looking directly in front). The highest point on the head was measured perpendicular to the measurement tool.

Body Mass Index

The BMI was used to distinguish normal from abnormal body mass. BMI has consistently been used and continues to be used in clinical and public health settings to identify persons whose body weight does not fall within the normal range. BMI is calculated using the formula: BMI = mass (in kilograms)/height^2 (in metres). BMI has recently been criticised as a screening tool for overweight and obesity because it does not discriminate between fat and lean body mass. It is, therefore, less useful as an index with increasing age and in populations with very small or larger than average statures (Batsis et al., 2016; Hung et al., 2017). However, because BMI is easy to measure and calculate and does not involve high-cost equipment or advanced skill, it is still recommended by the World Health Organization (WHO) as a valuable tool to predict obesity-related risk. It is also recommended to monitor obesity-related risk reduction (World Health Organization, 2017). Using the calculated BMI, participants could be classified according to categories established by the WHO (World Health Organization, 2017). These categories are tabulated in Table 5. BMI was calculated by the researcher using measurements obtained by the researcher at each assessment time point (enrolment, 12 weeks, and 12 months post-enrolment).

Table 5

BMI Categories as Presented by the World Health Organization, (2017).

Category description	BMI (kgs/m^2)
Underweight	<18.5
Normal mass	18.5 to 24.99
Overweight	25 to 29.99
Obese I	30-34.99
Obese II	35 and 39.99
Obese III	> 40

Note: BMI = Body mass index measured in kilograms per meter squared

Waist Circumference

The WHO STEPS protocol for measuring waist circumference defines the waist as midway between the iliac crest and the lowest palpable rib (World Health, 2008). Measurements were reported in centimetres. Central obesity has been determined as a better predictor of health risk, especially risk associated with cardiovascular disease and T2DM, than BMI or body mass. It is therefore increasingly recommended in most literature that additional anthropometric measurements, e.g., waist circumference and waist to hip ratio, are used along with BMI in a 'matrix' to categorise health risk (Brambilla et al., 2013; Guasch-Ferré et al., 2012; Schneider et al., 2010). Waist circumference measurement has been recommended as a complementary tool, provided it is done scientifically using the recommended technique (World Health Organization, 2017). Waist circumference measurements associated with increased health risk by gender and ethnicity are tabulated in Table 6. The researcher made waist circumference measurements according to the WHO STEPS protocol. The WHO STEPwise Approach to Surveillance (STEPS) provides simple, standardised data collection, analysis and dissemination methods for member countries (World Health, 2008). The WHO STEPS protocol for measuring waist circumference states that the type of tape used needs to be stretch resistant and be placed in such a way that it is snug but not constricting. The position of the tape should be midway between the iliac crest and the lowest palpable rib. The measured individual must be standing erect, with arms at the side, feet positioned close together, and weight distributed equally across the feet. The tape should be maintained in a horizontal position parallel to the floor around the entire circumference. Abdominal wall tension can affect measurement accuracy; therefore,

individuals must be relaxed during measurements. It is advised that the individual being measured take a few deep, natural breaths before the measurement is made to minimise the inward pull of abdominal muscles. The point of measurement should coincide with the end of normal expiration. The most accurate results are achieved after a night's fast to minimise the possible effects of water, food or gas in the gastrointestinal tract (World Health, 2008). Waist circumference was measured in centimetres. Waist circumference measurement error has been determined to be 1.31cm from intra-measurer error and 1.56 cm from inter-measurer error (Lohman et al., 1988). The researcher performed measurements at each assessment time point (enrolment, 12 weeks, and 12 months post-enrolment).

Table 6

At-risk Waist Circumference Measurement (International Diabetes Federation, 2006).

Ethnic group	Gender	Waist circumference (cm)
Europid	Men	>94
	Women	>80
South Asian	Men	>90
	Women	>80
Chinese	Men	>90
	Women	>80
Japanese	Men	>90
	Women	>80

Note: cm - centimetre

Waist-to-height Ratio

In a study conducted by Schneider et al. (2010), data were analysed from two extensive cohort studies, namely the Diabetes Cardiovascular Risk Evaluation: Targets and Essential Data for Commitment of Treatment study (6355 participants) and the additional Study of Health in Pomerania study (4297 participants). It was determined that waist to height ratio represented the best indicator for cardiovascular mortality. The following best indicators were waist circumference and waist-to-hip ratio. Due to the absence of large prospective studies comparing the correlation between obesity-related morbidity and mortality and anthropometric measurements, the WHO still recommends using the BMI. Where possible, waist circumference and waist-to-hip ratio are recommended indicators of obesity-related risk. However, studies suggest that waist-to-height ratio is a more sensitive

indicator of obesity-related mortality (Ashwell & Gibson, 2016; Ashwell & Hsieh, 2005; Lee et al., 2008; Schneider et al., 2010). A waist-to-height greater than 0.5 indicates increased health risk (Ashwell & Gibson, 2016). Waist-to-height ratios were calculated by the researcher in Microsoft

The blood samples were drawn at the same time as the fasting FBG sample at either the Morisset or Cooranbong Douglass Hanly Moir Pathology blood collecting depot. Specimens were transported to the central laboratory in Sydney for analysis. One participant had one blood test at an alternative laboratory as it was the only available laboratory in their vicinity when the test was due. The blood lipid tests undertaken and the Australian recommended guidelines for blood lipid levels for persons with diabetes are tabulated in Table 7.

Table 7

Blood Lipid Levels Recommended by the Australian Diabetes Association (Royal Australian College of General Practitioners (RACGP) and Diabetes Australia, 2020).

Blood lipid	Diabetes	Diabetes with established CVD
Total Cholesterol	< 4.0mmol/L	
Triglycerides	< 2mmol/L	< 2mmol/L
HDL	> 1.0mmol/L	> 1.0mmol/L
LDL	< 2.0mmol/L	< 1.8mmol/L

Note: CVD - cardiovascular disease. HDL – High-density lipoprotein. LDL – Low-density lipoprotein.

Blood Pressure

The systolic and diastolic blood pressure was measured in millimetres of mercury (mmHg) at each assessment point.

Level of Physical Activity

The level of daily activity was assessed as a secondary outcome measure of adherence and was measured using the Revised Active-Q survey (Bonn et al., 2012). The Revised Active-Q physical activity questionnaire was developed to assess adults' total activity and inactivity levels. The Active-Q includes 35 questions covering occupational activity levels, transport to and from a daily occupation, leisure, and sporting activities. All activities link to a corresponding Metabolic Equivalent Task (MET) value. The activities are scored based on kilocalorie consumption related to MET value. The complete questionnaire can be viewed in Appendix B. This questionnaire was developed and validated as a web-based survey (Bonn et al., 2012). Permission for use was granted from the lead author of the publication reporting on the validation of the web-based version of this tool. See Appendix A. The paper version was never validated however, the questions in the online and paper versions are identical. The

paper version was used because several participants did not have computer literacy or did not have regular access to the software to complete the digital version. Scoring was performed manually utilising the scoring methods described in (Ainsworth et al., 2000). Appendix C contains a scoring list of Active-Q activities and their corresponding MET values (Ainsworth et al., 2000).

Dietary Intake

A food frequency questionnaire was completed to assess adherence to the CHIP dietary recommendations. The CHIP does not prescribe any specific diet or require a calorie restriction; however, a predominantly plant-based diet is recommended based on the calorie density of plant foods being significantly lower than animal products. Participants are also encouraged to reduce the amount of highly processed food and to eat "food as grown" as much as possible. Highly processed foods generally contain high levels of trans-fat, salt, sugar, preservatives, and other chemicals (Ponzo et al., 2021) that contribute to adverse health outcomes (Pagliai et al., 2021). The use of artificial stimulants, including sugar, artificial colourants, caffeine, and alcohol, is discouraged as these foods impact sleep and mood and may contribute to food addictions (Favrod-Coune & Broers, 2021; Schiestl et al., 2021). Sugar and alcohol provide calories and little nourishment and may inhibit weight loss (León et al., 2022).

A survey was administered with questions about the frequency of food consumed, including animal and vegetable-based proteins and fats, whole and refined grains, fruit and vegetables, sugar, condiments, and beverages. In addition, questions relating to meal regularity and cooking methods were also asked. This information was used to assess dietary change in response to the intervention. Participants were asked how frequently they ate breakfast, skipped lunch, and bought canteen food. These questions were asked to ascertain the regularity of meals and the frequency with which commercially prepared foods were consumed. Historically, canteen foods are more likely to be highly processed and have more sugar and fats (Lassen et al., 2014). There may be some physiological benefits to consuming a more significant proportion of calories in the morning compared to the evening which requires consuming a morning meal. A longer fasting period between meals may improve health outcomes and weight management (Paoli et al., 2019). The complete questionnaire is available in Appendix B.

Quality of Life

The primary goal of lifestyle medicine has been to alter the course of chronic diseases of lifestyle through lifestyle modification. The British Society of Lifestyle Medicine (2022) describes lifestyle medicine as, 'evidence-based clinical care that supports behaviour change through person-centred techniques to improve mental well-being, social connection, healthy eating, physical activity, sleep and the minimisation of harmful substances and behaviours. Based on this definition, an integral part of lifestyle medicine addresses the factors that determine quality of life (QOL). Significant changes in biometric or laboratory measurements indicate decreased morbidity and mortality risk. However, improvement in functional capacity, social and emotional well-being, reduced pain, and a perception of general health are QOL determinants, which are important clinical indicators of well-being for the patient (Bullinger & Quitmann, 2022). In addition, perceived improvement in QOL contributes to improved adherence (Bullinger & Quitmann, 2022).

Quality of life was measured using the RAND 36-item survey (SF-36). The RAND-36 survey was developed at RAND HEALTH as part of the Medical Outcomes Study and is acceptable to clients, has internal consistency and is a valid measure of health status in various individuals. The survey contains 36 questions categorised into the following broad categories of function: functional capacity, physical role limitations, emotional role limitations, energy, social functioning, emotional well-being, pain perception and general perception. The RAND-36 has been recommended as an acceptable survey for research by the National Health Service in the United Kingdom (Garratt et al., 1993). The complete survey may be viewed in Appendix B.

Demographic and Medical Data

Demographic and medical information were collected using a participant information sheet. Each participant completed the sheet before attending an appointment for anthropometric measurement. The researcher reviewed the information with the participant at the appointment to clarify any changes in client details, medications listed or diagnoses and to fill in any missing data. Specific information relating to the collection of demographic and medical data is described.

Gender

Gender was reported as being physiologically either male or female.

Age

Age at enrolment was determined from the date of birth.

Level of Education

The highest level of education was reported as; having not completed year 12 schooling, having completed year 12 schooling, having received a technical or college tertiary qualification, having received a university degree or a post-graduate university degree.

Current Medication Use

Participants reported the name, dose, and frequency of their current prescribed and unprescribed medication use at each assessment time point.

Previous Medical History and Current Diagnosis

A brief medical history relating to the participant's diabetes status, cardiovascular, neuro-musculoskeletal health and history of significant illness or surgery was obtained prior to enrolment to establish co-morbidities and confirm suitability for inclusion in the study. The information was updated at each data collection point to include any potentially new diagnoses.

Sample Size Calculation

The sample size was calculated using pre-intervention and post-intervention fasting blood sugar results and the respective standard deviation from various lifestyle intervention studies. Table 8 provides the data from which the effect size was calculated for each study. In the studies where individuals with diabetes formed a large portion of the participants, the effect size was considerably larger than in studies in which the general population was represented.

Table 8

Fasting Blood Glucose with Standard Deviation for Selected Lifestyle Intervention Studies.

Author	Initial FBG	Post int. FBG	Group division	Population	Effect size
Aldana et al. (2005)	102.8 (23.08)	-4.11 (15.74)	Int	Gen pop	0.21
	99.62 (19.45)	-2.4 (13.00)	Control		0.14
Diehl (1998)	111.3 (34)	-11.8 (23)	Male	Gen pop	0.4
	104.3 (42)	-6.7 (26)	Female		0.19
Rankin (2012)	105.4 (32.2)	96.87 (22.27)	Male	Gen pop	0.31
	92.2 (26.82)	93.8 (20.24)	Female		0.067
Davis Smith (not CHIP)	109 (8.3)	102 (7.5)		Pre-diabetes and diabetes	0.88
Kent (2013a)	101.29 (28.94)	94.86 (20.99)		Gen pop	0.25
Kent (2013b)	5.17 (0.29)	5.06 (0.30)	Nondiabetic	Gen pop	0.37
	6.64 (1.26)	5.85 (0.76)	Pre-diabetic /diabetic		0.76

Note: FBG denotes fasting blood glucose.

The *a priori* power analysis tool (Soper, 2023) was used to calculate the required sample size. The total sample required for this study was 220, with an equal number of participants in each arm of the study.

The sample size was calculated on the following assumptions:

- A reduction of 3.5 per cent of fasting glucose in the intervention group which was based on the average reduction achieved in other CHIP studies.
- An equal allocation of participants to each group
- A ten per cent drop-out rate

The study was sufficiently powered d>80% to detect a 3.5% reduction in fasting glucose using a significance of 0.05 (95% confidence interval).

Randomisation and Concealment

Randomisation

Individual participants were randomised rather than the practices from where they were recruited. The names of consenting participants were placed on a list. Enrolment was slow, and to ensure the participants were able to join a scheduled CHIP when the list grew to between ten and twenty names, the participants were randomised. Due to this lag in enrolments, participants were randomised at four different time points, and those in the intervention group subsequently attended four different CHIP programmes over 30 months. Similar and overlapping teams of volunteers conducted the four programmes at two similar venues during that period.

Concealment

Randomisation was performed using Microsoft

the biometric measurements from baseline to 12 weeks and from baseline to 12 months was assessed using a paired sample *t*-test with an α of .05. The assumptions of normality and normality of difference scores were checked for violations by visually inspecting the relevant histograms. The Shapiro-Wilk test was used to determine normal distribution to decide on whether to use parametric or non-parametric testing for correlations and variance analysis. A paired sample t-test (dependent t-test) was used to compare pre-and post-intervention data. An independent t-test was used to compare data between intervention and control groups. Pearson's correlation was used to explore relationships between continuous variables.

Active Q-survey

The Active-Q-survey was scored according to instructions published in Ainsworth et al. (2000). Energy expenditure (EE) was estimated based on the assumption that 1 MET is equivalent to the expenditure of 1 kcal per kilogram (kg) per hour (Ainsworth et al., 2000). The estimated participant's energy expenditure based on the Active-Q was calculated by multiplying the participant's body mass at the time of assessment (kg) by the average daily duration of the activity (hours per day) and the MET rating of the activity.

EE of activity (kcal/day) = MET of activity X Mass (kg) X Duration of activity (hours/day)

The sum of the energy expenditure was calculated for each activity recorded in a week, which comprised the total energy expenditure per week. This number was divided by seven to obtain the average daily estimated energy expenditure. The crude total energy expenditure was obtained by summing the energy contributions from each activity in Active-Q. The total energy expenditure over a 24-hours was calculated by adding the reported hours of sleep and naptime to the crude results from the Active-Q. Where the resulting time did not add up to 24 hours, time was added to obtain an adjusted total energy expenditure per 24 hours. A MET value of 2.0 was used as an assumed value for the time not accounted for (Bonn et al., 2012; Norman et al., 2001).

Food Frequency Survey

The food frequency data were analysed by calculating the number of servings per week for every food type surveyed. Where food types could be combined into a similar food category, this was done, and the serving amounts were calculated per category. For example, all whole grain products were categorised into a single food category. Descriptive statistics were used to obtain mean values for the servings of each category of food consumed at

baseline, 12 weeks, and 12 months. The difference between the baseline to 12-week and baseline to 12-month means was assessed using a paired sample *t*-test with an α of .05.

RAND-36 Survey

Quality of life was measured using the RAND-36 survey. The questions were scored and categorised into eight categories of function. Each participant's data was scored based on their responses to the questions in each category. A total score was calculated for each category. Descriptive statistics were used to obtain the mean value for each scored category across the intervention and control groups. The difference between the category means measured from baseline to 12 weeks and from baseline to 12 months were assessed using a paired sample *t*-test with an α of .05.

Ethical Considerations

The National Statement on Ethical Conduct in Human Research (National Health and Medical Research Council, 2015) was used to ensure the design, methods and data analysis met the required ethical standards to protect the identity and safety of the clients involved. The specific principles relevant to the study are research merit and integrity, justice, beneficence and respect (National Health and Medical Research Council, 2015). The Avondale Human Research Ethics Committee approved the ethics for this study under the identification number 2017:02.

The study was registered with the Australian and New Zealand Clinical Trial Registry (ANZCTR) on 23 August 2017 under registration number ACTRN12617001233314 and can be accessed at http://www.anzctr.org.au /ACTRN12617001233314.aspx. The description of the methods used for undertaking this RCT study has been outlined according to the CONSORT document (Moher et al., 2010). The published protocol paper and poster presentation relevant to this chapter are included at the end of the chapter. The following chapter will outline the data analysis and results of the quantitative data.

Conclusion to the Chapter

The description of the methods used for undertaking this RCT study has been outlined according to the CONSORT document (Moher et al., 2010). The published protocol paper and poster presentation relevant to this chapter are included at the end of the chapter. The following chapter will outline the data analysis and results of the quantitative data.

Publications Related to this Chapter

The following pages present a publication and presentation from 2019 which describe the original intended study protocol for this thesis. Linda Cloete was the major contributor and lead.

Cloete et al. BMC Endocrine Disorders (2019) 19:74
https://doi.org/10.1186/s12902-019-0396-x

BMC Endocrine Disorders

STUDY PROTOCOL Open Access

Protocol: investigating the effectiveness and cost benefit of a lifestyle intervention targeting type 2 diabetes in Australia

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Abstract

Background: Type 2 Diabetes Mellitus (T2DM) has become an endemic disease. A number of interrelated factors increase the risk of the onset of T2DM, however much of the pathogenesis of the disease is associated with lifestyle. A number of studies have indicated that adopting positive lifestyle changes can successfully prevent or delay the onset of T2DM in a number of different population groups. The CHIP intervention is a lifestyle program that has been shown in over more than 30 published papers have indicated that the CHIP intervention leads to dramatic improvement in the indicators of T2DM these diseases of lifestyle.

Methods: A randomized control trial will be conducted involving 150 individuals with an established diagnosis of T2DM. All participants will continue to receive usual ongoing diabetes care, however, the intervention group (75 individuals) will in addition participate in a 12-week CHIP lifestyle intervention programme followed by a further 9 months of monthly follow-up appointments. Approval for funding was obtained on 30 June 2017.

Discussion: The outcomes of this study have the potential to inform decisions about patient treatment and potentially provide incentive for the provision of funded lifestyle-based preventive and restorative programs for patients diagnosed with T2DM.

Trial registration: This trial is registered as an initial version with the Australia New Zealand Clinical Trials Registry (http://www.anzctr.org.au/), registration number ACTRN12617001233314. Registered on 23/08/2017. No enrollments in the study to date.

Keywords: Type 2 Diabetes Mellitus, Lifestyle, Diabetes, CHIP, Cost benefit

Background

Type 2 Diabetes Mellitus (T2DM) has become an endemic disease [1]. A number of interrelated factors increase the risk of the onset of T2DM, however much of the pathogenesis of the disease is associated with lifestyle, particularly the lifestyle habits associated with obesity [2].

The relationship between the onset of insulin resistance and the presence of obesity has been recognized for decades and is present in all ethnic groups and across the full spectrum of age, gender and body weight [3–5]. Both total and central (intra-abdominal) adiposity are strongly linked to insulin resistance as well as to other metabolic variables including increased plasma glucose, insulin, blood pressure, total cholesterol, low density lipoprotein (LDL) cholesterol and triglyceride concentrations and decreased plasma high-density lipoprotein (HDL) cholesterol concentration [6, 7].

Data from the DECODE study [8] indicated that myocardial infarction (MI), stroke or non-ischaemic cardiovascular disease cause 80% of deaths among patients with T2DM and over 60% of people having T2DM will develop cardiovascular disease. Indeed, T2DM and associated insulin resistance have been recognized as factors that independently increase the risk of cardiovascular morbidity and mortality. They also act synergistically with other major risk factors for cardiovascular disease such as smoking, hypertension and dyslipidaemia to increase cardiovascular disease risk [9].

A number of studies have indicated that adopting positive lifestyle changes can successfully prevent or delay the

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onset of T2DM in a number of different population groups [10–13]. Lifestyle changes recommended in these studies relate to those associated with reducing obesity such as increasing physical activity levels and consuming a low energy-density diet [13]. The eating pattern recommended in these studies was largely comprised of plant based foods that are low fat and cholesterol but high in fibre, which is in contrast to the traditional Western diet.

The Complete Health Improvement Program (CHIP) is a lifestyle intervention that was primarily designed to reverse coronary artery disease (CAD). Since its inception in 1988, researchers have become increasingly aware that the intervention was also effective in improving clinical outcomes for diseases like hypertension and T2DM. More than 30 published papers have indicated that the CHIP intervention leads to dramatic improvement in the indicators of these diseases of lifestyle. [14–17].

With no known medical cure for T2DM as well as the current and predicted increasing prevalence of the disease, it is important that the benefits of improved lifestyle in the population with diabetes continue to be explored. Increasing healthcare costs associated with chronic diseases and their complications make it necessary to employ programs that are effective and demonstrate a cost benefit.

Methods/design

Aims and research questions

There are two aims of this study:

1. To assess the effectiveness of the CHIP intervention in reversing abnormal fasting blood sugar levels in people with T2DM.
2. To determine the cost benefit of the CHIP intervention for persons with a diagnosis of T2DM.

The study will address three main questions;

In a diabetic population within a general practice group on the Central Coast of New South Wales, Australia:

1. When compared to a control group receiving routine diabetic care, what changes occur in fasting blood sugar levels (FBSL), HBA1c, fasting lipogram with triglycerides (FLT), blood pressure (BP), abdominal girth, body mass index (BMI) and medication use among individuals participating in the CHIP intervention delivered over a period of 12 weeks with additional monthly follow up for another 9 months?
2. Over a 12-month period, what levels of compliance with the intervention are observed in participants?
3. When compared to routine diabetic care, what is the cost benefit (over a 12-month period) of implementing a CHIP intervention delivered over a period of 12 weeks with an additional follow up for another 9 months?

Study design

A parallel randomized control study design will be used. A cohort of 150 patients will be randomized into either an intervention or control group. There will be 75 participants in each of the two groups. For the purpose of this study Group 1 will be the intervention group and Group 2 the control group.

Study setting

The CHIP intervention will be conducted by CHIP trained volunteers in selected community halls on the Central Coast of NSW. A demographic and lifestyle survey will be administered at the venue the intervention is conducted. Anthropometric measurements and blood collection will occur at the venue at which the CHIP intervention is being conducted unless the facility is not suited for medical data collection in which case it will be collected at selected general practices.

Study participants

a. Patients, who have a diagnosis of T2DM will be recruited from general practice medical centers (where practitioners have agreed to refer) on the Central Coast of NSW, Australia. Recruited patients will be invited to participate in the study. Enrollment of consenting participants will continue until the required sample size is met. The source population will be monitored at each participating General medical practice in order to ascertain what percentage of diabetes patients would be suitable to join the programme. Potential participants will be excluded based on the criteria below.

Exclusion criteria

Persons will be ineligible for the study if:

a. they are aged less than 18 years
b. the consulting medical practitioner considers that an alteration in nutrient or calorie consumption or that participating in regular moderate exercise could result in an increased health risk. This may include but may not be limited to:
   i. persons having a history of uncontrolled hypertension with consistent resting blood pressure readings greater than 180 mmHg systolic and or greater than 110 mmHg diastolic;
   ii. persons having a BMI lower than 21 kg/m^2, and making use of weight-loss medication;
   iii. persons experiencing recurrent chest pain or unstable angina;
   iv. pregnant or lactating females, or females planning to become pregnant in the next year;

v. persons who have undergone angioplasty or experienced a myocardial infarction or cardiac surgery within the previous three months;

c. they have any condition that precludes them from increasing their level of physical activity;

d. they have any physical condition or language barrier that would preclude them from understanding or safely adopting the lifestyle changes recommended by the CHIP intervention.

Allocation of participants to a study group

Invitees who are willing to participate will be recorded on a list until such time as there are between 30 and 40 individuals listed. At this point, the individual participants will be randomized into either Group 1 or Group 2.

Once allocated, participants in Group 1, will receive the CHIP intervention over a period of 12 weeks. At the end of the 12 weeks period, Group 1 will receive monthly follow-up for a further 9 month period. This process will be repeated, until the full number of participants have been collected and assigned.

An overview of the study design and allocation of participants is illustrated in Fig. 1.

Randomisation

The randomisation of participants will be performed by a person independent of the research team. The process of randomisation will occur with the aid of a computer. No blinding will be applied.

Interventions

Group 1- intervention group

All participants in Group 1 will participate in the CHIP intervention for 12 weeks. The CHIP intervention consists of 18 education sessions, each of 90 min duration. Approximately half of each session is devoted to viewing

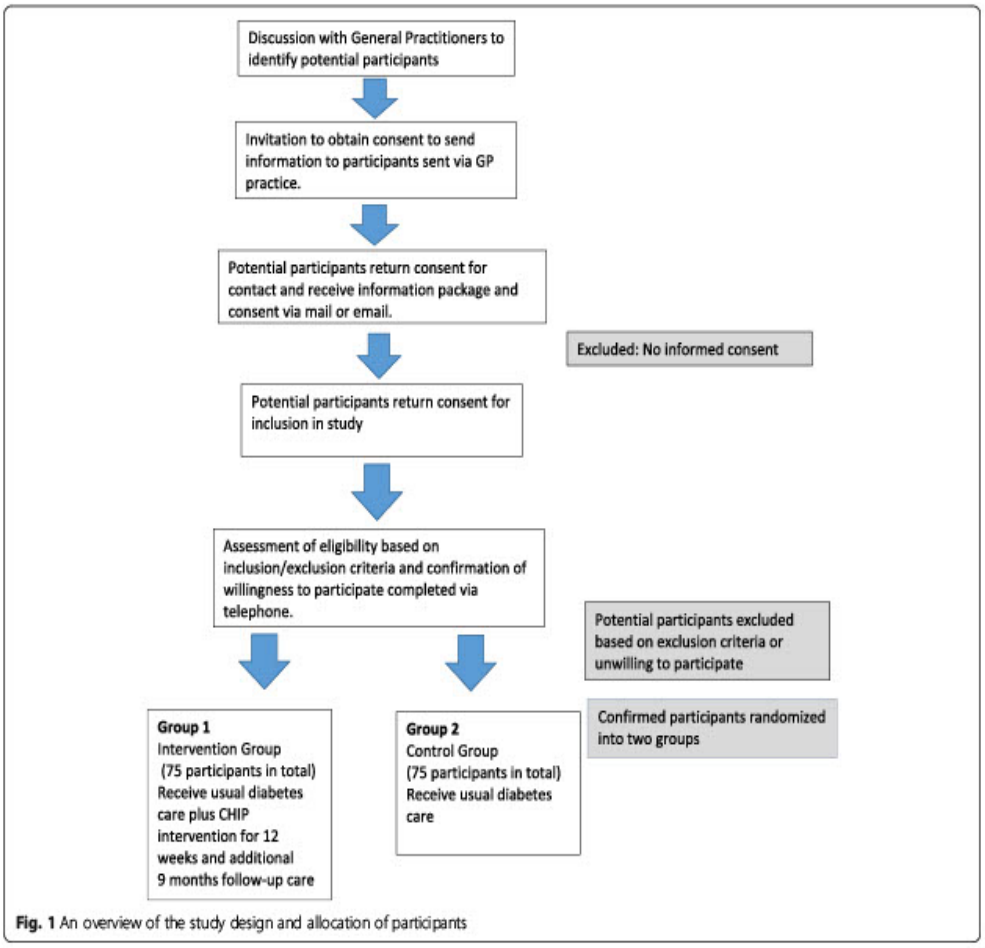

Fig. 1 An overview of the study design and allocation of participants

pre-recorded visual material delivered by lifestyle medicine professionals, while interactive group discussions and activities, including food preparation and exercise demonstrations delivered by CHIP trained volunteers, make up the remaining time. An outline of the topics covered over the 18 sessions can be viewed in Table 1.

Sessions 1 to 11 provides information on the aetiology, risk factors and pathological mechanism responsible for lifestyle related chronic disease. Emphasis is placed on the links between obesity, diabetes, hypertension, hyperlipidaemia and cardiovascular disease. Participants are provided with information relating to how lifestyle changes, particularly in diet and levels of physical activity, can positively alter the risk factors for as well as the course of chronic diseases. Specifically, the adoption of a plant-based, restricted sugar and salt diet is encouraged as well as daily physical activity involving a combination of aerobic and strengthening exercise most days of the week. Sessions 12 to 18 provide information related to other important lifestyle behaviors like substance use, rest, and sleep and stress management. Participants are provided with strategies that will assist them in assuming a position of control of their health, to overcome barriers, to manage and maintain behavior change and to cope with environmental pressures and stressors. At the end of the 12-week program, participants will be contacted for the purpose of assessing compliance and providing motivation and support on a monthly basis for an additional 9 months. Participants who receive less than 80% (4 sessions) of the program content will be regarded as having dropped out from the intervention and therefore will be excluded from the study. Self reported reasons for dropout will be noted.

Table 1 CHIP sessions as per topic

Session number	Topic
1	The rise of chronic disease
2	Lifestyle as medicine
3	The common denominator of chronic disease
4	The optimal lifestyle
5	Eat more, weigh less
6	Fibre, your new best friend
7	Disarming Diabetes
8	The heart of the matter – heart healthy
9	Controlling blood pressure and discovering protein
10	Bone health essentials
11	Cancer prevention
12	Understanding your results and taking action
13	Become what you believe. Your DNA is not your destiny
14	Practicing forgiveness
15	Re-engineering your environment
16	Stress relieving strategies
17	Fix how you feel
18	From surviving to thriving

Group 2 – control group

The control group will continue to receive their usual diabetes care and not receive any intervention or details about the CHIP intervention.

Data collection

Data collection consists of a standard participant survey (including questions on food frequency, daily levels of occupational and recreational activity, smoking, hours of sleep, medical conditions and medication use), anthropometric data, blood tests, an inventory of activity, the completion of validated health, stress and diabetes quality of life surveys and cost. The costs will include cost associated with the program, monitoring and ongoing medical care. Initial data collection will occur prior to commencement of the CHIP intervention. Repeat data collection time points for both groups will be at the end of the 12-week intervention and again at 12 months from the initial commencement date.

Sample size estimate

The total sample required for this study is 150, with an equal number of participants in each arm of the study. The sample size was calculated on the following assumptions: a reduction in 3.5% of fasting glucose in the intervention group, an equal allocation of participants to each group as well as a 10% drop out rate. A standard deviation of 20 was used. This study is sufficiently powered d > 80% to detect a 3.5% reduction in fasting glucose using significance of 0.05 (95% confidence interval).

Statistical analysis

All data collected will be coded and entered into IBM® SPSS® version 22 for Windows® (SPSS Inc., 2013) before analysis.

Analysis for research question 1 and 2

Descriptive statistics will be used to analyze demographic data, anthropometric measurement data, blood results and activity levels on commencement of the program and also at the described re-evaluation intervals. Descriptive statistics will include frequencies, percentage distribution, means, and medians as well as standard deviation from the mean.

The Shapiro-Wilk test will be used to determine normal distribution to decide on whether to use parametric or non-parametric testing for correlations and variance analysis. A paired sample t-test (dependent t-test) will be used to compare pre intervention data with post

intervention (12 weeks) and pre intervention data with post intervention (12 months) data. An independent t-test will be used to compare data between intervention and control groups. Pearson's correlation will be used to explore relationships between continuous variables. The dietary inventory, health survey, and quality of life survey will be independently scored and the results between groups compared using linear regression. The level of significance is set at $p < 0.05$.

Analysis for research question 3

To determine the cost benefit of the intervention, a cost-benefit analysis will be undertaken. The cost benefit analysis will involve assessment of beneficial effects of the intervention. The analysis will include benefits and costs attributed to the project and indirect costs. Therefore, where B represents all the benefits and C represents all the costs, the project will be considered beneficial if B-C > 0. A cost benefit ratio will also be calculated. Costs included in the analysis will include opportunity costs. Costs from published literature and from government agencies will be used wherever possible, for example, the Medical Benefits Scheme and Pharmaceutical Benefits Scheme.

Dissemination of results

Results of this study will be disseminated to participants through the means of a newsletter. It is also the authors intention to communicate results through conference proceedings and journal publication. This protocol as well as further results are required to be presented at research forums held by Avondale College of Higher Education.

Discussion

This study addresses a gap in knowledge, in that while there have been a number of studies exploring changes in diet and or exercise and effect on T2DM, no specific randomized controlled study investigating the effectiveness of a holistic health programme in targeting T2DM has been undertaken. Further, while a number of studies using the CHIP lifestyle programme have indicated significant improvements in blood glucose and lipid profiles, the proposed study investigates the cost benefit of such a programme, thus informing decisions about appropriate allocation of scare health resources.

Ethical considerations

Ethics has been approved by Avondale Human Research Ethics Committee. Approval identification number 2017: 02. The specific principles relevant to this study are research merit and integrity, justice, beneficence and respect (The National Health and Medical Research Council et al., 2007 Updated 2015).

This study has been designed to be low risk, and is likely to provide valuable insight into lifestyle management of T2DM. Patients approached for participation will be offered equal opportunity to participate in the study. No potential participants will be coerced and no monetary or other rewards offered other than potential health benefits achieved. The outcomes of the study will be made known to all participants. Other than laboratory testing requiring the drawing of blood samples no harm to participants is anticipated. Informed consent will be obtained from all participants. Participants may elect to opt out of answering questions, participating in surveys and are free to exit the study at any time without any consequence to their medical management. All data will be collected in a de-identified format using coding to match data. Once coding has been completed, the original coding descriptors will be destroyed. Following the data analysis process, any information that allows the data to be identified in any way will be permanently destroyed. Data collected will be entered into SPSS and stored on an external hard drive which will be kept under lock and key while not in use for analysis. All original data will be stored in paper format in a locked filing cabinet in the researcher's office on Avondale College of Higher Education's Sydney campus until the completion of data collection and analysis. Thereafter the data will be permanently destroyed. The results of this study will be published in a format that will protect all participant's identity. No individual results will be published. Participants will not be required to personally fund any part of the study or laboratory tests required for data collection.

Medical management of participants

Participants will be referred to their General Practitioner for any medically related symptoms or medication changes that may be required due to alterations in blood sugar or blood pressure measurements.

Limitations

Several factors may influence the results obtained in this study. Firstly, compliance with the intervention is paramount to the success of lifestyle modification programmes, but it is also difficult to measure actual compliance reliably. Some data collection, namely dietary analysis, exercise compliance and medical costs will rely on patient integrity and accurate reporting which may not necessarily be reliable.

A potential confounder is that of the Hawthorne effect in that the participants' behaviour may be affected by the fact that data is collected at baseline and again at future intervals.

The outcomes of this study have the potential to inform decisions about patient treatment and potentially provide incentive for the provision of funded lifestyle-based preventive and restorative programs for patients diagnosed with T2DM.

Study status

At the time of submission for publication the researcher is about to begin the process of participant recruitment.

Conclusion

The outcomes of this study have the potential to inform decisions about patient treatment and potentially provide incentive for the provision of funded lifestyle based preventive and restorative programs for patients diagnosed with T2DM.

Abbreviations

BGL: Blood glucose level; BMI: Body mass index; CAD: Coronary artery disease; CHIP: Complete Health Improvement Programme; LDL: Low-density lipoprotein cholesterol; NSW: New South Wales; T2DM: Type 2 Diabetes Mellitus

Acknowledgements

Not applicable.

Authors' contributions

This study will be undertaken for doctoral research purposes. All authors have contributed to the design and development of this protocol and will have access to the data. The first author has prepared the manuscript, while the second and third authors have contributed as consultants and reviewers in their capacity as research supervisors. Authors will take full responsibility for the integrity of the data and the accuracy of the data analysis. All authors read and approved the final manuscript.

Funding

A grant has been obtained from the Lifestyle Research Centre at Avondale College of Higher Education. The Lifestyle Research Centre has played no role in the development of the study design, assisting with data analysis and interpretation or in the writing of the manuscript other than in reviewing the protocol for the purpose of awarding funding. The funding obtained was used to pay for blood testing and therefore assisted in data collection. Sanitarium Health and Wellbeing have subsidized educational materials. The organization has played no role in developing the study design, contributing toward data analysis and interpretation or in the writing of the manuscript other than in reviewing the protocol for the purpose of awarding funding.

Availability of data and materials

Not applicable.

Ethics approval and consent to participate

Ethics has been approved by Avondale Human Research Ethics Committee. Approval identification number 2017.02. Potential participants will all receive information relating to the study design and randomization process as well as their role as participants. Written consent to participate will be obtained from all participants.

Consent for publication

Not applicable.

Competing interests

Funding, as explained below is the only declared potential competing interest. Sanitarium health and well being are the licenced owners of the intervention (CHIP) programme. The authors declare that they have no other competing interests.

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Publisher's Note

PROTOCOL FOR A RANDOMIZED CLINICAL TRIAL INVESTIGATING THE CLINICAL EFFECTIVENESS AND COST BENEFIT OF A LIFESTYLE INTERVENTION TARGETING TYPE 2 DIABETES MELLITUS

By Linda Cloete [1], Brett G. Mitchell[2] and Darren Morton[3]
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Introduction

Type 2 Diabetes Mellitus (T2DM) has become an endemic disease [1][2]

About 86% of the current 422 million people who are living with diabetes in the world are diagnosed with T2DM. The global prevalence has almost doubled since 1980 and now includes about 8.5% of the world's population [3]

In Australia more than 1.2 million people are registered with the national Diabetes Service Scheme. Of these, just over 1 million individuals have T2DM. It is estimated a further half million people in Australia have undiagnosed T2DM [4].

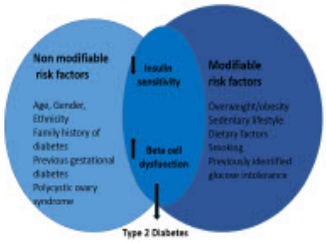
A number of interrelated factors increase the risk of the onset of T2DM, however much of the pathogenesis of the disease is associated with lifestyle, particularly the lifestyle habits associated with obesity [5].

Background

The relationship between the onset of insulin resistance and the presence of obesity has been recognized for decades and is present in all ethnic groups and across the full spectrum of age, gender and body weight [6][7][8].

A number of other risk factors also contribute to the development of the disease. These are illustrated in Figure 1.

Figure 1 Risk factors for T2DM



Cardiovascular diseases cause 80% of deaths among patients with T2DM and over 60% of people having T2DM will develop cardiovascular disease [9].

T2DM and insulin resistance have been shown to be independent risk factors for the development of cardiovascular disease [10]

Reducing the prevalence of diabetes will also make a significant contribution towards the incidence and prevalence of Australia's number one killer, cardiovascular disease.

A number of studies have indicated that adopting positive lifestyle changes can successfully prevent or delay the onset of T2DM in a number of different population groups [11][12].

Lifestyle changes recommended in these studies relate to those associated with reducing obesity such as increasing physical activity levels and consuming a low energy-density diet [13]

Plant based foods are optimal as they are generally not energy dense, are low fat and have zero cholesterol but high in fibre, all of which is in contrast to the traditional Western diet.

With no known medical cure for T2DM as well as the current and predicted increasing prevalence of the disease, it is important that the benefits of improved lifestyle in the population with diabetes continue to be explored.

Increasing healthcare costs associated with chronic diseases and their complications make it necessary to employ programs that are effective and demonstrate a cost benefit.

The Complete Health Improvement Program (CHIP) is a lifestyle intervention that was primarily designed to reverse coronary artery disease (CAD). Since its inception in 1988, researchers have become increasingly aware that the intervention was also effective in improving clinical outcomes for diseases like hypertension and T2DM.

More than 30 published papers have indicated that the CHIP intervention leads to dramatic improvement in the indicators of these diseases of lifestyle. (Diehl, 1998; Morton, Rankin, Kent, & Dysinger, 2014; Morton et al., 2013; Rankin et al., 2012).

Aims

1. To assess the effectiveness of the CHIP intervention in reversing abnormal fasting blood sugar levels in people withT2DM.
1. To determine the cost benefit of the CHIP intervention for persons with a diagnosis of T2DM.

Research Questions

The study will address three main questions;

In a diabetic population within a general practice group on the Central Coast of New South Wales, Australia, when compared to a control group receiving routine diabetic care;

1. What is the effect of implementing the CHIP intervention on changes in fasting blood sugar levels (FBSL), HBA1c, fasting lipogram with triglycerides (FLT), blood pressure (BP), abdominal girth and body mass index (BMI) in individuals participating in the CHIP intervention delivered over a period of 12 weeks with additional monthly follow-up for another 9 months?
2. Over a 12-month period, what levels of compliance with the intervention are observed in participants?
3. What is the cost benefit (over a 12-month period) of implementing a CHIP intervention delivered over a period of 12 weeks with an additional follow-up for another 9 months?

Ethics and Clinical Trial Registry

This study has been funded by Avondale College of Higher Education with subsidised educational materials from Sanitarium Health and Wellbeing.
The authors declare that there are no funding or other conflicts of interest that will have an impact on the integrity of this study.
Avondale College HREC Status: Approved
ANZCTR Trial No: ACTRN12617001233314
Contact: Linda.cloete@avondale.edu.au

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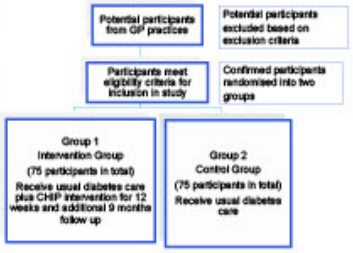
Methodology

Design: Randomised control study
Setting: Community halls on the Central Coast of NSW
Participants: Patients from general practice centres on the Central Coast of NSW
Randomisation:

Figure 2 Randomisation into intervention and control groups



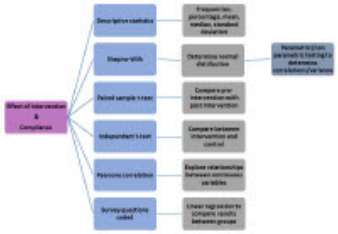
Exclusion criteria
Age less than 18.
Persons where an alteration in nutrient, calorie consumption or physical activity could result in an increased health risk.
Physical condition or language barrier that would preclude understanding or safely adopting recommendations.

Intervention

Figure 3. Breakdown of Interventional Stages

Analysis

Figure 4. Analysis of the effectiveness of the intervention and compliance of the participants



Cost benefit analysis: Where B is equal to all the benefits and where C is equal to all the cost, the intervention will be beneficial if: B – C >zero. A cost benefit ratio will also be calculated.

Timeline
September 2017 : Commence enrolment in study
April 2019 : Complete data collection
December 2019 : publication of results

Avondale COLLEGE OF HIGHER EDUCATION

CHAPTER 4: STUDY 1 RESULTS

The results of Study 1, which addressed the first and second Research Questions of this thesis are reported in this chapter. The volunteer-based intervention programmes were run between February 2018 and November 2019 in the Lake Macquarie region of New South Wales, Australia. Enrolment for this study was slow from the outset and was then further impacted by COVID-19 restrictions. The COVID-19 restrictions prevented implementation of the intervention for participants enrolling after November 2019. The study was therefore significantly underpowered; however, the results of the analysis of completed data sets are reported in this chapter.

Recruitment, Randomisation, and Intervention Dates

The number of individuals initially randomised for this study was 35. These individuals were randomly divided into an intervention (n=18) and a control (n=17) group. Due to slow enrolment, the first randomisation was performed after ten participants had enrolled in April 2018. Those randomised into the intervention group commenced the CHIP in May 2018. A further randomisation was performed once another eight participants had enrolled in February 2019, with participants in the intervention group commencing the CHIP in March 2019. The final randomisation was performed with the remaining group in May 2019, with the intervention group commencing the CHIP in June 2019. Before the baseline assessment, one participant dropped out of the intervention group due to work commitments, and five participants dropped out of the control group once they were informed that they were not part of the intervention group. The enrolment and drop out of participants are illustrated in Figure 3

After the baseline assessment had been partially completed, another participant dropped out in each group, leaving 17 participants in the intervention and 11 persons in the control group. After dropout the completed data set for this study consisted of 28. The two participants who dropped out post-baseline assessment were of different gender and in different age groups and had diverse biometrical measurements. The male was retired and in his 70s (control group), whereas the female was in her 50s and was working full-time. The baseline measurements available for these two are tabulated in Table 9

The trial was discontinued to meet Avondale University's submission timeline requirements for this thesis.

Figure 3

Participant Enrolment and Dropout

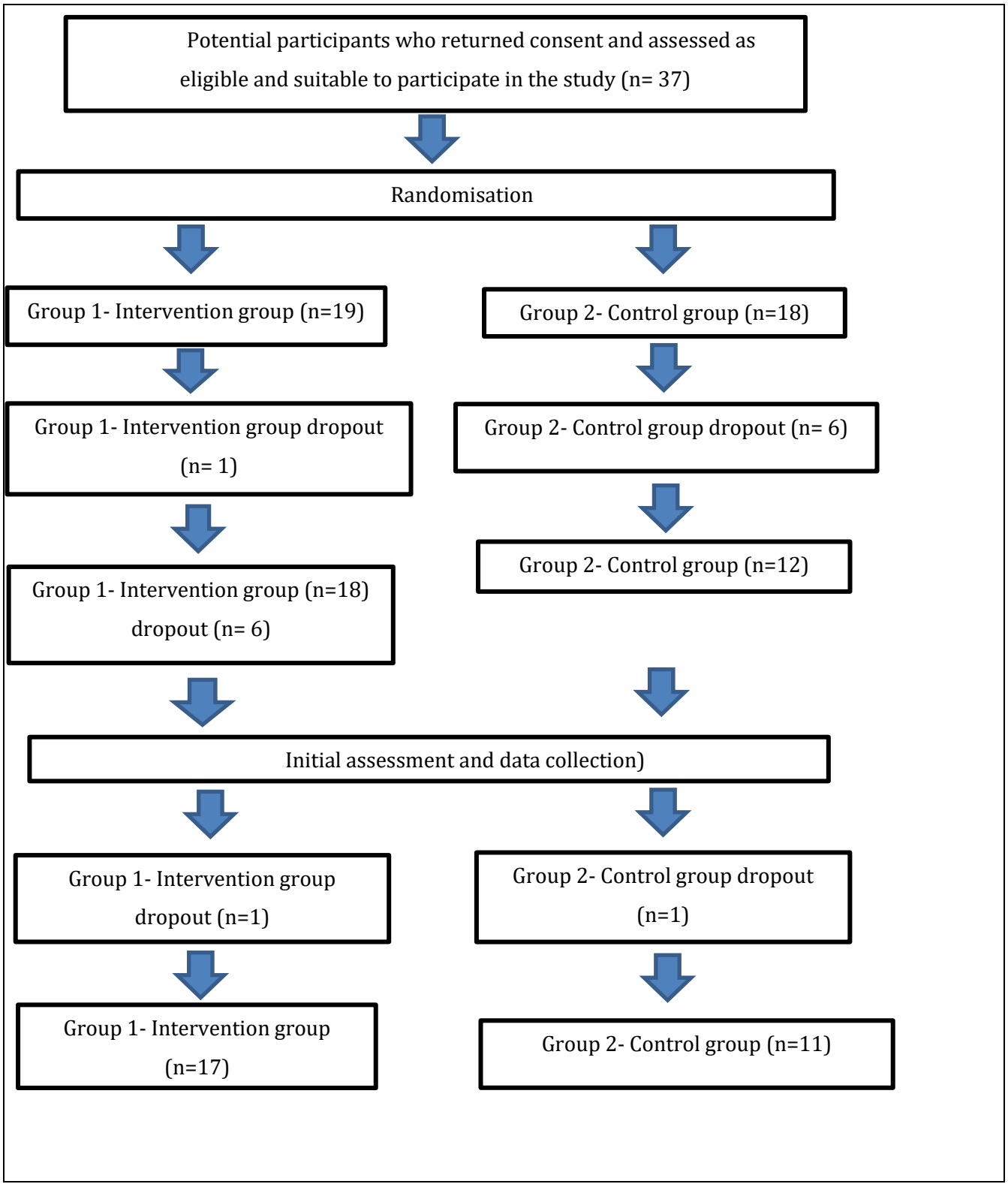


Table 9

Baseline Measurements of Participants Who Dropped Out After Baseline Assessment.

Measurement	Male dropout client 1	Female dropout client 2
Height	169.7cm	155cm
Weight	83.8kg	85.8kg
BMI	29kg/m^2	35kg/m^2
Waist circumference	112cm	125cm
Hip circumference	113cm	120cm
Blood pressure	132/62mmHg	130/60 mmHg

Note: mmHg denotes millimetres of mercury.

Demographic Differences between Participant Groups

In recognition of the fact that the study was underpowered the data were explored using demographic details obtained at baseline and at subsequent assessment points (12 weeks and 12 months). This data included the participant's name and address details, highest level of education and treating or referring doctor details. Demographic, educational and referral details for the intervention and control groups are depicted in Table 10

Summary of Demographics, Education and Referral Results

Age

An independent samples *t*-test was used to compare the average ages of participants in the two groups. Neither Shapiro-Wilk statistic was significant, indicating that the assumption of normality was not violated. This was confirmed through visualising leaf and stem plots (distribution 43 to 88 years) as well as a histogram representation of participant ages. Levene's Test for Equality of Variances showed a significance of .816, indicating that equal variances can be assumed. The *t*-test for equal variances was not significant at t=1.150, df= 26 *Sig* (2-tailed) = .260. The Mean age in the Intervention (M=68.47, SD 11.046) and Control groups (M=73.55, SD= 11.945) was not significantly different. Cohen's d =.46 indicated a near-medium effect size.

Gender

There was an almost equal distribution of gender within each group; the intervention had eight males and nine females, and the control group had five males and six females.

Highest Level of Education

The intervention group contained a high proportion of university-educated professionals (30%) as opposed to the control group (0%), while the control group contained a higher proportion of TAFE-qualified and high school-qualified persons (with a year 12 as their highest level of education) (46%) than the intervention group (36%). The proportion of individuals who had not completed a year 12 qualification was similar in both groups.

Medical Practice Referral

Participants were mainly referred from two medical practices. Doctors from Practice 1 and Practice 2 were very supportive of the study and encouraged their clients to participate. Participants whose doctors practised in the practices designated Practice 3 and 4 were self-referred and obtained permission from their doctor to participate.

Medical History Differences between Participant Groups

A component of the demographic information form was dedicated to describing the participants' previous medical history, current health problems, and the then-current pharmacotherapy.

Table 11

*Previous Medical History of Participants in Intervention and Control Groups*is a summation of the previous medical history of participants in both the intervention and control groups, providing context and insight into the participant's general health and the health challenges that have previously been experienced.

Table 12 depicts the current medical diagnoses of participants in the intervention and control groups at the time of the first assessment. These diagnoses remained static throughout the study period except for two participants who obtained an additional diagnosis during the study period which is listed at the end of the table. All (100%) of the participants had a diagnosis of T2DM, and 64 per cent (n=11) of the intervention group and 45 per cent (n=5) of the control group presented with complications of T2DM, namely vascular disease, neuropathy, affected vision or renal disease. Therefore, 57 per cent of the cohort had T2DM in advanced stages. Diagnoses were grouped under main headings; namely diabetes risk-related, diabetes complications, pain and mobility and other conditions. An individual's current and previous health status may contribute to an increased risk of systemic

inflammation, which could impact the course and severity of T2DM. Current health status may also impact the degree to which lifestyle modification activities are adopted; for example, pain and mobility may limit the degree to which a person is active, and certain gastro-intestinal conditions may impact dietary choices.

Primary Outcome Results

More sophisticated analyses utilising repeated measures ANOVA and General Linear Modelling were planned to examine differences between the intervention and control groups, but these were not permitted due to a reduced sample size from recruitment and COVID-19 related challenges previously discussed.

Glycaemic Control

Fasting blood glucose and HbA1c were primary outcome measures designed to inform the first research question. Scores obtained for the paired sample *t*-test for both intervention and control groups are presented in Table 13. Statistically significant differences between means were detected in the change in HbA1c between baseline (Mean = .72, SD = 1.14) and 12 weeks in the intervention group (p = .024). No other changes in blood glucose levels or HbA1c demonstrated statistically significant differences between means for any of the time-periods. Table D 1

Changes in Hypoglycaemic Medication in the Intervention Group Over the First 12 Weeks.

(See Appendix D1) provides the medications used for glycaemic control by the intervention group across the first 12 weeks. There was some alteration in medication in the intervention group during this period, namely a single instance of medication being commenced after baseline and two cases where medication dosage was increased during the first 12 weeks. Three participants had an oral hypoglycaemic agent ceased, and one had their insulin ceased.

Table 10

Summary of Demographics, Education and Referral Results.

Descriptor	Intervention group	(n)	Control group	(n)	Total mean
Numbers	61%	17	39%	11	
Age (years)					
Mean (SD)	68.47 (11.04)		73.54 (11.94)		70.46
Range	43-87 (44)		52-88 (36)		43-88
Gender					
Male	47%	8	46%	5	46%
Female	53%	9	55%	6	54%
Highest level of education					
Post-graduate degree	18%	3	0%	0	10%
University degree	12%	2	0%	0	7%
TAFE/College	24%	4	36%	4	28%
Completed year 12	12%	2	27%	3	18%
Did not complete year 12	35%	6	36%	4	36%
Medical practice					
Practice 1	59%	10	55%	6	57%
Practice 2	24%	4	46%	5	32%
Practice 3	6%	1	0%	0	4%
Practice 4	12%	2	0%	0	43%

Note: This table illustrates the demographic characteristics of the intervention and control SD- Standard deviation, n- number. Medical practice denotes the practice with which the participant's primary GP is associated.

Table 11

Previous Medical History of Participants in Intervention and Control Groups.

Previous history	Control group %	Control group number (n)	Intervention group %	Intervention group number (n)	Total %
Heart disease (Rheumatic fever)	9%	1	0%	0	3.5%
Stroke or trans ischaemic attack (TIA)	9%	1	12%	2	11%
Cancer (Breast, Prostate, Liver, Skin)		3	24%	4	25%
Surgery (Brain aneurism, back surgery, Cholecystectomy, rectal polyps, caesarean section)	36%	4	41%	7	39%
Haematological (Pulmonary embolus)	0%	n=0	6%	n=1	4%

Note: Medical terms are defined in the table of definitions. The letter n denotes the number of participants.

Table 12

Current Medical Diagnoses in Intervention and Control Group.

Diagnosis	Control group %	Control group number (n)	Intervention group %	Intervention group number (n)	Total %
Type 2 diabetes	100%	11	100%	17	100%
Diabetes risk related					
Hypertension	64%	7	65%	11	64%
Hypercholesterolaemia	73%	8	47%	8	57%
Diabetes complications					
Neuropathy	36%	4	24%	4	29%
Circulatory disease	0%	0	6%	1	3.5%
Claudication (Raynaud's disease)	9%	1	12%	2	11%
Vision	9%	1	12%	2	11%
Renal disease	9%	1	0%	0	3.5%
Pain and mobility					
(Neck or back pain,	64%	7	47%	8	54%
joint pain,	36%	4	24%	4	29%
difficulty walking)	36%	4	24%	4	29%
Asthma	18%	2	18%	3	18%
Mental health					
Anxiety/depression	9%	1	35%	6	25%
Other present conditions					
Autoimmune disease (Hypothyroidism, congenital muscular atrophy, disseminated granuloma annulare, Lupus)	18%	2	12%	2	14%

Diagnosis	Control group %	Control group number (n)	Intervention group %	Intervention group number (n)	Total %
Gastrointestinal disease (GORD, gastric ulcer)	27%	3	6%	1	14%
Atrial fibrillation	18%	2	0%	0	7%
Gout	9%	1	0%	0	3.5%
New diagnoses during study					
New diagnosis 12 weeks (Hip replacement)	0%	0	6%	1	3.5%
New diagnosis 12 months (Post-traumatic stress disorder)	0%	0	6%	1	3.5%

Note: Medical terms are defined in the table of definitions.

Table 13

Means and Paired Sample t Test Scores across Intervention and Control Groups for Glycaemic Control Measurements.

	Initial			12 weeks			12 months			Initial to 12 weeks			Initial to 12 months		
Variable	***n***	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*t*	*df*	*Sig* (2-tailed)	*t*	*df*	*Sig* (2-tailed)
Fasting blood glucose (I)	16	7.73	1.42	17	7.32	2.43	12	7.01	1.711	.58	15	.57	.61	11	.55
Fasting blood glucose (C)	11	7.30	1.49	11	7.14	1.31	11	7.01	1.55	.69	10	.51	.62	10	.55
HbA1c (I)	16	7.48	1.27	17	6.68	.88	12	6.91	1.169	2.50	15	.024	1.34	11	.21
HbA1c (C)	11	6.71	.70	11	6.66	.66	11	6.65	.60	.38	10	.71	.28	10	.78

Note: (C) denotes the control group, (I) denotes the intervention group, *n* denotes the number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes the significance.

Secondary Outcome Results

Body Weight, BMI, Waist Circumference, Hip Circumference, and Blood Pressure

As presented in

Table 14

Means and Paired Sample t-test Scores across Intervention and Control Groups for Selected Biometric Measurements improvements were achieved in the intervention group for mass (Mean = 7.09, SD = 4.02, $p < .001$) and BMI (Mean = 2.54, SD = 1.5, $p = <.001$) between baseline and 12 weeks and for mass (Mean = 4.48, SD = 5.36, $p = .003$) and BMI (Mean = 1.63, SD = 2.04, p=.005) between baseline and 12 months. Improvement was also shown in the intervention group for diastolic blood pressure (Mean = 6.77, SD = 9.24, $p = .008$), hip circumference (Mean = 4.97, SD = 3.82, $p < .001$), waist circumference (Mean = 7.62, SD = 5.81, $p = .001$) and height-to-waist ratio (Mean = .002, SD = .002, $p < .001$) between baseline and 12 weeks. Improvements were also shown between baseline and 12 months for hip circumference (Mean = 4.03, SD = 5.16, $p = .005$), waist circumference (Mean = 5, SD = 6.83, $p = .008$) and height-to-waist ratio (Mean = .001, SD = .003, $p = .008$). In Appendix D, Table D2 a comparison of antihypertensive medication used across the 12 months of the study is provided. More participants in the intervention (58%) than in the control group (45%) ceased an antihypertensive drug in the first 12 weeks of the study. Significant changes in some biometric measurements were associated with participation in CHIP, however, over time, the changes became less significant. There were no significant changes in biometric measurements in the control group.

Lipid Profile

No statistically significant changes in lipid profile measurements were obtained for any of the time periods and across all blood level tests, as shown in Table 15
Means and Paired Sample t Test Scores across Intervention and Control Groups for Selected Lipid Profile Measurements. In Appendix D, Table D3 provides a comparison of lipid-lowering medication used in both the intervention and the control groups across the full 12 months of the study are provided. One participant in the intervention group had lipid-lowering drugs ceased at 12 weeks.

Table 14

Means and Paired Sample t-test Scores across Intervention and Control Groups for Selected Biometric Measurements.

		Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
Variable	N	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2-tailed)	*t*	*df*	*Sig* (2-tailed)
Mass (C)	11	83.30	12.31	82.95	11.90	83.45	14.18	.52	10	.61	-.09	10	.93
Mass (I)	17	101.70	14.22	94.61	12.44	97.23	15.23	7.28	16	<.001	3.45	16	.003
BMI (C)	11	29.28	3.83	29.24	3.82	29.41	4.63	.15	10	.89	-.25	10	.81
BMI(I)	17	36.15	5.43	33.61	4.68	34.52	5.65	6.99	16	<.001	3.30	16	.005
Systolic blood pressure (C)	11	134.55	16.71	135.82	23.18	130.18	12.31	-.255	10	.81	1.18	10	.27
Systolic blood pressure (I)	17	135.65	8.11	130.06	11.10	134.47	14.69	2.15	16	.05	.27	16	.79

		Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
Variable	N	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2-tailed)	*t*	*df*	*Sig* (2-tailed)
Diastolic blood pressure (C)	11	75.64	6.80	73.64	9.24	73.18	6.94	.78	10	.46	1.01	10	.34
Diastolic blood pressure (I)	17	79.53	9.63	72.76	7.53	73.74	9.07	3.02	16	.008	2.30	16	.04
Hip Circumference (C)	11	111.59	8.41	110.45	9.26	108.23	9.08	.91	10	.38	1.88	10	.09
Hip Circumference (I)	17	125.38	13.24	120.41	12.33	121.35	14.73	5.36	16	<.001	3.22	16	.005
Waist Circumference (C)	11	109.32	13.42	108.82	13.59	108.27	12.76	.57	10	.59	.58	10	.58
Waist circumference (I)	17	109.32	13.42	108.81	13.59	108.27	12.76	5.405	16	<.001	3.02	16	.008
Waist-to-hip ratio (C)	11	0.98	0.7	0.98	0.6	1.00	0.7	-.85	10	.41	-2.82	10	.018
Waist-to-hip ratio (I)	17	0.98	0.07	0.96	0.07	0.98	0.07	2.43	16	.03	.68	16	.51
Height-to-waist ratio (C)	11	0.65	0.7	0.65	0.7	0.64	0.7	1.17	10	.27	1.05	10	.32
Height-to-waist ratio (I)	17	0.73	0.7	0.69	0.6	0.70	0.7	6.16	16	<.001	3.04	16	.008

Note: (C) denotes the control group, (I) denotes the intervention group, *n* denotes the number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes the significance.

Table 15

Means and Paired Sample t Test Scores across Intervention and Control Groups for Selected Lipid Profile Measurements.

	Initial			12 weeks			12 months			Initial to 12 weeks			Initial to 12 months		
Variable	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*t*	*df*	*Sig* (2-tailed)	*t*	*df*	*Sig* (2-tailed)
Total Cholesterol (I)	15	4.37	1.18	17	4.16	1.01	12	4.56	.91	1.42	14	.18	-.92	11	.38
Total Cholesterol (C)	11	4.30	1.01	11	4.44	1.17	11	4.28	1.03	-1.0	10	.34	.12	10	.91
HDL Cholesterol (I)	15	1.23	.21	17	1.16	.22	12	1.25	.25	1.02	14	.33	-.52	11	.62
HDL Cholesterol (C)	11	1.32	.48	11	1.36	.46	11	1.30	.42	-1.24	10	.24	.28	10	.98
LDL Cholesterol (I)	15	2.32	.99	17	2.19	.82	12	2.41	.87	1.20	14	.25	-.73	11	.48
LDL Cholesterol (C)	11	2.25	.84	11	2,25	.88	11	2.18	.64	-.08	10	.94	.56	10	.59
Triglycerides (I)	15	1.81	.63	17	1.70	.64	13	1.92	.84	.35	14	.73	-.71	12	.49
Triglycerides (C)	11	1.75	1.10	11	1.85	1.57	11	1.92	1.13	-1.47	10	.17	-1.03	10	.33

Note: (C) denotes the control group, (I) denotes the intervention group, *n* denotes the number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes the significance.

Level of Activity

Results for the number of hours spent in activity per week, the average hours of sleep combined with naptime per week and the average daily energy expenditure (kcal) for each group are reported in Table 16

Means and Paired Sample t Test Scores Across Intervention and Control Groups for Hours of Activity and Sleep and Energy Expended. Statistically significant differences between means were detected in the change in hours of weekly activity between baseline and 12 weeks in the intervention group (Mean = -11.91, SD = 16.47, p = .01). No other changes in activity or energy expending parameters demonstrated significant differences between means for any of the time periods and across all parameters.

Food Frequency

Results have been tabulated according to different food groups for ease of presentation and viewing. These tables may be viewed in Appendix E

Eating Habits. Both the intervention and control group showed no significant alteration in the amount of salt used on their food. The control group showed no alteration in the frequency with which they consumed foods not prepared at home, however a decrease in the amount of canteen food bought was demonstrated by the intervention group at 12 months (Mean = .82, SD = 1.47, p = .03).

Protein Foods. Significantly altered protein dietary changes included a decreased consumption of animal protein in the intervention group at both 12 weeks (Mean = 2.62 SD = 2.10, p = <.011) and at 12 months (Mean = 1.97, SD = 1.95, p = <.011). The intervention group decreased their consumption of processed grains at 12 weeks (Mean = 7.53, SD = 11.90, p = .02) however, by 12 months the change was no longer significant (Mean = 6.85, SD = 13.88, p = .06). The control group displayed no significant dietary alteration concerning protein.

Vegetables and Fruit. The consumption of fried potatoes dropped significantly (Mean = .47, SD = .86, p = .04) between 12 weeks and 12 months in the intervention group and was somewhat compensated for by consuming more boiled potatoes (Mean = -1.29, SD = 7.21). This was, however, not significant at a p = .470. The consumption of fruit also increased significantly in the intervention group at 12 weeks (Mean = -6.41 SD = 11.07 p = .03) and at 12 months (Mean = -6.18, SD = 9.79, p = .02). While the 12-month time point may have been associated with a change in season, it was unlikely that the increase in consumption could be contributed solely to seasonal change at both 12-week and 12-month assessment periods. The control group displayed no significant dietary alteration concerning grains or fruit and vegetables.

Table 16

Means and Paired Sample t Test Scores Across Intervention and Control Groups for Hours of Activity and Sleep and Energy Expended.

Variable	*n*	Baseline Mean	SD	12 weeks Mean	SD	12 months Mean	SD	Initial to 12 weeks *t*	*df*	*Sig* (2- tailed)	Initial to 12 months *t*	*df*	*Sig* (2-tailed)
Control group													
Hours of weekly activity	11	106.09	21.59	115.06	24.80	115.70	23.85	-2.11	10	.06	-1.77	10	.11
Hours of weekly sleep	11	50.95	8.53	50.05	6.735	50.0	6.27	.69	10	.51	.64	10	.54
Average daily Kcal expenditure	11	2232.46	740.39	2175.69	603.31	2213.25	730.41	.37	10	.72	.10	10	.93
Intervention group													
Hours of weekly activity	17	109.77	18.02	121.67	20.15	121.25	21.09	-2.98	16	.009	-2.07	16	.055
Hours of weekly sleep	17	49.85	6.80	50.88	6.68	49.18	6.98	-1.15	16	.27	.43	16	.67
Average daily Kcal expenditure	17	2399.54	594.64	2672.51	861.76	2546.16	936.58	-2.07	16	.056	-.85	16	.41

Note: n denotes the number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes the significance.

Dairy and Dairy Alternatives. The dietary intake of milk and yoghurt decreased significantly at 12 weeks (Mean = 9.29, SD = 9.02 p = < .001) and at 12 months (Mean = 6.38 SD = 6.53, p = < .001) in the intervention group. A significant rise in the use of non-dairy alternatives occurred over the same period (mean = -3.59, SD = 6.45 and a p <.001 at 12 weeks). The 12-month values were; mean = 5.38, SD = 1.46 and a p = .02. The use of yellow cheese by the intervention group decreased significantly at 12 weeks (Mean = 4.74, SD = 6.98, p = .01) and at 12 months (Mean = 3.38, SD = 5.20, p= .02). There were no significant alterations in the control group's consumption of dairy products and dairy alternatives.

Fats and Oils. The use of butter and margarines and cooking oil decreased significantly in the intervention group at 12 weeks. Values for butter and margarine were mean = 8.12, SD = 7.70, p = <.001 and for cooking oils Mean 3.74, SD = 4.38, p = .003. By 12 months the reduction was no longer significant with the p value for butter and margarine consumption being p = .08 and for cooking oils being p = .09. The consumption of various nut butters increased in the intervention group significantly by 12 months (Mean = - .47, SD = .86, p = .04). Avocado and olives use both increased in the intervention group at 12 weeks (Mean = -1.38, SD = 1.98, p = .01) and then increased further by 12 months (Mean = -1.94, SD = 2.30, p = .003). There were no significant alterations in the control group's consumption of fats and oils and high fat vegetables.

Treats and Beverages. There was a decrease in the intervention group's consumption of sweet bakes (Mean = .94, SD = 1.78, p = .04) and salty snacks (Mean = 1.11, SD = 1.66, p = .01) between baseline and 12 weeks however, the analysis indicated no other significant changes in the use of treat foods. The consumption of water increased significantly in the intervention group between 12 weeks (Mean = -12.00, SD = 16.28, p = .01) and 12 months (Mean = -9.94, SD = 12.02, p = .004). The consumption of coffee without sugar also decreased significantly in the intervention group between baseline and 12 weeks (Mean = 5.29, SD = 8.45, p = .02). The control group showed no significant difference in treats or beverage use across all time points.

Quality of Life

Statistically significant differences between means for QOL were detected only in the intervention group (See Table 17). Improvement in physical function in the intervention group was significant at 12 weeks (Mean = 15.0, SD = 21.65, *p* = .01) and 12 months (Mean = -12.94, SD = 19.37, *p* = .01). General health improvements were also significant in the

intervention group at 12 weeks (Mean = -12.65, SD = 15.92, p = .01), and at 12 months (Mean = -13.53, SD = 16.08, p = .003).

Improvement in level of energy (Mean =-10.59, SD = 17.31, p = .02), emotional well-being (Mean = -8.71, SD = 10.79, p = .004), and social function (Mean = -17.65, SD = 27.62, p = .02) were significant only at 12 weeks. The intervention group also perceived a decrease in the level of pain. This was significant only at 12 weeks (Mean = -11.03, SD = 20.69, p = .04), but not at 12 months. There was no significantly different quality of life changes in the control group.

Table 17

Comparison of Well-Being Scores From RAND-36 Survey.

		Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
Variable	*n*	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2-tailed)	*t*	*df*	*Sig* (2-tailed)
Physical function (I)	17	55.88	23.40	70.88	17.34	68.82	19.81	-2.86	16	<.011	-2.76	16	.01
Physical function (C)	11	56.36	28.56	58.64	28.64	63.18	27.50	-1.24	10	.24	-1.70	10	.12
Role limitation physical (I)	17	50.00	44.19	69.12	39.06	48.53	47.98	-1.80	16	.09	.12	16	.90
Role limitation physical (C)	11	63.64	40.87.	63.64	43.82	65.91	37,54	.000	10	1.00	-.275	10	.80
Role limitation emotional (I)	17	60.78	39.50	76.47	38.67	66.67	44.10	-1.65	16	.12	-.57	16	.58
Role limitation emotional (C)	11	84.85	34.52	81.82	34.52	78.79	34.23	1.00	10	.34	1.49	10	.17
Level of energy/fatigue (I)	17	42.65	22.16	53.24	17.04	45.88	25.81	-2.52	16	.02	-.82	16	.43
Level of energy/fatigue (C)	11	50.00	21.79	55.45	18.09	52.27	20.54	-1.71	10	.12	-.49	10	.64
Emotional well-being (I)	17	66.12	19.09	74.82	18.43	73.18	24.65	-3.33	16	.004	-1.43	16	.17
Emotional well-being (C)	11	77.45	12.68	77.09	12.28	479.27	13.61	1.00	10	.34	-1.61	10	.14
Social function (I)	17	66.92	30.60	84.56	24.82	82.35	33.97	-2.63	16	.02	-2.03	16	.06
Social function (C)	11	86.36	22.68	82.96	22.55	88.64	25.89	1.15	10	.28	-.33	10	.75
Pain (I)	17	55.88	26.29	66.91	18.08	60.74	24.07	-2.20	16	.04	-1.21	16	.25
Pain (C)	11	63.86	27.03	61.82	24.14	68.18	27.43	.41	10	.69	-.58	10	.57

		Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
Variable	*n*	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2-tailed)	*t*	*df*	*Sig* (2- tailed)
General health (I)	17	51.18	18.25	63.82	19.57	64.71	23.15	-3.28	16	.005	-3.47	16	.003
General health (C)	11	50.91	18.41	51.82	20.16	63.18	18.21	-.45	10	.66	-1.81	10	.10

Note: (C) denotes the control group. (I) denotes the intervention group. *n* denotes the number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes the degrees of freedom. *Sig.* denotes the significance.

Conclusion to the Chapter

The outcomes demonstrate that while participants in CHIP made some lifestyle changes in response to the programme, many of those changes were only sustained for a short time beyond the duration of the programme. This lack of adherence was also reflected in the durability of changes in biometrical measurements. There were no significant changes in biometrical measurements, blood levels, quality of life indicators or lifestyle factors in the control group.

CHAPTER 5: STUDY 1 DISCUSSION AND RECOMMENDATIONS

The key findings of the study presented in the previous chapter suggested the potential for the CHIP participants to achieve statistically significant reductions in HbA1c and diastolic blood pressure by the end of the 12-week programme. Changes in mass and BMI, hip circumference, waist circumference and height-to-waist ratio between baseline and 12 weeks and baseline and 12 months also improved. While participants in the CHIP made some lifestyle changes, many of those changes were not sustained for any appreciable time beyond the duration of the 12-week programme. This lack of adherence was also reflected in the durability of changes in blood levels and some biometrical measurements. The control group demonstrated no statistically significant changes in biometrical measurements, blood levels, quality of life indicators or lifestyle factors in the control group. A detailed discussion of the limitations of the study and findings will be presented in this chapter.

Discussion of Key Findings of Study 1

The first research question addressed whether CHIP resulted in improved glycaemic control. FBG measures blood glucose regulation in the absence of the dietary intake of glucose or carbohydrate.

Glycaemic Control

Historically FBG has been traditionally used to determine blood glucose levels at screening or interim care medical visits. However, their value as predictors of glycaemic control is questionable (Rohlfing et al., 2002), particularly in people using insulin. Blood sugar levels may vary substantially over 24 hours depending on the types of food consumed, individual activity level and time of medication use. Therefore, the lack of improvement in FBG for participants in the intervention or control group is on its own not a reliable indicator of the degree of glycaemic control or variation. Using a FBG as a sole measure for predicting glycaemic control is also open to some manipulation by the client to gain approval or avoid perceived disapproval for poor adherence. The literature recommends using one or more additional measures to obtain a more accurate picture of long-term control (American Diabetes Association, 2021; Sacks et al., 2011; Tay et al., 2015).

A pilot RCT study using the CHIP was conducted in Fijian villages in the South Pacific. Participants were screened for elevated risk for chronic disease based on elevated waist circumference. After a 30-day low literacy REFLECT version of the programme,

fasting blood glucose levels had dropped by ten per cent. No HbA1c levels were tested; therefore, since isolated blood glucose measurements are perceived not to be a reliable indicator of glycaemic control, no definite conclusions could be drawn regarding improved glycaemic control in this group. Aldana et al. (2005b) conducted an RCT in Rockford, Illinois, in which 167 individuals completed CHIP over four weeks. The number of individuals in the intervention group who were diagnosed as having diabetes (using a fasting blood glucose test) was reduced from 21 to 13, which represented a 38 per cent reduction in prevalence. None of the control group participants changed their diabetes status. However, based on the unreliability of fasting glucose as a sole indicator of glycaemic control, it is difficult to make assumptions about diabetes reversal (Aldana et al., 2005a).

CHIP cohort studies have shown a reduction in fasting blood sugars from between 2.4 per cent to 14.4 per cent, with the most significant drop being in participants who had the highest baseline levels (Aldana et al., 2005b; Diehl, 1998; Drozek et al., 2014; Englert et al., 2004; Englert et al., 2012; Kent et al., 2013b; Morton et al., 2014b; Morton et al., 2013; Rankin et al., 2012). Rankin et al. (2012) conducted a cohort study on data collected from CHIP participants. Again, only fasting blood glucose was measured to indicate glycaemic control. A total of 525 participants had blood glucose levels in the diabetic range of greater than 125mg/dL (6.94 mmol/L). During the intervention period, this group reduced to 301 participants, an overall 42.7 per cent reduction in prevalence. While the reported reduction in the number of persons presenting with elevated blood sugars is impressive, Rankin et al. (2012) was a cohort study where only FBG was used to determine diabetes status. There were also no follow-up results that would provide information on the cohort's longer-term sustainability of blood glucose levels.

A significant reduction in HBA1c was shown by the end of the 12-week programme; however, the reduction was not sustained for the 12 months. An analysis of medication use indicated that during the 12-week programme, two participants in the intervention group had their oral hypoglycaemic medication ceased. An additional person in the intervention group had insulin ceased. The dosage of oral hypoglycaemic agents was increased in another two intervention group participants. A further intervention group participant was commenced on an oral hypoglycaemic agent. These results indicate that one participant in the CHIP intervention group did manage to reverse their T2DM and maintained that reversal for the 12-month follow-up period. Most of the intervention group improved their glycaemic control but

were not able to completely reverse their T2DM. This conclusion is based on the definition of diabetes reversal being the presence of normal blood sugar levels in the absence of medication use. The improvement in the HbA1c levels suggests that the CHIP participants can improve glycaemic control by adhering to selected lifestyle adjustments. The philosophy behind the CHIP is one of self-responsibility. The CHIP participants are invited to set their own health goals, and they individually decide on what lifestyle changes they wish to adopt. Therefore, the participants do not follow a prescribed lifestyle intervention programme. This format allows for varying degrees of lifestyle adjustment from the outset and may account for less remarkable changes in outcomes than depicted by other lifestyle intervention programmes.

Changes in Diabetes Risk Factors

Changes in Body Mass, BMI, Hip and Waist Circumference and Height-to-waist Ratio

Significant improvements in mass, BMI, hip circumference, waist circumference and height-to-waist ratio between baseline and 12 weeks and between baseline and 12 months were shown in the intervention but not the control group. Other studies have shown that a lifestyle intervention that, similar to the CHIP, emphasises the use of a predominantly plant-based, high-fibre, low-fat diet in conjunction with exercise results in weight loss and may prevent the onset of T2DM, slows the onset of T2DM and reduce the risk of developing T2DM. The Finnish Diabetes Prevention Study (Lindström et al., 2013), the China Da Qing Diabetes Prevention Study (Li et al., 2008) and the US prevention Program Outcomes Study (Knowler et al., 2009) consistently show that a lifestyle intervention that lasts for between two and six years can result in a degree of protection from T2DM for 10 to 15 years. In a group of people with a diagnosis of pre-diabetes, compared to a placebo, lifestyle intervention resulted in a 58 per cent reduction in the incidence of T2DM as compared to only 31 per cent for Metformin (Knowler et al., 2009). While HbA1c was not measured in these studies, glucose tolerance testing in combination with fasting blood glucose was used to determine glycaemic control. Long-term adherence to the lifestyle programme and sustained weight loss was also problematic in these prevention studies.

Using a different approach, Wing (1994) evaluated a 50-week-long weight control programme for 93 persons with T2DM that utilised a very low-calorie diet to facilitate weight loss. Persons were randomised into two groups, one of which consumed a low-calorie diet of between 1000-1200kcal per day throughout the treatment period while the other group

consumed between 400 and 500kcal per day alternating with the 1000-1200 kcal per day diet for two 12-week periods. Initially, very low-calorie diet participants lost significantly more weight, 14.2kg vs 10.5kg over the first 12 weeks. The intervention group also remained off diabetes medication longer than the control group. Attendance waned over the last weeks of the trial, and weight was regained. There was also marked recidivism in the year following the trial, with the longer-term effects being very modest. The authors could not justify the clinical use of very low-calorie diets to achieve long-term glycaemic control. Even though the CHIP was unsuccessful in reversing T2DM, improvements in diabetes risk factors, namely BMI and elevated abdominal girth measurements, are likely to have some clinical benefit in preventing T2DM, slowing the onset and maintaining glycaemic control if lifestyle modification is sustained in the long term.

The intervention group of the Diabetic Remission Clinical Trial (DiRECT) (Leslie et al., 2016) was conducted with primary outcomes being 15kg weight loss and a reduction in HbA1c to less than 6.5 per cent. The intervention comprised a total diet replacement formula providing 825–853 kcal/day for 3–5 months, followed by stepped food reintroduction for another 6–8 weeks and then structured support for weight loss maintenance. In the event of more than 2kg weight regain, the participants were offered a partial meal replacement formula for a further two to four weeks, and if weight gain was more than 4kg, a total diet replacement plan was instituted. At 24 months, 11.4 per cent of participants in the intervention versus 2 per cent in the control group had maintained more than 10kg of weight loss. Diabetes was in remission for 41.1 per cent of the intervention and 3.4 per cent of the control group.

In the DiRECT study, weight regain was strongly associated with the re-accumulation of fat within the liver and pancreas (Al-Mrabeh et al., 2020), impairing insulin sensitivity consistent with the onset of T2DM. The remission of T2DM is also determined by getting below a predetermined ‘personal fat threshold’ within the liver and pancreas (Taylor et al., 2018; Taylor & Holman, 2015).

The most significant predictor of reversal in the DiRECT trial was weight loss. Other predictors included fewer prescribed glucose-lowering agents, having lower HbA1c and triglyceride levels, older age, less anxiety or depression and better reported quality of life; however, these were not regarded as being sufficiently significant to identify subgroups for targeted remission intervention (Thom et al., 2021).

While the results of the DiRECT study appear more efficacious in achieving remission than Study 1, the participants included were recently diagnosed (<6 years) and were not reliant on insulin for glycaemic control. They were, therefore, less likely to have advanced beta cell derangement. Studies conducted by Steven et al. (2016) and Gregg et al. (2012) indicate that having diabetes for more than six years impedes remission. The CHIP participants in Study 1 had been diagnosed with T2DM for varying lengths of time, from as recently as six months to 25 years. The larger proportion had T2DM for more than six years. Several were on multiple therapies, including insulin. Despite the increased potential for beta cell derangement and the decreased likelihood of remission or reversal, improvement in overall glycaemic control may still have clinical benefits.

The intervention used in DiRECT (Leslie et al., 2016) was intensive, requiring staffing and training to run. In comparison, the CHIP is predominantly implemented by volunteers and is community-based and therefore is likely to be less costly to implement.

A recent systematic review by Seidelman (2018) has suggested that long-term low-calorie diets are associated with increased mortality. Both high and low-carbohydrate diets were associated with increased mortality, while the least risk was associated with a diet consisting of between 50–55% of calories from carbohydrates. The quality of carbohydrate consumed was not evaluated. Generally, low carbohydrate diets favour animal-based fat and protein sources associated with higher mortality. In contrast, the intake of plant-based protein and fat, along with high-fibre whole grains recommended by the CHIP, was associated with lower mortality.

Korsmo-Haugen (2019) concluded that several dietary patterns, including the traditional Mediterranean diet, appeared suitable for managing glycaemic control in persons with diabetes. The CHIP-recommended lifestyle is directed at all of health, and dietary recommendations like the Mediterranean diet promote “a food as grown”, plant-based and varied dietary intake.

Goldenberg et al. (2021) conducted a systematic review with meta-analysis to ascertain the effect of low-calorie diets on the remission of T2DM. Twenty-three trials (1357 participants) were reviewed, including unpublished HbA1c and medication use data from five trials. Compared to control diets at six months, low-calorie (mostly low fat) diets achieved higher remission rates (0.32 risk difference at 95 per cent confidence interval). However, when the definition of remission included a lack of medication use and the HbA1c is less than 6.5 per cent, non-significant effect sizes occurred. Remission rates in studies where

participants on low-calorie diets used insulin were markedly reduced. Clinical improvements in weight loss, triglycerides, and insulin sensitivity had diminished by 12 months, which was attributed mainly to the lack of dietary adherence. These results are consistent with previous reviews (Korsmo-Haugen et al., 2019; Sainsbury et al., 2018) and what was observed in this CHIP RCT (Study 1). Korsmo-Haugen suggests that HbA1c is only significantly altered in studies with a duration of less or equal to 6 months which likely has much to do with low levels of adherence beyond that time.

Changes in Blood Lipids

Participants in both the intervention and control groups in Study 1 demonstrated no significant improvement in fasting blood lipids. This finding was consistent with the two previously discussed systematic reviews by Goldenberg et al. (2021) and Korsmo-Haugen (2019). Goldenberg et al. noted a non-significant worsening of LDL cholesterol at 12 months and no clinically relevant difference in blood lipids in trial participants who consumed low-calorie diets. The participants in Study 1 diagnosed with elevated cholesterol were prescribed lipid-lowering medications, which could confound any lipid-lowering effect from a change in diet or lifestyle. However, two participants in the intervention group had their prescribed lipid-lowering drugs ceased by the 12-week assessment point and were not recommenced on the medication during the remaining study period.

Change in Blood Pressure

The participants in the intervention group of Study 1 showed no significantly improved systolic blood pressure. The intervention group participants did, however, present a significant improvement in diastolic blood pressure at the end of the 12-week programme, but this was not sustained for the entire 12-month period. During the initial 12 weeks, seven (41%) participants in the intervention group had at least one of their antihypertensive drugs ceased versus three (27%) in the control group. The ceasing of blood pressure medication may indicate a drop in blood pressure that is clinically significant. However, where such a large proportion of participants are affected by medication change is likely to impact the validity of the results.

By the 12-month assessment, adherence to physical activity and dietary changes had shown some recidivism which may have also contributed to higher readings at 12 months. Korsmo-Haugen identified that blood pressure did not differ significantly between groups in a systematic review of 23 studies and 2178 participants. Another community-based, open-

label, two-group, cluster-randomised controlled trial was conducted in Nepal using female community health volunteers to conduct a lifestyle intervention through home visits. The aim of the study was to reduce blood pressure and the results demonstrated significantly lower mean systolic pressures in the intervention group than in the control group. The difference in the normotensive group was −2·28 mm Hg (95% CI −3·77 to −0·79, p=0·003), −3·08 mm Hg (–5·58 to −0·59, p=0·015) – in the prehypertensive group, and −4·90 mm Hg (–7·78 to −2·00, p=0·001) in the hypertensive group. Previous CHIP cohort studies have also demonstrated reductions in systolic and diastolic blood pressure (Morton et al., 2013; Morton et al., 2014b; Rankin et al., 2012).

Adherence

The second research question related to adherence levels. Adherence was measured through changes in dietary intake, weekly activity levels, and planned exercise throughout the duration of the CHIP programme (12 weeks) and for a further nine months.

Adherence to Dietary Recommendations

Englert et al. (2004) compared the percentages of macronutrients in the average American diet and the optimal CHIP diet. The advocated CHIP diet showed lower protein and fat content with higher complex carbohydrate content and lower simple carbohydrate content. Adherence to specific diets for managing T2DM is generally low (Alhariri et al., 2017; Ganiyu et al., 2013; Pandey, 2018; Parr et al., 2020).

However, Kent et al. (2013a) showed that CHIP participants who reported adherence to CHIP lifestyle principles demonstrated improved long-term outcomes. In Study 1, some significant dietary alterations were recorded in the intervention group. CHIP participants consumed less animal protein (milk, cheese, and yoghurt) and fried potato for the 12-month study period. They also significantly reduced the number of processed grains, butter and cooking oils, coffee, salty snacks, and sweet bakes for the 12-week programme but only for part of the 9-month follow-up period. CHIP participants demonstrated statistically significant increases in consumption of water, fresh fruit, avocado, olives, and non-dairy milk varieties for the whole 12-month period. The amount of canteen food purchased was also significantly decreased by 12 months while the change was not significant at 12 weeks. These reported changes were consistent with the recommended changes advocated by the CHIP.

The recommended CHIP diet, like the Mediterranean diet advocates for a varied dietary intake, food ‘as grown’ and is plant-based. Korsmo-Haugen (2019) concluded that the

Mediterranean diet was one of several dietary patterns suitable for managing glycaemic control in persons with diabetes. However, the lack of sustained biometrical and blood lipid changes may be related to the lack of dietary adherence for the 12-month study period.

Adherence to Exercise Recommendations

A significant change in the Study 1 intervention group participant's weekly activity levels as (measured in METS) between baseline and 12 weeks was demonstrated. This increase was not sustained during the additional nine months of follow-up. Most adults with diabetes do not meet recommended exercise guidelines and are generally less active than adults without diabetes (Zhao et al., 2011). Adherence to exercise regimes is renowned for being poor in cohort studies where participants with diabetes are enrolled (Alhariri et al., 2017; Forhan et al., 2013; Mu et al., 2014; Mumu et al., 2014). Results from the Rio de Janeiro type 2 diabetes cohort study conducted through the outpatient clinic of a tertiary university teaching hospital, showed a 22.5 per cent adherence rate (Marinho et al., 2018). Several trials investigating the effectiveness of different exercise programmes on glycaemic control or metabolism have demonstrated high levels (above 70 per cent) of adherence for the duration of the programme. The mostly very structured clinic-based programmes varied in length from between 12 and 52 weeks (Balducci et al., 2014; Lee et al., 2015; Nam et al., 2012; Sigal et al., 2007).

Adherence was defined as maintaining 150 minutes of moderate to high-intensity exercise per week. CHIP participants use predominantly unstructured, non-prescription exercise regimes that are self-managed and community-based. Some CHIP participants may use gym facilities or attend community classes; however, they typically use walking as their form of exercise. This lack of structured, supervised exercise opportunities requires that the adherent individual be more self-accountable rather than being accountable to a programme organiser or exercise therapist. Lack of adherence when one is self-accountable results in disappointing self, whereas when one is having to be accountable to another, it may be more difficult to be non-adherent. Because the CHIP is a non-prescription programme that relies on self-accountability, participants are likely to set different goals or levels of achievement, and therefore, they will implement strategies that are likely to vary in intensity. The definition of adherence therefore becomes subject to each participant's ideals and goals which is essentially the essence of self-responsibility.

A potential confounder for participants in Study 1 is that about 20% of the individuals who participated in the CHIP experienced at least part of their 9-month follow-up during the

COVID-19 lockdowns. The lockdown may have affected their ability to engage in physical activities due to the sporting field, gym and public pool closures. Participants may have needed a suitable area in which to walk close to home and travel restrictions may have prevented them from accessing their usual walking routes. Results from a cross-sectional study conducted by Abate et al. (2022) during August and September 2020 using a total of 576 persons with diabetes were analysed by binary logistic regression to investigate the relationship between COVID-19 lockdowns and exercise adherence. The overall prevalence of exercise during the COVID-19 lockdown period was 26.4 per cent, with 73.6 per cent being non-adherent (Abate et al., 2022). In north India, exercise adherence among persons with T2DM also dropped by 42 percent during the COVID-19 lockdown period (Ghosh et al., 2020). Similar results were shown in Turkey, with only 14 per cent of the 100 diabetes clients exercising regularly during the lockdown (Önmez et al., 2020).

Exercise has been shown to have some benefits in improving the quality of life in persons with T2DM, as reported in a systematic review conducted by Cai et al. (Cai et al., 2017) and Jing et al. (Jing et al., 2018). The fact that regular exercise waned over the 12 months could contribute to the lack of significant change seen in quality-of-life parameters by the end of the follow up period.

Adherence to dietary recommendations

Englert et al. (2004) compared the percentages of macronutrients in the average American diet and the optimal CHIP diet. The advocated CHIP diet showed lower protein and fat content with higher complex carbohydrate content and lower simple carbohydrate content. Adherence to specific diets for managing T2DM is generally low (Alhariri et al., 2017; Ganiyu et al., 2013; Pandey, 2018; Parr et al., 2020).

However, Kent et al. (2013a) showed that CHIP participants who reported adherence to CHIP lifestyle principles demonstrated improved long-term outcomes. In Study 1, some significant dietary alterations were recorded in the intervention group. CHIP participants consumed less animal protein (milk, cheese, and yoghurt) and fried potato for the 12-month study period. They also significantly reduced the number of processed grains, butter and cooking oils, coffee, salty snacks, and sweet bakes for the 12-week programme but only for part of the 9-month follow-up period. CHIP participants demonstrated statistically significant increases in consumption of water, fresh fruit, avocado, olives, and non-dairy milk varieties for the whole 12-month period. The amount of canteen food purchased was also significantly decreased by

12 months while the change was not significant at 12 weeks. These reported changes were consistent with the recommended changes advocated by the CHIP.

The recommended CHIP diet is close to that which is commonly referred to as the Mediterranean diet. Korsmo-Haugen (2019) concluded that the Mediterranean diet was one of several dietary patterns suitable for managing glycaemic control in persons with diabetes. However, the lack of sustained biometrical and blood lipid changes may be related to the lack of dietary adherence for the 12-month study period.

On a deeper psychological level, situational factors that not only create intense obstructions to an individual's plans but modify the essence of what is regarded as normality inevitably interfere with the intentions and efforts of the individual and disturb the inner psyche. This intrusion into the core of existence affects mood and willingness to perform. If significantly intense, it will impact the desire to function and live (Armour et al., 2021; World Health Organization, 2020b). The absolute disruption of everything previously regarded as expected during the initial phases of the COVID-19 pandemic was, for many, a situational factor that intruded into the very core of their existence. Adherence to some recommended lifestyle changes would not be a priority in these circumstances.

Quality of Life

Study 1 intervention group participants recorded improvements in their energy level, emotional well-being, and social function and decreased perceived pain at the climax of the 12-week intervention programme. A perceived improvement in quality of life was consistent with what participants experienced in other lifestyle intervention programmes (Eaglehouse et al., 2016; Lidin et al., 2018).

The CHIP is presented in a community setting where participants are encouraged to participate in small group discussions and feedback. The dynamics are conducive to a socially supportive environment where participants are encouraged to provide encouraging feedback, engage in problem-solving and provide some accountability partnership. This dynamic is particularly relevant to what is described in the Health Promotion Model. Similarly, the assumptions of the model are relevant in developing self-efficacy and improving aspects of quality of life. Some of these assumptions include the capacity for self-awareness and reflection to assess competency, the value attributed to growth and self-control and the interaction with others in changing behaviour (Pender et al., 2011).

Exercise has been shown to have some benefits in improving the quality of life in persons with T2DM, as reported in a systematic review conducted by Cai et al. (2017) and Jing et al. (2018). The fact that regular exercise waned over the 12 months could contribute to the lack of significant change seen in quality-of-life parameters by the end of the follow-up period.

The recommended CHIP diet promotes foods that have been identified as important for anti-inflammation and are recommended for pain related inflammation management (Cooper et al., 2022; Rondanelli et al., 2018). The dietary changes recorded by the intervention group in response to the CHIP during the first 12 weeks may have contributed to decreased pain. The lack of adherence over the next nine months may also, however, have contributed to the fact that the reduction in pain was no longer statistically significant by the 12-month assessment. By 12 months, the only significant improvement noted was an overall general improvement in health.

Conclusion to the Chapter

The results of Study 1 clearly indicated that adherence to lifestyle recommendations was associated with improved HbA1c levels, body weight, BMI, blood pressure and reported improvement in lifestyle and quality of life measurements. Outcomes demonstrate that while participants in the CHIP made some lifestyle changes in response to the programme, many of those changes were not sustained for any appreciable time beyond the duration of the programme. This lack of adherence was also reflected in the durability of changes in biometrical measurements. The control group had no statistically significant changes in biometrical measurements, blood levels, quality of life indicators or lifestyle factors. Limitations of the study and recommendations for further research were presented.

While clinical trials provide a rigorous way of testing specific outcomes and have the capacity and potential to impact treatment modalities significantly, a gap often exists between the outcomes tested and their relevance for the client and clinical implementation (Heneghan et al., 2017). The results from Study 1 in this thesis provided some insights into how the CHIP may improve biometrical measurements and blood values and, to some degree, influence behaviour modification in persons with T2DM in the short term. However, understanding some of the client and programme factors may be more clinically relevant for implementing education that has longer-term benefits. During the monthly follow-up contact times, and while the researcher was performing the 12-month assessment, several participants

openly discussed some of the problems they were experiencing with the definition of diabetes reversal, communication with and access to their healthcare team and various factors related to adherence. It was therefore decided to extend this thesis by adding a second study that would explore the participants' knowledge of reversal, their experience of CHIP and adherence to lifestyle recommendations.

CHAPTER 6: STUDY 2 THEORETICAL UNDERPINNING AND METHODS

This chapter includes an overview of the background to and the theoretical underpinnings of the qualitative component of this thesis. A description of the study design, the aim and methods, the Research Questions, the participants, the selection process, and the study setting for Study 2 are presented. The CHIP has never been evaluated by its participants for its suitability or usefulness as a lifestyle education programme and more specifically as a programme suitable for diabetes reversal education. Interpretation of the concept of diabetes reversal, client involvement in diabetes management and significant life events were issues that emerged from anecdotal conversations held with participants that could potentially impact long-term adherence. These conversations arose while doing 12-week and 12-month assessments for Study 1. It was therefore decided to initiate a qualitative study to discover how both the intervention and control groups in Study 1 understood the concept of diabetes reversal, and what was their experience of participating in management decisions and of adherence to lifestyle recommendations.

Background to Study 2

When performing the final assessments for Study 1 of this thesis, several participants spoke spontaneously about their experience of diabetes management, their perceptions of diabetes reversal, their experience of the CHIP and challenges they experienced with adherence. The understanding of how diabetes reversal is defined and understood by healthcare professionals may vary greatly from the client's perception. Consequently, an incomplete perception of diabetes reversal may result in participants believing they have achieved a set goal when the reality is the definition of the terms of the goal was inaccurate. The client and health professional may have very different views on what are desired management goals and how to go about achieving them. Therefore, to help evaluate the suitability of the CHIP for diabetes reversal the researcher wanted to ascertain the baseline level of understanding participants had of reversal of T2DM and whether they perceived CHIP or other diabetes education to be useful in assisting them in making lifestyle changes that could potentially result in diabetes reversal.

The results from Study 1 clearly indicated that adherence to lifestyle recommendations was associated with improved HbA1c levels, body weight and blood pressure measurements and reported improvement in lifestyle and quality of life measurements. Several studies have shown that improved adherence to lifestyle

recommendations achieves improved diabetes outcomes (Korsmo-Haugen et al., 2019; Seidelmann et al., 2018; Thom et al., 2021). Study 2 aimed to further investigate the factors associated with adherence in Study 1 through identifying any common motivators and barriers to lifestyle modification that may affect adherence. Having a better understanding of these motivators and barriers may provide a better understanding of how to adequately support and initiate the re-engagement of clients, thereby improving long-term adherence. As part of Study 2, the intervention group who had participated in the CHIP were also asked questions relating to how they had experienced the CHIP and its relevance for diabetes reversal.

The circumstances that led to the researcher's interest in understanding the participants knowledge of diabetes reversal and the factors that impacted adherence, together with the theoretical principles of person-centred care and the need to obtain knowledge were practically applied to improve diabetes care contributed to the design of Study 2.

Theoretical Underpinnings of Study 2

Healthcare, more specifically nursing, is concerned with person-centred, holistic care (Delaney & Bark, 2019). Therefore, research that focuses on understanding human behaviour and interaction and that is concerned with caring, communication, emotions, and the human experience requires an approach whereby the researcher can focus on how people make sense of their experiences in the world in which they live. While quantitative research methods provide a general understanding of the problem, qualitative methods allow for a detailed and deeper analysis (Polit & Beck, 2020) that complements and supplements quantitative methods. In Study 2, the qualitative component of the research has assisted the researcher in gaining a deeper perspective of the unique cultural, social, and personal aspects of the way in which the study's participants made lifestyle adjustments with the view to better manage or potentially reversing T2DM. By investigating the participants' experience of the intervention, the clinician is better equipped to comprehend the reasons for adherence or recidivism, and to obtain a greater understanding of participant motivation, values, and expectations (Polit & Beck, 2020).

Aim of Study 2

The aim of Study 2 was to obtain an understanding of participant's knowledge of diabetes reversal prior to commencing Study 1 and their experience of the CHIP intervention and long-term adherence to lifestyle recommendations. An additional aim was to obtain a

better understanding of the participants previous knowledge and their experience of diabetes reversal to provide practical relevance to what was learned. This focus on data collection for the purpose of problem solving and discovering consequences of action, that informs "real-world" practice is defined philosophically as pragmatism. (Creswell & Piano Clark, 2018). The pragmatist understands philosophical topics as best being viewed through the lens of practical use or practical application. It is anticipated that an improved application of lifestyle intervention for T2DM can be achieved through the understanding gained of the participant's knowledge and experience of diabetes reversal and the intervention applied. The results from Study 2 will contribute to an improved transfer of the research findings into clinical practice.

Research Design for Study 2

Qualitative approaches to research strive to understand a particular phenomenon from the perspective of those who experience it (Vaismoradi et al., 2013). Therefore, the researcher's role is to select a research approach that best answers the Research Questions. To obtain information on the study participants' understanding of diabetes and diabetes reversal, their lived experience of lifestyle adjustment post-diagnosis, as well as of the CHIP for those in the intervention group from Study 1, a suitable design needed to be selected (Vaismoradi et al., 2013). A descriptive qualitative design was best suited to obtain this data. Individual illustrative case study examples were provided to support the emerging themes and subthemes.

Classically the approach used to understand or explore lived experience and the meaning associated with that experience is described as phenomenology. The defining aspect of phenomenology also seeks to bracket out the world or any pre-conceived suppositions (Polit & Beck, 2020). However, the outside world and influences of the participants' physical, psychological, social, and emotional environment are integral to their lived experience. The literature review and experience obtained in conducting Study 1 would be difficult to bracket out of Study 2. A broader descriptive approach was, therefore, most suited to address the research aim. Polit (2020) describes a descriptive qualitative study as being accepted as a different research design where an organised, straightforward descriptive summary of information or data is required (Lambert & Lambert, 2012). The descriptive qualitative study design was best suited for obtaining this descriptive summary of holistic data.

Individual case studies provided additional illustrative examples of the participants' perspectives. Where case studies are used as components of descriptive qualitative research invariably the case is studied within the context of the participant's environment, situational factors and experience (Merriam, 1998; Polit & Beck, 2017; Yin, 2003). In this study, illustrative case studies were used to complement the descriptive aspect of the study. The case studies demonstrated how the participants in this study were impacted by their social, psychological, and emotional environment and how these environments affected their decisions for or against adherence. This demonstration of the inter-relationship of the case with the environment is consistent with Merriam's interpretation of the qualitative case study (Merriam, 1998).

Research Questions for Study 2

To further explore the aim of Study 2 the following Research Questions were developed:

- What was the participant's knowledge of the concept of diabetes reversal?
- What was the participant's experience of CHIP as an intervention for diabetes reversal?

Setting and Participants for Study 2

Setting

Shortly after designing Study 2, New South Wales was significantly impacted by COVID-19 lockdown. Restrictions prevented any face-to-face contact with participants. Since a large proportion of the group was elderly and unfamiliar with the technology required for audio-visual interviewing, such as ZOOM or Microsoft Teams (Microsoft, 2020), it was decided to obtain qualitative data through recorded individual telephonic interviews. The participants were provided with a list of the interview questions at the time of scheduling the interview to provide them opportunity prepare for the interview. Interview times were arranged with each participant to suit their individual requirements and all the participants were at their place of residence when interviewed which ensured the participant had access to their desired level of privacy. Further details relating to the research setting are described in detail in Chapter 3.

Participants

The researcher attempted to contact all Study 1 participants for possible inclusion in Study 2; however eventually, only 22 of the 28 participants enrolled in Study 1 were available for contact during the Study 2 enrolment period. At the point of initial contact with the available 22 participants, the researcher explained the reason for the second study and asked whether they would be willing to receive an information letter with a consent form. If after reading the information letter they agreed to participate in the study, they could notify the researcher via email or telephone. The information letter was subsequently emailed to those where contact was made and where inclusion was deemed appropriate. Sixteen participants who had previously been enrolled in Study 1 consented to be interviewed at which point a specific date and time was arranged to conduct the interview. Twelve of the consenting participants were from the Study 1 intervention group; and a further four were from the Study 1 control group. Table 18 depicts the breakdown of participants in Study 2.

Table 18

Breakdown of Participants Contacted and Interviewed for Study 2.

	Intervention group	Control group	Total
Number of participants who completed Study 1	17	11	28
Number of participants available for contact for Study 2	12	4	16
Number of participants from Study 1 not interviewed	5	7	12

There were several reasons why 12 participants originally participating in Study 1 were not involved in Study 2:

- One participant from the Study 1 intervention group was suffering recent onset severe mental illness, and the researcher felt contacting them would be inappropriate.
- One participant was battling other significant health issues, and the researcher felt that requesting further involvement was inappropriate at the time.
- Two participants from the Study 1 intervention group could not be contacted.

- One participant from the Study 1 intervention group had subsequently moved, and the researcher had no updated contact details.
- Two participants from the Study 1 control group had entered institutional care, and the circumstances made access and interviewing difficult due to COVID-19 restrictions and the lack of reliable telephone access.
- One participant from the Study 1 control group was on an extended holiday and declined.
- Two participants from the Study 1 control group could not be contacted.
- Two participants from the Study 1 control group declined.

A more detailed description of the process used for the original participant referral, inclusion and exclusion criteria for Study 1 can be reviewed in Chapter 3

Data Collection for Study 2

The aim of Study 2 was to explore their knowledge of diabetes reversal, experience of CHIP and adherence to lifestyle change recommendations. To achieve this, four Research Questions were developed, and peer reviewed by two research supervisors.

Data Collection Method

The choice of data collection method was guided by those typically used by researchers when exploring participant experience (Hunter et al., 2019). Data collection for descriptive qualitative studies usually involve the use of open-ended, structured interview or focus group interviews. Observation, record keeping and reports, photographs or perusal of documents are also accepted data collection methods (Lambert & Lambert, 2012). For Study 2, semi-structured telephone interviews were used to collect data from participants. COVID-19 restrictions and lockdown precluded the organising of any face-to face interviews or focus groups.

Interview Questions

The interview questions were drafted with the intention to answer the additional Research Questions which were developed for Study 2. The relationship between the interview and Research Questions can be viewed in Table 19. The interview questions for Study 2 were peer-reviewed by two research supervisors and were used in a pilot study which was conducted with two persons not enrolled in the study. The pilot study was performed to test for any confusion or misunderstanding in language or context related to the interview

questions. Changes made to the interview questions were informed by the pilot study and included the use of the word ‘adherence’ rather than ‘compliance’. The words ‘prior to participation in the study’ were included in the first interview question to clarify the participants’ knowledge of reversal prior to participating in the CHIP. In addition, the words ‘medical team’ were included rather than just referring to the ‘doctor’. A copy of the piloted and final interview questions can be viewed in Appendix F.

The interview questions were included in an interview guide which also provided prompts for the interviewer when introducing and concluding the interview process. The interview guide was designed to promote consistency of the interview process and to ensure that each interviewee was asked the same questions. The order of questions presented was adjusted based on the content already provided by the participant. This enabled the interview to be structured in a similar way to a conversation rather than a typical interview style. This structure also allowed for probing of responses to obtain more detail or clarification (Roulston & Choi, 2018) of responses.

Participants from the Study 2 intervention group, and participants from the Study 2 control group were asked the same four questions as follows, as set out in the interview guide:

- Describe your knowledge and understanding of diabetes reversal before participating in the study, and whether you believed it possible to reverse your T2DM.
- Describe the contribution made by your medical team to your understanding of diabetes reversal and any goals discussed with you concerning diabetes reversal and diabetes management.
- Describe your experience as a participant in the CHIP programme and its usefulness as an intervention for T2DM.
- Describe your experience of adherence to lifestyle changes as recommended by the CHIP programme and advocated as a treatment option for T2DM.

These questions were followed up with additional prompts such as ‘Can you provide an example of that?’ to elicit clarification or more profound responses. Refer to Appendix F for the full interview guide.

Table 19

Relationship Between Research Questions and Interview Questions.

Research question	Interview question
What was the participants' knowledge of the concept of diabetes reversal?	Describe your knowledge and understanding of diabetes reversal before participating in the study, and whether you believed it possible to reverse your T2DM.
What was the participants' knowledge of the concept of diabetes reversal?	Describe the contribution made by your medical team to your understanding of diabetes reversal and any goals discussed with you concerning diabetes reversal and diabetes management.
What was the participants' experience of CHIP as an intervention for diabetes reversal?	**Intervention group** Describe your experience as a participant in the CHIP programme and its usefulness as an intervention for T2DM.
What was the participant's experience of CHIP as an intervention for diabetes reversal?	**Intervention group** Describe your experience of adherence to lifestyle changes as recommended by the CHIP programme and advocated as a treatment option for T2DM. **Control group** Describe your experience of adherence to lifestyle changes you initiated or were recommended by your medical team as a treatment option for T2DM.

Data Collection Procedure

Data gathered during the semi-structured interviews was used to answer the Research Questions. Participants who consented to participate were telephoned to make an interview appointment. During this telephone conversation, the researcher reiterated the contents of the information letter and confirmed consent. The participant was then sent a confirmatory email with the date and time of the interview appointment and a list of the questions that would be asked to afford them time to think about their responses. The researcher telephonically contacted each participant at the pre-arranged appointment time and once more obtained consent for recording the interview. Participants were assured that the interview and recording could be terminated at any point by them.

All the participants who agreed to be interviewed were interviewed using a semi-structured telephonic interview style during September and October 2021. Each of the sixteen interviews lasted between 45 and 60 minutes. The interviews were recorded using an Olympus digital voice recorder and were transcribed verbatim. For the full details of the interview process, please refer to the interview guide in Appendix F.

Each interview transcript was de-identified by replacing the participant's name with a pseudonym. A copy of the transcribed interview for each interviewee was stored along with data records obtained from Study 1. This collection of information formed the core data from which the case studies were generated.

Data Analysis

Data analysis of the interview transcripts took place in four distinct phases. The first phase consisted of preparing the data. This included transcribing and rechecking the transcribed data and then cleaning the data. The second phase, the thematic analysis included identifying nodes from the transcribed data, placing the relevant transcribed interview excerpts from multiple participants into the respective nodes and then organising the data in the nodes into themes and sub-themes. The third phase, the data consolidation phase consisted of identifying relevant data obtained from each participant separately and collating that data with previously obtained records from Study 1 to provide a holistic overview of the information relating to each case. The fourth phase, the case study preparation phase consisted of selecting cases as examples to illustrate specific themes generated from the thematic analysis.

Phase I: Data Preparation

Transcription of Data

Each participant interview was transcribed verbatim. The process of transcription was completed with the aid of a virtual transcription programme, Otter.ai (Otter.ai 2022^{TM}). Each participant's recording was uploaded into the software, and the virtual transcription took about 45 minutes to generate a downloadable document. Once the transcribed document had been downloaded, the researcher then listened to the audio recording while checking the document for any incorrectly transcribed words. Any incorrectly transcribed words were corrected in the document and names were replaced with a pseudonym. Other corrections were made where the virtual transcription had the speaker incorrectly labelled. In addition, to ensure the transcription was as authentic as possible, punctuation, sighs, laughs or periods of silence were inserted that were consistent with the audio recording.

Data Cleaning

Once a transcribed document had been generated, for each interview, the transcribed interview was read again, and any excess irrelevant greetings or excerpts of conversation generated by the participant were cleaned from the transcribed document to ensure the interview transcripts were accurate and the relevant data was ready for thematic analysis. A summary can be viewed in Table 20

Phase 2: Thematic Analysis

Analysis of data gathered within a descriptive research study, unlike other qualitative approaches, is purely data-derived, meaning that codes are elicited from the data during the study. Generally, descriptive qualitative research is characterised by simultaneous data collection and analysis (Holloway & Galvin, 2016).

In this study, interviews were transcribed into documents as they were generated which is consistent with the approach described by Holloway and Galvin (2016). Both content and thematic analysis are suitable approaches to obtain the desired answers to questions relating to client experience and reporting issues commonly mentioned in interview data. Both approaches are also primarily based on the researcher wanting to learn about actual behaviour, attitudes, motives, or experiences. Content analysis describes data in terms of text, images or expressions, whereas thematic analysis addresses and interprets aspects of the topic (Vaismoradi et al., 2013).

Thematic analysis was selected as the approach best suited to this study since a detailed, nuanced account of data was more important than the quantitative interpretation of text or counts of the codes identified. Thematic analysis may be inductive or deductive. Inductive approaches seek to gain new knowledge by deciphering the meaning of text or patterns of behaviour. Deductive approaches, on the other hand, determine the degree of support obtained for an existing construct or theory, explanation or result (Patton, 2015). An inductive approach to thematic analysis was used in this study to interpret the meaning and details of the information received from participants during interview.

Braun and Clarke's (2006) process of thematic analysis was used to analyse interview data gathered during this study. Once correcting and cleaning of the transcribed documents was completed each document was read a few times to gain a general idea of the interviewee's response to the interview questions. This process ensured the researcher was very familiar with the data. Once this process was completed, the researcher was immersed in the views expressed by the participants, and the transcripts were uploaded to NVivo 12. Notes relating to potential codes were then made in the notes section of NVivo 12. Each transcript was then read again sentence by sentence, each sentence being coded according to the main thought expressed in the sentence or part of the sentence. Where more than one thought was expressed in a sentence, each thought expressed was coded separately, and recorded in NVivo 12 as nodes. Once this process had been followed for every transcript the coded data in the nodes was re-organised into themes and sub-themes. Researcher triangulation was completed whereby a research supervisor independently coded a selection of transcripts. This coding was compared to the original codes applied. Additional triangulation was performed by the researcher reviewing and comparing sections of coded transcripts to notes made in participant records in Study 1 to establish consistency in messaging. Based on team consensus the name of each theme was confirmed. A summary of the process can be viewed in Table 20 and provides a sequential description of the three phases of qualitative data analysis. Although the steps listed are itemised in linear fashion, in reality the reflective process requires a continuous moving back and forth through each phase to reassess and confirm the understanding and the interpretation of the text (Braun & Clarke, 2006).

Table 20

Summary of Process of data Collection and Analysis for Study 2.

Phases of Analysis	Steps of Each Phase	Activity
Phase 1	Step 1 Transcribe audio-recording.	The audio-recording was transcribed using virtual transcription software. The transcribed document was checked by listening to the audio and reading the document simultaneously to check that it was correctly transcribed and punctuation, pauses, sighs and exclamations were added to accurately reflect the interview.
	Step 2 Data cleaning	The transcribed document was re-read and irrelevant introduction, conversational and concluding excerpts were removed.
Phase 2 Thematic analysis	Step 1. Become familiar with the data	Each transcript was read and re-read to obtain a general idea of the messages the interviewee was conveying, and the general context of the conversation (Creswell & Creswell, 2017). Notes were made on each transcript about key ideas presented and inductive and deductive thoughts (Braun & Clarke, 2006). Ideas were generated about potential codes or themes (Braun & Clarke, 2006). Transcripts were uploaded into NVivo.

Phases of Analysis	Steps of Each phase	Activity
	Step 2 Generate initial codes	Transcripts were read individually, coding text systematically in such a way that specific text was categorised to represent the emerging phenomenon of interest (Creswell & Creswell, 2017).
	Step 3 Generate ideas for themes	Coding was reviewed and similar or related codes were sorted into themes and sub-themes (Braun & Clarke, 2006). Researcher triangulation (Creswell & Piano Clark, 2018) was performed with a research supervisor who compared original transcripts to what was coded in NVivo. Notes in NVivo continued to be made relating to researcher inductive and deductive ideas (Patton, 2015).
	Step 4 Review themes	The raw data was revisited to check that the themes accurately represent the original message conveyed and that understanding within context was accurately expressed. Researcher triangulation (Creswell & Piano Clark, 2018). Sections of coded transcripts were also compared with notes made on participant assessment records (Study 1 – 12-month assessment) to establish consistency in messaging.
	Step 5 Define and name themes.	Based on researcher triangulation and team consensus, the naming of themes was defined and confirmed (Braun & Clarke, 2006).

Phases of Analysis	Steps of Each Phase	Activity
Phase 3	Step 1 Consolidate data	Data from thematic analysis and quantitative data from Study 1 was collected.
	Step 2 Reduce data by identifying helpful information	Data which would be useful to include in cases was identified. Contextual information was included and supported by elaborating cases to support themes (Merriam, 1998).
Phase 4	Step 1 Identify the most suitable case studies	Case studies to support major themes were identified. Case examples presented were those that best supported the emerging themes (Merriam, 1998).

Phase 3: Consolidation of Data

A constructivist approach (Merriam, 1998; Stake, 1995; Stake, 2009) was used to gather, interpret and present case data. This process is described by Merriam (1998) as a process of data consolidation, the reduction of data to identify relevant information, and finally, interpreting the data to construct meaning (Merriam, 1998).

At the completion of the thematic analysis (Phase 2) several themes emerged. These themes and subthemes were composed of participants knowledge of diabetes reversal, views on collaborative goal setting for their diabetes management, their experience of CHIP and adherence. The emerging themes were used to answer the Research Questions.

Phase 3 analysis consisted of reviewing the transcripts again and extracting relevant comments related to adherence from individual participants. These comments were then compared with the adherence data from Study 1 (food frequency questionnaire, and the Active-Q survey). This consolidation of data allowed the researcher to better understand the relationship between adherence in Study 1 and the factors and stories that emerges in Study 2.

Phase 4: Identification of Case Studies

Data relating to the individual participant's understanding of reversal of T2DM was then also added to create complete case summaries. The case summaries were then reviewed. The case summaries which contained stories that provided multiple or exceptional examples

of the themes presented were isolated. Four cases summaries emerged as being the most suitable for providing an illustration of the common factors and circumstances that resulted in participants being more adherent or less adherent to lifestyle recommendations. These four summaries are included in Chapter 8 as case studies.

Evaluation Criteria

Because data based on human experiences are complex, and multifaceted and often carry meaning on multiple levels (Patton, 2015), achieving accuracy in interpretation, understanding and presentation requires attention to stringent processes in analysis. The integrity of qualitative research is gauged on the quality of evidence provided by evaluating the 'conceptual and methodological decisions' made through analysis (Vaismoradi et al., 2013).

In qualitative research, the researcher becomes the tool for analysis, reading, interpreting, and making decisions and judgements about coding (Nowell et al., 2017). Therefore, it is essential to acknowledge the researcher's position. Having had some discussions with participants at the end of Study 1 relating to their preparedness for diabetes reversal and the challenges faced by them concerning adherence, the researcher had some pre-conceived opinions about the participant's understanding of diabetes reversal, the degree to which participants received information relating to lifestyle change as a means of managing and potentially reversing their diabetes as well as some of the factors that contributed toward different rates of adherence in the groups. It is, however, crucial that the interpretations of the data and outcomes described remain credible, and therefore, the researcher is required to ensure that any pre-conceived ideas do not bias the outcomes of the study. Recording, and systematically disclosing the details of the methods used for analysis allows the reader to make judgement regarding the credibility of the process.

The same criteria used to evaluate quantitative research, namely validity, reliability and generalisability are not deemed appropriate for qualitative evaluation (Stake, 2009). Researchers are still, however, required to present a research methodology that is valid and reliable, and therefore, Trustworthiness, Auditability, Credibility and Transferability (TACT) have been established as criteria for evaluating qualitative research (Daniel, 2019).

Trustworthiness is established through researcher experience, trustworthy sources, and quality of data collection processes, and is evidenced by dependable outcomes. Trustworthiness is also evidenced by a description of a systematic approach to data

collection, coding, and identification of themes. (Daniel, 2019). In this study, the researcher, therefore, developed a research design and followed a specific research method. Participants consented to be interviewed and were not pressured or coerced. They were also individually interviewed which prevented any interference from possible peer pressure. Data analysis was conducted systematically in line with processes well defined and acknowledged in the literature (Braun & Clarke, 2006; Merriam, 1998; Stake, 2009). The same procedure for analysis was consistently applied to each interview transcript.

Transparent data collection and data verification processes along with systematic methods of data analysis are required to determine auditability (Daniel, 2019). The data collection methods and analysis processes are described in detail in this chapter and the interview guide used is provided in Appendix F. Data verification was conducted through peer-review and triangulation procedures.

Credibility relies on triangulation, is supported by theory, and is improved in a mixed-method or multi-method approach. The appropriateness of the research design, questions and application of data collection and reporting methods are indicative of credibility (Daniel, 2019). In this chapter, the description of the design has been supported by the literature and has been systematically described. Examples of triangulation include where quantitative data from Study 1 supports or does not contradict data obtained in Study 2 and where during the interpretation of interview data, the application of codes to transcripts was verified.

Transferability is the ability to reproduce results by reproducing the study. An accurate description of the study has been provided. The context and data collection sources have been described in such a way that would allow for the duplication of this study (Daniel, 2019).

In addition to ensuring a qualitative study achieves accuracy in interpretation, understanding and presentation and that the process is trustworthy, auditable, and credible consideration for the participants' autonomy, privacy, confidentiality, and well-being is necessary. Protecting participants engaging in a study process whereby their views and experiences are being examined may lead to unintentional vulnerability and emotional sequela and therefore additional ethics approval for Study 2 was sought.

Ethical Considerations

Conducting interviews and collecting data to assemble into case histories are personally invasive activities and obtaining audio recordings increases the risk to the participant. It was necessary for the researcher to takes steps to protect the privacy of the participant and provide support for participants who may find the process distressing. Additional ethics approval was therefore necessary for this study.

Additional ethics approval was sought in July 2021 for approval to conduct the qualitative study (Study 2). The proposed variation did not alter the risk to the participant. Additional consent to participate in an interview and permission to record the audio of the interview was obtained with the understanding that all information disclosed by the participants would be kept confidential, and reporting would maintain their anonymity.

The researcher was aware that participants may become uncomfortable with some questions and that a specific line of questioning may elicit an emotional reaction. Participants were made aware that interviews could be terminated at any point in time without fear of retribution. The researcher ensured that should any participant become distressed, the interview would be ceased, and the participant had access to a source of emotional and psychological support and or provide resources for such support. Any participants suffering undue distress would have been referred to their GP had this occurred. This study was approved by Avondale University's Human Research Ethics Committee, identification number ETH.2017.002.

Conclusion to the Chapter

This chapter included an outline of the theoretical underpinnings and methods for undertaking a descriptive qualitative study for Study 2, using interviews as data collection methods and thematic analysis to analyse whole group data. Illustrative case studies were included in the design to provide perspective on how themes emerging from the thematic analysis may illustrate the journey of the individual client. Evaluation criteria, relevant to a qualitative descriptive research approach were used to ensure that the research processes conducted in Study 2 were of a high quality and relevant to the research techniques used. The ethical considerations for conducting the study were also disclosed. The following chapter outlines the results of the data analysis process adopted during Study 2.

CHAPTER 7: STUDY 2 RESULTS

Study 2 evolved out of the results of Study 1. Despite recruitment challenges the RCT conducted as Study 1 indicated that improvements in lifestyle were associated with improved biometric measurements. It was also apparent that adherence to lifestyle recommendations were not sustained and subsequently the changes in several biometrical measurements also deteriorated. Study 2 was designed to investigate the participants' (from Study 1) experience of adherence, their understanding and knowledge about diabetes reversal and the intervention group participants' experience of the CHIP.

In the previous chapter the descriptive qualitative design (with accompanying illustrative case studies) for Study 2 was discussed, and the Research Questions and methods were presented. In this chapter the qualitative results of Study 2 are presented. Thematic analysis of transcribed interview data resulted in the emergence of four major themes. Each of the major themes were constructed from several sub-themes. How these themes and subthemes relate to the Research Questions may be viewed in Table 21.

Table 21

Alignment between Research Questions and Emerging Themes and Sub-themes.

Research Question	Themes and Sub-themes
Research Question 1 What was the participants' knowledge of the concept of diabetes reversal?	Theme 1: Reversal • the interviewees perception and knowledge of what diabetes reversal meant or how it is defined • the degree of involvement of the participant's medical team in addressing the possibility of reversal • collaborative goal setting • the participants belief as to whether reversal was possible for them as an individual

Research Question	Themes and Sub-themes
Research Question 2 What was the participants' experience of CHIP as an intervention for diabetes reversal?	Theme 2: Participants' experience of the CHIP • Participant views about the content • Participant views about the format • Participant views about the presenters • Participant views about the learning activities • Suggestions for improvement
	Theme 3: Participants' perceived benefits of CHIP for reversal • Benefits of CHIP • Role of CHIP in reversal
Research Question 2 What was the participant's experience of CHIP as an intervention for diabetes reversal?	Theme 4: Adherence • Difficulties experienced that impacted adherence • Strategies that assisted in maintaining adherence • Self-responsibility as an approach to adherence

In this chapter, each theme is presented along with relevant examples obtained from extracted text that illustrates the most pertinent and commonly emergent sub-themes. These are presented in-text. Additional responses relevant to each emerging subtheme are tabulated with examples from the participant interview transcripts. These are in Appendix G.

Illustrative case studies were developed as part of the study design to provide contextual examples of how each of the emerging themes were demonstrated in the participant's particular journey. Qualitative data extracted from each of the participant's interviews were collated with quantitative data obtained from Study 1 records. A case history was constructed from these two sets of data. Four cases emerged as being particularly suitable to provide context and real-life examples of how the emerging themes contributed to their individual journey and added meaning to the emerging themes. The four cases are presented in Chapter 8.

Results for Theme 1 – Reversal

The theme Reversal emerged from the data to represent the participants' understanding of the concept of diabetes reversal. Diabetes reversal is defined as the volte-face of diabetes symptoms in the absence of medication designed to reduce diabetes symptoms. The client who has reversed diabetes in essence no longer takes any hypoglycaemic medication and has blood levels that do not fulfill the criteria for diabetes diagnosis.

Responses to the first interview question; "Describe your knowledge and understanding of diabetes reversal before participating in the study, and whether you believed it possible to reverse your T2DM" classified under the theme of reversal answered the first two Research Questions (See Table 21). Three sub-themes emerged under the theme of reversal namely:

- the participants' perception and knowledge of what diabetes reversal meant or how it is defined,
- the degree of involvement of the participant's medical team in addressing the possibility of reversal,
- the participants belief as to whether reversal was possible for them as an individual.

The first sub-theme that emerged provided answers about the participant's knowledge about what diabetes reversal is and the criteria they applied to define diabetes reversal.

Knowledge of Definition and Criteria for Reversal of T2DM

The first question asked of the participants during the semi-structured interview was 'What was your understanding of the concept of diabetes reversal?' This interview question was designed to obtain information from the participants that would answer the first research question. The first research question and primary outcome of Study 1 was to investigate whether participation in the CHIP would lead to the reduction of blood sugar levels which if sustained without the use of medication could potentially lead to reversal of T2DM. For a client to be motivated to work to achieve an improved blood sugar level or diabetes reversal it is important they understand what diabetes reversal involves and that the possibility exists.

All the participants from the Study 1 intervention and control groups understood that diabetes reversal meant the normalisation of blood sugar levels through dietary modification and regular exercise. One participant from the Study 1 control group included stress management as an added means of reversal, however, six (five in the intervention and one in the control group) of the sixteen participants interviewed did not grasp the concept that diabetes reversal required blood sugar normalisation in the absence of glucose lowering medication. Some of the misconceptions included the 'control of symptoms', 'only having to take mild tablets to control blood sugar and 'not having blood sugar 'spikes'. Two participants, both from the Study 1 intervention group believed that reversal included an 'alteration or minimisation of the effects of diabetes on the body'. Another three of the participants (two in the intervention and one in the control group) had some previous experience of reversal in that a family member or they themselves had previously successfully reversed T2DM. Examples of responses can be viewed in Appendix G.

When the participants were probed about how they came to their understanding of diabetes reversal and from where they obtained their knowledge a further subtheme emerged. This subtheme contained content relating to the role of the participants' healthcare team in providing information about diabetes reversal.

Role of the Healthcare Team in Discussing Diabetes Reversal with Participants

The healthcare team, comprised of the client's doctors, diabetes educators and other allied health professionals are mostly responsible for diabetes education and management. This care is formalised within the Diabetes Care Plan which is a type of Chronic Disease Management Plan recommended for use in GP practices.

Participants were asked whether their doctors or members of their medical team had discussed diabetes reversal with them or talked about lifestyle options for reversing their T2DM. The responses were mixed where one participant who was part of the Study 1 control group acknowledged that her doctor had discussed reversal with her when she was first diagnosed, and she had attended some education sessions and had reversed her T2DM for a few years by losing weight. Another person who was part of the Study 1 control group couldn't remember very well but thought her doctor may have mentioned that it was possible to reverse T2DM but had not offered her any options for education or support to do so. Most of the remaining participants who responded with information to this question indicated that no discussion from their healthcare team about reversal had occurred. Examples of comments are included below:

> *'They just look at you. They don't say anything you know. You don't know really. I went to the doctor in Sydney and I remember seeing the diabetic instructor or something like this every quarter and she tells you what you to do….Never, never.'*
>
> *'No, no, nothing I mean you know to eat properly and all that of course, but yeah, but no-one. Thats all.'*
>
> *'Nothing, not really. No, not from a reversal perspective. It was a no, no…..I don't remember that, I mean, ever sitting down with anyone and saying, Okay, we're going to work out a plan for how to reverse this. Okay. It was just for you, you got this and here's, here's the meds you need to take to manage it.'*

Four participants from the Study 1 intervention group and one in the control group indicated that they were prescribed medication without any discussion relating to lifestyle measures to manage or reverse their diabetes. One comment was, *'No, nothing…. they said "Take care and be good. And take this medication".'*

Six participants in the intervention and all four from the Study 1 control group indicated that they had been referred to a dietician for dietary intervention, however, two participants in the intervention and one from the Study 1 control group found the dieticians appointment to be unhelpful. They experienced difficulties understanding the food exchanges and restrictions around when to eat. Some of the comments were:

> *'It wasn't, it wasn't put across like that. And they still don't, you know, it's still... it was just, well, this isn't happening. So, we'll give you some more medication, give you this side of things. And then, like, initially, what had started it that was like, the*

dietitian bit. It was quite confusing, you know, like, the pinch of this and a sliver of that and a piece of this. And nothing after three o'clock and all that sort of stuff. It was just here, there, and everywhere.'

'No because I struggled so much with the instructions via the dietician. ……I don't know, I just, I just found it hard. I found it confusing.'

Other interviewees from the Study 1 intervention group declined the dietician referral and stated that the fact that they never attended the dietician appointment was never followed up.

'No, they didn't. One doctor tried to steer me towards a dietitian.'

'And, and sometimes I wonder if I should, you know. Am I just sort of floating around? ...No, I mean, management was, you got to go, do your, have your eyes tested all the time, and podiatrist and see a dietitian. But, you know, even that's never been checked as…. I think when we started out there, there was a talk of, you know, there's you're under this plan, and you're going to be, but I don't think there's… I haven't had any follow up anyway.'

Another interviewee from the Study 1 intervention group thought that his doctor may have mentioned him not having to take tablets if he ate better and exercised more. His response was as follows:

'No, no. No, so when I was diagnosed with diabetes, the, the, I guess, the standard response is; 'these are the pills you need to take', and that's what happened for me. .....so I mean, I suppose to be honestly fair, probably the doctor at the time did say something about - something along the lines of, 'well, you know, if you did a lot more exercise and ate better, then you might not need the medication'.

The remaining participants were all made aware of weight control and engaging in regular exercise to achieve better blood sugar control by various members of their medical team however they found the support and follow-up was lacking. Several participants felt that their only option had been medication prescription. Examples of this include:

'No, not at all. All they talked about was medication put me on medication, nothing to do with my problem.'

'Theirs was more of a control approach. They didn't really…. they, they just saw it as getting worse, in my view, and um it just seemed to be a slippery slope, you know, you had a [sigh] you know a progression from...um. It all seemed to start with medication and then uh with me, [sigh] and I guess anyone who gets worse, uh you go onto insulin, and the doses increase and then uh… an insulin pump [laugh] to cap it all, that was just, just one of those…. Uh, they weren't really offering any hope of …uh. It was more of a control thing, trying to educate you to control.'

While most participants' response indicated that their medical practitioner had not provided options other than medication prescription for managing their diabetes, almost all acknowledged that they thought this was largely due to a lack of time available to engage in discussion.

Perceived Degree of Discussion of Diabetes Reversal by Doctors and Medical Team

A few participants gave reasons why they thought that doctors specifically were not spending time discussing reversal, options for management, and consulting clients about health care goals. Participants largely perceive that their doctors are very time pressed, where appointments are structured with ridged time limits that don't allow for much doctor-client interaction. An example of this is provided in the comment below.

'…. a doctor is so pressed now you know. It's a 10-minute time slot and you're, you're shown the door you know. There's, there's no time to chat really um, um …… If you go longer, you're paying more than $100 a visit [laugh].'

'I don't think there's time, do you know? I really, I think it's a … with a very busy practice. And there's no....'

While most participants had at least some knowledge about diabetes reversal it was interesting to know whether their knowledge had been translated into a belief about their own self-efficacy in being able to achieve reversal. The third subtheme emerged from responses to prompts relating to whether they as participants believed that diabetes reversal was achievable for them.

Participants' Beliefs about their Ability to Reverse T2DM

The internalisation of health education is more important for the application of what is learned than the education itself (Champion & Skinner, 2008). Even though clients may be

educated about the potential to reverse diabetes they are unlikely to be motivated to work towards it if they do not believe what they are taught or do not believe it is possible for them to achieve. The participants were asked whether before they enrolled in the research project, they believed that they could reverse their diabetes through lifestyle interventions.

Most participants displayed a lack of confidence in being able to reverse their diabetes. Participants in both the Study 1 intervention and control groups did not believe that T2DM could be completely reversed by CHIP (Study 1 intervention group) or lifestyle interventions (Study 1 control group). Two participants had previously reversed their diabetes and were therefore confident they could achieve it again. Another participant ascribed efficacy in terms of capacity.

Two participants from the original Study 1 intervention group believed before they enrolled in CHIP that it would be possible to reverse their diabetes. The reason given for this was that they had years before previous experience of reversal. *'The only the only thing I used to do, and I could get it down ……was my exercises.'* One other person did however acknowledge that they thought reversal was possible but whether it was achieved would depend on how willing and capable the individual was. *'Well, because I'm an RN myself I did, so with what I had yes, I mean, we that it would depend also very, very much on the person's wish, the person's capabilities.'* None of the other participants (both in the intervention or control group) who believed reversal was a possibility thought they would be able to or had much confidence in the fact that they would be able to reverse their T2DM. They did have some hope that CHIP would help them lose weight and control their diabetes better. Four of the participants indicated that their doctor had referred them to CHIP because the doctor thought it would help their diabetes management or would offer a diet that may help control their T2DM. The reasons provided by the participants for this lack of confidence were varied and included one participant who believed that his diabetes was too far advanced and because he had an issue with a type of muscular dystrophy his muscles would never burn off enough carbohydrate to reverse his diabetes, expressed as follows:

> '*I've heard of people you know who have got, lost a lot of weight and gone on a really, really strict diet, but I don't think their diabetes was -had reached the level that mine had reached, you know……. Because I don't burn up muscle like... If the average person like me did what I did, you know, exercise would bring, you know, would burn up the carbs. With me because I've got this form of muscular dystrophy that I call a*

girdle dystrophy, I don't burn up as much as, as. I haven't got as much muscle mass as a normal person.'

Another participant believed that reversal was not possible for him because he had struggled so much previously with a dietician's protocol. *"No because I struggled so much with the instructions via the dietician."* However, most participants, both from the Study 1 intervention and control group believed that T2DM was possible to control, prevent from worsening or that complications could be prevented. They did not believe that T2DM could be completely reversed by altering their lifestyle and therefore had little confidence in reversing their own diabetes. Examples of this include:

'It offered a way of reducing the diabetes symptoms, and like I couldn't see a reversal, you know, complete reversal. It's just a reduction in symptoms, because it was reducing the impact of the disease' and *'No, not at all. I always thought yea that diabetes was diabetes, and that was it. Once you got it, you got it.'*

'I'm not optimistic about reversing. I, I see it as a reduction of the impact of the disease but I, I see, I still view it as progression. I don't think one can magically get rid of it. You know, just the process you know can never, never be rid of it, in my view. But that's just something that maybe I should approach it from another way and think, 'Oh, yes, I can get rid of this totally. I see it as helping me reduce the impact of the disease and being able to live a better life.'

One of the participants from the Study 1 control group did not believe it was possible for them to reverse her T2DM. However, she stated that she was curious to try to find out how it was done.

'I didn't think it was possible for me, but I was reading about people who were doing it and I thought, and that was one of the reasons I thought, I'm gonna find out a bit more about this because I don't know what to do.'

Another participant expressed that he would have liked to be given an option to reverse in the early stages of his diagnosis rather than to be told that medication was his only option.

'So, when I was first diagnosed, ... they did say it was a lifestyle disease but didn't really say anything about how it was possible to reverse it. If doctors could, when they sit their patient down for the first time and say, you've got type two diabetes, here are your options. One of those options was you can go on ... a 12-week program? It'll cost you 200 bucks or 300 bucks or you start spending, you know, 70 bucks a month

on medication. …and I would have then gained a lot more knowledge, the knowledge I did end up getting from CHIP. I would gain all of that.'

Most participants were not confident that it was possible to reverse their diabetes. The two participants who showed confidence about being able to reverse their diabetes both had previous experience of reversal. All the participants were hopeful of being able to improve some of their risk factors the most prominent one mentioned being body weight. The participants were therefore asked about whether they had discussed with their healthcare team about achieving these aims and what goals had been established.

Collaborative Goal Setting

Collaborative goal setting is defined as goal setting that emerges from a process of consultative management where health care provider and client participate in open dialogue about the direction of the client's disease management. One of the common comments made by Study 1 participants over the period in which the study was being conducted was that they felt they would be helped better if they were permitted to be more involved in decisions relating to their diabetes management. This issue of involvement in decision making was regularly repeated by different participants in the study. Participants largely viewed the medical team as not being very forthcoming about information regarding the potential to reverse diabetes, however while interviewing the participants the discussion seemed to suggest that a proportion of participants also had experienced very little discussion from the medical team about goals for general diabetes management. The participants were therefore asked whether their doctors and or healthcare team members had involved them in any discussion about their diabetes management or in setting goals for their diabetes management and or potential for reversal.

Two participants acknowledged that management goals had been set for them, however the tone and context indicated that these were clinical goals rather than participation in management goals.

'But um yea no, no, no, really. I think when we started out there, there was a talk of, you know, that you're under this plan, and you're going to be, but I don't think there's, … I haven't had any follow up anyway, and any um talk about, you know, come in, and, you know, we'll measure you, weigh you. Look, I must admit, when I visit the doctor, I am weighed, and I'm always told, you know, you've put on weight and

dadadada. sort of thing. But yeah no, I can't, I can't say I'm, I don't feel like I'm on any plan um that I know.'

Another four participants indicated that although goals were set, there was little consultation that occurred, and the participant didn't feel part of the process of goal setting. An additional four participants perceived that diabetes management goals were not being set with them, with one participant expressing that she felt there was a lack of a plan in managing her diabetes. Two examples of views expressed are provided below.

'I don't remember that, I mean, ever sitting down with anyone and saying, 'Okay, we're going to work out a plan for how to reverse this. Um it was just a 'Poor you, you got this and here's, here's the meds you need to take to manage it.'

'They said, 'Take care and be good. And take this medication.'

Even though several participants acknowledged that they were being referred to multidisciplinary team members for care, the check-ups, doctors' visits, and referrals were being viewed as isolated events rather than as being part of a planned approach to care, derived from a background of collaborative goal setting. Three examples of participant views are provided below.

'They recommended I went to a dietitian as well. They recommended, um I went to the polyclinic at Toronto, and I went to like a information sessions there…. And I went back a few times after…. um yea to get information and you know to just talk about diabetes…. and um ask them about different… my diet and you know.'

'Even the first time, it's all about; "Well here's your, here's your authority. If you, if you need a physio, you get so many consultations and then when that runs out- it lasts a year, come and we'll…" They get the sister to draw up the programme for you and then they sign it and away you go.'

'No, no, I mean, management was 'You got to go to um the pod…, have your eyes tested all the time and the podiatrist and see a dietitian, but, you know, even that's never been checked as…. and I have had a referral to a podiatrist, and I didn't even go. Um I do check my eyes all the time. Um and um nothing's really sort of followed up. But yeah, um yeah it's, it's really just, and it's just medication, which I'm always worried about that might be increased you know.'

The views expressed and collated into Theme 1 answered the first Research Question. Most participants didn't have a very clear understanding of the criteria involved in diabetes reversal confusing glycaemic control with the absence of disease symptoms while not using hypoglycaemic agents. Most participants were also not confident about being able to reverse their diabetes through lifestyle management. It was also apparent that most participants felt under educated about lifestyle options for diabetes management and under involved in decision making about or goal setting for their diabetes management. Almost all participants expressed a desire for more consultation and involvement in their treatment but acknowledged that their doctors were too pressed for time to make this a reality. Theme 1 demonstrated more clinical significance and evolved from discussions with participants who had experienced the CHIP intervention as well as those who had not. Theme 2 emerged from responses to questions that were only asked from the CHIP participants.

Results for Theme 2 – Participants' Experience of CHIP

The CHIP has never been evaluated as part of a study. Consequently, the participants' views on the content, the programme design and its usefulness in helping them manage or reverse their T2DM was pertinent to understanding the relevance of the programme and whether programme factors were seen to contribute to the factors associated with adherence to lifestyle recommendations. The responses that resulted in the emergence of Theme 2 answered the second research question 'What was the participants' experience of CHIP as an intervention for diabetes reversal?' The CHIP participants were asked to describe their experience as a participant in the CHIP and its usefulness as an intervention for lifestyle management or reversal of T2DM.

Overall Experience of CHIP

When asked about their overall experience of CHIP, all the twelve participants from the Study 1 intervention group who were interviewed stated that they had enjoyed the programme. A comprehensive list of types of responses and their examples can be viewed in Appendix G, however the most illustrative comments from the participants during their interviews are provided below.

> *'And I really enjoyed and, and I, I, I really waited for that day to come. To come again to see everybody, to visit, just because you feel like as if you're all friends there.'*

'I enjoyed it for the company yeah, and it's educational.'

'Going to the CHIP programme gave me a degree of joy.'

Several participants in Study 1 had commented very positively about the CHIP during the study. Their comments during the interviews were investigated to determine the participants views about the suitability of the CHIP as an intervention for diabetes lifestyle education and possible diabetes reversal. The participants interviewed provided some very specific information as to what was enjoyed, what was helpful and offered suggestions or comments for improvement.

Subthemes Emerging from Theme 2

Five subthemes emerged from Theme 2, namely:

- Participant views about the content
- Participant views about the format
- Participant views about the presenters
- Participant views about the learning activities
- Suggestions for improvement

Views about the Content

The most frequent response to the question asked about their experience was with respect to the content of the programme. The content of the CHIP addresses the predominant lifestyle issues that are common to most chronic diseases of lifestyle namely a highly processed, low nutrient-dense diet and a low level of physical activity mostly resulting from a lifestyle based around convenience, a lack of participation in exercise and increasing hours of sit-time. More specific information related to the more common lifestyle disorders like coronary artery disease hypertension and diabetes is presented. However, the focus of the CHIP is not on T2DM per se. Most participants also had other chronic conditions and therefore it was interesting that most respondents found the content very relevant to them possibly because the principles could be applied across several health conditions. None of the participants had any negative comment about the content, most finding it very informative, interesting, valuable, positive, modern, and easy to understand. Some of the responses are presented as examples below.

'Information was not gobbly gook or, talking in riddles and everything. Everything was a positive side of things. And like I say, very descriptive. That you can understand what was being said and why you know. ……And then to go into it in all such great detail…. Made it all come together or understandable.'

'The CHIP programme is excellent for understanding in all levels. The visual presentations were so easy to understand.'

'…. some really valuable information. I thought that was really interesting. Modern, wasn't oldy oldy.'

Views about the Programme Format

Aspects of the programme that were highlighted as being especially helpful were the monitoring of biometric measurements and blood levels, group discussions, the food demonstrations and exercise sessions, the accountability measurements, and reports as well as the group support. The learning environment was found to be conducive to learning and was described as comfortable and non-threatening. Examples of these descriptions are provided below.

'…comfortable with a whole group of nice people. …a great environment for me to learn.'

'It was basically a really encouraging environment to be in, you know. Once you realize that you were there to, you know, basically deal with an illness or disease that you're trying to combat. Everyone was in the same boat, you know, you didn't feel unusual. We were all there for a purpose.'

Several participants expressed that they enjoyed the social experience, with one participant likening their experience to that of a spiritual encounter. Some examples are provided.

'I enjoyed it for the company and it's educational.'

'It was good that I've been able to meet people.'

'You know, it was a great camaraderie.'

'Mate you know what? CHIP, CHIP gives me the feeling what the same as finding the spirit and having him with me…. Suddenly blew me away that I never knew.'

Overall, the presentation of CHIP was viewed as well organised. One participant commented, *'I appreciated the CHIP program very, very much… I certainly appreciated the way it was presented, what was, what I heard, what was presented. I, I'd give it top marks as far as that's concerned…. I just felt it was all well organized, very well presented.'* Another said it was *'Very engaging.'* Other participants commented that the programme was varied and motivating, *'….and varied. There was nothing went for more than - none of it went for more than half an hour at a time …. So, it was attention getting. It was motivating.'* Another commented, *'But it was……well-modulated and, and what. You could not leave there and say, "I was bored".'*

Views about the Presenters

Several of the participants commented on the engagement and professionalism of the presenters, describing them as knowledgeable, helpful, and engaging. Some examples of the comments are listed below.

> *'And the, the course was very well done. And it was very easy to understand. And the people were really professional, you know, it was really good.'*
>
> *'The speakers were excellent, knew their subject.'*
>
> *'Especially there were so many people that were nice…Z helped me with the writing down things'.*
>
> *'You felt like that the whole team was very engaging.'*
>
> *'Very comfortable, so with a whole group of nice people. It was really, really uplifting, it was a friendly environment. Very nice……. A great environment for me to learn.'*

Views about the Learning Activities

The most common learning activities that were mentioned as being particularly enjoyable were the food demonstrations and tasting sessions. One participant commented, *'Just the whole fun of doing that (food tasting), as well as the social exercise as well".* The group discussions were also mentioned as being enjoyable. An example of a comment was, *"I did, did enjoy you know, like the discussions and everything you had with going through your book.'* The exercise sessions were viewed to be fun and engaging, *'The little part of it with exercise. It was really good. It was fun. I really enjoyed it.'* And the monthly follow up meetings were appreciated. One participant remarked, '*They were really good (monthly*

follow up). The food was good. Everyone brought a plate of course. The food was good. The lecture was good. As a rule, and they quite often demonstrated how to make most things.'

Reflections on Helpfulness of CHIP and Suggestions for Improvement

Participants were asked what about CHIP did they find helpful, not helpful or needing improvement. All the participants found CHIP helpful, and the responses could be categorised into those relating to the presentation of the programme, the learning and engagement activities and the content. The information and content presented was the most frequently cited as being helpful. Most of the content was presented via video talks. However local health professionals also contributed toward some content delivery. A selection of examples illustrating participant views are listed below. A comprehensive list of examples of responses can be viewed in Appendix G.

'The talks by Dr H, I think it was, were very, were very helpful.'

'Ah, the material like, and just a lot of factual information.'

'Things like leaving the skin on the vegetables and that instead of peeling it off where all the vitamins are.'

A variety of activities that formed part of the structure of CHIP were also regarded as being particularly helpful to participants. These included cooking demonstrations, exercise sessions and exercise reporting, group discussions, attending to what participants had to say as well as the follow-up assessment. Some examples of comments are presented below.

'And getting down to the demonstrations were good. Because you could go away and go. Oh, yeah. Well, that that tasted nice, or, that was good, and that was easy to make.'

'At the start of the programme I was given a step counter and encouraged to get to a target of 10,000 steps a day.'

'As far as listening to the people you knew, that added a lot of credence…as far as we were concerned.'

'They tested us, you know, beforehand and afterwards and, and that. They kept an eye on our how successful we were being in overcoming diabetes.'

None of the CHIP participants found any aspect of the CHIP unhelpful or unpleasant. Some examples of responses are provided below, and a more extensive list can be viewed in Appendix G.

'No, there's nothing I would say, you know, 'well do this, do this, instead of that kind of thing' because I just thought the whole program was very well presented.'

'So I…it's nothing that stood out that I'd say I didn't like that bit.'

'I don't think. There wasn't anything that stood out as being, you know, obnoxious, or that I really didn't like, there's nothing that stood out.'

Three participants offered suggestions for improvement. One participant would have preferred having the opportunity to mix with a greater variety of participants.

'It's better when you just walk in and you sit with who you want to…. It's okay, there's nothing wrong with having someone that like looks after that table. …. When you're segregating people to the same table every week, you're doing a 10-week course with the same five people. You don't get the mix of 50 or 60 people …. where you come in and you swap around so you get to know.'

Another participant suggested having less focus on presenting recipes and food demonstrations and having less of a focus on vegan food choices. *'For my point, maybe there was too much of a recipe side, but that's, that's just me. I think maybe that there was a little bit too much of the, the catering side.'*

An additional participant offered as a suggestion that monthly follow up meetings be used as recruiting and advertising events for the CHIP.

The results in Theme 2 have indicated that all the CHIP participants enjoyed the CHIP, found the content and learning activities enjoyable and helpful and were pleased with the format of the programme. Theme 2 partially answers the third research question. Participants found the programme informative, enjoyable, supportive, and well designed and implemented. To obtain a clearer picture of how these positive perceptions translated into usefulness for educative purposes the participants were asked specifically how they perceived the CHIP had helped them manage their diabetes and whether they believed the CHIP had helped them achieve diabetes reversal.

Results for Theme 3 – Participants' Perception of the Benefits of CHIP for Reversal

Obtaining participant views about how a programme is organised or implemented, does not necessarily translate into information about how a programme benefitted or contributed towards the participant improving their quality of life or health status. To answer research question 3 the participants also needed to provide some information on the perceived benefit of the CHIP in assisting them to better manage and possibly reverse their T2DM. This theme was drawn from the comments of those study participants who had been part of the intervention group in Study 1 and had therefore participated in the CHIP. Two subthemes emerged namely the perceived benefits of the CHIP and the perceived role the CHIP may have had in diabetes reversal.

Perceived Benefits of the CHIP

Participants' perception of the benefits of the CHIP included mostly weight loss and an improvement in well-being, both physically and mentally. Most participants were intensely focused on weight loss. The CHIP focuses more on consuming unprocessed and high nutrient dense foods and while weight loss is mentioned as a desirable effect of eating healthfully it is not promoted as the primary objective. Example of comments about the CHIP being helpful in reducing weight included, *'And yeah, I've lost weight of late, I think I mentioned to you'* and *'…new clothing size.'*

The improvement in well-being was largely perceived to be associated with the lifestyle changes made. Two examples of comments related to improved well-being are provided below, however a more comprehensive list can be viewed in Appendix G.

> *'I did feel a lot better because I was exercising you know. Doing the walking. Then I was walking a mile or two kilometres at least, least everyday sort of things. So, you know, health wise, I felt a lot better in myself too, and probably eating the right, you know, the right foods too. But yea other than that, that was good that part of it.'*

> *'I'm so happy that I do feel good…. I went through a stage where I was full on with post-traumatic stress, and I was on maximum doses of a lot of antidepressants. Well, I'm not in that situation now. It's still present, but it's not as bad as it was. …Some people say yes, if you improve the quality of your life and, and get the diet and exercise sorted out, then a lot of the other issues can be helped.'*

A less commonly cited benefit was that of an improved diet. An example is '*I've changed my food so that's been good.'* Some participants indicated that they had made a connection between an improved diet and the health literacy associated with knowing what was best for one's body. One participant commented, *'It gave me an awareness of what the different foods in you affects different parts in your blood, organs and body in general'.* Other participants were not as specific and merely indicated that knowing about healthy lifestyle options was beneficial in their journey with diabetes, for example, *'Learning about all the different health things.* One person identified that the education he received and was able to implement may have improved his long-term outcome as demonstrated by the following comment: *'Oh, yeah, I'd say, it may have added years to my life. No joke it could have you know.'*

All the participants who attended the CHIP believed that attending had improved their knowledge surrounding T2DM. The most common benefits cited were being able to lose weight and improve their general well-being. Very few participants were forthcoming about their beliefs about the role of CHIP in the reversal of their own diabetes and therefore they required probing.

Perceived Role of CHIP in Reversal of T2DM

The CHIP participants were asked whether they believed that their diabetes had been reversed at some point over the duration of the study and what role they believed the CHIP played in providing information and support for them to achieve reversal. A variety of responses relating to the role played by CHIP in the reversal of their own diabetes were received. Please see Appendix G for a comprehensive list of these responses.

All the participants acknowledged that they had obtained some physiological benefit from the programme. The changes commented on were however exclusively related to diet and exercise or level of activity. Half of the CHIP participants made very bold statements about their reversal status. Two were very emphatic about the fact that their glycaemic control was improved or stabilised but that their diabetes had not been reversed. An example of one such comment was, *'I felt that it stabilized me a lot to, to you know. While I was on the programme, things seem to just get stable, I wouldn't get any worse.'* Another three participants expressed that they believed their diabetes had been reversed even though only one of these participants was no longer taking any hypoglycaemic agents and demonstrated glycaemic control for more than six months.

'People were saying I was diabetic. I'm not anymore. Doing the right thing here and you'll get rid it. At the CHIP programmes it enlightened me do, yeah. I can get rid of this. B got me onto the CHIP programme and show me a whole different aspect, to control this by eating right and doing the right things and exercising. Which I done. Definitely, I'm not a diabetic anymore. Levels range between five and seven and a bit, never over never under.'

The remaining participants were less outspoken about their perceived reversal status and spoke about aspects of CHIP that could possibly influence reversal. These responses included an improved knowledge of the role of lifestyle measures in reducing weight, and an awareness of the need to make changes to lose weight. One example of a participant's comment was, *'It made me more aware of my food. It certainly made me more aware that I should really knock my weight back.'*

Several participants commented that the CHIP had provided a greater appreciation and awareness of a healthy diet. This awareness included an ability to critically evaluate the foods consumed and take active approaches to addressing glycaemic control. Examples of typical comments given were, *'It's made me more aware, definitely more aware of, um what I'm eating. I sort of watch everything now you know, when I buy anything…there's the sugar and the sodium content and things like that',* and *'It gave me an awareness of what the different foods can affect different parts of the blood, organs and body in general.*

For some participants the information provided educated them about the fact that diabetes reversal was a possibility and they felt that the programme activities were intentionally focused on providing the tools with which they could improve their disease outcomes. Examples of some comments include, '*I think everything revolved around the programme, and probably the reversal of the diabetes but it was also the [pause] yea what everything was doing……that was, that all went hand in hand in everything that the programme was',* and *'I haven't regularly tested blood sugar, I've just started doing that. I can. I did at the beginning of last week 7.8 and it was 4.4 this morning.'*

One participant perceived that CHIP had provided the necessary education for him to have the freedom to make wise health choices.

'It's given me the freedom because I'm more educated. And I just reap the benefits you know. I know if I don't do that, then things will go wrong. Long term, especially if you have a disease like diabetes, but I like to feel I'm in control still. But I do it in a way

that a more educated me is conducting my lifestyle through adopting the ideas that come from came to me from the CHIP programme. Again, it's it's an education, it's part of an education.'

All the participants from the Study 1 intervention group altered their lifestyle for the better to some degree. The focus for all the participants was on food and exercise with only two participants mentioning stress as an additional lifestyle factor requiring some attention. An example of a comment is provided below.

'...and what you eat and reducing your carb intake, especially in the evenings and increasing your protein in your meals. And to have proper gaps between meals. While I do that, I really make sure I've got. I tried 12 hours between my last eating at night and breakfast in the morning, it's even longer sometimes and it gives your body a chance to restabilize the insulin. And yeah, what else did it say? Oh, it says, to get exercise, improve your stress and sleep and walking, which studies have shown to reduce body fat and insulin resistance.'

No other lifestyle factors for example the amount and quality of sleep, exposure to fresh air and sunlight, drinking enough water, work-life balance, recreation as rest, and spiritual renewal were talked about by any of the participants. This was despite all these lifestyle factors being addressed by the CHIP.

The participants provided several comments relating to the lifestyle adjustments they had made. A comprehensive list of comments can be viewed in Appendix G.

Participants from the Study 1 intervention group all increased their level of activity. This was mainly achieved during CHIP by aiming toward achieving a goal of 10,000 steps per day and therefore the predominant type of exercise engaged in was actively walking as exercise and increasing incidental activity by walking more flights of stairs, parking further away at shopping centres or decreasing sit-time.

'At the start of the programme, I was given a step counter and encouraged to get to a target of 10,000 steps a day. The first couple of weeks or so I thought it was a target too far away to achieve however I now sit around 18,000 – 26,000 steps per day and feel it is a requirement that I start each day with a 10,000 step in the morning and a further 5,000 steps in the late afternoon, the remainder is gained with home and yard duties.'

'I don't do a lot of exercise because I just can't do a lot of exercise…. So I'm trying to do more of doing things because I walk a little bit more in the house and outside and doing little things to keep me busy.'

Participants from the Study 1 intervention group were encouraged to follow CHIP recommendations which entailed making food choices that were largely plant based, high fibre and of low calorie-density. Most participants followed a vegan or close to vegan diet consisting of very little processed foods including processed fats and sugar.

'I can't say….at home we are all fully vegetarian. S is 100%. I am 80% because I used to eat a little bit of chicken. But now I've stopped that as well. So, I don't think you know, it was not difficult to follow the, the recipes or whatever.'

'What do I put? …. About 11 different components to the salad, I counted. You know it's like I've got kale in the garden, kale, carrots, beetroot, corn, pineapples sometimes. All that sort of thing it's just, just a big, it's a big plate of salad.'

'I still, still do the vegetarian side of things.'

To answer the second part of research question three which related to whether the CHIP had been useful as an intervention for reversing T2DM, participants were asked whether they found the CHIP to be a useful intervention for reversing T2DM. Participants in the CHIP indicated that the CHIP had assisted them in making significant changes to their diet and in increasing the amount of exercise they participated in. While not all the dietary changes were maintained, and the regularity and intensity of exercise also dropped over the study period most participants maintained the mainly plant-based nature of their diet and continued to be more active than what they were prior to participating in the CHIP. Most CHIP participants acknowledged that, the CHIP was helpful in gaining knowledge which they could apply to help improve their diets and levels of activity and exercise, which for some may have contributed to diabetes reversal. However, on the most part participants did not reverse their T2DM.

Recidivism is common in most lifestyle change programmes. Responses making up Theme 4 indicate participants' beliefs about their level of adherence to recommendations and reveal some of the factors that contributed toward recidivism and adherence to recommendations. The subject of adherence was addressed with both the Study 1 intervention and control group. The intervention group were asked about adherence to the CHIP

recommendations, whereas the control group were asked about their adherence to recommendations made by their healthcare team.

Results for Theme 4 – Adherence

Adherence can be described as the ability of an individual, to over a period of time continue to follow recommendations or instructions. This fourth theme answered Research Question 4 and emerged from responses to questions which addressed the participants' perception of whether they adhered to lifestyle recommendations and which factors contributed to recidivism or alternatively which factors contributed to their adherence. The twelve participants for the Study 1 intervention group were asked about their adherence to lifestyle recommendations made by the CHIP whereas the four participants from the Study 1 control group were asked about their adherence to lifestyle recommendations made by their healthcare team.

The participants from the Study 1 control group reported basing the foods they consumed on education they had received from a diabetic educator or dietician. These diets were varied with a focus on carbohydrate exchanges, low carbohydrate or a high fibre Mediterranean diet.

'I think they recommend 45 grams (of fibre) in a meal, but I try to even get less than that.'

'….you cannot get through life without eating vegetables.'

'And we have gone mainly vegetarian anyway.'

These same participants from the Study 1 control group all reported to be engaged in exercise prior to the commencement of Study 1 and continued to exercise over the duration of the study. Examples of the comments relating to their continued levels of activity are provided below.

'Walking about the same 3 kilometres a day. We have a 3-storey house now, so I'm up and down the stairs, like a yoyo.'

'The yoga has helped too with relaxing, and you know that sort of difference. That's been very helpful too.'

The twelve study 2 participants for the original Study 1 intervention group as recorded under the previous Theme 3 had all reported to have improved their diet by

consuming mostly naturally occurring, unprocessed, plant-based, high-fibre, low energy-dense foods. They had also reported to have increased their weekly activity levels and had introduced exercise, mainly walking into their daily routine.

Participants were asked to describe their experience of adherence to lifestyle recommendations promoted by the CHIP (Study 1 intervention group) or by their healthcare team (Study 1 control group). Additional prompts were included for most participants to elicit responses about the factors that led to increased recidivism and the factors that led to increased adherence to lifestyle recommendations. Three subthemes emerged to make up Theme 4, namely:

- Difficulties experienced that impacted adherence.
- Strategies that assisted in maintaining adherence.
- Self-responsibility as an approach to adherence.

Difficulties Experienced that Impacted Adherence

Body weight

Type 2 diabetes mellitus is predominantly associated with being overweight or obese and for some individuals carrying excess weight resulted in feelings of guilt and shame. This guilt led to a reluctance in admitting the diagnosis but also prevented them from being adherent to recommendations in public. One participant clearly expressed her feelings of guilt associated with her diagnosis.

> *'I actually felt quite guilty about it, too. I always felt that diabetes is kind of a disease of being overindulgent. You know, and I didn't feel very pleased or felt, you know, really not, not good about myself having that diagnosis. I don't like even talking to people saying, I've got diabetes, I really feel.'*

Another participant acknowledged that the consequences of being overweight and having T2DM if dwelt on could be harmful as it contributed to the guilt, and that a more positive approach was recommended.

> *'I think it's good to re-mention the impact that it can have on you and the fact that long term it'll be harmful..., I think establishing that people are aware of it I think that's important. And it should get a mention, but it shouldn't be dwelt on. I think a more optimistic approach is good.'*

A third participant commented on the deleterious effects on an individual where health professionals appear to demonstrate an air of superiority. This person felt this type of relationship was not conducive to respect or open communication which impacted adherence to recommendations made within the setting. The original comment is presented below.

> *'One thing that p….me off with professional's, is when they tend to look down their nose right when you're not in their level. It's another thing when you walk into a doctor's practice, and this blokes' talking to you on your same level.'*

Participants were more focused on and concerned about managing their weight than they were on glycaemic control, on expressing the observation, *'Well, I've been overweight all my life and that was my most major motivation that.'* Losing weight was largely cited by participants as being the reason for referral to a dietician, and when lifestyle advice was given by the medical team, it was reported to be largely associated with weight loss. For those who did their own reading, they inevitably reported that losing weight was the prime objective in managing T2DM. Participants from both the Study 1 intervention and control groups struggled with weight loss over the longer term. When asked what was particularly problematic with respect to adherence during the follow-up period, having difficulty in losing weight was a dominant theme. Losing weight was reported as being slow and the perceived lack of progress often demotivating. Some examples of responses are provided below; however a more comprehensive list can be viewed in Appendix G.

> *'Anyhow, its (losing weight) easier said than done, well, at my age, I'm finding."*

> *"It's harder to control to control (weight) when you're in midlife. I do get disappointed, because I feel like at times, I work really hard. You know. I have this soup that I made that has 12 vegetables in it and I love it. I can eat it morning, afternoon dinner and tea and I love salads. And I drink black tea with lemon and no sugar. And I love it. But they're not enough.'*

> *'And my weight, it could be less. I'm 90 kilos or 89 kilos. But I think yeah, because I'm heavy. I think I'm just heavy boned. I've always been like that. But I've never…. I was 95, and I've got it down to 89 ,90. now, but I find it very, very hard to get below that.'*

Several difficulties experienced by participants that either interrupted their lifestyle adjustment for a period or resulted in them abandoning a good deal of the changes they had

made were captured during the interviews. The predominant interruption was reported to be the COVID-19 restrictions and lockdown periods.

COVID-19 Lockdown and Restrictions

The arrival of COVID-19 along with restrictions on social and sporting activities and associated lockdown led to a few participants not having access to their usual means of exercise and incidental activity. Examples of typical responses were, *'You know and then when, when COVID came and last year I couldn't do much things', and, 'It's a pity, then COVID came, and everything was you know couldn't do anything anymore.'* For some the physical and psychological impact of the pandemic led to recidivism. One participant responded by saying, *'I lost I think seven kilos when I was on the CHIP programme. But then that, with this COVID I've put it all back on.'*

Some participants reported that resuming activities had been difficult whereas others acknowledged that even during the lockdown, a lack of motivation was responsible for their lack of adherence and getting back on track requires an element of self-responsibility. One such response was, *'Sure you can use COVID right. I was locked down; couldn't go the gym and you know even looking for a Nautilus machine to do weights, and me relocating, but it's up to me.'*

Pain as a Factor in Exercise Adherence

For those participants from the Study 1 intervention group, difficulty in maintaining a regular exercise programme and being physically active was mostly limited by conditions that were associated with substantial discomfort or pain while being active. In one instance major abdominal surgery was the limiting factor whereas back, knee and hip pain were the other common reasons provided. All the participants who were experiencing painful conditions were at least retirement age with the majority being octogenarians. An example of the comments made was, 'I *get pains in My leg. I should walk more. You know, I feel as though I'm coping as well as I can. I turn 80 this year.'*

There were, however, several individuals who, despite being in the same age category they were extraordinarily active. Therefore, age was much less of a limiting factor for exercise than the debilitating effect of pain. An example of an older active person's comment was, *'I like exercising. Oh, yeah. I tire more now being 76, but I do a fair bit. I go for a kayak for an hour and a half. For my walking around with my monitor thing, me watch you know. I get up to six or seven thousand steps a day.'*

For one individual, the time she was dedicating to exercise became too inconvenient and resulted in her gradually going out less and less, and then finally over time, she stopped altogether. Her comment was:

> *I wouldn't be home before 10 o'clock usually and that, that probably was one thing why I stopped doing it. It was the time factor. It wasn't a conscious decision to stop. It just was just ended up taking up too much of my time, you know.*

Veganism and Rigid Diets

Most participants in CHIP enjoyed the food demonstrated at CHIP and the recipes provided to them. For some, however, choosing to not consume meat was difficult to maintain long term. One participant explained that she enjoyed her meat too much to give it up entirely. Her comment was *"I'm always going to be a meat eater."* Another participant was told by her doctor to re-introduce meat into her diet because her ferritin level was too low. The original comment is presented below.

> *'I mean cooking and I have absolutely, you know, miles apart. I hate cooking…. I had to go on red meat again because my ferritin level dropped. That's the only reason I went off the vegan diet.'*

Several participants appreciated the CHIP recommended diet because it was not prescribed. Participants expressed that ridged diets were difficult to adhere to long-term. Talking about other prescribed diets this participant noted, *'And it was very hard. I found it very hard to stick to a really rigid diet. Where even though I exercised and everything, it's quite easy. But to stick to a really strict meal diet, you know...'*

Participants from both the Study 1 intervention and control groups expressed that they found the recommended CHIP diet to be limiting especially when socialising with others who ate quite differently. Eating out with people who ate differently was especially challenging for some. In the short term they tended to 'cheat' and in the long term they tended to opt for a less limiting version of the 'diet'.

> *'And that I must admit that in Mauritius, I probably didn't do as well, because, you know, back in there, we ate a lot of bread and a lot of rice even though I tried not to, to eat all that. Vegetables, there were plenty. But I've got a feeling that sometimes because I love bread so much, I've been cheating a little.'*

> *'It's a very isolating kind of eating pattern. The diet was, was very socially unfriendly…. Well, I can only say that that strict CHIP diet would be extremely anti-*

social to maintain. You could barely eat with anybody else, you know, without it being noticeable and becoming a topic of discussion all the time, you know what I mean. Anyhow, I'm eating healthy and feeling really good.'

'Although restaurants and things got a little bit better with healthier eating. But I mean, I know I was never a McDonald person or anything. But um, Yeah, you know, it was hard when you went out to eat. Some of the menus weren't good. You know, we had to try and get, order something. But I was always aware of it and always tried to do the right thing.'

Guilt Related to Inconveniencing Others

Participants who had a partner who was unwilling to alter their own food choices or participants who did not want to inconvenience the rest of their household found it difficult to plan a meal that would address the dietary needs of both their and their partner. The psychological battle between whose needs should be prioritised and the potential discomfort of requiring their household to make too many adjustments led some participants to make less of an effort to alter their eating habits or maintain already altered food choices. Examples of comments related to these difficulties can be read below.

'You're brought up to want to please and to serve a meal that everybody loves, and it tastes nice and, and it is it's just being strong, and I guess it's putting yourself first too and not second, third, fourth behind everybody's else's wishes, you know.'

'My family were very supportive of me doing it for me. But it's, it's still very hard, you know, when the rest of the family are just doing what they're normally done. We have made changes; we've done things differently since I started doing CHIP but only little bits. And although I could probably cope with a, quite a radical change if it was just me you know. I have to factor in that we're cooking for more than just me, and, and so it's very easy just to resort to the usual. The same old, same old. So, I just found it hard you know, it's probably, probably that I just need to be a bit stronger about it, but I haven't been strong enough.'

Living alone

Having to cook for oneself was viewed by some as requiring a lot of effort, especially in circumstances where they were also eating alone. Heating up a store bought, often more processed and therefore less healthy meal was perceived to be more convenient for this group of individuals. However, it was also cited as being more expensive to find healthy ready-

made meals or partially prepared meals that would be more convenient. An example of the comments made is "*If you want to buy bites and couscous. All that made up out without mucking around, it's expensive it's expensive mate. The only way it's not expensive if you're eating just trying like to eat your veges and you're cooking and doing it yourself.* Some participants found that they had to negotiate cooking two meals which they were not prepared to do long-term due to the inconvenience and the expense. An example of a typical comment is presented below.

> '*…but I've found with my partner, because he eats meat too yea, he's a big meat eater, but me, I, I like my steak. If I had somebody here with me that was more into doing things, I would be a lot more inclined to do you know stick to the programme. Yeah, but because my partner you know being like he's German and yea you just find it very hard you know when you gotta cook for someone. If I was by myself, I would have no problem sticking virtually to it. But just being sort of, I don't know, you just don't want to cook one meal for you and with our one meal, eat something else yea, and especially, especially being on a pension, you just can't afford to do those sorts of things. I just thought I'm not cooking two separate things all the time.'*

Stressful Life Events

Significant life events that contributed toward a lot of stress for participants were perceived to directly affect their glycaemic control as well as indirectly affect their ability to adhere to lifestyle changes. One participant had been suffering severe mental illness. He commented as follows.

> *'I kind of clammed up for a bit there you know when I was full on with the depression and the post-traumatic stress. I just lost interest in so many things. But now (since CHIP) I just love things like taking photos and learning how to use what's available to produce good results and I love reading books and watching documentaries….'*

Several participants had experienced severe stress related to home or family situations. Examples of their comments are as follows.

> *'So, and the situation at home was not very good at all. And I was so stressed. And, and I know that this would have put, made it (blood sugar) go up. Yes. And because I was so stressed out, I was discouraged…. I was so, so, so angry you know. And I just, you know, very, very bad. But that's the thing you know. How can you try to put, bring your blood sugar down, when you're always stressful…. At the moment I'm a bit*

calmer so I'm trying to do really well. Well, well trying what I can, and I can find that the blood sugar is going down. Some circumstances sometimes doesn't help. And you're not linked to the right thing... You do the wrong thing. And so that's the only thing that really got me.'

'And I think it does, really, because I am a bit of a stressed person. I think that really does raise your blood sugar, you know, by stressing and stuff like that. So, a couple of years ago, probably three years ago now when I was having a lot of stress at work. And yeah, that's when my blood sugar went up again. I think a lot was to do with stress. I broke up with my partner and in the same year my mom passed away.'

Other participants had experienced severe illness in the families. One, due to COVID-19 could not visit her family member which created a lot of stress for her. Her comment is included below.

'*I've put a couple a couple of kilos in the well the last, last couple of months, but I've had I've got a sister in Perth that's in palliative care, so I think that's been a bit of a stressful thing on me that I know. I've got to get that back off very quickly, but they will come off in very - you know I've started to settle down with that. And of course, I can't get over there you know that's been hard. My weight has really been pretty well except for these last couple a couple of months. It's put a cap on that.'*

The support and camaraderie experienced at CHIP was also perceived to be of great help in managing these stressors. Two examples are presented below.

'Being with people in a .... Which I think having the same problems that I am, made me think, you're not alone. You're not the only one. So, it just gave me more you know, courage to go on and to do things you know. And people were just so nice and friendly and helpful and everything. So, I felt I felt like I belonged in the in the group you know.'

'I'm finding a lot harder to do them on my own, you know. Then, then I felt I could do. When I was going along to the, to the sessions, and everyone was sort of jeering everyone along.'

Almost all participants had experienced one or other factor that they could attribute to some degree of recidivism. However, several participants also contributed strategies that helped them address some of the difficulties or at least return to practicing some of the recommendations they had temporarily not adhered to.

Strategies that Assisted in Maintaining Adherence

Not all participants found adherence problematic. Some participants from both the Study 1 intervention and control groups identified they had made changes easily and that adherence is about making the right choices consistently. Examples of their comments are presented below.

> *'It's didn't bother me at all. I just chose if I went out to dinner, I just chose food without meat. You know, or fish or anything.'*

> *'You just got to buy the right stuff. I think it's quite easy… No, no you just choose, choose carefully.'*

> *'It was seamless with me. I just adopted the, the ideas you know and introduced them into my life. I didn't see it as a magic fix. I'm probably less optimistic than some folk. But yeah, I just seamlessly incorporated the principles into my life. And, and it has worked.'*

> *'Just I found it an easy diet to follow, because I think yea it was easy.'*

Monthly 'Club CHIP' meetings were implemented by the CHIP team in the Lake Macquarie region as a mechanism through which previous CHIP participants (CHIPPERS) can maintain contact with each other and with the CHIP delivery team. The programme at Club CHIP varies from month to month; however, at most meetings a local health professional will deliver a talk based on healthy lifestyle and the demonstration of at least one food recipe will be presented. CHIPPERS are also invited to bring along a plate of CHIP approved food and the CHIPPERS will then sit down to a community supper. Not all participants from the Study 1 intervention group attended CHIP follow up meetings regularly, however those who did invariably found them enjoyable and helpful for maintaining lifestyle changes.

> '*I liked going to the …. once a month…. thing because that keeps you…. They were quite good because they just keep… you're in touch with it all. That did help a lot so you know that you can... makes you think about it a bit more.'*

Another participant from the Study 1 control group identified that keeping a food diary assisted her in maintaining glycaemic control. She did however also perceive that if she had the ability to self-test she may have been able to practice more self-accountability.

'When I saw the dietitian, I took along my, my fitness pal, which had all my food. I'd kept a food diary for months, and it had everything on it so she could see what I was eating and that. …. If I had been testing myself, I might have woken up and thought, Gosh, I'm, you know, 'I'm seven today', or 'I'm eight today' or whatever. But I never know, I never know what I am. I just take the pills…. doing my fitness pal which is the same thing.'

One respondent recognised that she was mostly externally motivated. Having some sort of reward or recognition was motivating for her and when provided it assisted her in maintaining adherence. When not provided it often resulted in her becoming despondent and relapsing.

'So, I want to reward. I want someone to say, 'you're doing good, you know, keep it up. What you're doing is great.' And that's, I don't get much of that. You know, it's almost like you, you want to be the best in the class and say I've got good results. And I'm thinking, you know, am I at the stage where I'm starting to get really bad results and things now. And so anyway, I'm trying to keep on top of everything and get all my tests done when they're necessary.'

Self-responsibility as an Approach to Adherence

Participants expressed how they approached adherence in several ways; however, the responses could be easily categorised into a sub-theme of self-responsibility. Several participants found being active and participating in exercise very enjoyable and therefore found it was not difficult to maintain healthy levels of activity. Several participants also expressed that they enjoyed the plant-based foods advocated by the CHIP or for those from the Study 1 control group, the food recommended by their dietician.

Almost all participants admitted to 'cheating' on some occasions but because they were accustomed to exercise and enjoyed their food, they did not find it difficult to return to exercise or to make healthy food choices. One participant managed her occasional "cheating' by accommodating with extra exercise. She stated, *'Because sometimes I'm a bit naughty, so when I am, I do make sure I do a bit of extra walking.'*

Those participants who found exercise difficult or missed some of the less healthy food options they approached adherence using a risk benefit analysis. One participant explained that her approach to adherence was one of electing to take control in determining what lifestyle changes would be of benefit without adversely affecting her quality of life.

Another explained that the degree to which she believed changes should be made was based on a risk benefit ratio. Changes that she perceived to result in a reduction in the quality of life, she was less likely to adopt. Even though she wasn't close to being an octogenarian, she recognised that the older one is, the less likely one is to make uncomfortable lifestyle changes because it's perceived to not be worth it.

> *'There's something about like a quality or a happiness of life as well. If you're in your 80s and you think well, you know, is, is it going to give me such a nice, happy feeling if I eat that ice cream, or am I going to get really, really sick if I eat that ice cream? I think you're going to take the happy feeling and say, you know, I want the happiness for the little time that I've got left.'*

Another participant expressed something similar in that he felt the CHIP had provided him with the knowledge, and he would make lifestyle decisions that are comfortable for him to maintain.

> *"It's given me the freedom because I'm more educated. And I just reap the benefits you know. I know if I don't do that, then things will go wrong. Long term, especially if you have a disease like diabetes, but I like to feel I'm in control still. But I do it in a way that a more educated me is conducting my lifestyle through adopting the ideas that come from came to me from the CHIP programme. Again, it's, it's an education, it's part of an education."*

A few other participants acknowledged that the CHIP had provided the knowledge they needed and that it was then their responsibility to apply that knowledge to effect improved health.

> *"I could reach goals if I applied the principles of CHIP. It was really up to me".*
>
> *"It's up to me now to apply it…I can talk until the cows come home, but it's up to me. It's up to the individual. It's will power. It's the same as if you're in club sports. You only get there if you put the effort in."*

One of the participants from the Study 1 control group expressed a very similar attitude in that despite being shocked at her diagnosis, she recognised the need to be proactive and take control. She stated,

> *'Once I um well once I sort of. I think it was a little bit of a shock when you first find out that you have diabetes and then then I sort of took control and, and started to do the dietary changes and that.'*

A second participant from the Study 1 control group explained that when she was initially diagnosed, she had applied the same principle of taking control but felt less knowledgeable and capable of managing when her glucose levels were uncontrolled. She said,

> *'Oh, at that stage. I would probably have said I was always capable of just doing it myself. However, now what are we a couple of years down the track. I would say I need it because on my figures are wrapped around the 14, 15 mark every day.'*

The factors that largely contributed to recidivism were feelings of guilt about being diagnosed as having diabetes, particularly if associated with being overweight which led to difficulty in acknowledging the issues at stake. Also, difficulty in losing weight led to becoming demotivated about trying lifestyle interventions. Interruptions like the COVID-19 restrictions, severe pain or illness and stressful life events often disrupted habits and resuming activities became more difficult. Dietary recidivism was largely associated with the inconvenience of cooking different meals or the perception that eating habits were inconveniencing others. This was particularly relevant when socialising and eating out with others. Having to prepare meals for one when living alone was perceived as being inconvenient. It was preferred to make use of ready-made meals or at least partially prepared food, the healthy versions of which was expensive.

Several participants contributed strategies that assisted them in maintaining adherence to lifestyle recommendations. The most cited was enjoyment of the exercise and food. The second most cited strategy was to make accommodations for times when 'cheating' occurred and then to resume the recommended lifestyle. Support through community groups (CHIPPERS) and making use of food diaries, regular testing and eliciting a reward system were other recommendations. The participants were very forthcoming that they selected the lifestyle modifications that were easily implemented or enjoyable as those that they would adhere to. Less convenient recommendations were rejected on a risk benefit analysis approach. Most participants elected a level of adherence for which they would be self-responsible.

Conclusion to the Chapter

In this chapter Research Questions 3 and 4 of the thesis have been addressed and answers provided. From the analysis of participant transcripts conclusions can be made concerning their knowledge and understanding of diabetes reversal and experience with

CHIP. At the outset 50 per cent of the participants did not have an accurate understanding of diabetes reversal and only 25 per cent were told that an option for reversal existed. Due to perceived lack of time and opportunity for client engagement and collaborative goal setting almost all participants felt they were not included in decision making regarding management methods and felt under prepared for managing their diabetes.

Most felt that they were given little option but to rely largely on prescription medication for glycaemic control. Participants in the intervention group who had completed CHIP were very positive about their experience. They all expressed that they had gained a lot of knowledge, that the format, presentations and learning activities were helpful in making lifestyle adjustments.

All the CHIP participants had reported ways in which lifestyle adjustments they had made had benefitted their health, mostly through weight loss and improved well-being, however other benefits cited where improvements in diet, general health literacy, social engagement and improved levels of activity.

Most study participants, both in the intervention and control group expressed having some difficulty with adherence. The most prevalent issue related to exercise was pain related to a co-morbid condition. Restrictions on gathering and closures of facilities during COVID-19 and a lack of time were other reason for participants finding exercise difficult to maintain. The most common reasons provided for a temporary or more consistent lack of adherence to dietary recommendations from CHIP or other health care team members was guilt or discomfort about eating differently to other members of their household or requiring ‘special foods’ when eating out. For CHIP participants the ‘strict’ vegan diet was cited as problematic and for the control group finding food outlets that catered for diabetic options was cited as difficult. The effort required to cook, or to cook wholefoods from scratch especially when eating alone was a barrier. Making use of ready-to-eat or partially prepared wholefoods was cited as being very expensive. Interestingly long periods of stress were viewed as being a reason for blood sugars becoming uncontrolled even when participants perceived they were doing the ‘right’ things. Stress was also seen to be a principal reason for non-adherence due to lack of energy and motivation.

Those participants who found exercise difficult or missed some of the less healthy food options they were accustomed to approached adherence using a risk benefit analysis approach. They were willing to adhere to lifestyle changes they enjoyed or were comfortable

with but neglected implementing lifestyle factors that they perceived would alter their quality of life. This was typically expressed more frequently in the older age groups.

In the following chapter four case studies are presented. These case studies are compiled with data from both Study 1 and Study 2 and illustrate the interrelationship between the conclusions made from both studies. These case studies provide a real-world holistic illustration of each of the participant's experience.

CHAPTER 8: STUDY 2 CASE STUDIES

Four case studies have been selected to illustrate the real-world context of the participants' experience. The case studies were developed using data from Study 1 and Study 2 which enables the reader to obtain a perspective of the relationship between the conclusions made from each of the two studies. Case Study 1 provides context for a participant who initially obtained notable changes in biometrical data in response to the CHIP. Significant life stress resulted in recidivism and a rapid deterioration in the changes observed. Case Study 2 illustrates a situation where a participant enjoyed the lifestyle education and made some changes but from the outset made decisions about limiting the degree of change she was prepared to make so as not to alter her perceived quality of life in any way. Case Study 3 demonstrated the success achieved by a participant who made extensive changes and was very determined to take control of her diabetes diagnosis. Case Study 4 provided context for a participant who was in the control group and who despite receiving his diabetes diagnosis in the late stages of the disease had developed a high level of self-responsibility in the way he maintained glycaemic control. He was largely adherent to the education he had received within the boundaries of maintaining an acceptable perceived quality of life.

Case Study 1: Ms D

This first case history is presented as an example of rapid changes in biometrical data in response to adherence to lifestyle recommendations followed by the steady deterioration in response to recidivism. In addition, this case history demonstrates how significant life events and stressors impact an individual's well-being and potential adherence to lifestyle recommendations.

Ms D enrolled in the research project at the beginning of 2018 after being referred by her GP. She was 72 years old and had been diagnosed with T2DM in 2003. She was a non-smoker, had previously undergone cataract surgery and had difficulty engaging in physical activity due to her being significantly overweight and suffering from neck and back pain and some numbness in her left leg. Her medication included 100mg of Salicylate (Aspirin) and 500mg of Metformin hydrochloride (Diaformin).

Results for baseline assessment are provided in **Error! Reference source not found.**.

Note: The higher numbers on the RAND-36 indicate better functioning and less impairment of function.

Ms D was randomised into the intervention group and commenced the CHIP in February 2018. She understood the concept of diabetes reversal and believed that she could achieve better glycaemic control if she improved her lifestyle and, most of all, if she managed to lose some weight. She was not entirely convinced that she would be able to go off her diabetes medication but was very motivated to make changes in her diet. Within a week, she started experiencing hypoglycaemic episodes, and her doctor ceased her Metformin hydrochloride (Diaformin).

The recorded dietary changes included eliminating eggs, dairy products, and sweet desserts. Dairy products were replaced with dairy-free milk and yoghurt, sweetened processed cereal with unsweetened wholegrain cereal/porridge and refined bread with wholegrain bread. Ms D also consumed less bread and dropped her fruit from four pieces per day to two pieces per day. At this point, she was feeling optimistic about her weight loss, reduced blood pressure and cholesterol levels and the fact that she was no longer prescribed the Metformin hydrochloride (Diaformin).

Ms D had for some time been experiencing relationship difficulties with an extended family member, but toward the end of the CHIP the problems with this relationship became significantly worse. She maintained her physical functioning, but most of her other well-being scores on the RAND-36 had dropped by the 12-week assessment. She was recommenced on Metformin hydrochloride (Diaformin) 500mg as her blood sugar was elevated at a doctor's appointment shortly before her 12-week assessment.

Due to the change in season and the extra stress she had been experiencing, she was also less active than she had been during the first few weeks of the programme. Ms D had always been fearful of walking on the road alone and had no one available at home to walk with her. So even though she was motivated to increase her physical activity and attempted to do that by walking laps inside her house and garden, the lack of access to facilities in the long term became a significant barrier to exercise adherence.

When interviewed, Ms D expressed that she had enjoyed CHIP very much and had looked forward to attending each evening. She had particularly appreciated the socialisation and the group support mostly because she identified herself as introverted and found it challenging to socialise and find friends. However, she found the helpfulness of the presenters and group leaders and the friendliness and support of fellow participants warmly and looked forward to attending each night.

Within a few weeks after the completion of the CHIP, Ms D was expressing extreme stress levels, an inability to sleep and difficulty coping with life in general. She also started experiencing cardiac symptoms for which no diagnosis could be found on investigation and was attributed to the stress. At this time, she had difficulty obtaining appointments with her GP practice and expressed feeling that she was being dismissed. When she did manage to get an appointment, she felt that she was not being listened to and that the team was not addressing her concerns, which resulted in her changing to another GP practice. In the meantime, her blood sugar levels became more uncontrolled, and an additional hypoglycaemic agent was prescribed.

Over the next few months, the situation became increasingly stressful at home. She also spent some time visiting her family overseas in her country of origin. She described that it was somewhat more difficult to maintain some of the health choices she had previously made. Once back in Australia, with the resurgence of the stressors, she largely abandoned the dietary changes she had made, and her level of activity dropped even further with the increase in physical pain she was suffering with at the time.

By the 12-month reassessment appointment at the beginning of 2019, she had regained all her weight, her cholesterol levels had returned to their pre-CHIP levels, and she was still taking the additional hypoglycaemic agent to control her blood sugar levels. At the time of being interviewed in the middle of 2021, Ms D reported that she had required gall bladder surgery shortly after her 12-month assessment and, post-surgery had resumed a range of light activity and body weight exercises. She had also largely resumed the diet she was on at the end of CHIP but was finding it extremely difficult to lose weight, impacting her ability to remain motivated. She was still experiencing the same stressors but reported that she was being more assertive and was managing the stress better. She expressed that she was trying to 'be good' with her diet, but with the increase in her weight, she was finding it difficult to mobilise. Due to the lack of a place to walk, she was constrained to the body weight exercises she had been prescribed.

Her predominant barrier to sustained motivation was the difficulty she was experiencing in managing her weight. Ms D also commented that she missed the support she had obtained while participating in the CHIP and no longer had access to the monthly meetings due to them being ceased because of COVID-19 restrictions. She expressed that her diet and exercise could be better managed had she more support from her family.

This case study demonstrates several factors that contributed to recidivism. Even though this individual had progressed very well in the early stages of the study. The severe family relationship problems resulted in significant stress, followed by stress-induced cardiac symptoms. These symptoms further exacerbated her stress and resulted in a decline in feelings of self-efficacy. Ms D also lost a significant source of support due to the completion of the CHIP at 12 weeks. In addition, she felt that her medical team was not supporting her either. Her family sent her overseas to remove her from the primary source of her stress at the time, however, the different dietary patterns of her family there and being on holiday living in a different environment led to recidivism in her diet and exercise. Her exercise was further limited by the gall bladder problems, which took some time to accurately diagnose and treat. Therefore, by the time Ms D was well enough to recommence the lifestyle recommendations, she felt she had regressed so much that it was difficult to become motivated, especially without the support she initially had experienced.

Case Study 2: Ms B

This case history is presented as an example of a participant who thoroughly appreciated and enjoyed the CHIP and the food promoted. Her ability to exercise became increasingly hampered by knee pain. Regarding her diet, she was only prepared to make the changes in her lifestyle that she felt she could manage without significantly disrupting her quality of life and family situation. In addition, this case history demonstrates that a poor client-health professional relationship may significantly impact adherence to recommendations made by the health professional and possibly negatively impact other health choices.

Ms B enrolled in the research project at the beginning of 2018 after being referred by her GP. She was 77 years old and had been recently diagnosed with T2DM in 2017. She was an ex-smoker of less than 15 years, had asthma and underwent femoral bypass surgery in 2011. Other co-morbidities included gout, hypertension since 1998 and elevated cholesterol levels since 2006. She was being treated on Metformin hydrochloride (Diabex) 500mg, Lipitor 20mg and Ezetimibe **(**Ezetrol) 10mg, Furosemide (Lasix) 40mg, and Candesartan cilexetil (Adesan) 32mg in addition to Allopurinol and regular Salbutamol (Ventolin) inhalation. Ms B also had chronic knee pain, making it difficult to exercise and for which she was using Paracetamol (Panadol Osteo) and Glucosamine. Results for baseline assessment are provided in Table 22

Table 22

Assessment Results Ms B.

Parameter	Baseline	12 weeks	12 months
Weight	105.5kg	98.6kg	104.2kg
BMI	38.75	36.22	38.27
Hip circumference	141cm	136cm	141cm
Waist circumference	128cm	120cm	128cm
Blood pressure	145/82mmHg	128/70mmHg	120/64mmHg
Fasting blood sugar	5.2 mmol/L	5.00 mmol/L	5.00 mmol/L
HbA1C	6.6 %	6.3 %	6.2 %
Total Cholesterol	5.7 mmol/L	5.5 mmol/L	5.8 mmol/L
HDL	1.3 mmol/L	1.2 mmol/L	1.3 mmol/L
LDL	3.7 mmol/L	2.7 mmol/L	3.7 mmol/L
Triglycerides	1.5 mmol/L	3.4 mmol/L	1.7 mmol/L
Activity	1800kcal/day	2000kcal/day	2900kcal/day
RAND-36 Score			
Physical functioning	45	85	60
Role limitations physical	25	75	100
Role limitations emotional	100	67	100
Energy	75	65	70
Emotional well-being	48	60	68
Social functioning	75	88	87.5
Pain	32.5	77.5	70
General health	50	70	80

Note: The higher numbers on the RAND-36 indicate better functioning and less impairment of function.

Ms B was randomised into the intervention group, commencing the CHIP in February 2018 and made some dietary modifications. She reduced her consumption of red meat and dairy foods from once a day to two to three times a week or less. Some of the dairy was replaced with non-dairy milk alternatives. She also eliminated fried foods, salty snacks, sauces and condiments, desserts, chocolate, cordial and coffee. Refined grains, bread and cereal were replaced with wholegrains and servings of salad vegetables, and fresh fruit increased from a few times a week to at least one per day.

Due to chronic knee pain, Ms B was limited in the amount of exercise she could tolerate. Climbing stairs or walking gradients was challenging, but she started a slow-paced walk for an hour each morning. She enjoyed the early morning walks and noticed some benefit from the increased physical activity but was limited by her knee pain.

At the 12-week assessment, Ms B had lost weight, her blood pressure was reduced, and her activity and well-being scores had improved. Due to increasing knee pain Ms B ceased her morning walk at 12 months. She had further increased her incidental daily activity level beyond the 12-week level.

Ms B did not enjoy cooking, and her partner enjoyed his red meat and dairy. To avoid cooking separate meals for herself and her partner, she largely resumed eating similar foods to what she had eaten before the CHIP; however, she ate them less frequently. For example, she enjoyed steak and cheese, and would eat steak and cheese only once a week. She had learned to enjoy wholegrain and fresh salads and therefore continued to eat whole grain cereals and large fresh salads at the main meal each day. By the 12-month assessment, she had also resumed eating two eggs a day and consumed fried food, condiments, snack foods, chocolate, cordial and coffee again but in smaller quantities. At 12 months, her RAND-36 quality of life scores, except for pain, had remained stable or improved.

Ms B, when interviewed in mid-2021, had just turned 80 years old. She did not have a perfect understanding of reversal and believed that reversal meant having stable blood sugar readings that did not exhibit large fluctuations. Ms B expressed a great appreciation for what she had learned at CHIP and attributed her improved feelings of well-being to the changes she had made to her lifestyle. She openly admitted to the fact that she was not entirely adherent to CHIP recommendations but that, at the age of 80 years, she did not want to sacrifice some of the things she enjoyed (particularly mentioning her steak) when a very drastic lifestyle change was unlikely to provide her with a dramatically extended lifespan or quality of life. She also felt that she already did not enjoy cooking and therefore was not keen

to learn how to cook a whole new range of foods her partner was not particularly partial to. Cooking two different meals was too expensive on a pensioner income. She, therefore, elected to continue eating what she enjoyed but to eat it less frequently. By the time Ms B was interviewed, her knee had deteriorated to the point that she was recommended a knee replacement. She was not enthusiastic about the proposition and tried to extend that prospect as far as possible. She reported that the deterioration in her knee has meant that her ability to be active has been significantly impacted.

Ms B demonstrated a self-responsible approach to decision-making. When interviewed, she expressed very definite opinions about her doctor being a fantastic doctor for men. However, she felt that he was dismissive of women, and she could not communicate with him regarding her diabetes management. She approached her doctor's recommendations with a risk-benefit analysis approach, explaining that when referred, she elected not to see a dietician because, at 80 years old, she was not going to make significant changes to her diet and that the referral was just a box-ticking exercise on the part of the doctor. If she had a better relationship with her doctor, one wonders whether she would have been open to receiving more education and possibly be willing to risk further lifestyle changes.

Several factors contributed to the overall changes made. Very early in the study, a moderate response to lifestyle recommendations was noted, because Ms B made an early decision about her willingness to 'give up' certain foods. Her dislike of cooking ensured that she was less willing to make a significant effort in the kitchen, and her perception of her partner's unwillingness to adjust his diet made it more challenging to make significant changes. She was, however, willing to make changes relating to the frequency with which she consumed less healthy foods. She enjoyed the fresh salads and some CHIP recipes, which she was willing to incorporate into her regular menu.

Pain is a realistic and significant deterrent to exercise; however, she was never provided with options from her healthcare team about other forms of exercise that could provide health benefits as well as maintain mobility and manage pain in the knee. This lack of access to information may have also been due to Ms B's poor relationship with her GP. One wonders whether a better relationship with her health professionals may have led to access to better support concerning exercise. However, Ms B did have a realistic attitude to life in that at the age of over 80; lifestyle change would not likely provide her with a significantly longer life. The question remains whether her quality of life may have been further improved.

Case Study 3: Ms E

This case history is an example of a participant who demonstrated a very high level of adherence and self-responsibility. Even though she did not reverse her diabetes, she achieved the best improvement in blood glucose levels in the intervention group. In addition, she demonstrated healthy ways of managing dietary differences in a household. Ms E cited that the main reason for her continued adherence was enjoying both the exercise and the new diet. She felt that they had contributed to her improved well-being.

Ms E enrolled in the research project at the beginning of 2018 after being referred by her GP. She was 70 years old. When interviewed, she had some knowledge of diabetes reversal. She understood that blood sugar levels needed to be sustained within the normal range; however, her doctor told her she had reversed her diabetes even though she continued to take a low-dose oral hypoglycaemic agent. Her impression was that reversal was possible, and she had achieved it despite being on medication.

Ms E was a non-smoker and was treated for hypertension with 4mg of Candesartan and 10mg of Rosuvastatin for elevated cholesterol. She was also using Thyroxine sodium (Eutroxsig) to manage an underactive thyroid and was taking a daily dose of Clopidogrel. She had been diagnosed with glucose intolerance in 1998 and managed to control her blood sugar levels entirely through regular exercise. In 2006 she had dropped off some of the exercises, and her blood sugar levels were raised to the point where she was diagnosed with T2DM. Her GP wanted to start hypoglycaemic medication; however, she opted to try resuming the exercise to reverse the diabetes. She was successful until 2010, when she was referred to a dietician to consult her regarding her diet. She was also commenced on Metformin and Saxagliptin (Kombiglyze XR) 5mg/1000mg. Ms E was randomised into the intervention group and commenced CHIP in February 2018. Results for her baseline assessment are provided in Table 23.

Table 23

Assessment Results Ms E.

Parameter	Baseline	12 weeks	12 months
Weight	81.55kg	77.30kg	73.50kg
BMI	27.57	26.13	24.84
Hip circumference	116.5cm	112cm	110cm
Waist circumference	103cm	98.5cm	100cm
Blood pressure	118/72mmHg	121/78mmHg	138/78mmHg
Fasting blood sugar	6.8 mmol/L	6.1 mmol/L	4.9 mmol/L
HbA1C	7.9 %	6.2 %	5.6 %
Total Cholesterol	2.3 mmol/L	2.7 mmol/L	4.00 mmol/L
HDL	0.9 mmol/L	0.6 mmol/L	0.8 mmol/L
LDL	0.9 mmol/L	1.10mmol/L	2.70 mmol/L
Triglycerides	1.1 mmol/L	1.3 mmol/L	1.2 mmol/L
Activity	3900kcal/day	4100kcal/day	4400kcal/day
RAND-36 Score			
Physical functioning	95	95	100
Role limitations physical	100	100	100
Role limitations emotional	100	100	100
Energy	65	75	80
Emotional well-being	84	84	88
Social functioning	100	100	100
Pain	80	90	90
General health	85	90	85

Note: The higher numbers on the RAND-36 indicate better functioning and less impaired function.

Ms E was active at the time of commencing CHIP. Despite being retired, she did volunteer work one day a week and walked every morning for about an hour. Her total energy expenditure at baseline was about 3900kcal per day. By the end of CHIP at 12 weeks, she was doing an additional 200kcal per day, adding regular swimming to her activities. Over the next nine months, being highly motivated by her pedometer readings, she increased her activity to around 4400kcal per day.

Before commencing the CHIP, Ms E reported that she had not changed much about her diet when she was diagnosed with diabetes other than being careful about not consuming sugary foods. She had generally eaten healthily and said the dieticians' recommendations were not far from what she was already doing regarding her diet. At the commencement of the CHIP, she eliminated all animal products from her diet, replacing protein with tofu and increased the amounts of legumes and regulated amounts of nuts. At 12 months, she had also included small amounts of dairy alternative milk. She also eliminated bread and consumed wholegrain cereals, brown rice, and other whole grains. She increased the amount of cooked and salad vegetables but kept the fruit servings to 2-3 per day, replaced caffeinated with non-caffeinated beverages, and increased her water consumption. She consistently maintained this diet throughout the study period and beyond. Even though her husband was eating differently, she said she had, with some planning, managed not to cook two completely separate meals. She managed by having her wholegrain cereal in the morning instead of processed cereal, eating largely salad and fruit at lunch instead of sandwiches with her husband. She made a meal according to her dietary requirements for dinner and added some animal protein to her husband's meal.

When interviewed in mid-2021, she acknowledged that she had gained a few kilograms. That was mainly because she had not exercised as frequently. The pool was closed due to COVID-19, and she also had a family member in palliative care whom she was not allowed to visit, which caused her substantial stress, and she had slacked off on the exercise. By the 12-month assessment, her doctor had stopped her antihypertensive and lipid-lowering medication and cut the dosage of Metformin and Saxagliptin (Kombiglyze XR) by half. Her RAND-36 quality of life score was good from the start; however, they continued to improve, and even though she had increased her activity level, she perceived her energy level had improved over the study period.

Ms E became very involved in supporting the CHIP participants in subsequent programmes. She enjoyed the CHIP and found it highly relevant and helpful in making the

lifestyle changes that resulted in discontinued hypertensive and lipid-lowering medication and reduced oral hypoglycaemic agents.

The factors that mainly contributed to Ms E's ability to maintain adherence to lifestyle recommendations was the ability to enjoy the new lifestyle. Even though she admitted to 'cheating' at times, she made up for those lapses in the diet by exercising more on those days, which ensured glycaemic control. Ms E had a good relationship with her doctor, and she reported that he gave her much positive reinforcement. She was also asked on various occasions to speak to other CHIP participants about her journey and felt very pleased with her progress. She felt that this positive reinforcement had helped maintain her adherence to recommendations made by the CHIP.

Case Study 4: Mr B

This case history is being presented as an example of a participant in the control group who demonstrated a very high level of adherence and self-responsibility in the managing his diabetes.

Mr B was diagnosed late in the diseases process and was commenced on insulin at diagnosis making his prognosis for reversal less likely. Even though the lifestyle choices he made did not lead to the reversal of his diabetes, he did manage to maintain glycaemic control and reduced insulin slightly. In addition, he demonstrated the ability to make healthy food choices, which he recognised he was more likely to maintain in the long term while eating alone most days. Like Ms E, Mr B cited the main reason for his continued adherence to recommendations made by the rehabilitation centre he attended was the enjoyment received from the exercise and the planning around his diet. Mr B demonstrated that even with advanced diabetes, maintaining a healthy lifestyle appeared to improve his quality of life and could have prevented the progression of his diabetes and prevented possible diabetes complications.

Mr B enrolled on this research in mid-2018 after being referred by his GP when he was 73 years old. He was an ex-smoker of more than 15 years. He was being treated for hypertension with 32mg of Candesartan and 180mg of Diltiazem (Cardizem CD) and Moxonidine 6 micrograms and with 80mg of Atorvastatin and 10mg of Ezetimibe for elevated cholesterol. He was also using Prazosin 1mg daily. He had been diagnosed as a young child with a genetically inherited type of girdle muscle dystrophy which had affected his core muscle development, but it was not progressive. Mr B had been diagnosed with

T2DM in 2001, and despite trying to reverse it using diet and exercise, his blood sugars remained elevated. He was finally prescribed Biphasic Insulin Aspart (Novomix), of which he was initially taking 30 units in the morning and another 40 units at night in addition to Metformin hydrochloride (Diabex) 100mg and Empagliflozin (Jardiance) 25mg.

When interviewed, he explained that once he became aware that his symptoms were caused by diabetes, he believed he had been diabetic for a long time before he was diagnosed. He explained that he experienced some of the symptoms for several years before his diagnosis. He experienced some peripheral neuropathy in his feet and required cardiac stenting just before being enrolled in this research. At that time, he was referred for cardiac rehabilitation and received education about managing his diabetes and cardiovascular risk factors during the rehabilitation programme. The dietician who saw him recommended a dietary exchange eating plan which he preferred to a strict menu-based diet. He does find the exchange diet more difficult to follow during the winter months as he then must spend more time cooking vegetables, whereas in summer, he is happy to eat salads. He also finds cooking for one, because he lives alone, more tiresome and challenging, but he does do it. He, like Ms B, felt that at his advanced age, he wanted to enjoy his meals and recognised that he was less likely to stick to a strict menu.

Throughout the 12-month study period, Mr B maintained a relatively consistent diet. The frequency with which he consumed processed fats, nuts, bread, and cheese decreased but then he consumed milk and starchy vegetables more frequently. His overall intake of servings of fruit and vegetables increased. By 12 months he introduced alcohol into his diet a few times a week.

During the rehabilitation programme, he was regularly exercising at the rehabilitation centre. Once that programme ceased, because he lived on the lakeshore and he enjoyed kayaking, he started kayaking every morning for an hour. He also attended a local gym three times a week where he did some resistance training. If the weather was too bad for the kayak, he walked. He also enjoyed gardening and spent time each day in his garden. He increased his daily energy expenditure from 2000kcal at baseline to 2600 at 12 weeks and 2800 at 12 months. By the 12-week assessment, Mr B’s insulin was reduced slightly to 28 units in the morning and 38 units at night, and the Prazosin was ceased. Results for all three assessment periods are provided in Table 24

Table 24

Assessment Results Mr B.

Parameter	Baseline	12 weeks	12 months
Weight	92.45kg	92.0kg	92.20kg
BMI	31.99%	31.83%	31.9%
Hip circumference	116cm	122cm	107cm
Waist circumference	124.5cm	127cm	122cm
Blood pressure	135/80mmHg	140/78mmHg	124/77mmHg
Fasting blood sugar	7.0 mmol/L	7.9 mmol/L	7.4 mmol/L
HbA1C	7.0 %	7.2 %	7.1 %
Total Cholesterol	3.5 mmol/L	3.3 mmol/L	3.4 mmol/L
HDL	1.4 mmol/L	1.4 mmol/L	1.4 mmol/L
LDL	1.6 mmol/L	1.2 mmol/L	1.4 mmol/L
Triglycerides	1.1 mmol/L	1.5 mmol/L	1.2 mmol/L
Activity	2000kcal/day	2600kcal/day	2800kcal/day
RAND-36 Score			
Physical functioning	55	75	75
Role limitations physical	50	100	100
Role limitations emotional	100	100	100
Energy	70	80	80
Emotional well-being	80	80	80
Social functioning	100	100	100
Pain	55	45	45
General health	50	70	70

Note: The higher numbers on the RAND-36 indicate better functioning and less impaired function.

Mr B understood the concept of diabetes reversal. He was very aware that he was unlikely to achieve reversal because he was diagnosed in the late stages of the disease and was dependent on insulin for glycaemic control. He also acknowledged that at his advanced age, he was more focused on maintaining his health and quality of life and that there would

be little benefit for him to expend much effort in making unwanted changes. Mr B did not participate in the CHIP as he was part of the Study 1 control group.

The factors that played an important role in Mr B's adherence to lifestyle recommendations were an initial intensive education and rehabilitation programme, which provided him with an excellent foundation and the ability to apply what he had learned to make healthy lifestyle choices. Mr B was not following the specific diet prescribed to him but had used the principles taught him to adjust his diet to make it easier for him to adhere to long term. He also reported that he enjoyed the food he made for himself. Even though at times food preparation required effort, he still made that effort. He also enjoyed his exercise and again made some adjustments to perform activities and partake in exercise modalities that he enjoyed which made it easy for him to participate in regularly. He had a supportive family, even though they lived far away. They did not see him very regularly especially during the COVID-19 restrictions, but they purchased a watch for him which recorded his daily steps. He found this watch very useful to keep him accountable in maintaining a good level of incidental activity.

Conclusion to the Chapter

Four cases were presented that provided examples of persons in the intervention and control groups where adherence was closely associated with enjoyment of or rewards obtained from participating in healthy lifestyle activities and where perceived discomfort, or reduced quality of life and actual physical or emotional difficulties inhibited the ability to participate in healthy lifestyle activities. In each of the four cases, the persons involved were, to some degree, persisting as they were willing and able to maintain lifestyle activities that they believed would provide them with an optimal quality of life in the situation they found themselves. These results provide some relevant material for discussion and recommendations for future research, which is presented in the following chapter.

CHAPTER 9: STUDY 2 DISCUSSION

The management of diabetes is complex and requires the client's engagement with the disease and its multimodal management components. To effect optimal outcomes and quality of life for the client, it also requires the engagement between the client and medical practitioners and the client with social and community support structures. An overview of the principal discussion points generated by the qualitative analysis of Study 2 is presented in this chapter. In summary, these discussion points include the lack of knowledge and understanding of the existence of diabetes reversal, that collaborative goal setting associated with diabetes management was primarily perceived as lacking, the study participants' experience of the CHIP and their experience concerning adherence to the lifestyle recommendations made by the CHIP.

Interpretation of the concept of diabetes reversal, client involvement in diabetes management and significant life events were issues that emerged from anecdotal conversations held with participants in Study 1. A qualitative study to obtain a better understanding of the participants' previous knowledge and their experience of diabetes reversal to gain practical relevance to what was learned was initiated. The discussion of the results presented in Chapter 8 follows.

Participants' Knowledge of Diabetes Reversal

At least 25 per cent of the study cohort did not understand that reversal of type 2 diabetes is possible in some circumstances, and several more participants had an inaccurate perception of the definition. Inaccuracies in the perception of the definition and details of diabetes reversal are plausible in that it is well established that errors in communication and the understanding of communicated material readily occur (Belasen & Belasen, 2018). It was somewhat concerning that medical practitioners referred some clients to a study investigating diabetes reversal, while those clients did not know that reversal of diabetes was even possible. Several of these clients had been diagnosed with T2DM for a few years and remained unaware of the potential to reverse their condition. These results suggest that the participants needed to be better informed about the potential for T2DM reversal or that the communication needed to be more significant to be remembered. No studies that specifically investigated the memory recall rates in clients educated about the reversal of T2DM could be found. Studies do indicate that communication gaps readily occur between doctors and their clients (Bensing et al., 2013; Mazzi et al., 2013), and care recipients focus on relationship

building during consultations, whereas caregivers tend to focus on the transmission of information (Bensing et al., 2013). This communication gap and focus disparity may result in messages not being heard or remembered (Korzh & Tsodikova, 2019). Practice nurses involved in diabetes follow-up care and education similarly ask appropriate questions. They are proficient at providing information but appear to lack the ability to provide the appropriate supportive communication that would optimally engage the client (Mulder et al., 2015). Supportive communication techniques are essential for promoting self-management and overcoming barriers to adherence to recommended behaviours or therapy (Mulder et al., 2015).

The Australian National Standards for Diabetes Education Programs (2001) has established five primary outcomes of diabetes education. The first outcome is to enable persons with diabetes to understand how diabetes affects their body and the implications of healthy living with diabetes, and the second is to enable persons with diabetes to make informed decisions and initiate steps towards healthy living with diabetes. These statements suggest that clients are informed that lifestyle adjustments eliminate some of the risk factors for diabetes, but the document stops short of discussing education for the reversal of T2DM. The best practice guidelines, including The Royal Australian College of General Practitioners (2020) management of type 2 diabetes handbook and the Australian National Standards for Diabetes Education Programs (Australian Diabetes Educators Association, 2001) do not explain or promote diabetes reversal. The focus for the generalist practitioner and diabetes educator is, therefore, likely to be on the stated guidelines for diabetes management and control, resulting in diabetes reversal being overlooked.

Colagiuri (2009), in the National Evidence-Based Guideline for Patient Education in Type 2 Diabetes, stated that both the knowledge and understanding of what is required to change, as well as the why (which incorporates the health and other life benefits that can be achieved) change is necessary, is crucial in effecting improvement in health status. The Health Promotion Model requires that health professionals form part of the interpersonal environment and influence individuals through interpersonal interactions (Pender, 2010). Bandura (2001) explained self-efficacy as the ‘belief in one’s capabilities to execute an action in prospective situations. He, therefore, proposes that individuals will only engage with lifestyle changes which they believe are successful. Therefore, if clients do not know or understand that the lifestyle measures being advocated have the potential to reverse their condition, they are not likely to engage with those recommendations. The lack of adherence

to lifestyle recommendations by some in Study 1 may be related to a disbelief in the recommendations being effective in reversing T2DM because the notion was not promoted or referred to frequently by usual care providers.

If clients are only encouraged to symptomatically manage their T2DM using a medication, their blood sugar and HbA1C readings may be within the normal ranges, but the pathophysiology is not altered. The pathophysiology will continue to impact the risk for degenerative sequela negatively. When the optimal goal for health education is to provide the means through which clients can access the best health outcomes, then it is imperative that health professionals provide and regularly reinforce the comprehensive range of options (including reversal) relating to risk reduction and diabetes management. Appropriate and relevant health education provides the client with several lifestyle mechanisms and therapeutic options to address the symptoms and various risk factors for complications. There is considerable evidence for diabetes reversal through several mechanisms (Athinarayanan et al., 2019; Fothergill et al., 2016; Purnell et al., 2016; Steven et al., 2015). A more concerted effort must be made to educate both the professional and the person with T2DM that diabetes reversal is a realistic option.

A perception emerged among several participants that the medical team, mainly due to time constraints, did not listen or communicate well enough about issues of diabetes management. Associated with this was a perceived lack of collaboration in goal setting or, for some participants, the perceived lack of management goals or a management plan. It is a requirement that all clients with T2DM in Australia be on a diabetes management plan (Australian Government Department of Health and Aged Care, 2021). During participant interviews, it was clear to the interviewee that all participants interviewed were on such a plan. Therefore, some discussion with the participants about the diabetes management plan likely occurred during consultations with the GP or allied health practices to which participants were referred. A study by Janes et al. (2013) cited that one of the significant barriers to glycaemic control occurs when medical professionals do not consult with clients over their disease management plans and dictate to clients ‘what they need to do’.

The traditional Biomedical Model attributes the health professional with the responsibility for health outcomes (Willis & Elmer, 2007). Medical knowledge and information obtained from investigations are perceived as owned by the health professional or multidisciplinary team, who are responsible for informing the client of the optimal or recommended path of action (Ramos-Remus et al., 2000). The Biomedical Model (Willis &

Elmer, 2007) is starkly contrasted with the shared decision-making approach. The shared decision-making approach acknowledges that the health professional and the client have shared knowledge. The client has a more active role in discussing their views on a given subject and shared decision-making about what actions have the best potential for effectiveness. The client, therefore, shares responsibility for health outcomes (Lambrinou et al., 2019).

Adherence to healthy behaviours, preventive behaviours and self-management behaviours improve when the client can make decisions related to their care and disease management (Sacks et al., 2017). Therefore, it is essential to incorporate the client's views, values, preferences and context into the management plan to optimise adherence. Consequently, diabetes management processes must accommodate the time required to engage clients in dialogue concerning their management needs. Almost all participants in Study 2 cited a desire for extended open dialogue with their healthcare providers that would create the opportunity for more discussion about care options in contrast to their experience of being handed a regime of management.

The quality of the therapeutic relationship is fundamental to overcoming barriers created by interpretative structures (cultural, sociological, and psychological structures through which individuals interpret education), opposed points of view and different perceived needs. As clients become more confident in partnering with their health professionals and develop a more self-responsible approach to their care, they will inevitably challenge or question medical judgement (Snow et al., 2013). However, Tones (1991) believes questioning to be an 'explicit ingredient' of client empowerment. This potential for conflict based on the discrepancy between professional and client levels of expertise highlights the need for corresponding professional education. The collaborative relationship in diabetes management has been shown to improve client satisfaction, adherence and clinical outcomes (Heisler et al., 2002; Miller et al., 2012; Montori et al., 2006; Naik et al., 2011; Pearson, 2012). Clients who seek a more significant locus of control and empowerment in diabetes management cannot achieve long-term success without the support and cooperation of the healthcare team in facilitating this aspect of their personal development (Cooper et al., 2003b). A study by Webster et al. (2019) indicates that members of the healthcare team are not necessarily supportive of clients initiating self-management. It is, therefore, likely that healthcare team members will require education and training to accept the growing desire of clients to be partners in their care and to manage better the co-operative milieu required for

consultations in the future. Most participants in study 2 who indicated a desire for more interaction and consultation with their medical team also acknowledged that any discussion or consultative process was constrained by time, indicating that the practice model was not designed to accommodate the growing decision-making needs of clients with T2DM.

Lifestyle management is a fundamental component of diabetes management (American Diabetes Association, 2017; Colagiuri et al., 2009; The Royal Australian College of General Practitioners, 2020) however, it requires some knowledge and skill around self-responsibility. According to Orem et al. (2001), self-care is a human regulatory function where individuals must act for themselves. In the context of lifestyle modification, self-responsibility requires the client to be actively engaged in activities that improve behaviours and well-being. Self-responsibility includes engaging in lifestyle modification activities like exercise, planning healthy meals and managing sleep and stress. In order to facilitate self-responsibility, the relationship between medical professionals and the client needs to be collaborative and supportive, with shared decision-making, goal identification and goal setting, and opportunities for feedback and evaluation (Lambrinou et al., 2019). Unfortunately, not all health professionals are willing or feel they have the capacity or time to engage in collaborative goal setting with clients (Peel et al., 2007). The lack of available time for consultation was an issue raised by most participants in Study 2. An additional number of participants moved to an alternative practice, neglected to make appointments for the referrals given, or did not attend to recommendations made by professionals because of their perceived lack of opportunity to engage or be listened to. Some participants openly accused some healthcare professionals of not listening or being difficult to talk to. Some medical practices have discovered that using shared medical appointments altered the dynamics of the medical consultation in such a way that encouraged client engagement and increased client satisfaction.

One of the most challenging hurdles to overcome in modern medical practice is the paucity of time available to spend with each client. Indeed, most of the study participants recognised that medical practices are hectic, and doctors need more time to discuss problems.

A study examining time allocated for a range of client appointments in primary care practices across the USA, UK and Germany found significant disparities between the actual time allocated and the time medical doctors perceived was required to conduct effectual client visits (Konrad et al., 2010). Longer appointment times have also been associated with improved attention to psychosocial problems, lower prescribing rates, better quality

prescribing, lower referral rates, lower return visits and improved client satisfaction (Wilson & Childs, 2002). Extended visits were also perceived to reduce the risk of malpractice litigation potential (Levinson et al., 1997). The systematic review authors argued that the consultation length is less relevant to client satisfaction than the exploration of the client's psychosocial factors. By exploring psychosocial factors, the health professional acts as a mechanism for client empowerment, resulting in improved client satisfaction (Lemon & Smith, 2014). A study conducted by Zulman et al. (2020) addresses similar ideas. The study was conducted to attempt to identify effective interpersonal interventions or encounters.

Observations of care encounter across three diverse clinics, in addition to qualitative interviews with physicians, clients, and nonmedical professionals whose occupations involve intense interpersonal interactions, were conducted. Promising practices were reviewed in a 3-round modified Delphi process. After the third round, panellists selected their 'top 5' practices. These included:

- Prepare with intention (take a moment to prepare and focus before greeting a client)
- Listen wholly and intently (sit down, lean forward, avoid interruptions)
- Agree on what matters most (find out what the client cares about and incorporate these priorities into the visit agenda)
- Connect with the client's story (consider life circumstances influencing the client's health; acknowledge positive efforts; celebrate successes)
- Explore emotional cues (notice, name, and validate the client's emotions)

Shared medical appointments are a relatively new innovative way of simultaneously providing health care to several clients with similar chronic diseases. The client benefits from medical input and education across a wide range of client problems because they are present for the educative component addressing questions asked by multiple clients. The medical practice benefits because the practitioners do not need to repeat the same information multiple times with different clients. The busy practice is therefore managed more efficiently (Bronson & Maxwell, 2004). Shared medical appointments are not required to be doctor-led to be successful. However, a medical practitioner is required for diagnosis and medication prescription. The benefit to client outcomes has been sustained for up to 3 years after clients return to conventional individual medical appointments (Leung et al., 2018). Therefore, a shared medical appointment approach may be a suitable alternative for chronic disease management in busy practices.

Independent of shared medical appointments, goal setting has been recommended to improve outcomes over various disciplines. While a paucity of studies exists that examine goal setting in diabetes management independently of other therapeutic behaviours, enough is known about goal setting from other disciplines to recommend the practice in health settings (Anderson et al., 2010; DeWalt et al., 2009; Fredrix et al., 2018; Naik et al., 2011).

In a study by Naik (2011), diabetes clients were randomly assigned to one of two groups. The first group received two shared medical appointments in addition to usual care. The second group received four shared medical appointments in which collaborative goal setting and development of action plans were emphasised. The importance of effective client-doctor communication about goal setting and progress was discussed during the group sessions. HbA1c readings were significantly improved in the treatment group following the intervention, which was sustained for one year. Self-efficacy also improved throughout the study.

The following steps to goal setting are recommended by Miller & Bauman (2014) and are consistent with the Transtheoretical model of change (Prochaska et al., 2008):

- Assess the client's current behaviour compared to what is recommended and the client's commitment to problem-solving.
- Begin with a knowledge goal rather than a behavioural goal.
- Address any ambivalence and discuss and resolve any conflicting or competing goals. Select an area of focus where commitment is highest.
- Establish a task ladder that will address achieving the goal. Tasks should be difficult enough to create a challenge but should be achievable.
- Discuss and assess client efficacy and confidence in achieving tasks.
- Develop a detailed action plan with regular opportunities for feedback and reinforcement.

The CHIP encourages short and long-term goal setting as an essential programme component. Participants in Study 2 who had completed the CHIP had all completed a goal setting exercise to some degree. Many had not used the principles set out by Miller and Bauman (Miller & Bauman, 2014). A critique of the CHIP is that more focus could be placed on a more guided approach to goal setting. Most Study 2 participants reported that they had yet to be consulted about or encouraged to set goals by their medical team.

The CHIP was designed as a lifestyle education programme that balances participant assessment, goal setting, information content, experiential learning and social support to provide an approach to managing chronic diseases of lifestyle. It has endeavoured to address the causes and provide lifestyle options for reversing the risk factors related to lifestyle diseases. Based on the client responses to interviews, focusing more on the self-responsibility and goal-setting aspects of the programme may improve the programme's quality.

Participants' Experience of CHIP

Participants in Study 2 who had completed the CHIP in Study 1 were very positive about their experience. They all expressed they had gained extensive knowledge and the format, presentations and learning activities helped make lifestyle adjustments. Even though the CHIP was not specifically designed to manage T2DM, all the participants found the information personally relevant. This is further borne out by the fact that the attrition rate was zero, with all seventeen participants attending more than 95% of the sessions. In addition to providing information for risk reversal, the CHIP also provided a mechanism for individual goal setting and recording of progress throughout the programme. An RCT designed to evaluate the client's perspective on an education programme for the management of T2DM was completed using the "Look after yourself" (LAY) programme as the intervention (Cooper et al., 2003a). Results showed that participants, like those who experienced the CHIP, greatly appreciated the knowledge gained. It was interesting to note that clients in the LAY programme and CHIP received more information from the education programmes than from different healthcare team members. Like the CHIP participants, they also applauded the presenters for being knowledgeable, approachable and supportive (Cooper et al., 2003a). Participants in the LAY and the CHIP expressed the benefit of the group support afforded by group education. Possibly the experience of having a common diagnosis bonded them in a way that allowed for open discussion and a feeling of cohesiveness. Collaborative learning activities were perceived to maintain interest and involve participants in learning. This involvement reinforces the value of group education based on principles of adult experiential learning. Like those completing the CHIP, the LAY programme participants were disappointed that the knowledge that they had gained was not afforded them a lot earlier in their journey. This revelation highlights that clients perceive they require more knowledge and experiential learning than they receive through traditional means (Cooper et al., 2003a). The results of Study 2 and those reported in Cooper et al. indicate that participants in both

studies obtained more information from the CHIP and LAY programme than they had received from their health care team. Both sets of participants indicated they would like to receive that information a lot earlier after their diagnosis.

All the CHIP participants reported ways in which lifestyle adjustments made had benefitted their health, mainly through weight loss and improved well-being. Other benefits cited were improvements in diet, general health literacy, social engagement, and improved levels of activity. Participants in the LAY programme were not asked to report on the clinical effects of the course; however, they reported improved health literacy and were optimistic about the support they received and the social engagement that occurred during the group-learning activities (Cooper et al., 2003a). While no studies have evaluated the CHIP participants' experience of the programme, the CHIP was the first programme to be accredited as a Certified Programme in Lifestyle Medicine by the American College of Lifestyle Medicine (Lifestyle Medicine Institute, n.d.).

Most study participants from the Study 1 intervention and control groups expressed difficulty with adherence. Measuring adherence requires comparing a person's behaviour to an established standard. The literature, however, does not provide this clear standard or measure (Davies et al., 2008; Radhakrishnan, 2012) but it does indicate that long-term improvements in diabetic markers, quality of life or recommended behaviours for participants in intervention groups that form part of clinical trials for diabetes management are generally poor (Davies et al., 2008; Radhakrishnan, 2012). It is also generally expected that a person with T2DM will follow a set of prescribed or recommended behaviours to manage glycaemic control, regarded as self-care. One would assume that clients willing to participate in lifestyle management or client education programmes do so because they desire either an alternative means of managing their health condition or are interested in obtaining more information and more thorough knowledge. However, a resistance to the uptake of lifestyle recommendations may result from a conflict with a cultural climate that promotes dependency or may indicate a client's fear of or unwillingness to separate from passive roles. Several participants in Study 2 acknowledged that they had neglected to participate in various education programmes because they believed that the professional would not engage them in decision making or would prescribe lifestyle adjustments that would not suit their needs or taste. Other participants believed that lifestyle education would make little difference to their health outcomes because they were predisposed to T2DM, or they had always been overweight or had never been able to exercise which may have been indicative of passivity or a fatalistic

outlook. Those participating in the CHIP were confronted by a session entitled “Your genes are not your destiny” which challenged this fatalistic view and encouraged participants to embrace change to overcome current barriers.

Lawton et al. (2008), after having studied clients participating in usual care, and listening to multiple accounts of causality being expressed, concluded that a client’s treatment experience may mediate their perception of the disease. He provides an example where one client may attribute their disease to a poor diet or obesity, whereas another may perceive their condition has a hereditary cause. This thinking may be reinforced by another family member being diagnosed with the same condition later. These perceptions also serve to rationalise behaviours or lack of adherence in the long term. The goal of client education, is to reframe perceptions in a way which will allow the client to assume control, develop self-responsibility and empowerment to make choices that effect behaviour change.

Participants’ Experience of Adherence

Both CHIP participants and those from the Study 1 control group identified several barriers to what they would define as optimal adherence. It is expected that with any educational intervention, there will be factors that will, for one or another reason, create limitations for some participants. The goal, however, of a self-managed approach to diabetes education is that through open discussion, support and appropriate, collaborative goal setting, these limitations are minimised or overcome through practical problem-solving skills.

Pain induced by a co-morbid condition was the most prevalent complication related to exercise adherence. The typical response to pain is to cease using the painful joint. Participants in Study 2 who experienced pain while exercising, for the most part, limited or ceased the exercise which was inducing pain but did not seek an alternative mode of exercise which was not weight-bearing. Studies have irrefutably shown that a lack of exercise and reduced daily activity are deleterious and increase the risk of several chronic lifestyle diseases. (Bai & Wang, 2020; Booth et al., 2012) Alternative means of exercise training, which include strength training, non-weight bearing aerobic training, and flexibility exercises, improve outcomes related to relief of joint symptoms, improved mobility, quality of life, muscle strength, body composition and psychological well-being (Wellsandt & Golightly, 2018). Referring clients who experience pain with exercise to an exercise physiologist or physiotherapist for an alternative exercise plan will, therefore, not only maintain a reduced risk of chronic disease but may result in the alleviation of some of the

symptoms and be effective in maintaining activity levels for improved glycaemic control and long-term well-being. Some participants in Study 2 acknowledged improved control of joint pain when exercising moderately regularly. Several more CHIP participants might be supported better if encouraged to consult with an exercise physiologist about obtaining moderated activity and exercise recommendations that would most benefit them despite the restrictions brought on by co-morbidities.

Restrictions on gathering and closures of facilities during COVID-19 and a lack of time were other reasons participants found exercise challenging to maintain. Lack of access to facilities is inconvenient when one is accustomed to using those facilities. However, for some, finding alternative options for exercise may be challenging, especially for those participants who relied on public swimming pools for non-weight-bearing exercise options and for the few participants who elected to use gyms to access stationary bicycles, elliptical trainers, and strength-building equipment. For most participants in Study 2, the relatively short period in which these centres were unavailable was a transitory problem. However, for some, the lack of routine resulted in long-term exercise abandonment. This exercise abandonment during COVID-19 was confirmed by a study on clients with diabetes in Mexico City during the COVID-19 lockdown. The study showed that clients continued to perform other self-management activities like taking medication, monitoring blood sugar and planning meals; however, barriers to exercise increased, as did sit-time while activity was reduced (García Ulloa et al., 2022).

Similarly, activity levels in the United States of America dropped 18.2% in the general population during the lockdown. Conversely, previously low-active adults under 55 in Belgium increased their exercise frequency as being active was an opportunity to spend time outdoors. In the same study, sit time increased for all population groups, and the previously more active adult became less active (Constandt et al., 2020; Yang & Koenigstorfer, 2020). In circumstances where persons are at high risk of abandoning exercise habits, having access to a regular follow-up session with a health professional or community support group where goals can be reviewed and followed up can be helpful in re-establishing routine and maintaining adherence. The CHIP has a monthly support group meeting called CLUB CHIP that serves this function well. Unfortunately, during COVID-19 lockdowns, the CLUB CHIP was also not permitted to be active. An online or telephone follow-up alternative might have helped maintain momentum for some.

The CHIP participants who enjoyed exercise and achieved invigorating results were more active and adherent, even during the lockdown. A study conducted by Malpass (2009) showed similar results in those clients who felt good about or were rewarded by exercise. Participants in Study 2 who maintained their activity level because it continued to reward them, and they felt energetic or rejuvenated from the exercise were more adherent.

Modifying an exercise regime to accommodate for a lapse in dietary adherence, as illustrated in the case of Ms E (Case 3 Chapter 8), demonstrates an ability to maximise self-responsibility in a way that allows for a quality of life and blood sugar control. Similarly, the ACTID trial showed that clients with T2DM who developed a high self-responsibility level could make these lifestyle adjustments confidently (Cooper et al., 2003b). Clients who received an education that addressed diet and exercise were more successful in manipulating both to maintain optimal quality of life and glycaemic control (Malpass et al., 2009).

In Study 2, the most common reasons for a temporary or more consistent lack of adherence to dietary recommendations were guilt or discomfort about eating differently from other members of their household or requiring 'special foods' when eating out. Janes et al. (2013) studied clients with T2DM to discover their perceived barriers to glycaemic control. Guilt and shame related to developing diabetes and not managing it were commonly verbalised by the participants in this study. Similarly, some CHIP participants referred to 'good' and 'bad' foods, 'being naughty', and being embarrassed to acknowledge that they have diabetes. Family members and significant others also exacerbated guilt by policing participants' eating habits. A common misconception is that only people with diabetes need to eat healthfully, hence the necessity for different diets among family members (Janes et al., 2013).

A few CHIP participants also verbalised that their adherence was compromised by having to cook more than one meal because of different dietary requirements. The CHIP encourages family members to complete the programme together to afford all family members the benefit of education and the opportunity to make collective decisions about health. Where family members are supportive and engaged in the process of lifestyle management, adherence is improved, and some of the guilt associated with having different requirements is alleviated (Baig et al., 2015; Denham et al., 2011; Pamungkas et al., 2017). An example of how family engagement in disease management can support lifestyle modification was that of Ms E and her husband. Ms E's husband was not participating in the CHIP and was still consuming some foods that Ms E was avoiding or eliminating from her

diet. A workable compromise was reached by the couple, which allowed Ms E to manage the meal planning in a guilt-free environment and was able to adhere to the food choices she made.

Conversely, Ms B (Case 2 Chapter 8) wanted to avoid inconveniencing her husband by altering the frequency he consumed meat, which she chose to eliminate. She was also not inclined to cook something different for herself. She admitted that she 'loved her steak' and was not prepared to give that up indefinitely, which eventually led to significant recidivism in Ms B's diet. The participants in Study 2 (who had the support of their partners and family in the lifestyle changes they wished to make) displayed less recidivism and better self-management.

For some CHIP participants, the perceived 'strict' vegan diet was cited as problematic. However, two members from the Study 1 control group of their own accord adopted a near-vegan diet during the study. Food preferences are, therefore, personal, and while some participants could adapt to and even enjoy a different diet, others found the new food options to be a significant barrier. Finding food outlets that catered for diabetic options was cited as being the most common dietary barrier in those from the Study 1 control group. Similarly, a study investigating the experiences of persons with T2DM consuming a low-carbohydrate, high-fat diet showed that participants found eating out the most challenging part of their diet to manage. The reasons cited for the difficulty were the same as the participants in Study 2, namely the lack of suitable food outlets or options in the outlets and the feeling of being judged or scrutinised by their social group (Webster et al., 2019).

A systematic review has indicated that the vegan diet offers some clinical improvement in people with T2DM. Low-fat vegan diets can reduce total and LDL cholesterol reducing cardiovascular risk in persons with diabetes. Vegan diets also have the advantage of not involving complicated calorie restrictions, portion size calculations or food exchanges (Barnard et al., 2009; Kashyap et al., 2022). The vegan diet, being plant-based, high in fibre and nutrient-dense, contains abundant vitamins and antioxidants. This combination reduces weight-gain long-term and ameliorates inflammation commonly associated with consuming low-fibre, high-fat and high-protein diets (Kashyap et al., 2022).

While the vegan diet remains a good option for diabetes dietary management, it is not the only effective diet available for diabetes management (Cheng et al., 2017; Kashyap et al., 2022). Low carbohydrate ketogenic diets have demonstrated efficacy in reversing diabetes

symptoms. Where weight loss has been significant enough to reverse pathologies in glucose metabolism, diabetes has been successfully reversed (Kelly et al., 2020).

Some individuals may have perceived limitations with implementing veganism. However, building capacity through self-management education, and providing support and encouragement through goal setting, will enable these individuals to effectively problem-solve and either make accommodations for the difficulties they encounter or find healthy alternatives (Powers et al., 2020).

The effort required to cook or to cook whole foods, especially when eating alone, and the increased cost of ready-to-eat or partially prepared whole foods were identified as barriers to dietary adherence. Living alone has been identified as a barrier to self-care in general in persons with insulin-dependent diabetes (Toljamo & Hentinen, 2001). In addition, financial constraints have been recognised as a factor limiting the number of alternatives available to manage more expensive health-promoting alternatives (Adu et al., 2019). Unfortunately, some individual and situational factors are challenging to change; however, clients do require support and encouragement to source the best alternatives for managing these factors as best they can.

Interestingly long periods of stress were viewed as a reason for blood sugars becoming uncontrolled even when participants perceived they were doing the 'right' things. Stress was also seen as a principal reason for non-adherence due to a lack of energy and motivation. Ms D (Case 1 Chapter 8) verbalised that when experiencing significant stressors, she had increasing difficulty managing her blood glucose levels. She attributed some of this to lapses in her diet and exercise routine but also stated that stress seemed to independently negatively affect her glycaemic control.

A study conducted by Adu et al. (2019) demonstrated that participants from multiple countries worldwide when interviewed about the barriers they experience relating to self-care, identified that health professionals did not recognise stress as contributing to a lack of glycaemic control. In addition, the inability to manage stress appropriately created a barrier to performing some behaviours required to manage glycaemic control. Participants who perceived they suffered significant stress also reported greater diabetes distress, lower diabetes empowerment, greater insulin use, and poorer glycaemic control (Yu et al., 2020).

Clients with T2DM also show significantly higher rates of depression, anxiety, and stress than the general population. Therefore, screening for psychological distress and mental health conditions among clients with T2DM, along with an appropriate referral for

intervention, is advocated (Alzahrani et al., 2019). Health professionals must recognise stress's increased role in the development of most chronic lifestyle diseases and its role in limiting resilience and the ability of persons to cope with significant life events effectively. High-stress levels are included as a factor inhibiting significant lifestyle adjustments. Education, which aims to develop skills to recognise and acknowledge clients' stress and support them while they navigate through stressful situations so that their diabetes self-management skills are not abandoned in the process, is essential if diabetes care is to remain relevant to the client.

In Study 2, one of the ways the CHIP participants from both the Study 1 intervention and control groups managed lifestyle recommendations that were distasteful or inconvenient for them to implement was through a risk-benefit analysis approach. In a study conducted by Nair et al. designed to study risk and benefit analysis for persons with T2DM, it was concluded that participants continue to balance experiment and experience when deciding what treatment options to adhere to. The risk and benefits of treatments were not necessarily accurately conceptualised and were often done very broadly. Paterson et al. (1998) also found that clients learn to balance their diabetes by combining their experience with experimenting with new strategies. Successful self-management requires understanding and skill to manipulate diet, exercise, and medication to achieve optimal quality of life while maintaining glycaemic control. For many, this balancing act, even when less effective in managing glycaemic control, is preferred to submitting to regimental restrictions that impact family life and social and work activities. Nair et al. (2007) concluded that clients should have access to health professionals for continuing education and reinforcement, where opportunities for open discussion are made available to them. In addition, continued professional support and guidance are crucial while clients develop their self-management skills and decisions (Powers et al., 2020). The collaboration between health professional practices and community-based education programmes like the CHIP may facilitate improved education and adherence by equipping clients with self-responsibility skills.

Conclusion to the Chapter

Study 2 provided novel insights into the clients' understanding of diabetes reversal, their perceptions of involvement and collaboration in managing diabetes care, and their evaluation of the CHIP. The participant's perspectives of their achievements and the barriers to achieve what they perceived as being optimal adherence were identified. Participants in the study expressed that they would have preferred a higher degree of consultation concerning

their diabetes management. They wanted to know more about why the recommendations would be helpful to them. They perceived that health professionals needed more to offer in terms of time to engage with them regarding lifestyle options for management. Therefore, there remains scope for professional or community-organised group lifestyle management programmes like the CHIP, which may, in a more client-focused manner, augment or reinforce existing practice-based education. Study participants were generally inclined to adhere to recommendations perceived as comfortable and enjoyable and either reject or abandon recommendations perceived to reduce their quality of life. Therefore, diabetes education programmes need to provide information to increase knowledge, but perhaps more importantly, they need to offer a vital component of support along with self-management education. The benefit to the client could be exponentially enhanced where programmes like CHIP can operate in collaborative association with professional health practices.

CHAPTER 10: CONCLUSION TO THE THESIS

It is well recognised that rates of T2DM are increasing dramatically both in developed and, more recently, developing countries. Much of the pathogenesis of the disease can be attributed to obesity and, more specifically, visceral adiposity. The Western lifestyle which is associated with calorie-dense, highly processed, low nutrient-dense foods, decreased amounts of regular physical activity and more sit time, contributes to obesity and the development of multiple diseases of lifestyle. Even though other than bariatric surgery there are no medical options for curing T2DM, there remains scope for investigating possibilities for reversing the condition by addressing the lifestyle factors contributing to the onset. This thesis contributes to the body of knowledge of lifestyle medicine by:

- improving the understanding of utilising a community-based, volunteer-run lifestyle intervention programme to reverse the symptoms of T2DM;
- improving the understanding of the role of adherence in lifestyle management and the factors that contribute to or present as barriers to adherence; and
- improving the understanding of the client with diabetes' desire for involvement in decision-making for diabetes management.

The key findings and conclusions of both Study 1 and Study 2 are presented in this chapter, along with recommendations for further research.

Findings from Study 1

Study 1 was guided by two Research Questions:

1. When compared to a control group receiving routine diabetic care, what is the effect of implementing CHIP on changes in fasting blood sugar levels (FBSL), HbA1c, fasting lipogram with triglycerides (FLT), blood pressure (BP), abdominal girth and body mass index (BMI) in participants with previously diagnosed T2DM who participated in CHIP?
2. Compared to a control group receiving routine diabetic care, what adherence levels (measured through changes in dietary intake, weekly activity levels, and planned exercise) over 12 months are observed in participants with previously diagnosed T2DM who participated in CHIP?

Even though Study 1 was underpowered, the results of the RCT demonstrated that participants in the intervention group who completed the CHIP affected notable changes in selected parameters. Significant improvements occurred in HbA1c levels, diastolic blood pressure, mass, BMI, hip circumference, waist circumference and height-to-waist ratio measurements by the end of the 12-week programme. By 12 months, the HbA1C and diastolic blood pressure improvement was no longer significant; however, the remaining parameters remained significant at the 12-month assessment. All but one of the participants in the intervention group who were prescribed hypoglycaemic agents remained on at least one form of treatment for the entire 12-month study. Therefore, while improvement in HbA1c occurred, diabetes reversal was not demonstrated in all but one participant.

To address the second Research Question of Study 1, participants completed food frequency and weekly activity questionnaires. The outcomes demonstrate that CHIP participants made some significant lifestyle changes in response to the programme. However, many of those changes were only sustained for a short time beyond the duration of the programme. The CHIP is not a prescriptive programme and relies on the participant's willingness and ability to set goals and be accountable in implementing the recommendations. Participants will likely set different goals or levels of achievement and implement strategies that are likely to vary in intensity. The definition of adherence, therefore, becomes subject to each participant's ideals and goals which is essentially the essence of self-responsibility. Situational factors that create intense obstructions to an individual's plans but, on a deeper level, modify the essence of what is regarded as usual inevitably interfere with intentions and the deeper psyche. This deeper intrusion affects mood and willingness to perform and, if intense enough, will impact the desire to function and live (Armour et al., 2021; World Health Organization, 2020a).

Quality of life as measured by the RAND-36 survey showed improvements in the intervention group participants for reported energy level, emotional well-being, social function, and decreased perceived pain at the culmination of the 12-week intervention programme. The highly social, supportive, and encouraging dynamic created by the CHIP sessions, and the improved diet and activity levels likely contributed to this improved perception of well-being. The diet advocated and adopted by the intervention group in the first 12 weeks is anti-inflammatory and could have contributed to decreased pain perception during that time. The lack of long-term adherence was also reflected in the durability of changes in biometrical measurements and quality of life indicators. The control group had no

significant changes in biometrical measurements, blood levels, quality of life indicators or lifestyle factors.

Limitations of Study 1

Several limitations to Study 1 have been identified. The most significant was the access to suitable participants. It was challenging to access potential participants in primary care general medical practices without some incentive for involvement by the medical practice in the research and publication of the data. The larger hospital-based and private diabetes clinics approached were unwilling to participate, citing that they are actively engaged in other research projects of their own. The university also had no research-affiliated medical practices or diabetes clinics where potential participants could be accessed for research purposes by PhD students. The two medical practices that were willing to refer potential participants had a single doctor in each practice that was interested in and practised lifestyle medicine. Some practice nurses in these practices were also willing to engage potential participants. Medical practices are busy, and without the team being intrinsically or extrinsically (through publications or access to presentation opportunities or credentials) motivated involvement in third party research is unlikely. A large RCT of this nature is preferably conducted in collaboration with diabetes clinics or specialised practices where the team is research orientated and attends to large numbers of potential participants.

Due to the small sample size, the margin of error in this study may be increased due to being underpowered. Due to slow enrolment, randomisation was performed at four different intervals to accommodate enrolment into the CHIP which resulted in only 10 to 20 participants being randomised at any one point. The multiple randomisations conceivably could have compromised the concealment of allocated participants. The study was not blinded due to the participatory requirements of the intervention. The control group size was smaller than the intervention group, which may have compromised the validity of the results. The smaller control group occurred because several participants in the control group dropped out after finding out that they would have to wait until the end of the research period to participate in the CHIP. Access to a greater number of potential participants would accommodate these dropout numbers.

The participants were predominantly residents in a single local government area and were sourced from predominantly two GP practices which could limit the generalisability of findings to the broader population. This RCT can potentially be conducted across a larger

geographical area if a multicentre approach is used. The lack of access to resources and funding impacted the ability to engage research assistants to collect data across multiple centres over a wide geographical area. Accessing volunteers to manage and run the CHIP across multiple geographical regions was a further limitation. Conducting this RCT as a sizeable multicentre trial would require the training and willingness of local individuals to volunteer or be paid to run the intervention programme.

COVID-19 lockdowns and restricted access to participants led to several participants in both the intervention and control groups not completing the 12-month assessment timeously. In some instances, the 12-month assessment took place as late as 18 months after the initial assessment. The trial was also ceased due to COVID-19 restrictions preventing the CHIP from operating.

Findings from Study 2

The aim of completing a second study for this thesis was to explore the participant's knowledge of diabetes reversal and their experience of the intervention and adherence to lifestyle recommendations. To achieve this, the following Research Questions were addressed in Study 2:

1. What was the participant's knowledge of the concept of diabetes reversal?
2. What was the participant's experience of CHIP as an intervention for diabetes reversal?

Participants in Study 2 were individually interviewed and asked questions to explore the above Research Questions. Based on the answers received, it became apparent that at least 25 per cent of the study cohort did not understand that reversal of type 2 diabetes was possible. While inaccuracies in the definition or a poor understanding of criteria for reversal are likely to be forgotten or not well understood by the layperson it was apparent that only some participants had received any information from any healthcare professional that T2DM could possibly be reversed.

Almost all participants expressed at some point in the interview that their medical team was too busy to engage in dialogue about management goals or options for management. They described receiving a prescription and, in some cases, referral to allied health professionals for education but gained the impression that they were to follow instructions and 'be good'. It was clear to the interviewee that all participants interviewed

were on a management plan which included regular monitoring and referrals to diabetes educators, dieticians, exercise physiologists or therapists. However, the participant was not obtaining full benefit from these services because they did not correctly comprehend the role of these professionals or were not being engaged appropriately by the professionals offering the services. All participants across the intervention and the control group from Study 1 expressed the desire for more consultation and discussion with their healthcare providers concerning management decisions.

Participants in Study 2 who had completed the CHIP were very positive about their experience. They all expressed they had gained extensive knowledge and the format, presentations and learning activities helped them make lifestyle adjustments. They believed the content was relevant to the management of T2DM. They reported the perception that the lifestyle adjustments helped them improve their health literacy and general well-being, reduce weight, and improve their physical fitness and social engagement.

Most study participants in the intervention and the control group from Study 1 expressed difficulty with adherence. Measuring adherence requires comparing a person's behaviour and an established standard. However, the literature does not provide this clear standard or measure. Because the CHIP participants are encouraged to set personal goals and be accountable to themselves for adhering to practices to achieve individual goals, adherence is individually determined rather than measured against a set of prescribed criteria. Surveys were used to record behaviours over the 12-month study period, and differences in behaviours were apparent at the three assessment intervals. It would therefore appear that participants in the intervention group were generally more adherent to the CHIP recommendations at 12 weeks than at baseline or 12 months. However, when interviewed, almost all participants openly acknowledged recidivism to some degree.

Both CHIP participants and those in the control group identified several barriers to what they would define as optimal adherence. Pain primarily associated with a co-morbid condition, was the most prevalent issue related to exercise adherence.

Restrictions on gathering and closures of facilities during COVID-19 and a lack of time were other reasons participants found exercise challenging to maintain. For most participants, the relatively short period in which exercise centres were unavailable was a transitory problem. However, for some, the lack of routine and the significant disruption COVID-19 had on their lives generally resulted in long-term exercise abandonment.

The most common reasons for lack of adherence to dietary recommendations were guilt associated with or discomfort about eating differently from other members of their household or requiring 'special foods' when eating out. Some study participants (intervention and control group) referred to 'good' and 'bad' foods, 'being naughty', and being embarrassed to acknowledge that they have diabetes. Family members and significant others also exacerbated guilt by policing participants' eating habits.

Food preferences are a personal matter; while some participants could adapt to and even enjoy a different diet, others found the new food options a significant barrier.

Participants from both the intervention and control groups in Study 1 acknowledged adhering to lifestyle choices they perceive to be enjoyable, easy to adapt to and helpful. Some participants seek to perform more enjoyable behaviours to balance out times when they 'cheat' in other behaviour areas. Almost all participants acknowledge not adopting some recommendations due to the perceived barriers. Adopting uncomfortable behaviours was perceived to reduce their quality of life. For many, this balancing act, even when less effective in managing glycaemic control, is preferred to submitting to regimental restrictions that impact family life and social and work activities.

Limitations of Study 2

Study 2 of this thesis was novel in its exploration of client knowledge and perceptions of the reversal of T2DM and the evaluation of participants' experience of CHIP. The findings also illuminated possible ways that the CHIP may be developed to provide more direction and support for clients around goal setting and self-responsibility, which builds capacity for self-management.

Several possible reasons emerged for clients having poor knowledge of diabetes reversal. The study highlighted that the participants required more collaborative management from care providers. Lack of time and opportunity for discussion and information sharing was a barrier to their knowledge acquisition. Overcoming personal and situational barriers may be achieved by improved access to support from care providers and significant others. Improving access to these avenues of support may improve adherence to lifestyle recommendations.

This qualitative study in which sixteen persons were interviewed provided a small sample of opinions which may not be generalisable to a larger population. In addition, the

persons enrolling in this study were those willing to engage on some level with the educative process. Many more persons were invited to participate in the study but rejected involvement; therefore, the results may not reflect the opinions of those who rejected the invitation to participate in the study.

Contribution to Knowledge of Study 2

Several items emerged from the results of Study 2 that can contribute to poor adherence and could be considered for further research or implementation in practice. Persons with T2DM have poor knowledge of the possibility of type 2 diabetes reversal, mainly resulting from poor communication between the care provider and the client. The reasons for the lapse in communication may be due to the lack of emphasis on diabetes reversal in guidelines for practice, a practice model that does not allow sufficient time for meeting the education requirements of clients, poor therapeutic relationships, a lack of capacity for a proactive approach to care or self-management in the client or poor collaborative goal setting between care-provider and client.

Several well-known personal and situational barriers to adherence emerged, many of which may be minimised with improved communication between the healthcare team and the client. The supportive involvement of families and significant others in client care has been previously demonstrated to be effective in promoting adherence and was supported by Study 2. The challenge is to persuade practitioners to encourage the attendance and involvement of support persons in diabetes education and goal-setting exercises.

Rates of mental illness, particularly depression, are higher in persons with T2DM than in the general population (Holt & Mitchell, 2015). Stress was identified in Study 2 as a contributing factor to poor adherence. Implementing mental health assessment as part of diabetes care may assist in the early detection and management of mental health factors that impede adherence to lifestyle change and other healthcare recommendations.

The CHIP may be improved by a more deliberate and stronger focus on short-term, medium and long-term goal setting in collaboration with participants and instituting some accountability structures within the programme. Several communities regularly hosting the CHIP have ongoing support programmes like CLUB CHIP. In communities with less regular hosted programmes, access to a support group is likely helpful and could be achieved using an online or social media platform.

Recommendations for Practice

Implicit in the statements set out by the Australian National Standards for Diabetes Education Programs (2001) is that clients are informed that lifestyle adjustments that eliminate some of the risk factors for diabetes have the potential to reverse or at least result in the remission of diabetes. Therefore, more discussion and information regarding options for potential diabetes reversal needs to be included in diabetes education,

Clients with T2DM recognise the need to be more actively engaged in becoming health literate and making decisions about diabetes management. Health-care practices need to be encouraged to find ways in which health professionals can improve communication with clients.

The CHIP encourages family members to complete the programme together to afford all family members the benefit of education and the opportunity to make collective decisions about health. Where family members are supportive and engaged in the process of lifestyle management, adherence is improved, and some of the guilt associated with having different requirements is alleviated (Baig et al., 2015; Denham et al., 2011; Pamungkas et al., 2017). Therefore, it is recommended that families and significant others are strongly encouraged to participate in education and collaborative decision-making in health education programmes and healthcare practices.

Health professionals need to receive more education to recognise the increased role stress plays in developing most chronic lifestyle diseases and limiting resilience and the ability to cope with situational and significant life events more effectively. Improving collaboration between healthcare and diabetes education providers and their clients may provide clients with the knowledge and skill to make lifestyle choices that are enjoyable, rewarding, and helpful in managing their disease to promote adherence.

Recommendations for Future Research

Further research to investigating whether collaboration between the CHIP and health care providers can help clients with T2DM improve decision-making and develop self-responsibility skills that will result in better adhere to recommended lifestyle changes. It would also be interesting to investigate which behaviours are most amenable to and least influenced by collaborative goal-setting so that energy and finances are applied in the areas most likely to benefit the client.

In busy practice settings investigating whether mobile technology could be effectively used to implement collaborative health management discussions and goal-setting appointments may contribute to alleviating constraints on time for interactions. Investigating mechanisms through which health professionals can better engage with clients, including the option of shared medical appointments, may provide insight into improving communication between professionals and clients. Having an understanding why some people engage well with education while others avoid it may be helpful to determine the demographic and situational factors related to engagement. These factors if manipulated or catered for may be altered significantly enough to result in better engagement and improved adherence. The possibility of determining outcomes in individuals exposed to different duration or intensity of lifestyle education may provide insight into the most suitable educational methods for eliciting longer term change.

Research into stress recognition by health professionals and how they could best identify unhealthy responses to stress in clients is becoming an increasingly important avenue for intervention. In addition, investigating how collaboration between healthcare practices and community-based health education programmes like the CHIP may facilitate improved education and adherence by better-equipping clients with self-management skills.

To improve access to potential participants and enrolment, a large RCT of this nature would be preferably conducted in collaboration with diabetes clinics or specialised practices where the team is research orientated and attends to large numbers of potential participants.

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APPENDIX A: PERMISSIONS

Permission to use the Active Q questionnaire.

Permission to gain access to potential participants.

Reply Reply All Forward IM

Tue 15/08/2017 7:23 PM

Stephanie Bonn <Stephanie.Bonn@ki.se>

RE: Re Active Q

To Linda Cloete

You replied to this message on 15/08/2017 8:00 PM.

Hi Linda,

Thank you for your email and interest in the Active-Q questionnaire.

Please feel free to use the questionnaire in your study. However, we do not provide any tools for using the web-based questionnaire but you are free to replicate it in a system of your choice and refer to the published studies on the questionnaire. Here are links to full texts of the two validation studies of Active-Q; one using doubly labeled water (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3374527/) and another using accelerometers (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4527001/) as reference methods. We have not validated Active-Q in paper version.

Let me know if you have any questions!

Best wishes,
Stephanie

Stephanie Bonn, PhD
Department of Medicine (Solna), Unit of Clinical Epidemiology
Karolinska Institutet
Stephanie.bonn@ki.se

23/01/2017

Dear Sir /Madam

I am a registered nurse, conducting a PhD at Avondale College of Higher education, studying the effects of lifestyle in the reversal of symptoms of Type 2 Diabetes. I am needing to contact persons who have been diagnosed with Type 2 Diabetes in order to provide them information about the study and also to ask them as to whether they would be willing to participate in the study.

Your GP practice has identified you as a possible candidate, however they are required to ask your permission to release contact details to me in order for me to provide you with information.

I have included my contact email as well as a number where you may access me should you need more information.

If you are willing to have your contact details made known to me, could you please provide them below.

E-Mail OR postal address:

_____

_____

_____

Preferred phone number and hours of contact:

Telephone number_____

Preferred hours of contact _____

Thank you for your consideration

Yours sincerely

Linda Cloete

Linda.cloete@avondale.edu.au

94803627

APPENDIX B: SURVEYS

Demographic and medical information survey.

Active -Q questionnaire.

Food frequency questionnaire.

RAND-36 quality of life survey.

Measurement and blood test results.

Monthly follow up details.

Demographic and Medical Information Survey

1 Title: (Mr, Mrs, Ms)

2 First name:

3 Surname:

4 Address:

Suburb:

State:

5 Contact telephone number:

6 Contact mobile number:

7 Doctors name:

8 Suburb of practice:

9 Dr's telephone number:

10 Gender:

11 Date of birth:

12

Highest level of education	
Did not complete year 12 schooling	
Year 12 schooling	
TAFE/College tertiary qualification	
University Degree	
Post- graduate degree	

13

Smoking status	
Never smoked	
Ex-smoker < 15years	
Ex-smoker > 15 years	
Current smoker	
Sleep	

14

Average hours of sleep per night (not hours spent in bed)	

15. Current Medication (Please include herbal, vitamin and mineral and over the counter medication regularly consumed)

NAME	DOSE	FREQUENCY
E.g. Aspirin	100mg	Once a day

15b. When was your last blood test (approx. date)

_____

16. Previous medical history

Condition	Approximate year of occurrence	Symptoms in the last year	
		YES	NO
Diabetes – Type I			
Diabetes – Type II			
Prediabetes/glucose intolerance			
High blood pressure			
High cholesterol			
Heart attack or Cardiac chest pain			
Circulation problems			
Recurrent leg pain on effort			
Stroke/ministroke			
Loss of sensation/numbness of fingers or toes			
Neck or back pain			
Neck or back surgery			
Joint pain/surgery			
Difficulty walking/ engaging in physical activity			
Gall bladder problem/surgery			
Breathing difficulty/asthma			
Anaemia			
Special dietary requirements			
Cancer			
Other medical condition			
Other previous surgery			

Active-Q questionnaire

Active-Q - Revised version 2011-12-01

The following questions concern your physical activity during the last year

Physical activity level – daily occupation

What is your normal activity level during your daily occupation (work, studies or equivalent)?

- Mostly Sitting
- A combination of sitting and standing up
- Mostly standing up
- Some physical activity
- Heavy manual labour

Duration – daily occupation

Approximately how many hours per week do you normally conduct your daily occupation (work, studies or equivalent)?

- 5 hours or less
- 6 - 10 hours
- 11 – 20 hours
- 21 – 30 hours
- 31 – 40 hours
- 41 – 50 hours
- More than 50 hours
- Don't know / Don't want to answer

Means of transportation to daily occupation

How do you normally get to and from work, studies or other daily occupation?

- Walking
- Cycling
- By motorcycle, moped or scooter
- By car or taxi
- By bus, train, or other public transport
- Other
- Does not apply to me
- Don't know / Don't want to answer

Follow-up questions to means of transportation

How often do you get to your daily occupation in the following ways and approximately how long does it take?

Type of activity	Number of days per week	Time, one way per day
Walking	1	Less than 15 minutes
	2	15-29 minutes
	3	30-44 minutes
	4	45-59 minutes
	5	1-2 hours
	6	Longer than 2 hours
	7	
Cycling	1	Less than 15 minutes
	2	15-29 minutes
	3	30-44 minutes
	4	45-59 minutes
	5	1-2 hours
	6	Longer than 2 hours
	7	
Motorcycle, taxi or car	1	Less than 15 minutes
	2	15-29 minutes
	3	30-44 minutes
	4	45-59 minutes
	5	1-2 hours
	6	Longer than 2 hours
	7	
By bus, train or other public transport	1	Less than 15 minutes
	2	15-29 minutes
	3	30-44 minutes
	4	45-59 minutes
	5	1-2 hours
	6	Longer than 2 hours
	7	
Other	1	Less than 15 minutes
	2	15-29 minutes
	3	30-44 minutes
	4	45-59 minutes
	5	1-2 hours
	6	Longer than 2 hours
	7	

Leisure time activities

Which activities are you doing at least once a week in your leisure time?

- Watching TV/DVDs etc.
- Using the computer, reading emails, playing, play station, X-box etc.
- Sitting reading, writing, sewing etc.
- Playing a musical instrument or active computer games (e.g. Wii)
- Doing household chores (e.g. cleaning, laundry, child care, gardening etc.
- Shopping, or other errands
- Dancing
- Walking, walking the dog (not as transport to daily occupation)
- Bicycling
- Neither of these
- Don't know/ Don't want to answer

Follow-up questions to leisure time activities

How often do you dedicate time to the following leisure time activities and how much time do you spend doing them every day?

Type of activity	Number of days per week	Time, per day
Watching TV/DVDs	1	Less than 30 minutes
	2	30-59 minutes
	3	1-2 hours
	4	3-4 hours
	5	5-8 hours
	6	Longer than 8 hours
	7	
Using the computer	1	Less than 30 minutes
	2	30-59 minutes
	3	1-2 hours
	4	3-4 hours
	5	5-8 hours
	6	Longer than 8 hours
	7	
Sitting, writing, reading, sewing etc.	1	Less than 30 minutes
	2	30-59 minutes
	3	1-2 hours
	4	3-4 hours
	5	5-8 hours
	6	Longer than 8 hours
	7	

Playing a musical instrument or active computer games (e.g. Wii)	1	Less than 30 minutes
	2	30-59 minutes
	3	1-2 hours
	4	3-4 hours
	5	5-8 hours
	6	Longer than 8 hours
	7	
Doing household chores, cleaning, doing laundry, taking care of children, garden work etc.	1	Less than 30 minutes
	2	30-59 minutes
	3	1-2 hours
	4	3-4 hours
	5	5-8 hours
	6	Longer than 8 hours
	7	
Shopping or other errands	1	Less than 30 minutes
	2	30-59 minutes
	3	1-2 hours
	4	3-4 hours
	5	5-8 hours
	6	Longer than 8 hours
	7	
Dancing	1	Less than 30 minutes
	2	30-59 minutes
	3	1-2 hours
	4	3-4 hours
	5	5-8 hours
	6	Longer than 8 hours
	7	
Walking (not as transport to daily occupation)	1	Less than 30 minutes
	2	30-59 minutes
	3	1-2 hours
	4	3-4 hours
	5	5-8 hours
	6	Longer than 8 hours
	7	
Cycling	1	Less than 30 minutes
	2	30-59 minutes
	3	1-2 hours
	4	3-4 hours

	5	5-8 hours
	6	Longer than 8 hours
	7	

Overall sporting activity or exercise

Do you exercise or play sports regularly?

- O Yes
- O No
- O Don't know/Don't want to answer

Sporting activities

What kind of exercise or sports activities are you usually doing? If your type of activity is not included in the list below, please choose a similar one.

- O Aerobics or cardio fitness class
- O Weight lifting
- O Jogging, running or orienteering
- O Athletics (e.g. high jump, long jump or three-step)
- O Spinning or cycling in demanding terrain
- O Swimming
- O Ball sports (e.g. soccer, basketball, volley ball or floorball)
- O Golf
- O Dance class or competitive dancing (e.g. ballroom, ballet, jazz or street)
- O Horseback riding
- O Skating, ice hockey or bandy
- O Skiing downhill or cross country
- O Martial arts (e.g. judo or karate)
- O Boxing or wrestling
- O Tennis, badminton or table tennis
- O Squash
- O Sailing, surfing, canoeing or rowing
- O Motor sports (e.g. motocross)
- O Rock climbing
- O Yoga, Pilates or Tai chi
- O Other activity or sport (please state)_____
- O None of these
- O Don't know / Don't want to answer

Type of activity	Times per week	Time per day
Aerobics or fitness class	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Weight lifting	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Jogging, running or orienteering	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Athletics (e.g. high jump, long jump or three-step)	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Spinning or cycling in demanding terrain	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Swimming	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Ball sports (e.g. soccer, basketball, volley ball or floor ball)	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Golf	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes

	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Dancing	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Horseback riding	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Skating, ice-hockey	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Skiing, downhill or cross country	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Martial arts (e.g. judo or karate)	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Boxing or wrestling	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Tennis, badminton or table tennis	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Squash	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours

Sailing, surfing, canoeing or rowing	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Motor sports (e.g. motocross)	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Rock climbing	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Yoga, Pilates or Tai Chi	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours
Other	1-3 times per month	Less than 30 min
	Once a week	30-59 minutes
	2-3 times per week	1-2 hours
	4-5 times per week	2-4 hours
	6-7 times per week	More than 4 hours

Do you compete regularly in a sport?

- O Yes
- O No
- O Don't know/Don't want to answer

How many hours do you sleep a day? (Include day-time napping)

- O Less than 5 hours
- O 6 hours
- O 7 hours
- O 8 hours
- O 9 hours
- O 10 hours or longer
- O Don't know/ Don't want to answer

Key to serving sizes for food frequency questions.

Meat, fish, eggs and vegetarian meat substitutes.	
*One serving of **red/white meat** is equivalent to:*	*One serving of **processed meat** is equivalent to:*
2/3 cup (100g) minced beef	1 large hotdog/sausage
2 slices of roast meat	2 small sausages
5 chicken nuggets	4 slices salami
1 small chicken breast	3 slices deli meat
2 small pork chops/ chicken drumsticks	3 rashes of bacon (80g)
*One serving of **fish** is equivalent to:*	*One serving of **seafood** is equivalent to:*
1 small fish/salmon fillet	3/8 cup (100g) crab
½ small can tuna	6 medium oysters
5 small fish fingers	8 small or 5 large shrimp
3/8 cup (100g) salmon	3/8 cup (100g) clam
*One serving of **vegetarian meat substitutes** is equivalent to:*	
½ cup of meatless crumbles/mince	
1 vegetarian, bean or lentil patty	
2 small vegetarian sausages	
2/5 cup (100g) tofu or tempeh	
Grains and cereals	
*One serving of **refined bread** is equivalent to:*	*One serving of **wholegrain bread** is equivalent to:*
2 slices white bread/toast	2 slices whole grain bread/toast
1 whole English muffin	1 wholegrain English muffin
½ white bagel/bread roll	½ whole wheat bagel/bread roll
*One serving of **crispbreads** is equivalent to:*	*One serving of **grain** is equivalent to:*
2 rye crispbread slices	½ cup white rice
2 rice cakes	½ cup spaghetti or pasta
	1 cup brown rice/quinoa
*One serving of **unsweetened wholegrain cereal** is equivalent to:*	*One serving of **sweetened wholegrain cereal** is equivalent to:*
2 Weet-Bix biscuits	1 cup Honey Nut Cheerios ™
1 cup Shredded wheat™, Cheerios™ or Raisin Bran™	½ cup Granola/toasted muesli
¾ cup raw muesli or cooked oatmeal	
*One serving of **processed cereal** is equivalent to*:	

1 cup Rice Krispies™, Corn Flakes™, Froot Loops™	
Dairy	**Fat**
*One serving of **dairy/dairy alternative** is equivalent to:*	*One serving of **fat** is equivalent to:*
1 cup milk	1 teaspoon oil, salad oil, margarine or butter
1 cup soy/rice/almond milk	1 tablespoon nut butter
3/4 cup (175ml) yoghurt	10 Olives
½ cup cottage cheese	¼ Avocado
1 slice or 3 tablespoons hard cheese	
Vegetables and Fruit	
*One serving of **potat**o is equivalent to:*	*One serving of **starchy vegetables** is equivalent to:*
1 cup potato (boiled or mashed without fat)	½ cup eggplant, zucchini
Cup fried or roasted potato	½ cup carrots, parsnips or turnips
	½ cup sweet potato, pumpkin or corn
*One serving of **green leafy vegetables** is equivalent to:*	*One serving of **salad vegetables** is equivalent to:*
½ cup cooked cabbage, chard, Bok choy, spinach	1 cup tomato, cucumber, celery, capsicum
1 cup raw cabbage, chard bok choy or spinach	1 cup lettuce or salad greens
½ cup cooked broccoli, cauliflower, brussel sprouts	
1 cup raw broccoli, cauliflower, brussel sprouts	
*One serving of **seasoning vegetables** is equivalent to:*	*One serving of **legumes** is equivalent to:*
½ cup cooked mushrooms	½ cup lentils, chick peas, split peas, white or black beans
1-4 teaspoons onion, garlic, leek, chilli.	½ cup bean soup or stew
*One serving of **fruit** is equivalent to:*	*One serving of **dried fruit/spreads** is equivalent to:*
1 medium apple or pear, orange	4 halves apricot
1 cup melon, cantaloupe or pineapple	2 dates
20 grapes	2 tablespoons raisins
2 small fruits – apricot/plums/kiwi	
½ large banana	
1 cup berries	

Sweets and snacks	
*One serving of **baked goods** is equivalent to:*	*One serving of **savoury snacks** is equivalent to:*
1 medium slice cake	1 small bag ships or crisps
1 large cookie or 4 small cookies	1 small bag tortilla/corn chips
1 doughnut	1 cup buttered popcorn
1 small chocolate bar (10cm / 50-60g)	¼ cup nuts
1 scoop ice cream/dollop sweetened cream	¼ cup seeds
1 energy bar (10cm / 50-60g)	1 tablespoon sauce (tomato, mustard, barbecue)
10 candied lollies	1/3 teaspoon salt
1 teaspoon jam	Pickles (onions, gherkins, beetroot)
1 teaspoon honey	Preserved vegetables in oil (artichoke, capsicum)
Beverages	
*One serving of **sugar sweetened caffeinated** beverage is equivalent to:*	*One serving of **sugar sweetened non-caffeinated** beverage is equivalent to:*
1 cup sweetened / unsweetened coffee	1 cup hot chocolate
¾ (250ml) can or 1 cup cola or caffeinated drink	¾ can fizzy drink (non-cola)
1 can (250ml) energy drink	½ bottle (250ml) sports drink
	1 cup sweetened tea
	1 cup (250ml) fruit juice, coconut or flavoured water
	1 cup flavoured milk
*One serving of **alcohol** is equivalent to:*	
1 glass of regular ale or cider	
2 glasses light ale	
½ glass wine	
1 shot spirits or liquor	

Food frequency questionnaire

	Number of servings (see attached information sheet for volume per serve)										
	None	**1 per day**	**2 per day**	**3 per day**	**4 per day**	**5 per day**	**6+ per day**	**1 or less per week**	**2-3 per week**	**4-5 per week**	**6 per week**
Protein portions											
Red and white meat											
Processed meat											
Fish											
Seafood											
Vegetarian meat substitutes											
Eggs											
Tofu/tempeh											
Legumes (beans, lentils etc)											
Grains & cereals											
Refined breads											
Wholegrain breads											
Crispbreads & crackers											
Unsweetened wholegrain cereals											
Sweetened wholegrain cereals											
Processed cereals											
Other wholegrains											
Other processed grains											

	Number of servings (see attached information sheet for volume per serve)										
	None	**1 per day**	**2 per day**	**3 per day**	**4 per day**	**5 per day**	**6+ per day**	**1 or less per week**	**2-3 per week**	**4-5 per week**	**6 per week**
Dairy											
Milk											
Yoghurt											
Milk alternative											
Yoghurt alternative											
White cheese/cottage cheese											
Yellow cheese											
Soy cheese											
Fats											
Butter or margarine											
Nut butters											
Oil, salad oil, mayonnaise, salad cream											
Olives/Avocado											
Vegetables, and fruit											
Potato boiled or mashed without fat											
Fried potato											
Starchy vegetables (not potato)											
Green leafy vegetables											

Salad vegetables												
Seasoning vegetables												
Mushrooms												
	Number of servings (see attached information sheet for volume per serve)											
	None	**1 per day**	**2 per day**	**3 per day**	**4 per day**	**5 per day**	**6+ per day**	**1 or less per week**	**2-3 per week**	**4-5 per week**	**6 per week**
Legumes (beans, green beans, peas, lentils)												
Fruit												
Dried fruit												
Berries/cherries												
Snacks and desserts												
Sweet baked goods												
Sweet desserts, mousse, custard, ice cream												
Salty snacks												
Salt (1/3 teaspoon)												
Pickles												
Sauces, barbecue, tomato, mustard												
Nuts and seeds												
Candied lollies												
Chocolate bars (10 cm long/ 50-60g)												
Jam or honey												
Beverages												
Water												
Sugar sweetened caffeinated beverages												
Sugar sweetened non caffeinated beverages												

Sugar free caffeinated beverage											
Sugar free non caffeinated beverage											
Fruit juice 100%											
Fruit juice blends/ flavoured water											
	Number of servings (see attached information sheet for volume per serve)										
	None	**1 per day**	**2 per day**	**3 per day**	**4 per day**	**5 per day**	**6+ per day**	**1 or less per week**	**2-3 per week**	**4-5 per week**	**6 per week**
Cordial											
Flavoured milk or milk alternative											
Coconut water											
Alcohol											

During the past 2 weeks:	**Never**	**1 day**	**2 days**	**3 days**	**4 days**	**5 days**	**6 days**	**Everyday**
How many days did you eat breakfast?								
How many days did you skip lunch or dinner?								
How many days did you eat out or buy canteen lunch?								

Indicate how you use salt.	
Add while cooking	
Add at the table	
Add during cooking and at the table	

Rand-36 quality of life survey

RAND-36

Choose one option for each questionnaire item.

1. In general, would you say your health is:

- 1 - Excellent
- 2 - Very good
- 3 - Good
- 4 - Fair
- 5 - Poor

2. **Compared to one year ago**, how would you rate your health in general **now**?

- 1 - Much better now than one year ago
- 2 - Somewhat better now than one year ago
- 3 - About the same
- 4 - Somewhat worse now than one year ago
- 5 - Much worse now than one year ago

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	○ 1	○ 2	○ 3
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	○ 1	○ 2	○ 3
5. Lifting or carrying groceries	○ 1	○ 2	○ 3
6. Climbing **several** flights of stairs	○ 1	○ 2	○ 3
7. Climbing **one** flight of stairs	○ 1	○ 2	○ 3
8. Bending, kneeling, or stooping	○ 1	○ 2	○ 3
9. Walking **more than a mile**	○ 1	○ 2	○ 3
10. Walking **several blocks**	○ 1	○ 2	○ 3
11. Walking **one block**	○ 1	○ 2	○ 3
12. Bathing or dressing yourself	○ 1	○ 2	○ 3

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	Yes	No
13. Cut down the **amount of time** you spent on work or other activities	○ 1	○ 2
14. **Accomplished less** than you would like	○ 1	○ 2
15. Were limited in the **kind** of work or other activities	○ 1	○ 2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	○ 1	○ 2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

- 1 - Not at all
- 2 - Slightly
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?

- 1 - None
- 2 - Very mild
- 3 - Mild
- 4 - Moderate
- 5 - Severe
- 6 - Very severe

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- 1 - Not at all
- 2 - A little bit
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks**, how much of the time has **your physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time

How TRUE or FALSE is **each** of the following statements for you.

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

Measurements and blood test results

Measurement	Initial	3 Months	12 Months
Height			
Weight			
Hip circumference			
Waist circumference			
Blood pressure			
Stride length			
Total Chol			
HDL			
LDL			
Trigs			
Fasting glucose			
Hb A1C			
Hip waist ratio			
Height waist ratio			
BMI			

Monthly follow up details

Name	
Questions	
Goals	
Barriers	
Drs visits/illness – for what, when? Investigations – what, where, when, why?	
Hospitalisation – how long where, why?	
Medication prescription filled, which medication and size of supply or changes in prescriptions	

Purchase of testing equipment, what and size of supply	

APPENDIX C: SCORING FOR THE ACTIVE-Q QUESTIONNAIRE

Scoring for Active -Q questionnaire

The scoring for the Active-Q questionnaire was obtained from Ainsworth (Ainsworth et al., 2000)

Table 1

Questions included in Active-Q[a] and corresponding MET values.

Activity category	MET value
Daily occupation[b]	
Mostly sitting	1.5
A combination of sitting and standing up	2.3
Mostly standing up	3.0
Some physical activity	4.5
Heavy manual labor	6.0
Transportation	
Walking	4.0
Bicycling	4.0
By motorcycle or scooter	2.5
By car or taxi	1.0
By bus, train, subway, or boat	1.0
Leisure time activities	
Watching TV/DVDs	1.0
Using the computer	1.0
Sitting listening to music, sewing, etc	1.0
Playing a musical instrument or active computer games	2.0
Doing household chores	3.0
Shopping or other errands	2.3
Dancing	3.0
Walking	3.4
Bicycling	8.0
Regular sporting activities	
Aerobics	6.5
Weight lifting	6.0
Jogging or running	8.0
Athletics	6.0
Spinning	8.5
Swimming	6.0
Soccer, basketball, volleyball, or floorball (floor hockey)	6.0
Golf	4.5
Dance class	4.5
Horseback riding	4.0
Ice skating, ice hockey, or bandy	7.0
Skiing (downhill or cross country)	7.0
Martial arts	10.0

Martial arts	10.0
Boxing or wrestling	6.0
Tennis, badminton, or squash	7.0
Table tennis	4.0
Rowing, canoeing, surfing, or sailing	3.0
Motor sports	4.0
Rock climbing	8.0
Other	2.5

[a] All-domain activities (i.e., daily occupation, transportation, leisure time, and sporting activities), including frequency and duration, were assessed via an initial screening questionnaire.

[b] Participants ranked their overall effort in this category on a scale from 1 to 5.

APPENDIX D: TABLES INDICATING MEDICATION CHANGE

Table D 1

Changes in Hypoglycaemic Medication in the Intervention Group Over the First 12 Weeks.

Participant Number	Group	Biguinide baseline	Biguinide 12 weeks	Incretin mimics baseline	Biguinide/ SGLT2 inhibitor baseline	Biguinide/ SGLT2 inhibitor 12 weeks	Sulphonylurea baseline	Sulphonylurea 12 weeks	SGLT2 inhibitor baseline	SGLT2 inhibitor 12-weeks	dipeptidyl peptidase 4 inhibitor. baseline	dipeptidyl peptidase 4 inhibitor. 12-weeks	Insulin baseline	Insulin 12-weeks
3	(I)	Diabex 500mg	Diabex 500mg	-	-	-	-	-	Jardiance 25mg	Jardiance 25mg	Januvia 50mg	Januvia 50mg	-	-
4	(I)	-	-	-	-	-	-	-	-	-	-	-	-	-
7	(I)	Diabex 500mg	Diabex 500mg	-	-	-	-	-	-	-	-	-	-	-
8	(I)	-	Diaformin 500mg	-	-	-	-	-	-	Jardiance 25mg	-	-	-	-
9	(I)	-	-	-	Sitagliptin/Metformin 100/1000mg	Sitagliptin/Metformin 100/1000mg	Glicazide 60mg	Glicazide 120mg	-	-	-	-	-	-
10	(I)	Diaformin 500mg	-	-	-	-	-	Jardiance 25mg	Jardiance 25mg	-	-	-	-	
11	(I)	Diaformin 500mg	Diaformin 1000mg	-	Sitagliptin/Metformin 50/500mg	Sitagliptin/Metformin 50/500mg	-	-	-	-	-	-	-	-
13	(I)	-		-	Kombiglyze XR 5/1000mg	Kombiglyze XR 5/1000mg	-	-	-	-	-	-	-	-
14	(I)	Diaformin 1000mg	Diaformin 1000mg	-	-	-	-	-	-	-	-	-	-	-
15	(I)	Diaformin 1000mg	Diaformin 1000mg	-	-	-	-	-	-	-	-	-	-	
16	(I)	Diaformin 1000mg	Diaformin 1000mg	Byeta 10mcg	-	-	-	-	Jardiance 25mg	Jardiance 25mg	-	-	Lantus 10u	
17	(I)	-	-	-	Galvumet 50/1000mg	Galvumet 50/1000mg	-	-	-	-	-	-	-	
21	(I)	-	-	-	-	-	-	-	-	-	Alogliptin 25mg	-	-	

Participant Number	Group	Biguinide baseline	Biguinide 12 weeks	Incretin mimics baseline	Biguinide/ SGLT2 inhibitor baseline	Biguinide/ SGLT2 inhibitor 12 weeks	Sulphonylurea baseline	Sulphonylurea 12 weeks	SGLT2 inhibitor baseline	SGLT2 inhibitor 12-weeks	dipeptidyl peptidase 4 inhibitor. baseline	dipeptidyl peptidase 4 inhibitor. 12-weeks	Insulin baseline	Insulin 12-weeks
22	(I)	-	-	-	-	-	-	-	-	-	-	-	-	
23	(I)	-	-	-	-	-	-	-	-	-	-	-	-	
24	(I)	Diaformin 1000mg	Diaformin 1000mg	-	-	-	-	-	Jardiance 10mg	Jardiance 10mg	-	-	-	
25	(I)	-	-	-	-	-	-	-	-	-	-	-	Humalog 120u	

Table D 2

Comparison of Changes in Antihypertensive Medication Between Baseline, 12 Weeks, and 12 Months.

		Baseline		12 weeks		12 months	
Participant number	Group	Medication name	Dose	Medication name	Dose	Medication name	Dose
3	Exp	Diathizide	25 mg				
4	Exp	Diathizide	25 mg				
		Spiractin	25 mg				
		Nitroglycerine spray	400mcg				
7	Exp	Lasix	40mg				
8	Exp						
9	Exp	Metropolol	50mg				
		Lercanidipine	10mg				
10	Exp	Metropolol	50mg	Metropolol	50mg	Metropolol	50mg
11	Exp	Propanalol	40mg	Propanalol	40mg	Propanalol	40mg
13	Exp						

		Baseline		12 weeks		12 months	
Participant number	Group	Medication name	Dose	Medication name	Dose	Medication name	Dose
15	Exp	Norvasc	5 mg	Norvasc	5 mg	Norvasc	5 mg
16	Exp			Norvasc	5 mg	Norvasc	5 mg
17	Exp						
21	Exp						
22	Exp	Perindopril/ Amlodipine	10/5 mg				
23	Exp	Amlodipine	10 mg	Amlodipine	10 mg	Amlodipine	10 mg
		Diathizide	25mg				
24	Exp	Propanalol	40 mg	Propanalol	40 mg	Propanalol	40 mg
25	Exp	Perindopril/ Amlodipine	10/5 mg				
1	Control	Metropolol	25mg				
		Fendex	5mg	Fendex	5mg	Fendex	5mg
2	Control	Toprolol	180 mg	Toprolol	190 mg	Toprolol	190 mg
5	Control	Prazosin	1mg				
		Moxonidine	1 tab				

		Baseline		12 weeks		12 months	
Participant number	Group	Medication name	Dose	Medication name	Dose	Medication name	Dose
		Diltiazim	180 mg	Diltiazim	180 mg	Diltiazim	180 mg
6	Control	Amlodipine	5 mg	Amlodipine	5 mg	Amlodipine	5 mg
12	Control						
18	Control	Frusemide	40 mg				
		Spironolactone	25 mg				
19	Control						
20	Control	Nordip	5mg	Nordip	5mg	Nordip	5mg
		Lisinopril	20 mg				
26	Control	Quinopril	10mg	Quinopril	10mg	Quinopril	10mg
27	Control						
28	Control	Metropolol	25 mg	Metropolol	25 mg	Metropolol	25 mg

Table D 3.

Comparison of Changes in Lipid Lowering Medication Between Baseline, 12 Weeks and 12 Months.

		Baseline		12 weeks		12 months	
Participant number	Group	Medication name	Dose	Medication name	Dose	Medication name	Dose
3	Exp	Lipitor	20 mg	Lipitor	20 mg	Lipitor	20 mg
4	Exp	Cavastat	5mg	Nil	Nil	Nil	Nil
7	Exp	Lipitor	20mg	Lipitor	20mg	Lipitor	20mg
		Ezetrol	10mg	Ezetrol	10mg	Ezetrol	10mg
8	Exp	Nil	Nil	Nil	Nil	Nil	Nil
9	Exp	Nil	Nil	Nil	Nil	Nil	Nil
10	Exp	Crestor	10 mg	Crestor	10 mg	Crestor	10 mg
11	Exp	Nil	Nil	Nil	Nil	Nil	Nil
13	Exp	Rosuvastatin	10mg	Nil	Nil	Nil	Nil
14	Exp	Nil	Nil	Nil	Nil	Nil	Nil
15	Exp	Nil	Nil	Nil	Nil	Nil	Nil
16	Exp	Rosuvostatin	40mg	Rosuvostatin	40mg	Rosuvostatin	40mg

17	Exp	Nil	Nil	Nil	Nil	Nil	Nil
21	Exp	Nil	Nil	Nil	Nil	Nil	Nil
22	Exp	Atorvastatin	20mg	Atorvastatin	20mg	Atorvastatin	20mg
23	Exp	Nil	Nil	Nil	Nil	Nil	Nil
24	Exp	Cavastat	5mg	Cavastat	5mg	Cavastat	5mg
25	Exp	Cavastat	20mg	Cavastat	20mg	Cavastat	20mg
1	Control	Zimstat	40 mg	Zimstat	40 mg	Zimstat	40 mg
2	Control	Lorstat	20 mg	Lorstat	20 mg	Lorstat	20 mg
5	Control	Atorvastatin	80 mg	Atorvastatin	80 mg	Atorvastatin	80 mg
		Ezetemibe	10 mg	Ezetemibe	10 mg	Ezetemibe	10 mg
6	Control	Lipitor	20mg	Lipitor	20mg	Lipitor	20mg
		Baseline		12 weeks		12 months	
Participant number	Group	Medication name	Dose	Medication name	Dose	Medication name	Dose
12	Control	Nil	Nil	Nil	Nil	Nil	Nil
18	Control	Rosuvastatin	20 mg	Rosuvastatin	20 mg	Rosuvastatin	20 mg

19	Control	Fenofibrate	145 mg	Fenofibrate	145 mg	Fenofibrate	145 mg
20	Control	Zimstat	20mg	Zimstat	20mg	Zimstat	20mg
26	Control	Atorvostatin	20mg	Atorvostatin	20mg	Atorvostatin	20mg
27	Control	Nil	Nil	Nil	Nil	Nil	Nil
28	Control	Rosuvastatin	10mg	Rosuvastatin	10mg	Rosuvastatin	10mg

APPENDIX E: TABLES INDICATING COMPARISONS OF FOOD FREQUENCY

Table E 1

Comparison of the Number of Protein Servings Per Week Between Intervention and Control Groups from Baseline to 12 Weeks and Baseline to 12 Months.

		Initial		12 weeks		12 months	
Variable	*n*	Mean	SD	Mean	SD	Mean	SD
Servings meat/chicken per week (I)	17	4.35	5.590	1.44	3.682	1.91	3.585
Servings meat/chicken per week (C)	11	3.96	2.534	4.09	2.396	4.09	2.396
Servings fish/seafood per week (I)	17	1.50	1.299	1.03	1.317	.824	.967
Servings fish/seafood per week (C)	11	3.55	2.583	3.18	2.620	3.18	2.620
Servings eggs per week (I)	17	3.65	4.696	1.62	5.042	3.53	5.846
Servings eggs per week (C)	11	3.36	3.668	3.27	3.677	3.50	3.529
Servings meat substitutes per week (I)	17	1.41	2.108	1.47	3.333	2.09	3.611
Servings meat substitutes per week (C)	11	1.23	2.338	1.14	2.367	.73	2.102
Servings legumes/tofu per week (I)	17	2.03	1.980	3.71	3.382	4.50	4.458
Servings legumes/tofu per week (C)	11	1.36	1.398	1.27	1.272	1.27	1.272

Table E 1 (cont.)

		Initial		12 weeks		12 months		Initial to 12w eeks			Initial to 12 months		
Variable	*n*	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2-tailed)	*t*	*df*	*Sig* (2-tailed)
Servings of animal protein per week (I)	17	3.35	1.974	.735	.903	1.38	1.281	5.132	16	<.001	4.170	16	.001
Servings of animal protein per week (C)	11	5.82	3.157	5.68	3.011	5.956	2.734	.539	10	.602	-.222	10	.829
Servings of vegetable protein per week (I)	17	2.79	3.636	3.71	3.500	5.12	4.73	-.724	16	.480	-1.801	16	.091
Servings of vegetable protein per week (C)	11	2.59	2.587	2.32	2.581	1.91	2.072	1.399	10	.192	1.594	10	.142

Note: (C) denotes control group. (I) denotes intervention group. *n* denotes number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes significance.

Table E 2

Comparison of the Number of Grain Servings Per Week Between Intervention and Control Groups From Baseline to 12 Weeks and Baseline To 12 Months.

		Initial		12 weeks		12 months	
Variable	*n*	Mean	SD	Mean	SD	Mean	SD
Whole bread per week (I)	17	4.06	5.367	5.82	5.408	5.79	5.460
Whole bread per week (C)	11	7.41	7.242	6.46	6.231	7.09	6.689
Refined bread and crackers per week (I)	17	7.59	11.419	1.141	1.623	2.41	5.103
Refined bread and crackers per week (C)	11	5.23	5.284	3.86	4.621	6.41	6.636
Wholegrain cereal per week (I)	17	2.97	4.045	4.27	3.068	2.79	3.885
Wholegrain cereal per week (C)	11	1.59	2.871	1.91	2.871	3.09	3.308
Refined/sweetened cereal per week (I)	17	2.00	3.787	1.47	2.764	.77	1.592
Refined/sweetened cereal per week (C)	11	2.77	3.053	3.41	4.437	2.77	4.644
Wholegrains per week (I)	17	1.29	2.305	1.74	2.040	3.15	3.723
Wholegrains per week (C)	11	.64	1.002	.64	1.002	.64	1.002
Processed grains per week (I)	17	2.15	2.5311	1.32	1.912	1.71	2.284
Processed grains per week (C)	11	1.23	1.252	1.23	1.252	1.64	1.051

Table E 2 (cont.)

Variable	Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
	n	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2- tailed)	*t*	*df*	*Sig* (2- tailed)
Wholegrain products per week (I)	17	8.32	8.759	11.82	7.040	11.74	7.017	-1.569	16	.136	-1.473	16	.160
Wholegrain products per week (C)	11	9.64	8.041	9.00	7.124	10.82	6.615	.803	10	.441	-.902	10	.388
Processed grain products per week (I)	17	11.74	11.809	4.21	4.535	4.88	5.680	2.610	16	.019	2.036	16	.059
Processed grain products per week (C)	11	9.23	6.813	8.50	7.280	10.82	7.907	.617	10	.551	-1.708	10	.118

Note: (C) denotes control group. (I) denotes intervention group. *n* denotes number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes significance.

Table E 3

Comparison of the Number of Fruit and Vegetable Servings Per Week Between Intervention and Control Groups From Baseline to 12 Weeks and Baseline to 12 Months.

		Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
Variable	*n*	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2- tailed)	*t*	*df*	*Sig* (2- tailed)
Boiled/mashed potato (I)	17	3.97	4.021	3.35	2.364	5.27	6.697	.820	16	.424	-.741	16	.470
Boiled/mashed potato (C)	11	3.23	1.438	3.05	1.37	3.09	1.578	.669	10	.519	1000	10	.341
Fried potato (I)	17	1.15	.996	.706	1.687	.676	.967	.948	16	.357	2.266	16	.038
Fried potato (C)	11	1.00	.860	1.55	1.331	1.68	1.347	-1.466	10	.173	-1.808	10	.101
Salad/salad vegetables (I)	17	12.35	12.599	16.82	11.923	12.71	4.651	-1.240	16	.233	-.116	16	.909
Salad/salad vegetables (C)	11	10.91	3.337	11.32	3.849	11.64	5.767	-.598	10	.563	-.531	10	.607
Cooked vegetables (I)	17	10.27	6.617	11.03	3.826	13.38	4.672	-.511	16	.616	-1.877	16	.079
Cooked vegetables (C)	11	6.73	4.058	7.82	3.273	8.14	4.019	-1.604	10	.140	-1.563	10	.149
Fruits (I)	17	13.47	11.641	19.88	8.036	19.65	9.008	-2.389	16	.030	-2.601	16	.019
Fruits (C)	11	14.55	9.264	14.64	8.565	13.96	11.179	-.66	10	.949	.322	10	.754

Note: (C) denotes control group. (I) denotes intervention group. *n* denotes number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes significance.

Table E 4

Comparison of the Number of Dairy/Dairy Alternative Servings Per Week Between Intervention and Control Groups From Baseline to 12 Weeks and Baseline to 12 Months.

		Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
Variable	N	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2- tailed)	*t*	*df*	*Sig* (2- tailed)
Milk and Yoghurt (I)	17	12.71	9.196	3.41	7.107	6.32	8.191	4.247	16	<.001	4.031	16	<.001
Milk and Yoghurt (C)	11	10.05	7.670	9.77	7.505	8.14	4.433	.402	10	.348	.948	10	.183
Milk and Yoghurt alternative (I)	17	2.47	4.722	7.85	4.989	6.06	4.52	-3.698	16	<.001	-2.294	16	.018
Milk and Yoghurt alternative (C)	11	7.00	23.216	.64	2.111	1.91	4.527	1.000	10	.170	.770	10	.230
White cheese (I)	17	1.59	2.174	.68	.9673	.53	.8564	1.546	16	.071	2.045	16	.029
White cheese (C)	11	1.59	1.895	1.35	1.206	1.09	1.068	.575	10	.289	1.354	10	.103
Yellow cheese (I)	17	5.059	6.8895	.324	1.103	1.67	2.626	2.796	16	.006	2.681	16	.008
Yellow cheese (C)	11	2.23	1.539	1.68	1.055	2.23	1.752	1.636	10	.066	.000	10	.500
Soy cheese (I)	17	.15	.606	.15	.606	.00	.000	.000	16	.500	1.000	16	.166
Soy cheese (C)	11	.091	.302	.182	.405	.18	.405	-1.000	10	.170	-1.000	10	.170

Note: (C) denotes control group. (I) denotes intervention group. *n* denotes number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes significance.

Table E 5

Comparison of the Number Of High Fat Food Servings Per Week Between Intervention and Control Groups From Baseline to 12 Weeks and Baseline to 12-Months.

		Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
Variable	*n*	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2- tailed)	*t*	*df*	*Sig* (2- tailed)
Butter and margarine (I)	17	11.77	6.994	3.65	5.913	8.21	7.374	4.349	16	<.001	1.867	16	.080
Butter and margarine (C)	11	9.50	6.950	8.23	5.824	8.73	4.513	1.000	10	.341	.451	10	.661
Nut butters (I)	17	1.24	2.751	1.32	2.345	1.71	2.658	-.176	16	.863	-2.266	16	.038
Nut butters	11	.82	2.089	.82	2.089	1.09	2.023	NC	NC	NC	-1.936	10	.082
Oils (I)	17	5.74	4.887	2.00	3.808	5.56	5.483	3.516	16	.003	.143	16	.088
Oils (C)	11	5.00	3.808	4.82	3.881	5.00	3.808	1.000	10	.341	.000	10	1.000
Olives and avocado (I)	17	1,50	2.271	2.88	2.625	3.44	2.828	-2.878	16	.011	-3.484	16	.003
Olives and avocado (C)	11	2.41	2.406	2.68	2.305	3.14	2.430	-1.491	10	.167	-2.101	10	.062
Nuts and seeds (I)	17	4.27	4.667	4.85	3.686	5.21	3.632	-.708	16	.489	-.952	16	.355
Nuts and seeds (C)		5.46	7.860	5.23	5.777	6.14	7.750	.227	10	.825	-.801	10	.442

Note: (C) denotes control group. (I) denotes intervention group. *n* denotes number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes significance. NC denotes no change.

Table E 6

Comparison of the Number of Servings of Treats Per Week Between Intervention and Control Groups From Baseline to 12 Weeks and Baseline to 12 Months.

		Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
Variable	N	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2- tailed)	*t*	*df*	*Sig* (2- tailed)
Lollies (I)	17	.85	1.730	.21	.639	.941	1.776	1.575	16	.135	-.482	16	.636
Lollies (C)	11	.27	.467	.18	.405	.50	.806	1.000	10	.341	-1.456	10	.176
Chocolate (I)	17	.18	.3930	1.32	2.404	.65	1.693	1.902	16	.075	1.379	16	.187
Chocolate (C)	11	1.836	2.099	1.46	2.055	1.41	1.985	.329	10	.749	.166	10	.871
Jam/honey (I)	17	1.82	2.468	1.00	1.759	1.82	2.598	2.014	16	.061	.000	16	.1000
Jam/honey (C)	11	1.23	1.421	1.55	2.285	1.77	2.240	-.744	10	.474	-1.242	10	.243
Sweet bakes (I)	17	1.27	1.929	.32	1.103	1.47	2.080	2.186	16	.044	-.419	16	.680
Sweet bakes (C)	11	1.68	2.741	1.77	2.696	1.96	2.815	-1.000	10	.341	-.302	10	.769
Sweet desserts (I)	17	1.35	1.827	.912	1.513	1.32	1.904	1.085	16	.294	.063	16	.950
Sweet desserts (C)	11	2.50	2.086	2.41	2.177	2.36	2.134	1.000	10	.341	.191	10	.852
Salty snacks (I)	17	1.61	1.739	.500	1.118	1.47	1.763	2.755	16	.014	.515	16	.613
Salty snacks (C)	11	1.32	1.365	1.55	2.285	1.64	2.237	-.512	10	.620	-.744	10	.474
Pickles (I)	17	.71	1.687	.647	1.209	.647	1.209	.113	16	.911	.115	16	.910
Pickles (C)	11	1.18	1.875	.773	1.148	3.64	6.372	1.270	10	.233	-1.172	10	.268
Sauces (I)	17	3.24	3.692	1.44	2.128	1.74	2.450	1.838	16	.085	2.017	16	.061
Sauces (C)	11	2.55	2.797	1.77	2.696	1.77	2.696	1.150	10	.277	1.255	10	.238

Note: (C) denotes control group. (I) denotes intervention group. *n* denotes number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes significance.

Table E 7

Comparison of the Number of Beverages Per Week Between Intervention and Control Groups From Baseline to 12 Weeks and Baseline to 12 Months.

		Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
Variable	N	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2- tailed)	*t*	*df*	*Sig* (2- tailed)
Water (I)	17	24.65	13.210	36.65	9.434	34.59	10.921	-3.040	16	.008	-3.411	16	.004
Water (C)	11	25.27	14.015	27.91	12.692	25.36	11.570	-1.761	10	.109	-.029	10	.978
Coffee with sugar (I)	17	2.06	4.802	1.29	3.687	.41	1.698	.593	16	.562	1.461	16	.163
Coffee with sugar (C)	11	1.27	4.221	2.55	5.663	1.27	4.221	-1.000	10	.341	NC		
Coffee without sugar (I)	17	6.59	8.337	1.29	3.687	9.47	11.854	2.584	16	.020	-943	16	.360
Coffee without sugar (C)	11	7.86	10.383	10.41	12.435	11.36	15.135	-1.789	10	.104	-1.649	10	.130
Decaf with sugar (I)	17	2.53	8.538	2.12	8.477	2.47	8.552	1.000	16	.332	.098	16	.924
Decaf with sugar (C)	11	.64	2.111	.64	2.111	.64	2.111				1.461	16	.163
Decaf without sugar (I)	17	5.21	11.207	10.29	13.806	7	11.068	-1.746	16	.100	-1.234	16	.235
Decaf without sugar (C)	11	2.95	4.541	3.27	4.435	2.55	4.591	-1.000	10	.341	-1.000	10	.341

Note: (C) denotes control group. (I) denotes intervention group. *n* denotes number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes significance. NC denotes no change.

Table E 7 (cont.)

		Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
Variable	N	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2- tailed)	*t*	*df*	*Sig* (2- tailed)
Fruit juice (I)	17	.74	1.751	.32	.683	1.35	3.413	1.130	16	.275	-.714	16	.486
Fruit juice (C)	11	.82	1.454	.82	1.454	1.45	2.329				-1000	10	.341
Fruit juice blend (I)	17	1.15	3.427	1.41	3.658	1.71	4.634	-.559	16	.584	-.642	16	.530
Fruit juice blend (C)	11	.18	.405	.18	.405	.18	.405						
Cordial (I)	17	5	11.253	2.06	8.489	2.94	8.927	1.477	16	.159	1.426	16	.173
Cordial (C)	11	.09	.302	.09	.302	.18	.405				-1.000	10	.341
Flavoured milk (I)	17	4.74	9.172	5.76	12.676	3.56	8.902	-.370	16	.716	1.628	16	.123
Flavoured milk (C)	11	1.27	2.611	.18	.405	.18	.405	1.340	10	.210	1.340	10	.210
Alcohol (I)	17	1.76	3.755	.38	.961	2.85	7.348	1.541	16	.143	-.868	16	.398
Alcohol (C)	11	1.55	2.434	3.36	4.450	3.36	4.450	-1.429	10	.184	-1.429	10	.184

Note: (C) denotes control group. (I) denotes intervention group. *n* denotes number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes significance.

Table E 8

Comparison of the Eating Habits Between the Intervention and Control Groups From Baseline to 12 Weeks and Baseline to 12 Months.

		Initial		12 weeks		12 months		Initial to 12 weeks			Initial to 12 months		
Variable	N	Mean	SD	Mean	SD	Mean	SD	*t*	*df*	*Sig* (2- tailed)	*t*	*df*	*Sig* (2- tailed)
Days /week had breakfast	17	6.65	.862	6.82	.728	6.41	1.805	-1.376	16	.188	.775	16	.450
Days/week had breakfast	11	7	.000	7	.000	7	.000						
Days/week skipped lunch	17	1.00	1.871	.88	1.996	1.53	2.672	.382	16	.354	-1.089	16	.146
Days/week skipped lunch	11	.55	1.214	.27	.905	.27	.905	1	10	.341	1	10	.341
Days/week bought canteen food	17	1.53	1.00	1.06	.966	.71	.985	1.326	16	.102	2.313	16	.017
Days/week bought canteen food	11	1.27	.786	1.18	.751	1.00	.894	.559	10	.588	.896	10	.391
Added salt in cooking	17	1.35	1.00	1.65	.493	1.59	.507						
Added salt in cooking	11	1.27	.467	1.45	.522	1.45	.522						
Added salt at the table	17	1.41	.507	1.53	.514	1.53	.514						
Added salt at the table	11	1.45	.522	1.36	100	1.36	1.00						
Added salt in cooking and at table	17	1.71	.470	1.88	.332	1.88	.332						
Added salt in cooking and at table	11	1.73	.467	1.91	.302	1.91	.302						

Note: (C) denotes control group. (I) denotes intervention group. *n* denotes number. *t* denotes the ratio of the departure of the estimated value of a parameter from its hypothesized value to its standard error. *df* denotes degrees of freedom. *Sig.* denotes significance.

APPENDIX F: INTERVIEW GUIDES

Initial piloted interview guide

Final interview guide

Initial interview guide (piloted)

Greeting

Confirm that the participant is willing to participate and that they are willing for the interview to be recorded.

Use question Group A for Intervention group participants and question Group B for control group participants.

Group A questions

1. Describe your knowledge and understanding of diabetes reversal and whether you believed it possible to reverse your T2DM.
2. Describe the contribution made by your doctor to your understanding of diabetes reversal and whether any goals were discussed with you in relation to reversal and diabetes management.
3. Describe your experience as a participant in the CHIP and its usefulness as an intervention for Type 2 Diabetes reversal.
4. Describe your experience of adherence to lifestyle changes as recommended by the CHIP and advocated as a treatment option for Type 2 Diabetes.

Group B questions

- Describe your knowledge and understanding of diabetes reversal and whether you believe it possible to reverse your T2DM.
- Describe the contribution made by your doctor to your understanding of diabetes reversal and whether any goals were discussed with you in relation to reversal and diabetes management.

5. Describe your experience as part of a control group in a lifestyle intervention study.
6. Describe your experience of adherence to lifestyle changes you initiated or that were recommended by your medical team as a treatment option for Type 2 Diabetes.

These questions can be followed up with additional prompts to elicit clarification or deeper responses.

Examples of prompts:

Can you expand on that?

Repeat an answer and ask whether you have the correct understanding.

Can you give me an example of that?

Is this what you mean…….?

1. Complete the interview by asking whether there was anything else the participant would like to add.
2. Then thank them for their time.
3. Greeting

Final interview guide

Greeting

Confirm that the participant is willing to participate and that they are willing for the interview to be recorded.

Use question Group A for Intervention group participants and question Group B for control group participants.

Group A questions

1. Describe your knowledge and understanding of diabetes reversal prior to participation in the study and whether you believed it possible to reverse your T2DM.
2. Describe the contribution made by your medical team to your understanding of diabetes reversal and whether any goals were discussed with you in relation to reversal and diabetes management.
3. Describe your experience as a participant in the CHIP and its usefulness as an intervention for Type 2 Diabetes.
4. Describe your experience of adherence to lifestyle changes as recommended by the CHIP and advocated as a treatment option for Type 2 Diabetes.

Group B questions

1. Describe your knowledge and understanding of diabetes reversal prior to participation in the study and whether you believe it possible to reverse your T2DM.
2. Describe the contribution made by your medical team to your understanding of diabetes reversal and whether any goals were discussed with you in relation to reversal and diabetes management.
3. Describe your experience as part of a control group in a lifestyle intervention study.
4. Describe your experience of adherence to lifestyle changes you initiated or that were recommended by your medical team as a treatment option for Type 2 Diabetes.

These questions were followed up with additional prompts to elicit clarification or deeper responses.

Examples of prompts were:

Can you expand on that?

Repeat an answer and ask whether you have the correct understanding.

Can you give me an example of that?

Is this what you mean…….?

4. Complete the interview by asking whether there was anything else the participant would like to add.
5. Then thank them for their time.
6. Greeting

APPENDIX G: INTERVIEW RESPONSES

Participant's understanding of diabetes reversal

Participant's perception of diabetes education received and goal-setting

Participants belief about whether they could reverse their T2DM

Participants perceptions of collaborative goal setting with the medical team

Responses and examples of participants overall experience of the CHIP

Responses and examples of the elements of the CHIP participants enjoyed

Aspects of CHIP found to be helpful

Participant responses as to what was not helpful

Suggestions offered for improvement of the CHIP

Benefits of the CHIP as viewed by participants

Perceived role of the CHIP in reversal

Reported lifestyle changes made during CHIP

Difficulties experienced by participants that impacted adherence

Table G 1

Participant's understanding of diabetes reversal

Response: Having normal blood sugar levels
Examples: Mr A: "By looking at the, what you're eating and weight control, and some of those factors, it seems at least it can be, you can be brought back with your blood sugar's back to normal. Now, whether it's a complete reversal, I so that you're almost as it were cured of diabetes, I'm not medical enough to know whether that's what they're saying." Ms B: "That you, yea that your levels are down enough that it can be controlled through food and exercise" Ms K: "Being on, a on a diet that was such that it brought the sugar down to normal levels." Mr L: "Lowering of the blood sugars to normal readings. Blood sugars in to normal readings so, so that is constantly back to normal and that to me instead of having your spikes and all that."
Response: Having no symptoms
Example: Mr D: "Control like being able to control the symptoms and in complete reversal I'd be having very few side effects or symptoms."
Response: Having no side effects or effects on the body
Examples: Ms Me: "Reversal equates to changing or minimising the effects of diabetes on the body."
Response: Normal blood sugar levels without the use of medication
Examples: Mr B: "If you're on tablet form (of medication), and you control your weight and you exercise, then you might be able to reverse the diabetes and go off medication." Ms D: "Back to normal? so that I don't have to have any medication? Insulin and yes, everything. Okay, just get it back to normal". Ms F: "Well, I sort of think that it would be you wouldn't be on tablets or anything" Interviewer: So, it would basically be normal blood sugar without being on tablets? Ms F: "Yeah, yeah."

Ms J: “It’s reversing your sugars through diet and exercise and weight loss. A good range is when it gets to six …and you don't have to take medication for it.” Ms W: “I understood it to be the elimination of medication and your blood sugar levels getting to a normal range.”
Examples: Mr R: “…learning what to be, what to do, and how to train myself. I'm now fully fully not diabetic at all.” Mr S: “Reversal is to get your body where, like exercise and everything is to get your body out of that danger zone and back down to a level where ... See when I was on top of it, even Dr. M even said mate - he was, didn't class me as a diabetic in the finish.”
Response: That you only take ‘mild’ tablets to control blood sugar
Example: Ms E: “Reversal is it that you reverse the diabetics back to, back to pretty well, that you haven't got it and you're not taking you’re only taking mild well I take mild tablet and other than that now “
Response: Insulin levels are normal
Example: Ms E: “…….and insulin and that goes down”
Response: Retraining Islets of Langerhans
Examples: MS: Ma “So that's my understanding is basically you're retraining your, your islets of Langerhans of not having to work so hard to produce all that extra insulin.”

Table G 2

The degree to which the healthcare team discuss reversal with participants.

Response: Explained the role of diet and exercise in glycaemic control
Examples: Mr A: "…. they've explained to me the things I can do, to drop my blood sugar down, particularly…..And I have been certainly watching what I eat, I mean, the carbohydrates and that kind of stuff." Mr L: "Not diabetes reversal directly, only the way to live with it through the use of medicine and a dietician." Mr P: "Nothing, not really. No, not from a reversal perspective. It was a no, no….I don't remember that, I mean, ever sitting down with anyone and saying, Okay, we're going to work out a plan for how to reverse this. Okay. It was just for you, you got this and here's, here's the meds you need to take to manage it….. I mean, I suppose to be honestly, fair probably the doctor at the time did say something about something along the lines of, well, you know, if you did a lot more exercise and ate better, then you might not need the medication."
Response: Provided no option other than medication use
Examples: Ms B: "No, No, no option at all. He just put me on the tablet and said that you were on the verge and to keep me off being a diabetic that he'd use the tablets." Mr R: "No Not at all, all they talked about was medication, put me on medication, nothing to do with my problem. Not as good as the CHIP programme did."
Response: Doctor not spending time to discuss diagnoses
Examples: Ms B: "…. he's really queer, I reckon he's a man's doctor you know. He'll do anything for a man, but a woman all he wants to do is get her in and get her out of there…. I just find him you know, like rush in, rush out." Ms B: "He never really said anything to me about aw gees you know, the CHIPS programme has helped you, or he's never even mentioned, you know, even when I was on CHIPS, anything about it" Ms D: "But the doctors never really sat and talked to me about it……And he just told, 'Ah yes. you've got diabetes. And you have to take' he said. He was the first

one to give me medication, Metformin.” ….” I didn't know much about it until I came to the course.”
Response: Medical team talked about reversal
- Examples: Mr B: “They did. But for some reason or other, my pancreas, or you know, like, but when I was just on tablet form, and I tried everything, but it was the levels was still creeping up. The tablets weren't controlling it.” Ms K: “Maybe doctor T, initially.” Ms J: “They did when I was first diagnosed, and I did lose a lot of weight…. through diet changes. I was more aware of the diet, and they did recommend exercise of course.” Ms D: “And, and then…., when I heard about from you what you were saying. I went to ask C some questions, so that he was the one who told me few little things. Then, there was that lady who was the educator.”
Response: Explained as a slippery slope that would need more medication and possibly insulin over time
Examples: Mr D: “There’s was more of a control approach. They didn't really, they, they just saw it as getting worse, in my view, and um it just seemed to be a slippery slope, you know, you've had a [sigh] you know a progression from. Um it all seemed to start with medication, and then uh with me, [sigh] and I guess anyone who gets worse, uh you go into insulin. And the doses increase and then uh an insulin pump to cap it all. That was just just one of those. Uh, they weren't really offering any hope of uh. It was more of a control thing, trying to educate you to control.”
Response: Referred to CHIP for help but didn’t discuss reversal with respect to CHIP
Examples: Ms E: “No, he didn't but he did put me on to you for to to do the CHIP programme, so I'd say that he was thinking that way, but he didn't really talk about reversal, but he did say that. … he just one day said to me, hey he's got a programme you may be able to go on which might help you.”

Mr L: "…but it was never really mentioned to me that going, even when S mentioned that, about going to see you to contact you. He said, well, maybe this diet might work for you." Ms Ma: "No, no, no one's ever, ever spoken, except that I was referred to the CHIP programme from Dr. T. But he never actually spoke about it. He just said you; it will be helpful to do the CHIP programme." Ms Me: "But I was a bit surprised; at no time did any of the nurses or when I was first diagnosed, they didn't come up with options, but doctor T did discuss the CHIP program okay. As far as the staff at the- various staff at the W, no, no-one discussed it."
Response: Referred to a dietician
Mr L: "Like, initially, what had started it that was like, the dietitian bit. It was quite confusing, you know, like, the pinch of this and a sliver that and a piece of this, and nothing after three o'clock and all that sort of stuff. It was just here, there and everywhere." Ms W: "No, no, I'm sorry, I was straight to drugs and told to control my weight and eat less carbs. But then I did go on a program that sent me to a dietitian and a podiatrist and to have my eyes checked so that was all covered but really never ever given an option to reverse it. No."

Table G 3

Participants belief about whether they could reverse their T2DM.

Response: Didn't think it possible but had read about it. Curious to know more.
Examples: Ms W: "I did, I had been reading about it. I didn't think it was possible for me, but I was reading about people who were doing it and I thought and that was one of the reasons I thought I'm gonna find out a bit more about this because I don't know what to do."
Response: Had heard about it but sceptical.
Examples: Mr B: "I've heard of people you know who have got lost a lot of weight and gone on a really, really strict diet, but I don't think their diabetes was -had reached the level that mine had reached……. Because I've got this form of muscular dystrophy that I call a girdle dystrophy. I don't burn up as much as, as I haven't got as much muscle mass as a normal person." Ms Ma: …"I knew that from lifestyle changes, you could reverse a lot of things…" Interviewer: …."but practically you hadn't really had any experience of it? "Ms Ma: "And I didn't know anyone who had done it either"
Response: Didn't know about reversal and didn't believe it was something that could happen.
Examples: Mr D: "I'm not optimistic about reversing. I don't think one can magically get rid of it. You know, just the process you know can never, never be rid of it, in my view." Ms F: "I thought I thought you know; it was it was progress on to injections and whatnot… I just sort of thought was a natural progression to go off on to." Mr R: "I always thought, yea that diabetes was diabetes, and that was it. Once you got it, you got it."
Response: Was optimistic because had previous experience of reversal.
Examples: Ms E: "The only the only thing I used to do, and I could get it down…. was my exercises. If I made sure I did plenty of exercises I had got it down a couple of times.."

Response: Didn’t think it possible due to previous struggles.
Examples: Mr L: “No because I struggled so much with the instructions via the dietician. ……I don't know, I just, I just found it hard. I found it confusing.” Mr P: “…he didn't say it, but he thought and he said, This guy's never gonna change. He's gonna need the pills, rather than well... He was I think, he was right at the time.”
Response: Knew it was possible and depended on individual capacity and willingness.
Examples: Ms Me: “, because I’m an RN myself, I did. So, with what I had yes, I mean, we, that it would depend also very, very much on the person's wish, the person's capabilities.” Mr P: So when I was first diagnosed, ….they did say it was a lifestyle disease, but didn't really say anything about how it was possible to reverse it. If doctors could, when they sit their patient down for the first time and say, you've got type two diabetes, here are your options. One of those options was you can go on … a 12 week programme? It'll cost you 200 bucks or 300 bucks or you start spending, you know, 70 bucks a month on medication. …and I would have then gained a lot more knowledge, the knowledge I did end up getting from CHIP. I would gain all of that.

Table G 4

Participants perceptions of collaborative goal setting with the medical team.

Response: Team set goals.
Examples: Mr B: “Well, they do set goals and everything. But I don't think I could really reverse it and go off the off the medication. I think I've let it go too long.” Mr D: “The HbA1C seemed to be the determinant. And if you could get below seven, they were happy.”
Response: Teams don’t consult, they tell you what to do.
Examples: Ms D: “They just look at you. They don’t say anything you know. You don’t know really. I went to the doctor in Sydney, and I remember seeing the diabetic instructor or something like this every quarter and she tells you what you to do…. Never, never.” Mr L: “It wasn't it wasn't put across like that. And they still don't, you know, its still... it was just, well, this isn't happening. So, we'll give you some more medication. …..It's, it's completely different structure to the CHIP program you know. It's not... how it was more... chip was more interactive than going to a dietitian.” Mr R: “No, nothing…. they said Take care and be good. And take this medication”. Mr S: “Even the first time, it's all about; ‘well here's your, here's your authority. If you, if you need a physio, you get so many consultations and then when that runs out it lasts a year, come and we'll’… they get the sister to draw up the programme for you and then they sign it and away you go.” Ms J: “They recommended I went to a dietitian as well. They recommended um I went to the polyclinic at Toronto, and I went to like a information sessions there…. And I went back a few times after…. um yea to get information and you know to just talk about diabetes…. and um ask them about different… my diet and you know.”

Response: Teams don’t set goals with participants.
Examples: Ms E: “No, no, nothing I mean you know to eat properly and all that of course, but yeah, but no-one. Thats all.” Ms F: “No, they didn't. One doctor tried to steer me towards a dietitian” Ms Me: “Didn't even speak, didn't speak to anybody. Not in great detail? I think sometimes they know you're an RN they think, you know.” Ms W: “Another thing that I wasn't given, I don't test. I don't have, I don't do a test like a finger test. And, and sometimes I wonder if I should, you know. Am I just sort of floating around? …No, I mean, management was, you got to go, do your, have your eyes tested all the time, and podiatrist and see a dietitian. But, you know, even that's never been checked as…. I think when we started out there, there was a talk of, you know, there's you're under this plan, and you're going to be, but I don't think there's I haven't had any follow up anyway, and any talk about, you know, come in, and, you know, we'll measure you, weigh you. Look, I must admit, when I visit the doctor, I am weighed, and I'm always told, you know, people, you’ve put on weight and dadadadada, sort of thing. But no, I can't, I can't say I'm. I don't feel like I'm on any plan that I know of.”

Table G 5

Responses and examples of participants overall experience of the CHIP.

Response: Overall experience
Examples: Mr A: “I appreciated the CHIP program very, very much” Ms D: “Yes, I really enjoyed it. I really enjoy it.” Ms F: “It was good, thoroughly enjoyed it” Mr P: “I found it a really positive experience.” Ms Me: “It was a very nice personal and community touch.” Ms F: “The vegan diet. I really enjoyed that. Mr S: “The programme mate, it’s the best thing that’s ever happened.”
Response: Social experience
Examples: Mr. D: “I enjoyed it for the company and its educational” Ms D: “It was good that I've been able to meet people. And every twice a week and talk and you know, I've still got the lady's name….. And I really enjoyed and and I really waited for that day to come to come again to see everybody, just because you feel like as if your friends there you are in the same situation. So, you want to do something.” Ms F: “It was good, thoroughly enjoyed it, met up with people, you know, sort of that I hadn't thought I would….Yeah. I paired up with J. Mainly, we found out we lived there, four doors down from each other, you know. We both had the same sort of background as far as nursing went. Yeah, it was good. Yeah. And E, of course. came in, later and so, no they were good. D was always good news.” Mr S: “I can’t wait till the last Sunday (of the month) because I'll be driving the two hours down to Cooranbong for the CHIP dinner. …..that's something else about CHIP, you make friends for life.” Mr P: “I do actually enjoy that. Yeah, not everyone likes that kind of social gathering sort of thing. But I don't mind.” Mr P: “I found it a really positive experience. Yeah, I mean, I knew a lot of people which helped. But you know, even, even people who obviously, didn't know each other, soon felt encouraged by everybody. You know, it was a great camaraderie.”

Ms Me: “Oh, I quite enjoyed it. I think some people are quieter than others. It was good. There was a table at the back that was dominating a bit with the laughter and what have you, but that you can't. How do you stop that sort of thing? And it probably adds to the programme if the truth be known.” Mr S: “Well the best thing is everyone standing around the table watching you do it, and then when its prepared its almost; Everyone will have a portion and talk with one another like you're having, having a pre-dinner dance.”
Response: Spiritual experience
Examples: Mr S: “Mate you know what? CHIP, CHIP gives me the feeling what the same as finding the spirit and having him with me…. Suddenly, blew me away that I never knew.”

Table G 6

Responses and examples of the elements of CHIP participants enjoyed.

Response: Presentation
Examples: Mr A: “But I certainly appreciated the way it was presented, what was what I heard, what was presented. I give it top marks as far as that's concerned….I just felt it was all well organized, very well presented.” Ms D: “And the the course was very well done.” Mr L: “Very engaging” Ms Ma: “….and varied. There was nothing went for more than - none of it went for more than half an hour at a time and you were doing something else. So, it was attention getting. It was motivating. Ms Me: “But it was…well-modulated and, and what. You could not leave there and say, ‘I was bored’.” Mr P: “I liked the format of it, you know.
Response: Presenters
Examples: Ms D: And the people were really professional, you know, it was really good.” Ms Me: “with excellent presentation and speakers who are able to explain well the benefit of the healthy lifestyle.” Ms D: “Especially there were so many people that were nice…Zanita helped me with the writing down things, you know. That people were saying, and she was writing things down for me that was good.” Mr L: “You felt like that the whole team was very engaging.” Ms Me: “The speakers were excellent, knew their subject. It was interesting to hear from speakers with different backgrounds and cultures.”
Response: Content
Examples: Ms E: “…very interesting and very good.” Ms D: “And it was very easy to understand.” Mr D: “I enjoyed it for the company and its educational” Mr L: “Very…. informative, positive, educational and very descriptive.”

Ms Ma: “I thought the programme was so interesting I don't I can't conceive of a better programme actually.” Ms Me: “It was very informative…. It was a real learning curve.” Mr P: “…. some really valuable information. I thought that was really interesting. Modern, wasn't oldy oldy.” Ms Me: “The CHIP programme is excellent for understanding in all levels. The visual presentations were so easy to understand.” Mr L: “Information was not gobbly gook or, talking in riddles and everything, everything was a positive side of things. And like I say, very descriptive. That you can understand what was being said and why you know. ……And then to go into it in all such great detail…. Made it all come together or understandable.” Mr P: “Two things that stuck out to me was the information was, the factual information was, was good, you know. It wasn't mumbo jumbo. It was very clear and understandable.”
Response: Environment
Examples: Mr R: “comfortable with a whole group of nice people. …a great environment for me to learn”. Mr P: “It was basically a really encouraging environment to be in, you know. Once you realize that you were there to, you know, basically deal with an illness or disease that you're trying to combat. Everyone was in the same boat, you know, you didn't feel unusual. We were all there for a purpose.”
Response: Activities
Examples: Ms B: “…quite interesting down to the young boy that used to take us and do us the exercises.” Ms D: “The little part of it with exercise. It was really good. It was fun. I really enjoyed it.” Ms B: “I did did enjoy you know, like the discussions and everything you had with going through your book.” Ms Ma: “When L did the, the breakfast. I think it was her did the breakfast demo with the with the seven grains…They had they had bags of the grains there to buy as you left.”

Ms Me: ‘The practical, cooking were there… and the practical importance of cooking etc. Actually, the cooking things with another spear.”

Mr P: “Just the whole fun of doing that (food tasting), as well as the social exercise as well.”

Ms Ma: “I liked the practical examples of, you know, they had people going up the front to show their successes and how they had done well.”

Ms F: They were really good (monthly follow up). The food was good. Everyone bought a plate of course. The food was good. The lecture was good. As a rule, and they quite often demonstrated how to make most things.”

Ms Me: “…and it was a good one (monthly follow up) as far as keeping in touch with people.”

Table G 7

Aspects of CHIP found to be helpful.

Response: The format
Examples: Mr A: "The talks by Dr. H, I think it was, were very, were very helpful." Mr D: "Ah, the material like, and just a lot of factual information about the impact of some of the things like salt, too much salt in the diet or too much of the other things." Ms F: "And the lecture, I guess, you know, the. How should I put? The video." Mr L: "There was many, but to choose one I guess it would have to be the educational side." Mr A: "…the films that were shown were, were positive and helpful."
Response: The content
Examples: Mr L: "It gave me an awareness of what the different foods in you effects different parts in your blood, organs and body in general." Mr S: "Things like leaving the skin on the vegetables and that instead of peeling it off where all the vitamins are. I got to say not being a vegetarian lifestyle, you can see why they're living 20 years longer than the American and all that. But because what you're doing, you're cleansing your body, so that the system works."
Activities
Response: Food preparation
Examples: Mr D: "…. the food preparation, I thought that was significant. But yeah, being a male who, who doesn't really cook much." Ms F: "Well, the fact that they demonstrated how to cook was good, that part was really good. The book also was helpful, and the diet, the what do you call it the menu." Interviewer "You mean the cookbook?" Ms F: "The cooking part." Mr L: "And getting down to the demonstrations were good. Because you could go away and go. Oh, yeah. Well, that that tasted nice, or that was good, and that was easy to make."

Mr P: "…doing the food demos and stuff like that, which I think not only was useful to know how to make stuff, and that you could eat. You could actually try it out and, and see whether you liked it or not, as well.
Ms Me: "It's helped you find alternatives for like new recipes and……probably a greater use of grains. Okay, but which I don't think had entered my head much."

Response: Exercise

Examples:
Mr L: "At the start of the programme I was given a step counter and encouraged to get to a target of 10,000 steps a day.
Ms D: "The little part of it with exercise. And I think it did help a lot. It did help me It did help me."
Ms Ma "…and having the little bit of um you know cooperation with your group on um so many steps for the time, the days and, and all that, I thought that was motivating. And yeah, it was just everything was fantastic. And the map that A. put up of Australia to see how far we were walking, and all that was excellent. The cooking demonstrations were excellent. I can't fault it. It was a brilliant programme."

Response: Listening and support

Examples:
Ms Me: "As far as listening to the people you knew, that added a lot of credence…as far as we were concerned."
Ms Ma: "Everyone was excellently supportive."
Mr R: "Even when you go to the program was nice to get out and meet people and talk. It was good".
Ms Ma: "Everyone was excellently supportive. So, it was attention getting it was motivating. I don't, I can't conceive of a better programme actually."
Mr P: "And, yeah, it was basically a really encouraging environment to be in, you know, once you realize that you were there to, you know, basically deal with an illness or,or disease that you're trying to combat. Everyone was in the same boat, you know, you didn't feel unusual. We were all there for a purpose."

Response: Assessments

Examples:

Mr A: “They tested us, you know, beforehand and afterwards and, and that. They kept an eye on our how successful we were being in overcoming diabetes.”

Ms Me: “I personally feel that the pathology testing that's done at the beginning and the end.”

Table G 8

Participant responses as to what was not helpful.

Response: Nothing not helpful
Examples: Mr A: “No, there's nothing I would say, you know, ‘well do this, do this, instead of that kind of thing’ because I just thought the whole programme was very well presented.” Mr P: “Not, Not really, that I can think of no.” Ms E: “So I,…it's nothing that stood out that I'd say I didn't like that bit.” Mr L: “I feel I could not come up with anything.” Ms F: “I don't think. There wasn't anything that stood out as being, you know, obnoxious, or that I really didn't like, there's nothing that stood out. “ Mr R: “No nothing at all. Nowhere, no night was hopeless. No every night was helpful.” Ms B: “No, not really. As I said I found it quite interesting” Ms D: “No, I don't think so. I've never really came home and thought ‘Oh what was that that was not good’. No, no, no, no, no, it was very positive.”

Table G 9

Suggestions offered for improvement of the CHIP.

Response: Suggestions
Example: Mr S: “It’s better when you just walk in and you sit with who you want to…. It's okay, there's nothing wrong with having someone that like looks after that table. …. When you’re segregating people to the same table every week you're doing a 10 week course with the same five people. You don’t get the mix of 50 or 60 people …. where you come in and you swap around so you get to know.” Mr D: “For my point, maybe there was too much of a recipe side, but that's, that's just me. I think maybe that there was a little bit too much of the, the catering side.” Ms Ma: “They you know, they don't want to be called Vegan but it's like the vegan of the vegan that sort of. Do you know what I mean? That might be one criticism I had.” Mr S: “Aw look that CHIP dinner, and it's a great introductory…. If you can get people to open that up more. Advertise it to CHIPPERS that bring, that bring the one or two with them and introduce them to a CHIP dinner. That's how you can structure your next introduction of people for the next CHIP by making sure that CHIP dinners (on other than COVID-19) every Sunday night and get the names of the people before they go out.”

Table G 10

Benefits of CHIP as viewed by participants.

Response: Weight loss
Examples: Mr A: " I heard testimonies of people, you know, even losing weight and, and being transformed even in the short time of the CHIP program." Mr D: "And yeah, I've lost weight of late, I think I mentioned to you." Mr L: '…new clothing size."
Response: Well-being
Examples: Ms B: "I did feel a lot better because I was exercising you know. Doing the walking. Then I was walking a mile or two kilometres at least, least everyday sort of things. So, you know, health wise, I felt a lot better in myself too, and probably eating the right, you know, the right foods too. But yea other than that, that was good that part of it". Mr D: "I'm so happy that I do feel good…. I went through a stage where I was full on with post-traumatic stress, and I was on maximum doses of a lot of antidepressants. Well, I'm not in that situation now. It's still present, but it's not as bad as it was. …Some people say yes, if you improve the quality of your life and, and get the diet and exercise sorted out, then a lot of the other issues can be helped." Ms E: "Doing six k's in the morning, sets me up for a while…. it made me very much more energetic ……I think it's... that when you're feeling well and losing weight, you do feel better." Mr L: "My general health and well-being improved." Mr P: "I actually felt less tired. I don't know whether this is a bit of a hard one to judge as to whether it was a type of diabetes issue or other related factors. I mean, it could have been work related or stress related or whatever. But I did think at the time, that I was, I was feeling less tired than I had been." Ms Me: "…going to the CHIP programme, gave me a degree of joy."
Response: Improved indicators for other chronic diseases of lifestyle
Examples: Ms B: "Well, he hasn't never taken me off the tablets. But he said that I'm um, my levels are very good. The last time I went which wasn't that long ago, he did blood

tests on me, and he said my levels on everything was really good. …my cholesterol …. he did that, and he said even that was really good. Ms E: “I'm not on any blood pressure or anything now. He took me off them and my blood pressure is always very low, that's that's something I don't have to take anymore.” Ms F: “... my blood pressure dropped dramatically. So, I went off all medication for blood pressure.” Mr L: “After my 3 month course I had ….removal of blood pressure and cholesterol medication.”
Response: Longevity
Example: Mr D: “Oh, yeah, I'd say, it may have added years to my life. No joke it could have you know.”
Response: Diet changes
Example: Ms E: “I've changed my food so that's been good.”
Response: Knowledge
Examples: Ms E: “Learning about all the different health things.” Mr L: “It gave me an awareness of what the different foods in you affects different parts in your blood, organs and body in general? Mr S: “It's just taught me what you need to do and how to eat and everything”
Response: Social engagement
Examples: Mr S: “That's something else about CHIP…you make friends for life.”

Table G 11

Perceived role of CHIP in reversal.

Response: Made more aware of diet.
Examples: Mr A: “It made me more aware of my food. It certainly made me more aware that I should really knock my weight back. Ms B: “It’s made me more aware, definitely more aware of, um what I'm eating. I sort of watch everything now you know, when I buy anything…there's the sugar and the sodium content and things like that. Mr L: “It gave me awareness of what different foods can effect different parts of the bloods, organs and body in general.”
Response: More conscious of needing to lose weight
Example: Mr A: “It made me certainly reinforce my need to take steps to try and lose, lose weight.”
Response: Lost weight
Examples: Ms F: “I lost weight on it. That was good.” Ms Me: “Well, I lost weight”
Response: Aware of a need to be proactive about management
Examples: Ms Ma: ‘I haven't regularly tested blood sugar; I've just started doing that. I can. I did at the beginning of last week 7.8 and it was 4.4 this morning.
Response: Improved glycaemic control or diabetes reversal
Examples: Mr D: “Not really much. It got better, but not really reversing. Mr L: “After my 3-month course I had reached the goal of diabetes reversal with the removal of insulin” Ms Me: “I thought it was, produced results. I had a degree of weight loss. And daily testing of glucose levels showed me that was pretty well on track from, from what I was eating and choosing to do with the CHIP programme…… Can I say for me. I think the CHIP program, took my diabetes took it backwards it took a step backwards, and it probably saved me from having to go on to Metformin or insulin or whatever. Okay, so yeah. So, to me, it was positive in the fact that it holds the progress of my diabetes.

Mr P: “I felt that it stabilized me a lot to, to you know. While I was on the programme, things seem to just get stable, I wouldn't get any worse.

Mr R: “People saying I was diabetic. I'm not anymore. Doing the right thing here and you'll get rid it. At the CHIP programmes it enlightened me do, yeah. I can get rid of this. B got me onto the CHIP programme and show me a whole different aspect, to control this by eating right and doing the right things and exercising. Which I done. Definitely, I’m not a diabetic anymore. Levels range between five and seven and a bit, never over never under.

Response: Freedom to make educated health decisions.

Examples:

Mr D: “It's given me the freedom because I'm more educated. And I just reap the benefits you know. I know if I don't do that, then things will go wrong. Long term, especially if you have a disease like diabetes, but I like to feel I'm in control still. But I do it in a way that a more educated me is conducting my lifestyle through adopting the ideas that come from came to me from the CHIP programme. Again, it's it's an education, it's part of an education.”

Table G 12

Reported lifestyle changes made during the CHIP.

Response: Exercise during CHIP (intervention group)
Examples: Mr D: "…. walked further than I used to. And yeah, just took the stairs. Like, park the car further, you know, little things like that. Further away from where I had to go, and there was no trouble to walk, and it's still no trouble. I allow enough time but if I can exercise on the way, that's the sort of exercise I like, I'm not one for going to gyms and going on treadmills or machines or anything. I just love incorporating it into my life through places I've got to go and seeing that I'm getting the benefits. It's been good." Ms B: "I was a lot more active then than what I am now. See before I did the walks. and that but my knees have just got so bad you know both of them and my back well I just find problems doing even doing the walking and that now. Ms D: "I don't do a lot of exercise because I just can't do a lot of exercise…. So I'm trying to do more of doing things because I walk a little bit more in the house and outside and doing little things to keep me busy….Just, I'm doing a bit more exercise. Like you know, as my children live just behind me, so I can walk from my fence to D's place and things like this…I don't do it in on the road because I'm always frightened of falling…, so I do it alone in my house about 10 times and then I do it going to D's place at the back you know. And then there's … I don't know if it's the government who did that, they've sent me to see a lady who does who does exercise for diabetics. It's about the same thing that the gentleman taught us when we went for the course. You know there was a gentleman there who showed us what we are to do.
Response: Regular exercise (Control group)
Examples: Mr B: "I like exercising. I do a fair bit. I go for a kayak for an hour and a half. For my walking around, with my monitor thing, me watch you know, I get up to six or seven thousand steps a day. Now I go to the gym. And I do I go to the gym twice a week and I kayak and do gardening and go for walks. ….doing weights and yeah, like the weights I do, I can't lift heavy weights, but I do a lot of repetitions." Ms K: "Walking about the same 3k a day. We have a 3-storey house now, so I'm up and down the stairs, like a yoyo.

Response: Diet during CHIP (Intervention group)
Examples: Ms D: “I can't say….at home we are all fully vegetarian. S is 100%. I am 80% because I used to eat a little bit of chicken. But now I've stopped that as well. So, I don't think you know, it was not difficult to follow the, the recipes or whatever.” Ms Ma: “What do I put? …. About 11 different components to the salad I counted. You know it's like I've got kale in the garden, kale, carrots, beetroot corn, pineapples sometimes. All that sort of thing it's just just a big, it’s a big plate of salad. Mr L: “I still still do the vegetarian side of things.” Mr P: “Even, even of very recent times, you know, so, I've been looking at what we eat and and, and looking at growing more food in the garden and looking forward to being able to enjoy you know, that produce. And being able to do those sorts of things added a bit more sort of excitement to the whole you know, diet side of things.”
Response: Diet (Control group)
Examples: Ms J: “I'm probably even trying to lower them (carbohydrate exchanges). They recommended. I think they recommend 45 grams in a meal, but I try to even get less than that. I don't think in my opinion. I don't think I really need as many of what they say. Ms W: “I mean, I cannot understand people who don't eat vegetables, it's like, it can’t be real, you know, you cannot get through life without eating vegetables.” Ms K: “And we have gone mainly vegetarian anyway”

Table G 13

Difficulties experienced by participants that impacted adherence.

Examples:
Difficulty in losing weight
Examples: Mr A: “Anyhow, it’s easier said than done, well, at my age, I'm finding.” (losing weight) ….I just wish that this process of losing weight, could, could accelerate you know, because it would make a difference. From what I've read, and what I've heard at CHIP, it would make a difference to my to my diabetes overall.” Ms W: “It's harder to control to control (weight) when you're in midlife. I do get disappointed, because I feel like at times, I work really hard. You know. I have this soup that I made that has 12 vegetables in it and I love it. I can eat it morning, afternoon dinner and tea and I love salads. And I drink black tea with lemon and no sugar. And I love it, but they're not enough.” Mr B: “And my weight, it could be less. I’m 90 kilos or 89 kilos. But I think yeah, because I'm heavy. I think I'm just heavy boned. I've always been like that. But I've never…. I was 95, and I've got it down to 89 ,90. now, but I find it very, very hard to get below that.” Mr L: “I still, I probably want to try and get under the 100 kilos bit. I come from originally was 128 I think it was when I first started.” Ms Ma: “Well, I've been overweight all my life and that was my most major motivation that. I wasn't really thinking diabetes at the time because I've been a bit naughty. I've never been particularly conscious of my diabetic state.”
Difficulty exercising
Examples: Mr B: “I like exercising. Oh, yeah. I tire more now being. 76 But I do a fair bit. I go for a kayak for an hour and a half. For my walking around with my monitor thing, me watch you know. I get up to six or seven thousand steps a day.” Ms B: I get pains in My leg. Probably lack of exercise more than anything else. I should walk more. You know, I feel as though I'm coping as well as I can. I turn 80 this year.” Mr A: “because I haven't been able to walk at all, really. I've started some walking recently and with a walker, which does help me to walk but I'm still limited in the

distance I can walk because of the pain in the back. I mean, I did some work this morning. And when I go out into the garden, I really pay for it after a very short time the garden. So certainly, and I've had that back problem for such a long time. But it's it's certainly been getting worse in the last couple of years. Yeah, …. But it's still it is a little bit of the pain, but not not very much. And it's been been added to and I'm sorry to be sounding though I'm complaining a little bit it's been added to by the fact that I've been given, being treated for not that much success for bursitis in my right leg. And my the bursitis, you know, I've had several steroid injections into the leg to try and relieve the pain there, but that pain, while it's quite intense in the morning, because of maybe the way I've layed, laying in bed all night sort of thing. But while that's bad in the morning, when I get on the bike that is considerably eased up on not, not my back pain, but my bursitis. I mean, if I could be free of the back pain, life would be so different.

Ms F: I'm not good at exercise really. No, I had a double hip replacement…. I don't, don't walk a lot nowadays. My leg won't let me…I don't use one of those (stationary cycles). …

Ms Me: "but I've had major surgery three years run running on hips and knees"

Mrs D: "I started to put a lot of weight around my waist without me eating and it just, it (weight) was stable. It was stable until I had my operation. That's when everything was just went crazy. "

Ms Ma: I wouldn't be home before 10 o'clock usually and that, that probably was one thing why I stopped doing it was the time factor. It wasn't a conscious decision to stop it just was just ended up taking up too much of my time, you know.

Mrs D: "I started to put a lot of weight around my waist without me eating a . And it just, it (weight) was stable. It was stable until I had my operation. That's when everything was just went crazy."

Response: Difficulty with diet

Examples:

Ms W: "I actually felt quite guilty about it, too. I always felt that diabetes is kind of a disease of being overindulgent. You know, and I didn't feel very pleased or felt, you know, really not not good about myself having that diagnosis. I don't like even talking to people saying, I've got diabetes, I really feel."

Ms W: I mean, I'm associating pleasure with eating food, and that's wrong, but, but it was how we were brought up, you know, there was always, if you're a good girl, you'll have an ice cream, you know. That conditioning, that you've been rewarded by food, by a lolly by an ice cream buy, a dessert with your meal or something like that. It was always associated with a with a pleasure."

Ms B: "I'm always going to be a meat eater."

Ms F: "I mean cooking and I have absolutely You know, miles apart. I hate cooking….I had to go on red meat again because my ferritin level dropped. That's the only reason I went off the vegan diet."

Mr B: "It's very hard, especially when you're living on your own to cook your meals you know. And in the wintertime, I'm not a great salad lover. I like salads in the summer.

Mr S: "Because I live on my own, and I'm lazy, and all the mucking around to get to that stage preparing all that meal.

But when you live on your own it's just awful drinking and eating on your own. You can eat your meal but it's not the same as having some company sitting there eating it with you".

Ms E: "Sometimes it was very hard in the beginning of working out especially when you went out trying to find something to eat.

Ms W: "You're brought up to want to please and to serve a meal that everybody loves, and it tastes nice. And and it is it's just being strong, and I guess it's putting yourself first too and not second, third, fourth behind everybody's else's wishes, you know.

Ms D: And that I must admit that in Mauritius, I probably didn't do as well, because, you know, back in there, we ate a lot of bread and a lot of rice even though I tried not to, to eat all that. Vegetables, there were plenty. But I've got a feeling that sometimes because I love bread so much. I've been cheating a little toast in the morning or something.

Ms Ma: One, one criticism I have of the CHIP programme, if I was gonna give any was, I think it's very. It's a very isolating kind of eating pattern. It seemed to be very you know all this cashew butter for your bread and all that sort of thing.

They, you know, they don't want to be called Vegan but it's like the vegan of the vegan that sort of. I think you can eat healthy without it being cardboard. You know what I mean? Okay, so I never I never got on to the cashew butter thing.

The diet was, was very socially unfriendly. Well, I was brought up as a strict vegetarian. But over the years, I kind of got sick of eating omelettes. If ever you were on a plane and you wanted a vegetarian meal that was an omelette. It was very antisocial then and I just I sort of got into the habit of eating chicken occasionally and I don't really know how to cook fish well. I'd probably eat more fish but. Well, I can only say that that strict chip diet would be extremely anti-social to maintain. And you use the word isolating, you know, which I think is quite accurate. You could barely eat with anybody else. You know, without it being noticeable and becoming a topic of discussion all the time, you know what I mean. Anyhow, I'm eating healthy and feeling really good."

Mr B: "And it was very hard. I found it very hard to stick to a really rigid diet, where even though I exercised and everything. It's quite easy, but to stick to a really strict meal diet, you know. The way they explained it was, and which I think is the best way to explain it to people. Rather than dieting, you know, they said, your carb intake. Like …you should have two servings of carbs per meal to keep your levels down. Women are a little bit less. And two servings of carbs like oatmeal, like for breakfast are one piece of bread is one serving. So, if you had baked beans, you could only have that'd be your two servings your piece of toast and your baked beans.

Ms J: "Although restaurants and things got a little bit better with healthier eating. But I mean, I know I was never a McDonald person or anything. But um, Yeah, you know, it was hard when you went out to eat. Some of the menus weren't good. You know, we had to try and get, order something. But I was always aware of it and always tried to do the right thing."

Mr S: The difficult thing is when you haven't been a vegetarian or vegan or that like plant-based diet and it's all your life. It's, it's hard to eat like a rabbit all the time. What it is, when you go to a restaurant,

Mr S: "The CHIP programme we do every Sunday, last Sunday month. If I could eat that food every day of me life. I mean like I'd be on top of the world because you know that vegetarian love, so that when you go, yeah, I know you can go, go to a supermarket. But if you want to, if you want to buy bites and couscous all that made up, without mucking around, it's expensive. It's expensive mate. The only way it's not expensive, if you're eating, just trying like to eat your veges and you're cooking and doing it yourself.

Ms B: But I've found with my partner, because he eats meat too yea, he's a big meat eater, but me, I, I like my steak. If I had somebody here with me that was more into doing things, I would be a lot more inclined to do, you know stick to the programme. Yeah, but because my partner you know, being, like he's German and yeah.

you just find it very hard you know when you gotta cook for someone…. Myself, I would have no problem sticking virtually to it. But just being sort of I don't know. You just don't want to cook one meal for you and with our one meal, eat something else yea, and especially, especially being on a pension, you just can't afford to do those sort of things. I just thought I'm not cooking two separate things all the time."

Stress

Examples:

Mr D: "I kind of clammed up for a bit there you know when I was full on with the depression and the post-traumatic stress. I just lost interest in so many things. But now I just love things like taking photos and learning how to use what's available to produce good results and I love reading books and watching documentaries. I'm very interested in like the Bible and issues around religion. That, that dominates a lot of my thoughts and I do enjoy things like looking into the history you know, around the say 200 years before and after Christ's time on Earth and I find what went on most interesting.

Ms D: "So, and the situation at home was not very good at all. And I was so stressed. And, and I know that this would have put, made it (blood sugar) go up. Yes. And because I was so stressed out, I was discouraged…. I was so, so, so angry you know. And I just, you know, very, very bad. But that's the thing you know. How can you try to put, bring your blood sugar down, when you're always stressful when you're always you know, you can't do whatever you want to do, because you have to follow the orders and the guidance of everybody else. No, that was that was very bad. Yeah, but as I tell you. At the moment I'm a bit calmer so I'm trying to do really well. Well, well trying what I can, and I can find that the blood sugar is going down. Some circumstances sometimes doesn't help. And you're not linked to the right thing and I'm doing, then something happens and then you get so stressed and so nervous. And you sort of can't really do what you want to do. You do the wrong thing. And so that's the only thing that really got me.

Being with people in a .... Which I think having the same problems that I am, made me think, you're not alone. You're not the only one. So it just gave me more you know, courage to go on and to do things you know. And people were just so nice and friendly and helpful and everything. So, I felt I felt like I belonged in the in the group you know. Ms E: “I've put a couple a couple of kilos in the well the last last couple of months but I've had I've got a sister in Perth that's in palliative care so I think that's been a bit of a stressful thing on me that I know I've got to get that back off very quickly but they will come off in very - you know I've started to settle down with that and of course I can't get over there you know that's been hard. o but yeah, now my weight has really been pretty well except for these last couple a couple of months it's put a cap on that”. Ms J: “And I think it does, really, because I am a bit of a stressed person. I think that really does raise your blood sugar, you know, by stressing and stuff like that. So, a couple of years ago, probably three years ago now when I was having a lot of stress at work. And yeah, that's when my blood sugar went up again. I think a lot was to do with stress. I broke up with my partner and in the same year my mom passed away.” Mr P: “I'm finding a lot harder to do them on my own, you know. Then, then I felt I could do. When I was going along to the, to the sessions, and everyone was sort of jeering everyone along. My family were very supportive of me doing it for me. But it's, it's still very hard, you know, when the rest of the family are just doing what they're normally done. We have made changes. We've done things differently since I started doing CHIP but only little bits. And although I could probably cope with a quite a radical change, if it was just me, you know. I have to factor in that we're cooking for more than just me, and, and so it's very easy just to resort to the usual the same old, same old. So I just found it hard you know. It's probably, probably that I just need to be a bit stronger about it, but I haven't been strong enough.”
No difficulty
Examples: Ms F: “It's didn’t bother me at all. I just chose if I went out to dinner, I just chose food without meat. You know, or fish or anything.” Ms K: “You just got to buy the right stuff. I think it's quite easy… No, no you just choose, choose carefully.”

Mr D: “It was seamless with me. I just adopted the, the ideas you know and introduced them into my life. I didn't see it as a magic fix. I'm probably less optimistic than some folk. But yeah, I just seamlessly incorporated the principles into my lifestyle. And, and it has worked.”

Ms J: “Just I found it an easy diet to follow, because I think yea it was easy”