The feasibility and efficacy of the type 2 diabetes PULSE (Prevention Using LifeStyle Education) randomised controlled trial: a self-administered, gender-tailored, multi-component lifestyle intervention for men at high-risk for type 2 diabetes

Elroy Joseph Aguiar

BBiomedSc (Hons class 1)

The University of Newcastle, Australia

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Statement of originality

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Name: Elroy Joseph Aguiar

Date:

Supervisors

Primary supervisor

Professor Robin Callister

Priority Research Centre in Physical Activity and Nutrition

School of Biomedical Sciences and Pharmacy

Faculty of Health & Medicine

University of Newcastle, Australia

Co-supervisors

Professor Philip Morgan

Priority Research Centre in Physical Activity and Nutrition

School of Education

Faculty of Education & Arts University of Newcastle, Australia

Professor Clare Collins

Priority Research Centre in Physical Activity and Nutrition

School of Health Sciences Faculty of Health & Medicine

University of Newcastle, Australia

Professor Ronald Plotnikoff

Priority Research Centre in Physical Activity and Nutrition

School of Education Faculty of Education & Arts

University of Newcastle, Australia

Publications, presentations and awards arising from this thesis

This thesis includes a number of published/submitted manuscripts. To date, two have been published, one is accepted (in press) and one has been submitted to a journal for consideration. I have also presented research arising from this thesis at national and international conferences, as well as delivered a number of community presentations. During my candidature, I have also received a number of scholarships and awards. The details of these publications, presentations and awards are outlined below.

Manuscripts in peer-reviewed journals: Published/accepted for publication

1. **Aguiar EJ**, Morgan PJ, Collins CE, Plotnikoff RC, Callister R. Efficacy of interventions that include diet, aerobic and resistance training components for type 2 diabetes prevention: a systematic review with meta-analysis. *Int J Behav Nutr Phys Act.* 2014;11. doi:10.1186/1479-5868-11-2. Impact factor: 4.110 ISI Journal Citation Reports

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2. **Aguiar EJ**, Morgan PJ, Collins CE, Plotnikoff RC, Young MD, Callister R. The PULSE (Prevention Using LifeStyle Education) trial protocol: a randomised controlled trial of a Type 2 Diabetes Prevention programme for men. *Contemp Clin Trials.* 2014;39:132-144. doi:10.1016/j.cct.2014.07.008. Impact factor: 1.935 ISI Journal Citation Reports

Aguiar EJ, Morgan PJ, Collins CE, Plotnikoff RC, Callister R. Characteristics of men classified at high-risk for type 2 diabetes mellitus using the AUSDRISK screening tool. *Diabetes Res and Clin Prac.* 2015; 108(1): 45-54. Impact factor: 2.538 ISI Journal Citation Reports

3. **Aguiar EJ**, Morgan PJ, Collins CE, Plotnikoff RC, Young MD, Callister R. Reductions in weight and HbA_{1C} following a 6-month self-administered, gender-tailored lifestyle intervention for men: the type 2 diabetes mellitus PULSE Program randomized controlled trial. *Am J Prev Med.* 2015 (in press). Impact factor: 4.527 ISI Journal Citation Reports

Conference presentations

1. **Aguiar EJ**, Morgan PJ, Collins CE, Plotnikoff RC, Callister R. The effectiveness of multi-component type 2 diabetes prevention programs including diet, aerobic exercise and resistance training: a systematic review and meta-analyses. Australia New Zealand Obesity Society, Auckland, New Zealand, 2012. *Obesity research and clinical practice*, 2012, 6 (S1): 79. (doi: http://dx.doi.org/10.1016/j.orcp.2012.08.162). Poster presentation

2. **Aguiar EJ**, Morgan PJ, Collins CE, Plotnikoff RC, Callister R. Effectiveness of lifestyle interventions including resistance training for type 2 diabetes prevention: a systematic review and meta-analysis. Sports Medicine Australia "Be Active", Sydney, Australia, 2012. *Journal of Science and Medicine in Sport,* 2012, 15(S1): S49.

3. **Aguiar EJ**, Morgan PJ, Collins CE, Plotnikoff RC, Callister R. Preliminary outcomes from the PULSE randomised controlled trial - a multi-

component type 2 diabetes prevention program for men. Australia New Zealand Obesity Society, Melbourne, Australia, 2013. Oral presentation.

4. **Aguiar EJ**, Morgan PJ, Collins CE, Plotnikoff RC, Callister R. Characteristics of men evaluated as at high risk of type 2 diabetes based on the Australian diabetes risk assessment (AUSDRISK) tool. World Diabetes Congress, International Diabetes Federation, Melbourne, Australia, 2013. Digital abstract.

5. **Aguiar EJ**, Morgan PJ, Collins CE, Plotnikoff RC, Callister R. Improvements In Biomarkers Of Type 2 Diabetes Risk Following A Home-based Lifestyle Intervention: The PULSE Randomised Controlled Trial - A Multi-component Type 2 Diabetes Prevention Program For Men. International Congress on Obesity, World Obesity Federation. Kuala Lumpur, Malaysia, 2014. Poster presentation.

6. **Aguiar EJ**, Morgan PJ, Collins CE, Plotnikoff RC, Callister R. Improvements in weight, HbA1C and fitness following lifestyle intervention: the PULSE trial for type 2 diabetes prevention in men. Sports Medicine Australia "Be Active". Canberra, Australia, 2014. *Journal of Science and Medicine in Sport,* 2014, 18(S1): e68. (doi: http://dx.doi.org/10.1016/j.jsams.2014.11.298). Oral presentation.

*Asics medal winner (best paper overall) and Asics best new investigator (physical activity and health promotion).

Awards arising from this thesis

1. Australian Sports Medicine Federation Fellows Award - Asics Medal for best paper overall. Sports Medicine Australia "Be Active". Canberra, Australia, 2014.

2. Australian Sports Medicine Federation Fellows Award - Asics Award for Best New Investigator - Physical Activity and Health Promotion. Sports Medicine Australia "Be Active". Canberra, Australia, 2014.

Community presentations and media appearances

1. Radio interview – ABC Newcastle - Show us your PhD Interview (2012)

2. Radio interview – 2NUR (multiple, 2012)

3. Invited speaker – QR National training day – Men's Health, weight loss and Type 2 Diabetes (2012)

4. Invited Speaker – HMRI donors meeting – Anglican Men's dinner group - Men's Health and Type 2 Diabetes (2013)

5. Invited Speaker – HMRI donors meeting – Probus - Men's Health and Type 2 Diabetes (2013)

6. Invited Speaker – Lions Club International District 201N3 convention – The PULSE type 2 diabetes prevention study (2013)

7. TV interview – NBN (NINE) – HMRI Medical Research week - http://www.nbnnews.com.au/index.php/2013/06/06/medical-research-week-episode-3-solving-mystery-of-brain-tumour/ (2013)

8. University of Newcastle media interview - University of Newcastle Foundation Scholarship – "Donation funds research into Type 2 Diabetes prevention in at risk men" (2013)

9. Newspaper interview - Newcastle Herald - Bequest helps battle diabetes (2013)

10. Invited Speaker – Rotary club (Belmont) –- The PULSE type 2 diabetes prevention study (2014)

11. Invited Speaker – HMRI Open Day – The PULSE study - a type 2 diabetes prevention program for men (2014)

12. Invited Panel interviewee – University of Newcastle Foundation Donor meeting (2014)

13. Web Interview - Sports Medicine Australia – Asics medal award interview http://sma.org.au/2014/10/newcastle-researcher-awarded-for-tackling-type-2-diabetes-in-men/ (2014)

14. Magazine interview – Sports Medicine Australia: Sport Health Magazine, Spring 2014. Asics medal award interview (2014)

Scholarships held

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1. Callister, R., Morgan P.J., Collins, C.E., Plotnikoff, R.C., Aguiar, E.J. (student researcher) HMRI Diabetes Project Grant (Lions District 201N3 Diabetes Foundation), 2012. "Feasibility and efficacy of a diet and exercise prevention program for men at high risk of Type 2 Diabetes". *$51960*

2. Callister, R., Morgan P.J., Collins, C.E., Plotnikoff, R.C., Aguiar, E.J. (student researcher). HMRI and Aurizon (QR National) NCGF, 2012. "Reducing mid-aged men's risk of Type 2 Diabetes". *$19680*

3. Callister, R., Morgan P.J., Collins, C.E., Plotnikoff, R.C., Aguiar, E.J. (student researcher) HMRI Diabetes Project Grant (Lions District 201N3 Diabetes Foundation), 2013. "Long-term follow up of the PULSE Type 2 Diabetes prevention program for men". *$24900*

Contribution to this thesis

The central component of this thesis was the development and evaluation of the PULSE Program trial. As the sole PhD student and project manager of this trial, I have been intricately involved in all aspects of the trial from conceptualisation of the research project, to the implementation and evaluation of the trial. This included significant contributions towards the following:

- Drafting of grant applications

- Drafting of ethics, safety and clinical trial registry applications

- Development of PULSE Program intervention components

- Selection of outcome measures for the trial, development of assessment protocols, and training of research assistants

- Participant recruitment, including radio interviews

- Organisation of data collection, including management of staff and participants

- Data management and statistical analysis

- Drafting of manuscripts arising from this trial. To date, I am first author on all manuscripts

- Presentation of the results of this trial at national and international conferences

- Presentation of the results of this trial to funding bodies and community organisations

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List of common abbreviations

This list represents the common abbreviations used in the main text of the thesis. Additional abbreviations in are defined within chapters at first use and in the bottom row of tables.

AUSDRISK – Australian Diabetes risk tool

BMI – Body Mass Index

CI – Confidence Interval

DPP – Diabetes Prevention Program

DPS – Diabetes Prevention Study

E% – percentage of total energy intake

FPG – Fasting Plasma Glucose

GI – Glycaemic Index

HbA_{1C} – Glycosylated Haemoglobin

HOMA-IR – Homeostatic Model Assessment-Insulin Resistance

IDF – International Diabetes Federation

IFG – Impaired Fasting Glucose

IGT – Impaired Glucose Tolerance

MVPA – Moderate-to-Vigorous Physical Activity

PULSE – Prevention Using LifeStyle Education

QUICKI – Quantitative Insulin Sensitivity Check Index

RCT – Randomised Controlled Trial

RT – Resistance Training

SD – Standard Deviation

SHED-IT – Self-Help, Exercise and Diet using Internet Technology

T2DM – Type 2 diabetes mellitus

Thesis abstract

The rising prevalence of type 2 diabetes mellitus (T2DM) is a global health concern. Seminal trials have demonstrated the strong efficacy of lifestyle intervention for T2DM prevention, however several evidence gaps have been identified in the existing T2DM prevention literature, namely, a lack of lifestyle interventions that: i) are pragmatic and scalable, ii) are gender-targeted for men, and iii) utilise a multi-component approach combing diet modification, aerobic exercise and resistance training. Thus, the central component of this thesis was the development and evaluation of the *PULSE (Prevention Using LifeStyle Education) Program*, a 6-month, self-administered, gender-tailored, multi-component lifestyle intervention for men at high-risk for developing T2DM. The primary aim was to evaluate the feasibility and efficacy of the PULSE Program for improving a range of risk factors strongly linked with T2DM development, including weight (primary outcome) and glycaemic markers. This thesis is presented as a series of manuscripts that address the primary and three secondary aims related to the development and evaluation of the *PULSE Program*. Secondary aims 1 and 2 are presented first as they provide the context for the main analysis of this thesis.

Secondary Aim 1: To systematically review and meta-analyse the current evidence regarding multi-component lifestyle interventions (diet, aerobic exercise and resistance training) for type 2 diabetes mellitus prevention in adults at high-risk or with prediabetes

A systematic review was conducted to synthesise the evidence from T2DM prevention lifestyle interventions employing a multi-component lifestyle approach. In total 23 articles arising from 8 trials met the eligibility criteria. Methodological quality was mixed, with four of the eight trials classified with a high risk of bias. Meta-analysis favoured interventions over controls for weight loss (-3.79 kg [-6.13, -1.46; 95% CI], Z = 3.19, P = 0.001) and fasting plasma glucose (-0.13 mmol.L^{-1} [-0.24, -0.02; 95% CI], Z = 2.42, P = 0.02). The results of this systematic review support a multi-component approach for T2DM prevention.

Secondary Aim 2: To describe the characteristics of men identified at high-risk for developing type 2 diabetes mellitus using the Australian Diabetes Risk Assessment (AUSDRISK) tool, and determine the ability of the tool to identify men with prediabetes and metabolic syndrome

An analysis of the characteristics of men (n = 101) identified as at high-risk for developing T2DM (AUSDRISK score ≥ 12) was performed to evaluate the performance of the AUSDRISK tool. In total, 70% of men displayed elevations for FPG or HbA$_{1C}$ in the prediabetes range. Further, 62% were classified with metabolic syndrome. This study demonstrated the good ability of the AUSDRISK tool to identify men with substantial risk for the development of T2DM.

Primary Aim: to evaluate the feasibility and efficacy of the PULSE Program for improving a range of risk factors strongly linked with type 2 diabetes mellitus development, including weight and glycaemic markers in men at high-risk for developing type 2 diabetes mellitus

A 6-month assessor-blinded, parallel-group randomised control trial with wait-list control group was conducted to assess the feasibility and efficacy of the *PULSE Program.* Men in the intervention (n = 53) group received the *PULSE Program,* which consisted of print and video resources regarding weight loss (*SHED-IT Weight Loss Program*), and two novel components focused on diet and exercise modification for type 2 diabetes mellitus prevention. The wait-list control group (n = 48) received no information until six months. The primary hypothesis was supported, i.e., men who received the intervention experienced greater weight loss and improvements in glycaemic markers at six months (immediate post-program and primary time point) compared to men in the wait-list control group. Group-by-time differences (mean [95% CI]) favoured the intervention versus control group for weight loss (primary outcome; -5.50 kg [95% CI: -7.40, -3.61], P < 0.001, Cohen's d = 1.15) and HbA$_{1C}$ (-0.2% [95% CI: -0.3, -0.1], P = 0.002, d = 0.64). Changes in self-report dietary intake and physical activity (objectively measured and self-report) failed to reach statistical significance, despite within intervention group effects.

Secondary Aim 3: To conduct a process evaluation of the PULSE Program randomised controlled trial to examine the trial's design and its intervention program.

A process evaluation was conducted at six months to evaluate the feasibility of the trial's design and the intervention program. Overall, the design of the trial (wait-list control group design, recruitment and selection procedures, randomisation and stratification protocol, intervention length, selection of primary and secondary outcomes) was considered feasible. Further, intervention participants reported high levels of engagement and satisfaction with the program. Although adherence to self-monitoring was not optimal, with only 13% of men meeting the requisite criteria, significant associations were observed between self-monitoring of weekly weight and change in weight, waist circumference and fat mass. Self-monitoring of daily exercise was significantly associated with changes in waist circumference and objectively measured physical activity (all $P < 0.05$).

This thesis has evaluated the feasibility and efficacy of the PULSE Program and highlighted the potential of self-administered, gender-tailored and multi-component lifestyle interventions for T2DM prevention in men at high-risk for the disease. The information presented within this thesis has important implications for T2DM prevention research and practice, as effective interventions that are pragmatic, scalable, and gender-targeted for men are urgently required to combat the rising prevalence of T2DM.

Chapter 1 - Thesis Introduction

1.1 Chapter overview

This chapter begins with an overview of the pathogenesis of Type 2 Diabetes Mellitus (T2DM) and its precursor, prediabetes. National and international prevalence statistics for T2DM and prediabetes are then reported, along with prevalence statistics for overweight/obesity to demonstrate the strong association between the two metabolic disorders. This is followed by a summary of the health and economic consequences of T2DM. The evidence for lifestyle intervention for T2DM prevention will then be explored, and several key evidence gaps in the T2DM prevention literature are outlined. The central component of this thesis is then introduced; i.e., the evaluation of the feasibility and efficacy of the T2DM *PULSE Program* (Prevention Using LifeStyle Education), a self-administered, gender-tailored, multi-component lifestyle intervention for improving T2DM risk factors in men. The chapter concludes by presenting the primary and secondary aims of this thesis and providing a brief outline of the remaining chapters.

1.2 Background and context

1.2.1 Pathogenesis of type 2 diabetes mellitus

In healthy individuals, blood glucose levels are tightly regulated within an optimal physiological range [1]. Insulin, the key glycaemic regulatory hormone, controls the dynamic interplay between glucose uptake and release during the fed and fasted states through its interactions with skeletal muscle, adipose, hepatic and pancreatic tissues [2, 3]. T2DM is a metabolic disease that is brought about by insulin resistance in these target tissues, coupled with an inadequate

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compensatory insulin secretion from pancreatic β-cells in response to elevations in blood glucose [2]. As the disease progresses these functional defects lead to chronic hyperglycaemia, and augmented release of free fatty acids, hormones, and pro-inflammatory cytokines from adipose tissue [1]. The net result is an increasingly glucotoxic and lipotoxic metabolic environment [1, 4] that further impacts insulin resistance and β-cell function, and causes widespread damage to several organ systems in the body, particularly the cardiovascular system (Section 1.2.6).

1.2.2 Prediabetes

The term 'prediabetes' describes the transitional stage between normoglycaemia to development of overt T2DM [5]. Studies have reported that perturbations in glycaemic regulation may occur up to 13 years prior to diagnosis of T2DM [6-8]. 'Prediabetes' collectively refers to three distinct pathophysiological markers of dysglycaemia, namely: a) Impaired Fasting Glucose (IFG), b) Impaired Glucose Tolerance (IGT), and c) glycosylation of haemoglobin (HbA_{1C}). Individuals with IFG are primarily characterised by hepatic insulin resistance with normal muscle insulin sensitivity, whereas individuals with IGT may have normal hepatic insulin sensitivity with insulin resistant muscle tissue [5, 9]. Individuals with both IFG and IGT express both muscle and hepatic insulin resistance, and are considered to have progressed substantially towards development of T2DM [9]. Ackermann et al [10] reported that individuals with prediabetes have a 33.5% increased risk of T2DM within the following 7.5 years. However, not all individuals with prediabetes progress to T2DM [5], at least over the short-medium term (< 10 years). Nevertheless, even if

individuals with prediabetes do not progress to T2DM, they remain at increased risk for micro- and macrovascular complications [6, 11, 12] and cardiovascular disease-related mortality [13]. The early identification and treatment of individuals with prediabetes is therefore considered a key public health priority as it may prevent, or at least delay, the long-term complications of established T2DM.

1.2.3 Diagnostic criteria for type 2 diabetes and prediabetes

The clinical diagnosis of T2DM and prediabetes is determined by blood assays that assess abnormal glycaemic responses. IGT is evaluated using a 2 hr 75 g oral glucose tolerance test (OGTT), whereas IFG is assessed using a fasting plasma glucose test (FPG). Both of these tests assess the acute glycaemic response to a challenge on the system i.e. the fed and fasted state. A third glycaemic marker, glycosylated haemoglobin (HbA_{1C}) measures the adhesion of glucose to haemoglobin and provides a longer-term (~3 month) indication of average blood glucose levels [14].

Table 1 describes the diagnostic criteria for prediabetes and T2DM endorsed by the American Diabetes Association [15]. It should be noted that risk for T2DM is seen to be a continuum, rather than an absolute, based on these measures and respective cut-points.

Table 1 Diagnostic criteria for prediabetes and type 2 diabetes mellitus

Condition / test	Normoglycaemic	Prediabetes	Type 2 Diabetes Mellitus
IFG – Assessed by FPG	< 5.6 mmol.L^{-1} (< 100 mg.dL^{-1})	5.6 - 6.9 mmol.L^{-1} (100 - 125 mg.dL^{-1})	≥ 7.0 mmol.L^{-1} (≥ 126 mg.dL^{-1})
IGT – Assessed by 2 hr 75 g OGTT	< 7.8 mmol.L^{-1} (< 140 mg.dL^{-1})	7.8 - 11 mmol.L^{-1} (140 - 199 mg.dL^{-1})	≥ 11.1 mmol.L^{-1} (140 - 199 mg.dL^{-1})
Glycosylated Haemoglobin – Assessed by HbA$_{1C}$	< 5.7% (< 39 mmol.mol^{-1})	5.7 - 6.4% (39 - 46 mmol.mol^{-1})	≥ 6.5% (48 mmol.mol^{-1})

Diagnostic criteria for prediabetes and T2DM - American Diabetes Association [15]

FPG – Fasting plasma glucose, HbA$_{1C}$ – Glycosylated, IFG – Impaired fasting glucose, IGT – Impaired glucose tolerance, Haemoglobin, OGTT – Oral glucose tolerance test

1.2.3.1 Type 2 diabetes risk screening tools

While diagnostic blood testing is required for definitive diagnosis of T2DM, the high cost and burden of testing individuals poses a significant barrier for the identification of individuals at high-risk of developing T2DM. A number of T2DM risk screening tools have been developed as a first-line approach to aid in the early identification of individuals at risk of developing T2DM. The Australian Diabetes Risk Assessment (AUSDRISK) tool [16, 17], released in 2008, was developed and validated using data from the AusDiab study [18, 19]. The tool is comprised of 10-items, assessing four non-modifiable and six modifiable risk factors, with a maximum score of 38 points. The tool classifies individuals as being at low risk (≤ 5 points), moderate risk (6-11 points), or high-risk (≥ 12) for developing T2DM. It is estimated that 7% of individuals with scores between 12-15 points will develop T2DM within five years, 14% of individuals with scores between 16-19 points will develop T2DM within five years, and 33% of individuals with scores greater than 20 points will develop T2DM within five years [17].

1.2.4 Prevalence of type 2 diabetes mellitus and prediabetes

The International Diabetes Federation (IDF) recently estimated that diabetes affected 382 million individuals (8.3% of the world's population) in 2013, and projected this figure to rise to 592 million (10.1%) by 2035 [20]. It is estimated that T2DM accounts for approximately 85-90% of all diabetes cases [21]. Also, the IDF estimated a further 316 million people (6.9%) were affected by prediabetes in 2013; and that 471 million (8.0%) would be affected by 2030 [21]. Within Australia, the most recent data are from the Australian Health survey of 2011-12 (National Health Measures Survey, blood collections from ~11000 people) [22]. The survey reported that 5.1% of adults in the study sample had diabetes and that a further 3.1% had IFG (based on FPG and HbA_{1C} measures). This translates to a national diabetes prevalence of over 1.1 million adults. Prior to this, the Australian Diabetes, Obesity and Lifestyle study (AusDiab, n = 11247), a population based study of diabetes and its complications, reported a prevalence of diabetes in their study sample of 7.4%, with an additional 16.4% with IFG or IGT (based on FPG and 2 h OGTT measures) [23]. Differences in T2DM and prediabetes prevalence may be accounted for by the different glycaemic assessment methods used in these surveys (FPG, 2 h OGTT, HbA_{1C}). Regardless of prevalence discrepancies between these two studies, it is clear that diabetes prevalence in Australia is high. Furthermore, these figures represent a doubling of diabetes prevalence in Australia since 1981 [24]. Notably, both the Australian Health Survey [22] and the AusDiab study [23] reported a higher prevalence of diabetes in men than women (6.3% vs 3.9%; and 8.0% vs 6.4%, respectively [22, 23].

1.2.5 Obesity and type 2 diabetes mellitus

Over 40 years ago, Sims et al first used the term 'diabesity', to explain the inextricable link between T2DM and obesity [25]. Today, it is commonly accepted that the current T2DM pandemic is strongly linked to the rising prevalence of obesity and poor dietary and physical activity behaviours [2, 26, 27]. In 2011-12, the Australian Health Survey estimated that 63% of adults were overweight or obese [28]. Notably, obese adults were seven times more likely to have diabetes compared to normal weight or underweight adults [22]. Furthermore, the survey reported that more men than women were overweight or obese (69.7% vs 55.7%, respectively) [28]. This may explain, in part, the aforementioned higher prevalence of diabetes among men in Australia [23, 28].

Adipose tissue, particularly abdominal visceral adiposity, is a highly active endocrine tissue that secretes free fatty acids, hormones, and pro-inflammatory cytokines, which promote insulin resistance in muscle and hepatic tissues, and impairs β-cell function [1, 2, 4].

1.2.6 Health consequences of type 2 diabetes mellitus and prediabetes

It is estimated that individuals with T2DM have a life expectancy approximately 12 years less than individuals without T2DM [29]. The majority of those with T2DM will suffer from cardiovascular related-diseases, with studies indicating that individuals with T2DM have a 2-4 times higher risk of cardiovascular disease related mortality [30, 31]. Specifically, individuals with T2DM are at higher risk for developing macrovascular (coronary artery disease, peripheral arterial disease, stroke) and microvascular (retinopathy and nephropathy) complications [11, 32]. Notably, microvascular complications are reported to occur

up to eight years prior to clinical diagnosis of T2DM [6, 12], suggesting these conditions develop within the glucotoxic and lipotoxic metabolic environment that coincide with the prediabetes stage.

1.2.7 Economic consequences of type 2 diabetes mellitus

The economic burden of T2DM on individuals and national health care systems is substantial. The IDF estimated global health expenditure on diabetes in 2010 was between USD $376 - 672 billion [33]. Furthermore, the same study estimated that expenditure on diabetes accounted for 12% of global health expenditure [33]. Within an Australian context, the AusDiab study estimated the total annual cost of diabetes in 2005 was AUD $10.6 billion, the equivalent of AUD $14.6 billion in 2010 dollars [34]. Furthermore, the annual direct cost for individuals with diabetes was estimated to be AUD $4390, 2.3 times higher than individuals with normal glucose tolerance [34]. Notably, Nichols et al reported the medical costs of patients with T2DM begin to rise at least eight years prior to diagnosis of T2DM [35].

1.2.8 Type 2 diabetes mellitus prevention

Genome-wide association studies have established a strong genetic basis for T2DM [36]. However, it is commonly accepted that the onset and pathogenesis of the disease is brought about through adverse lifestyle behaviours [9, 27]. Risk for developing T2DM can therefore be attributed to non-modifiable risk factors including hereditary genetics, family history, race/ethnicity, sex and age; and modifiable risk factors including overweight/obesity, poor dietary intake and physical inactivity [27, 37]. Targeting modifiable lifestyle risk factors with lifestyle

behaviour change is considered the cornerstone of diabetes prevention [38, 39].
Studies have demonstrated that lifestyle intervention can prevent or delay the
progression to overt T2DM [40, 41], increase the number of disease-free years [42-44], improve health-related quality of life [45], and therefore reduce the financial
burden of T2DM [46].

The following subsections explore the evidence supporting the three key
lifestyle behaviour change for strategies for T2DM prevention, i.e., weight loss,
dietary modification and exercise. T2DM prevention guidelines from national
and international bodies are also reported.

1.2.8.1 Weight loss

As previously alluded to, overweight and obesity are strongly linked to T2DM,
with many studies highlighting it as the most important risk factor for T2DM
development [27, 38, 39, 47]. As such, T2DM prevention is strongly focused on
weight loss for people who are overweight/obese or maintaining a healthy
weight. The US Diabetes Prevention Program (DPP) reported a reduction in
T2DM incidence of 58% following 2.8 years of intensive lifestyle intervention
(compared to placebo control) [40], with weight loss the greatest predictor of
reduced T2DM incidence [48]. In addition, it was estimated that for every kilogram
of weight loss there was a 16% reduction in risk for the development of T2DM
[48]. While the exact mechanisms remain to be fully elucidated, studies have
clearly demonstrated that weight loss is associated with improvements in
glycaemic control and dyslipidaemia [40, 41, 49-51]. Furthermore, it appears that
short-term reductions in weight and the associated improvements in glycaemic

control are sufficient to significantly prevent or delay T2DM in the long-term, despite the challenges of long-term weight loss maintenance [43, 44]. Based on the body of evidence, the IDF has recommended that individuals try to achieve and sustain an acceptable body weight that can be maintained in the long-term (rather than achieving ideal body weight) [52], whereas the American Diabetes Association has specifically recommended that overweight/obese individuals aim to achieve ≥ 7% weight loss [53].

1.2.8.2 Diet quality

Changes in dietary intake, both total energy intake (for weight loss) and improvement in nutritional quality, are important for T2DM prevention [53]. In a meta-analysis of lifestyle interventions for T2DM prevention, Gilles et al [54] reported that diet-only lifestyle interventions (various time-frames) conferred a 33% reduction in risk for developing T2DM. Dietary advice generally consists of macro- and micronutrient targets, including increased vegetable and fruit intakes, increased fibre consumption, decreased saturated fat intake, decreased sodium intake, and a reduction in glycaemic load [52, 53]. Interestingly, in a meta-analysis of six prospective cohort studies (n = 223 512) there was no significant association between total vegetable or total fruit intake and risk of T2DM observed [55]. In contrast, Cooper and colleague's evaluation of an 11-year cohort study (n = 3704) indicated that greater vegetable intake was associated with a 24% reduction in risk for T2DM [56]. Furthermore, greater variety of vegetable and fruit intake was associated with a 39% reduction in T2DM risk. Notably, consumption of green leafy vegetables was associated with a reduction in T2DM risk in both studies [55, 56].

Due to the purported role of fatty acids in glycaemic regulation, changes in quantity and quality of fat intake have been a strong focus of dietary recommendations for T2DM prevention [57]. Several studies have reported that high-intake of saturated and trans fatty acids are associated with increased risk of T2DM [58-61]. The consensus is that saturated and trans fat intake should be reduced and replaced by monounsaturated and polyunsaturated fats, which are themselves associated with improvements in glycaemic control and reduction in risk of T2DM [52, 53, 57, 62]. Fibre intake has also emerged as an important dietary factor for T2DM prevention due to its role in macronutrient absorption and influence on post-prandial glycaemic control (insulin sensitivity) [63]. Large prospective cohort studies have reported that high intake of dietary insoluble fibre is associated with T2DM risk reduction of up to 33% [64, 65].

A summary of the IDF's macro- and micronutrient recommendations for diabetes [52] are described in Table 2. In addition to these dietary targets, the IDF also recommends consumption of carbohydrates with a low glycaemic index (GI); and consumption of 2-3 portions of fish per week, including one portion of oily fish rich in omega-3 fatty acids.

Table 2 Dietary guidelines for type 2 diabetes mellitus

Food group / dietary item	Recommendation
Carbohydrates	45-60% *(3915 - 5220 kJ.day^{-1})
Dietary Fibre (soluble/insoluble)	25-50 g.day^{-1}
Fats	20-35% *(1740 – 3045 kJ.day^{-1})
Saturated	< 7%
Polyunsaturated	$\leq$ 10%
Monounsaturated	> 10%
Protein	10-20% (0.8 g.kg^{-1}.day^{-1}) *(870 – 1470 kJ.day^{-1})
Sodium (salt)	1500-2300 mg.day^{-1}

Adapted from IDF Education modules [52].
kJ.day^{-1} amounts estimated based on an average intake of 8700 kJ.day^{-1}

1.2.8.3 Physical activity

In addition to its contribution to weight loss, physical activity is independently associated with improvements in glycaemic control and reductions in T2DM risk [39, 66]. The Finnish Diabetes Prevention Study (DPS) reported that individuals who were the most physically active after 4.1 years of follow up were 66% less likely to have developed T2DM compared to those who were the least active (independent of change in BMI and dietary intake) [66]. In addition to its long-term effects, physical activity plays an essential role in the short-term (0-72 hours) control of blood glucose [67, 68] and fatty acid oxidation [69-72], and is therefore viewed as an essential component of lifestyle intervention for individuals with prediabetes [73].

Aerobic exercises (e.g., walking, running, swimming, cycling) have been traditionally recommended [66, 73] for T2DM treatment and prevention. Over the last decade, resistance training (RT) has emerged as a viable adjunct or

alternative physical activity choice due to its effects on insulin sensitivity [74, 75] and glycaemic regulation [74-84]. A combination of aerobic exercise and RT is suggested to be the most beneficial approach for individuals with prediabetes or T2DM [73, 85]. Based on the body of evidence, Exercise and Sports Science Australia and the American College of Sports Medicine, have released position statements for T2DM and prediabetes with prescriptions for physical activity [73, 86]. Exercise and Sports Science Australia has recommended a minimum of 210 min per week of moderate intensity exercise or 125 min of vigorous intensity exercise with no more than two consecutive days without training. Within this total, it is recommended that individuals include 60 min per week of RT. These guidelines are explained in further detail in Table 3.

Table 3 Physical activity prescription for prediabetes and type 2 diabetes mellitus

Type	Intensity	Duration	Frequency
Aerobic (large muscle activities e.g., walking, running, swimming, cycling)	Moderate (55-69% HR_{max}) OR Vigorous (70-89% HR_{max})	210 min OR 125 min	No more than two consecutive days without training
Resistance Training (multi-joint, progressive, large muscle groups)	Moderate to vigorous 8-10 exercises 2-4 sets 8-10 repetitions 1-2 min rest intervals	60 min (included in above totals)	Two or more session per week

Exercise prescription for T2DM and prediabetes - Exercise and Sports Science Australia [86]
HR_{max} – Heart rate maximum

1.2.8.4 Type 2 diabetes mellitus prevention programs

Internationally, numerous T2DM prevention studies have assessed the impact of multi-component lifestyle interventions (weight loss, diet modification, exercise) on T2DM incidence in populations at risk for developing T2DM or with prediabetes. The most well-known of these, the US DPP [87]; the Finnish DPS [88]; the Chinese Da Qing IGT and Diabetes Study [89]; and the Indian Diabetes Prevention Program (Indian DPP) [90], reported that lifestyle intervention reduced T2DM incidence by up to 29-58% over a period of 3-6 years [40, 41, 89, 90]. Furthermore, the DPS, DPP and Da Qing studies reported long-term protective effects of lifestyle intervention, with lower incidence of T2DM compared to control/usual care treatment over nine [44], ten [43], and 20 years [42], respectively. A brief description of these studies and a summary of key outcomes are presented in Table 4.

Table 4 Design and outcomes from type 2 diabetes prevention trials

Study Name	Participants [a]	Design – Intervention/s & comparisons	Outcomes (major time point) [b, c]	Outcomes (long-term follow-up) [c, d]
US DPP [87]	n = 3234 Males = 32.7% • Adults ≥ 25 years old • FPG & IGT • BMI ≥ 24	Three arm RCT • Lifestyle INT (Diet + exercise) • Usual care + metformin INT • Usual care + placebo control	**3 year follow up** [40, 43] • Weight: -5.6 kg (lifestyle INT) -2.1 kg (metformin INT) -0.1 kg (CON) • HbA$_{1C}$: -0.04% (lifestyle INT) 0.4% (metformin INT) 0.13% (CON) • FPG: 0 mmol.L^{-1} (lifestyle INT) -0.02 mmol.L^{-1} (metformin INT) 0.22 mmol.L^{-1} (CON) Incidence of diabetes 58% lower in the lifestyle INT and 31% lower in the metformin INT compared to CON (at 4 years).	**10 year follow up** [43] • Weight: NR, figure only • HbA$_{1C}$: 0.06% (lifestyle INT) 0.01% (metformin INT) 0.11% (CON) • FPG: 0.45 mmol.L^{-1} (lifestyle INT) 0.28 mmol.L^{-1} (metformin INT) 0.53 mmol.L^{-1} (CON) Incidence of diabetes 34% lower in the lifestyle INT and 18% lower in the metformin INT compared to CON.
Finnish DPS [88]	n = 522 Males = 32.9% • Adults 40-65 years old • IGT • BMI ≥ 25	Two arm RCT • Lifestyle INT (Diet + exercise) • Standard advice control group	**3 year follow up** [41, 91] • Weight: -3.5 kg (INT) -0.9 (CON) • HbA$_{1C}$: -0.2% (INT) 0.0% (placebo) • FPG: -0 mmol.L^{-1} (INT) 0.1 (CON) • OGTT: -0.5 mmol.L^{-1} (INT) -0.1 mmol.L^{-1} (CON) Incidence of diabetes 58% lower in the INT group compared to CON.	**9 year follow up** [44] • Weight: NR, figure only • FPG: NR, figure only • OGTT: NR, figure only Incidence of diabetes 38% lower in the INT group compared to CON.

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Study	Sample	Design		
Chinese Da Qing [89]	n = 530 Males = 53.4% • Adults ≥ 25 years old • IGT	Four arm RCT • Lifestyle INT (diet) • Lifestyle INT (exercise) • Lifestyle INT (diet & exercise) • Usual care control group	**6 year follow up** [89] • BMI: 0.8 kg.m⁻² (diet INT) 0.2 kg.m⁻² (exercise INT), 0.4 kg.m⁻² (diet & exercise INT) 0.6 kg.m⁻² (CON) • FPG: 1.6 mmol.L⁻¹ (diet INT) 0.7 mmol.L⁻¹ (exercise INT) 0.95 mmol.L⁻¹ (diet & exercise INT) 1.87 mmol.L⁻¹ (CON) • OGTT: 1.4 mmol.L⁻¹ (diet INT) 0.52 mmol.L⁻¹ (exercise INT) 2.0 mmol.L⁻¹ (diet & exercise INT) 2.78 mmol.L⁻¹ (CON) Incidence of diabetes 33% lower in the diet only INT, 47% lower in the exercise only INT, and 38% in the diet & exercise INT compared to CON.	**20 year follow up** [42] • BMI: -1.2 kg.m⁻² (combined INT) -1.8 kg.m⁻² (control) • FPG: 2.3 mmol.L⁻¹ (combined INT) 3.2 mmol.L⁻¹ (CON) • OGTT: 2.5 mmol.L⁻¹ (combined INT) 4.8 mmol.L⁻¹ (CON) Incidence of diabetes 43% lower in the combined INT compared to CON.
Indian DPP [90]	n = 531 Males = 79.1% • Adults 35-55 years old • IGT	Four arm RCT • Lifestyle INT (diet & exercise) • Drug INT (metformin) • Lifestyle + drug INT (diet, exercise and metformin) • Control group	**3 year follow up** [90] • weight: NR, figure only RR was 28.5% lower in the lifestyle INT, 26.4% lower in the metformin INT, and 28.2% in the lifestyle & metformin INT compared to CON.	No long term follow up

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The PRISMA statement PICOS framework (participants, intervention, outcomes, comparators, study design) [92] for description of trials was used.

Within group changes reported.

CON – control group, HR – Hazard Ratio, INT – intervention group, NR – not reported, RR – relative risk, [a] sample size at baseline, [b] major time point varies between study based on availability of published data [c] within group change scores reported [d] long-term follow up time point varies between study based on availability of published data [e] Six year follow up data of overweight/obese (BMI ≥ 25) participants.

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1.3 Lack of self-administered, gender-tailored and multi-component lifestyle interventions

As demonstrated above, large-scale trials have been highly successful over the short and long-term in preventing or delaying T2DM in high-risk individuals. However, they are not without limitation. The following subsections explore a number of limitations identified in the literature and specifically address three evidence gaps in the field, namely, the lack of self-administered interventions, gender-targeted interventions, and multi-component lifestyle interventions combining diet modification, aerobic exercise and RT. These evidence gaps form the core rationale for this thesis.

1.3.1 Lack of self-administered lifestyle prevention programs

The most common criticism of the aforementioned large-scale T2DM prevention trials relates to the highly intensive face-face approach (multiple sessions per week for ≥ six months) and the substantial resourcing (financial, professional staffing, facility use, equipment) that was required to achieve the reported effects. Researchers have questioned the practicality, scalability and sustainability of this approach for community translation [93-96] and have suggested further investigation of alternative pragmatic approaches that are less time and resource intensive [93, 95, 97]. Self-administered lifestyle interventions, e.g., print-based or web-based delivery modes, have been suggested as possible alternatives [95, 97] as they are likely to require less resourcing and have potential for dissemination in varied community settings, including regional and remotes areas. However, further research is required to establish the efficacy of self-administered interventions for T2DM prevention [97].

1.3.2 Lack of gender-targeted and tailored prevention programs

Whether lifestyle intervention is equally effective for T2DM prevention for men and women is of interest as few studies have been gender-exclusive and only a small number have reported sex-differences for outcomes or T2DM incidence [98, 99]. A recent meta-analysis of 12 T2DM prevention lifestyle interventions found no significant difference in risk factor outcomes or incidence of T2DM between men and women over 1-6 years [100]. While this evidence suggests that lifestyle intervention is equally effective for men and women, a limitation is that lifestyle interventions including both men and women are likely to be gender-neutral, thereby minimising any sex-specific changes that might be observed.

Engaging men in lifestyle interventions remains a significant challenge, with men commonly under-represented in diabetes prevention [100] and weight loss [101] literatures. Recently, more emphasis has been placed on gender-targeted lifestyle interventions, particularly in the men's weight loss literature [102-114]. Gender-targeted lifestyle interventions, including gender-exclusive and gender-tailored interventions, are purported to be more appealing to men and more effective for health behaviour change by catering for the psychological and physiological preferences and needs of men [110, 115, 116]. There is currently a paucity of evidence for gender-targeted interventions for men at high-risk of developing T2DM [98]. This evidence is urgently required, particularly given the higher prevalence of T2DM and prediabetes among men in Australia and internationally.

1.3.3 Lack of multi-component prevention programs

As outlined previously, there is strong evidence supporting dietary and exercise behaviour modification for T2DM prevention in individuals at high-risk or with prediabetes. As such, recent T2DM prevention guidelines have promoted a multi-component lifestyle change approach, encompassing diet modification, aerobic exercise and RT [52, 53, 73, 117]. Due to the currently limited body of evidence, whether this multi-component approach is feasible and efficacious for T2DM prevention is uncertain. To address this, a systematic review and meta-analysis of multi-component interventions including diet, aerobic exercise and RT was conducted [98]. This investigation is presented in Chapter 2.

1.4 The type 2 diabetes mellitus PULSE Program

To address the aforementioned evidence gaps in the literature, the central component of this thesis is the development and evaluation of the T2DM *PULSE (Prevention Using Lifestyle Education) Program,* a self-administered, gender-tailored, multi-component lifestyle intervention for men*.* The *PULSE Program* builds on previous research conducted by our group on the *SHED-IT (Self-Help, Exercise and Diet using Internet Technology) Weight Loss Program,* a self-administered, gender-tailored weight loss intervention for men. The *SHED-IT Weight Loss Program* has been extensively evaluated through a series of trials [102, 103, 107-111, 118-120]. The *PULSE Program* intervention (described in detail in Chapter 3) included the *SHED-IT Weight Loss Program* and provided additional supplementary intervention components to bring the overall intervention in line with current diet and exercise guidelines for T2DM prevention.

1.5 Research Aims

1.5.1 Primary aim

The primary aim of this thesis was to evaluate the feasibility and efficacy of the *PULSE Program* for improving a range of risk factors strongly linked with type 2 diabetes mellitus development, including weight and glycaemic markers in men at high-risk for developing type 2 diabetes mellitus (Chapters 3, 5).

1.5.1.1 Primary hypothesis

The primary hypothesis is that men who receive the *PULSE Program* will experience greater weight loss (primary outcome) and improvements in glycaemic markers after six months (immediate post-program and primary time point) compared to men who receive no intervention (wait-list control group).

1.5.2 Secondary aims

A number of secondary aims were also examined:

1. To systematically review and meta-analyse the current evidence regarding multi-component lifestyle interventions (diet, aerobic exercise and resistance training) for type 2 diabetes mellitus prevention in adults at high-risk or with prediabetes (Chapter 2)

2. To describe the characteristics of men identified at high-risk for developing type 2 diabetes mellitus using the Australian Diabetes Risk Assessment (AUSDRISK) tool, and determine the ability of the tool to identify men with prediabetes and metabolic syndrome (Chapter 4)

3. To conduct a process evaluation of the PULSE Program randomised controlled trial to examine the trial's design and its intervention program (Chapter 6)

1.6 Thesis structure

This thesis is presented as a series of manuscripts that address the above aims. To date, two manuscripts have been accepted for publication, one is under review, one has been submitted to a journal for consideration, and one is an unpublished chapter. Due to the structure of this thesis and the inter-relationships between studies, there is minor overlap among some of these manuscripts. This is done purposefully so that each study can be viewed as a whole, independently of other chapters.

1.6.1 Chapter 2 – Systematic review of multi-component lifestyle interventions for type 2 diabetes prevention

This chapter presents the results of a systematic review with meta-analyses of multi-component lifestyle interventions (diet, aerobic exercise, RT) for T2DM prevention in individuals at high-risk or with prediabetes (*Secondary Aim 1*). Eight electronic databases were searched up to January 2012. Studies were eligible if they: 1) recruited prediabetic or individuals at risk of Type 2 Diabetes, 2) conducted diet and exercise [including both physical activity/aerobic exercise and RT] programs, 3) reported weight and plasma glucose. In total, 23 articles from eight studies were eligible including five randomised controlled trials, one quasi-experimental, one two-group comparison and one single-group pre-post study. Methodological and outcome data were extracted for all studies and a

risk of bias analysis was conducted to evaluate the quality of the studies. Studies with RCT designs were meta-analysed to examine the pooled effects for weight and FPG. This systematic review has been published in the International Journal of Behavioural Nutrition and Physical Activity [98].

1.6.2 Chapter 3 – The type 2 diabetes PULSE Program trial protocol paper

This chapter presents a manuscript describing the protocol for the PULSE Program RCT (*Primary Aim*). The design of the *PULSE Program* intervention is described in detail, including explanations of its theoretical grounding, the self-administered delivery approach, the gender-tailoring of intervention materials, and the incorporation of multi-component behaviour change approaches). A comprehensive description of the conduct of the trial is also provided, including details of recruitment, randomisation, study flow, outcomes measures and statistical analysis plan. This manuscript has been published in Contemporary Clinical Trials [121].

1.6.3 Chapter 4 – An evaluation of the AUSDRISK tool

A key component of eligibility screening for the *PULSE Program* RCT was the AUSDRISK screening tool. This chapter presents a study evaluating the AUSDRISK tool by a) describing the anthropometric, metabolic (glycaemic) and behavioural characteristics of men identified at high-risk for developing T2DM, and b) assessing the ability of the tool to identify men with prediabetes and metabolic syndrome (*Secondary Aim 2*). Despite the validity of the AUSDRISK tool for predicting T2DM incidence [16], uptake of the tool has been poor [122]. This study may provide further confidence in the usefulness of AUSDRISK screening

to positively identify individuals with prediabetes and multiple risk factors for T2DM. The study manuscript has been accepted for publication in Diabetes Research and Clinical Practice.

1.6.4 Chapter 5 – The type 2 diabetes PULSE Program trial outcomes

This chapter presents the evaluation of the efficacy of the *PULSE Program,* a self-administered, gender-tailored and multi-component lifestyle intervention, for improving risk factors in men at high risk of T2DM *(Primary Aim).* The study describes the changes in key outcomes (weight, glycaemic marker, lifestyle behaviours) following the 6-month T2DM *PULSE Program* trial. This manuscript has been submitted to the American Journal of Preventive Medicine.

1.6.5 Chapter 6 – Process evaluation of the type 2 diabetes PULSE Program trial

This chapter presents a process evaluation of the PULSE program trial examining the trial's design and its intervention components *(Secondary Aim 3).* This information supplements the efficacy data presented in Chapter 5 and will inform the design and conduct of future trials. The version of the manuscript included here will not be submitted until the main outcomes paper (Chapter 5) is accepted for publication, as feedback provided as part of the review process may also benefit this manuscript.

1.6.6 Chapter 7 – Thesis discussion

As this thesis is presented as a series of manuscripts, the detailed description of findings and discussion within the context of the T2DM prevention literature

can be found within the preceding chapters. The purpose of this chapter is to synthesise and discuss this body of work in relation to the development and evaluation of the *PULSE Program,* to acknowledge the strengths and limitations of this body of research, and to present a series of evidence-based recommendations for future research and clinical practice.

Chapter 2 – Efficacy of interventions that include diet, aerobic and resistance training components for type 2 diabetes prevention: a systematic review with meta-analysis

Preface:

This chapter presents a published peer-reviewed manuscript, which aligns with *Secondary Aim 1* of this thesis i.e., to systematically review and meta-analyse the current evidence regarding multi-component lifestyle interventions (diet, aerobic exercise and resistance training) for type 2 diabetes mellitus prevention in adults at high-risk or with prediabetes. This manuscript has been published in the *International Journal for Behavioural Nutrition and Physical Activity*.

Citation:

Aguiar EJ, Morgan PJ, Collins CE, Plotnikoff RC, Callister R. Efficacy of interventions that include diet, aerobic and resistance training components for type 2 diabetes prevention: a systematic review with meta-analysis. Int J Behav Nutr Phys Act. 2014;11. doi:10.1186/1479-5868-11-2

Abstract

Current recommendations for the prevention of type 2 diabetes advise modification of diet and exercise behaviours including both aerobic and resistance training. However, the efficacy of multi-component interventions involving a combination of these three components has not been established. The aims of this review were to systematically review and meta-analyse the evidence on multi-component (diet + aerobic exercise + resistance training) lifestyle interventions for type 2 diabetes prevention. Eight electronic databases (Medline, Embase, SportDiscus, Web of Science, CINAHL, Informit health collection, Cochrane library and Scopus) were searched up to June 2013. Eligible studies 1) recruited adults with prediabetes or individuals at risk of type 2 diabetes; 2) conducted diet and exercise [including both physical activity/aerobic *and* resistance training] programs; and 3) reported weight and plasma glucose outcomes. In total, 23 articles from eight studies were eligible including five randomised controlled trials, one quasi-experimental, one two-group comparison and one single-group pre-post study. Four studies had a low risk of bias (score ≥ 6/10). Median intervention length was 12 months (range 4 - 48 months) with a follow-up of 18 months (range 6.5 - 48 months). The diet and exercise interventions varied slightly in terms of their specific prescriptions. Meta-analysis favoured interventions over controls for weight loss (-3.79 kg [-6.13, -1.46; 95% CI], Z = 3.19, P = 0.001) and fasting plasma glucose (-0.13 mmol.L^{-1} [-0.24, -0.02; 95% CI], Z = 2.42, P = 0.02). Diabetes incidence was only reported in two studies, with reductions of 58% and 56% versus control groups. In summary, multi-component lifestyle type 2 diabetes prevention interventions that include diet and both aerobic and resistance exercise training

are modestly effective in inducing weight loss and improving impaired fasting glucose, glucose tolerance, dietary and exercise outcomes in at risk and adult populations with prediabetes. These results support the current exercise guidelines for the inclusion of resistance training in type 2 diabetes prevention, however there remains a need for more rigorous studies, with long-term follow-up evaluating program efficacy, muscular fitness outcomes, diabetes incidence and risk reduction.

2.1 Introduction

Type 2 diabetes mellitus (T2DM) is one of the fastest growing non-communicable diseases worldwide [21, 123]. Recommendations for T2DM prevention include maintaining a healthy-weight, consuming a healthy diet, and participation in exercise. Most T2DM prevention programs have recommended aerobic (cardio-respiratory) activities [73] with strong evidence supporting this approach. Large-scale prevention studies such as the Diabetes Prevention Program (DPP) [87] reported reductions in T2DM incidence of up to 58% [40] and improvements in risk factors such as weight and insulin sensitivity.

More recently, resistance training (RT) has been included in guidelines for T2DM based on evidence established over the last decade, which demonstrates benefits from RT including improved fasting plasma glucose (FPG) [75-79, 84], glycosylated haemoglobin (HbA$_{1C}$) [74, 75, 77-83], insulin sensitivity [74, 75] and the maintenance of fat free mass during energy restriction for weight loss [124, 125]. Current guidelines for T2DM prevention and management [73, 86] recommend at least 150 min per week of moderate-vigorous aerobic activity

and an additional two (ideally three) RT sessions per week (at least 60 min). Studies have reported that the combination of aerobic plus RT has additive benefits on glucose control [83, 85, 126] and can achieve greater reductions in T2DM incidence [127, 128] than the use of a single exercise modality. However, multi-component (diet + aerobic exercise + RT) lifestyle interventions have the potential to become excessively burdensome, which could compromise program adherence. Further, the long-term efficacy of multi-component programs remains unclear.

Therefore, the aim of this systematic review was to summarise the evidence of the efficacy of lifestyle interventions that include diet + aerobic exercise + RT components in at risk or prediabetes populations. Specifically, this review assesses the effects of these interventions on weight change, glucose regulation, and diet and exercise outcomes. A secondary aim was to conduct a meta-analysis of the impact on weight and FPG. Addressing these aims is necessary to validate the evidence supporting current dietary and exercise guidelines for T2DM prevention.

2.2 Methods

The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement [92] guided the conduct and reporting of this review.

2.2.1 Information sources

A systematic literature search was conducted using electronic databases (Medline, Embase, SportDiscus, ISI Web of Knowledge [Web of Science],

CINAHL, Informit health collection, Cochrane library, Scopus) until June 2013. No limit was placed on publication date. The search strategy included the use of terms in three broad categories: (i) population; (ii) intervention; and (iii) study type. The search terms list included the following items: pre-diabetic OR prediabetic OR pre-diabetes OR prediabetes OR glucose intolerance OR impaired glucose tolerance OR impaired fasting glucose AND exercise OR resistance training OR weight lifting OR aerobic training OR diet OR lifestyle OR life-style AND randomized controlled trial OR randomised controlled trial OR controlled clinical trial OR randomized OR randomised OR randomly OR trial OR groups OR intervention OR study OR program. Reference lists of included studies and key reviews in the area were also manually searched for additional articles.

2.2.2 Eligibility criteria

Studies were included if they: (i) targeted T2DM prevention in at risk or adults with prediabetes (> 18 years); (ii) employed a lifestyle diet and exercise intervention including both aerobic *and* RT; and (iii) reported weight and plasma glucose. All study designs were considered. Studies were excluded if they: (i) recruited individuals with T2DM; (ii) recruited individuals diagnosed with severe medical problems unrelated to prediabetes or from other special populations (e.g., mental illness, polycystic ovarian syndrome, gestational diabetes); (iii) used drug therapy or surgical procedures as part of the intervention.

2.2.3 Study selection

After duplicate deletion, one author (EA) screened all articles based on title and abstracts for preliminary inclusion; then screened remaining articles by full text based on inclusion criteria. In cases where there was uncertainty, a second reviewer (RC) assessed the article and consensus was reached by discussion.

2.2.4 Data collection process and data items

Characteristics and results of studies were extracted by one author (EA). Studies with multiple published articles were reported as a single group. For meta-analyses, final mean and standard deviation (SD) or change in mean and SD were extracted for weight (kg) and FPG (mmol.L^{-1}). In some studies, the required statistics for meta-analysis were not reported. If available, other statistics e.g., 95% confidence interval (CI) or standard error (SE) were converted to the required form according to the calculations outlined in the Cochrane Handbook for Systematic Reviews of Interventions [129].

2.2.5 Risk of bias in individual studies

Risk of bias for individual studies was assessed for randomised trials using a 10-item quality checklist adapted from the Consolidated Standards of Reporting Trials (CONSORT) statement [130]. The 10-item scale and explanations of the scoring for each item are available (Table 5). Each item was scored with a '1' for 'yes' or '0' for 'no'. Inter-rater reliability was calculated on a dichotomous scale using percentage agreement and Cohen's κ. Un-weighted sum totals were calculated for each study. Based on a dichotomy used in recent reviews [131, 132] studies were classified as having a low (score ≥ 6) or high risk of bias

(score ≤ 5). Two authors (EA and RC) assessed the risk of bias in the individual studies that met the inclusion criteria. In the case of disagreement, discussion took place until consensus was reached.

2.2.6 Summary measures and synthesis of results

The primary outcomes for the review were the between group difference in means for weight (kg) and FPG (mmol.L^{-1}). Secondary outcomes included 2-h oral glucose tolerance test (OGTT, mmol.L^{-1}) and HbA1c %, dietary outcomes (e.g., macronutrient composition) and exercise outcomes (e.g., physical activity, aerobic and muscular fitness). Meta-analyses for weight and FPG were conducted for eligible randomised controlled trials (RCT). Results were pooled in separate meta-analyses using RevMan 5.1.4 for Mac OS X. All data were continuous and reported on the same scale for weight (kg) and FPG (mmol.L^{-1}). Heterogeneity of studies included for meta-analysis was determined using Chi^2 and I^2 statistics. A significance level of $P < 0.10$ for the Chi^2 test and an I^2 greater than 50% indicated substantial heterogeneity [92]. The fixed-effects model was used for homogenous samples and the random-effects model was used where heterogeneity was present. The aggregate result was calculated as the weighted mean difference (WMD) between interventions and controls. Meta-analysis was deemed inappropriate for variables where results from fewer than three studies were available.

Table 5 Risk of bias assessment explanation

Criteria	Yes	No
i) Did the study report a power calculation and was the study adequately powered to detect intervention effects?	If a power calculation was provided and the sample size allowed for detection of intervention effects.	If power calculation was not provided or sample size was inadequate.
ii) Was the randomisation procedure adequately described and carried out?	If a random assignment sequence was used and described (computer generated random number tables; use of sealed opaque envelopes.	If the process was not random or adequately described.
iii) Did the study include a control group? (randomised participants not a comparison group)	If the study contained a control group (or usual care group) with randomised participants.	If allocation was not random or there was a treatment.
iv) Did the study present baseline characteristics separately for treatment groups?	If baseline characteristics were presented separately.	If baseline characteristics were not presented separately.
v) Did the study analyses account for potential differences at baseline?	If the statistical procedures accounted for potential differences at baselines e.g. ANOVA or ANCOVA.	If statistical measures did not account for potential differences at baseline.
vi) Were the assessors blinded to treatment allocation at baseline and post-test?	If assessors were blinded to participant allocation at baseline and post-test.	If assessors were not blinded to participant allocation.
vii) Did the study have a dropout of < 20% (< 6 month follow-up) or < 30% (> 6 month follow-up) for the primary outcome of weight?	If dropout was < 20% for < 6 months studies or < 30% for studies > 6 months.	If dropout was > 20% for < 6 months studies or > 30% for studies > 6 months
viii) Did the study use an intention to treat analysis?	If intention to treat analyses was used.	If intention to treat analyses was not used.
ix) Did the study report summary results for each group?	If summary results for each group were presented.	If no summary results were presented.
x) Did the study report precision estimates (e.g., 95% confidence interval) and/or effect sizes?	If precision estimates and/or effect sizes were included.	If precision estimates and/or effect sizes were not included.

10-item risk of bias assessment criteria and an explanation of the scoring details for each item

2.3 Results

2.3.1 Study selection

After duplicate deletion, 8048 original articles were identified (Figure 1). After title/abstract screening and further full-text screening, 23 articles arising from eight studies were deemed eligible. Of these, four studies were eligible for meta-analysis of weight and five studies for meta-analysis of FPG.
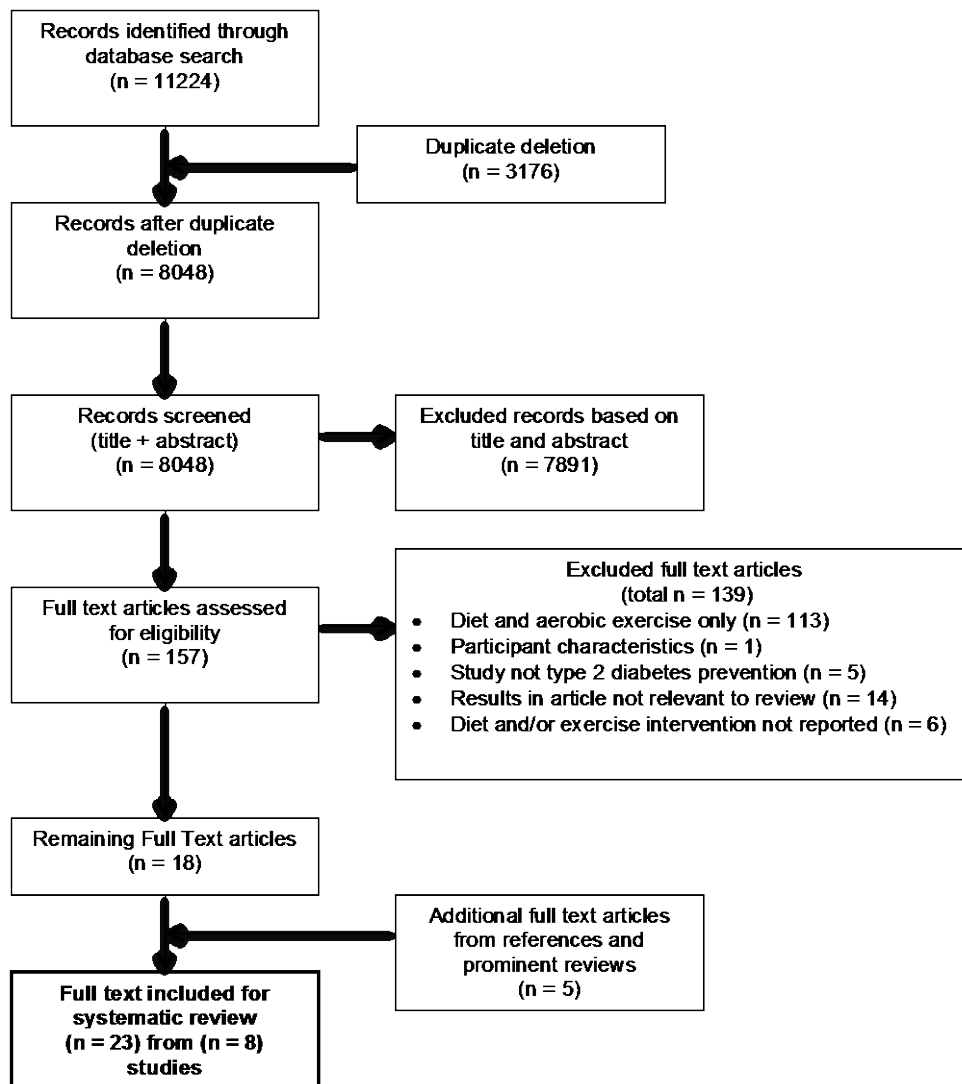
Figure 1 PRISMA flow diagram of study selection.

2.3.2 Study characteristics

Of the eight included studies, two were conducted in the United States [133-136], one in New Zealand [137, 138], Austria [139], the Netherlands [140-144], Australia [145], Finland [41, 66, 88, 91, 146-149] and the United Kingdom [150, 151]. Characteristics of these studies are presented in Table 6. Five studies [41, 66, 88, 91, 133-135, 137, 138, 140-144, 146-151] used an RCT design, with the remaining studies employing quasi-experimental [145] two-group comparison [139] or single-group pre-post designs [136]. Three studies specifically recruited impaired glucose tolerance (IGT) participants [41, 66, 88, 91, 137, 138, 146-151], one study recruited impaired fasting glucose (IFG) participants [139], one study recruited both IGT and IFG participants [136], and three studies recruited an 'at risk for prediabetes' population [133-135, 140-144]. The collective sample size of the studies at baseline was 1050 participants, with females comprising 62% of the sample. Mean (± SD) age was 54.5 ± 9.7 years. Five studies [41, 66, 88, 91, 137-144, 146-151] used an individual face-to-face mode as the primary means of intervention delivery, while three studies [133-136, 145] used a group face-to-face mode. All studies conducted supervised individual and group exercise programs for some period of the intervention (Table 6). One study had an initial one-week period with a physical therapist and thereafter the exercise program was self-driven [136]. Most studies used gym facilities, however one study used an unsupervised home-based RT component for one of their intervention groups [145].

Median intervention length was 12 months (range 4 - 48 months) with a follow-up of 18 months (range 6.5 - 48 months). Details of the diet and exercise interventions are reported in Table 6. Briefly, participants were advised to

perform aerobic exercise for an average of 5.0 ± 1.5 days.week^{-1} (mean ± SD), with an average duration of 157.5 ± 44.4 min.week^{-1} and to perform RT for an average of 2.3 ± 0.7 days.week^{-1} for an average duration of 90.0 ± 24.5 min.week^{-1}. Five studies prescribed energy restriction for weight loss and seven studies prescribed a specific dietary macronutrient profile.

2.3.3 Risk of bias within studies

The 10-item risk of bias analysis results for seven of the eight included studies are presented in Table 7. Bersoux et al [136] was excluded, as it was a non-randomised trial. Inter-rater reliability demonstrated a high initial level of agreement across all risk of bias items (percentage agreement 100%, Cohen's κ = 1), with no further discussion required. In total, three studies were classified as having a high risk of bias (score ≤ 5) [139, 145, 150, 151] and four studies as having a low risk of bias (score ≥ 6) [41, 66, 88, 91, 133-135, 137, 138, 140-144, 146-149].

Table 6 Characteristics of included studies

Author, year and study name	Design	Participants	Intervention groups (n) Intervention Length Follow up	Description of dietary intervention	Description of exercise intervention
Author Bersoux et al 2010 **SN:** DEAL study	single group pre-post	IFG and/or IGT n = 47# M: n = 21* F: n = 71* Age (mean ± SD) = 62 ± 12 years	**Groups** lifestyle INT group only **Intervention** 1 yr **Mode** group face to face **Follow up** nil	- weight loss goal of 7% - information sessions on healthful food choices, food labels, portion control, dining out healthy, shopping for healthful foods, decreasing dietary fat, food records and goal setting	- Initial supervised one on one sessions with physical therapist (1 week) to develop exercise program, then self-directed for remainder of study - 150 min PA.wk^{-1} - personalised exercise program that emphasised aerobic exercise - instructed to perform RT for upper extremity, lower extremity and core muscle groups flexibility exercises included - pedometer: 10000 steps.day^{-1}
Author Burtscher et al 2009	two group comparison	IFG n = 36# M: n = 20* F: n = 16* Age (mean ± SD) = 57.5 ± 6.9 years	**Groups** counselling only INT n = 18 and counselling + supervised exercise INT n = 18 **Intervention** 1 yr **Mode** individual face to face **Follow up** nil	**Both groups** - weight loss goal of 5% - achieve diet where total fat intake < 30% and saturated fat intake < 10%	**Both groups** - moderate intensity PA for 30 min.day^{-1} **Counselling + supervised exercise group** - supervised, progressive, individually tailored aerobic exercise program and circuit-type RT sessions for 1 hour two times.wk^{-1} (6-8 strength training exercises with 8-12 repetitions)

Author, year and study name	Design	Participants	Intervention groups (n) Intervention Length Follow up	Description of dietary intervention	Description of exercise intervention
Authors Lindstrom et al 2003, (Eriksson et al 1999 (Laaksonen et al 2005, Lindstrom et al 2006, Lindstrom et al 2003b, Tuomilehto et al 2001, Uusitupa et al 2003, Uusitupa et al 2000) **SN:** Finnish DPS	RCT	IGT n = 434[#] M: n = 172* F: n = 350* Age (mean ± SD) = 55 ± 7 years	**Groups** lifestyle INT (n = 231) and CON (n = 203, single education session at baseline) **Intervention length** median of 4 yr across the 5 study centres Note: Data for 3 yr used as the 4 yr results were only presented as means. **Mode** individual face to face **Follow up** median of 7 yr Note: data not reported in original article as a specific time-point of follow up.	- BMI goal of < 25 kg.m^{-2} (> 5% weight loss) - diet comprising > 50% carbohydrates, < 30% fat (<10% saturated fat, < 20% from mono-unsaturated and poly-unsaturated fat), 1 g protein.kg^{-1} ideal body weight - < 300 mg.day^{-1} cholesterol - > 15 g fibre per 1000 kcal - VLCD was implemented if BMI at 6 months still > 30 kg.m^{-2}	- moderate intensity aerobic exercise for at least 30 min.day^{-1} - supervised progressive, individually tailored circuit-type resistance training 2 days.wk^{-1} . Exercises included RT for large muscle groups of the upper and lower body

Author, year and study name	Design	Participants	Intervention groups (n) Intervention Length Follow up	Description of dietary intervention	Description of exercise intervention
Author McAuley et al 2002, (Dale et al 2009)	RCT	IGT n = 77[#] n = 43 completed 2 year follow up (See Note) M: n = 26* F: n = 53* Age (mean and range) = 43.3 [30-38] years	**Groups** intensive lifestyle INT (n = 25), moderate lifestyle intervention (n = 29) CON (n = 23, 2 week education after 4 month intervention) **Intervention length** 4 months **Mode** individual face to face **Follow up** 2 yr NOTE: intensive and modest INT groups collapsed into single intervention group after 4 month assessments	**Modest program** - diet comprising 50% carbohydrates, 32% fat (11% saturated fat, 14% monounsaturated fat, 7% polyunsaturated fat) and 18% protein - cholesterol 200 mg.day^{-1} - dietary fiber 25 g.day^{-1} **Intensive program** - diet comprising 55% carbohydrates 26% fat (6% saturated fat, 13% monounsaturated fat, 7% polyunsaturated fat) and 18% protein) - cholesterol 140 mg.day^{-1} - dietary fiber 35 g.day^{-1}	**Modest group** - 30 min.day^{-1} of PA for 5 days.wk^{-1} - NB no RT **Intensive group** - individual and group exercise sessions - supervised by exercise consultant (at least once per week) - 20 min.day^{-1} of PA at 80-90% for max heart rate - gym membership to encourage vigorous PA and resistance training at least 2 days.wk^{-1}

Author, year and study name	Design	Participants	Intervention groups (n) Intervention Length Follow up	Description of dietary intervention	Description of exercise intervention
Authors Page et al 1993 & Page et al 1992	RCT	IGT n = 25# n = 23 completed 2 year follow up M: n = 17* F: n = 8* Age (mean ± SD) = INT 39 ± 11 years vs CON 40 ± 10 years	**Groups** lifestyle INT groups for the first 6 wk with Diet only, exercise only, diet and exercise. Then all collapsed into Healthy Lifestyle INT group (n = 18), CON (n = 7, placebo pill). Drug group not included in analysis **Intervention Length** 6 months **Mode** individual face to face **Follow up** 2 yr	- reduction in energy intake (where appropriate) to achieve BMI goal < 25 kg.m^{-2} - diet comprising 50-55% carbohydrates and 30% fat - poly-unsaturated:saturated fat ratio of 1.0 - fiber intake 20 g.1000 kcal^{-1}	- 20 min of aerobic exercise for 3 days.wk^{-1} (minimum) - supervised exercise classes provided aerobic and anaerobic exercise, circuit training, swimming and aerobic weight training

Author, year and study name	Design	Participants	Intervention groups (n) Intervention Length Follow up	Description of dietary intervention	Description of exercise intervention
Author Payne et al 2008	Quasi-experimental	at risk for diabetes and/or IGT or IFG n = 122[#] M: n = 58* F: n = 64* Age (mean ± SD) = 52.6 ± 8.6 years	**Groups** lifestyle + gym-based RT INT (n = 62) and lifestyle +home-based RT INT (n = 60) **Intervention length** 1 yr **Mode** group face to face **Follow up** nil Note: No between groups differences for key diabetes measures. Results are presented in manuscript as combined pre-post results at 1 year	- weight loss goal of > 5% - diet comprising < 30% fat and < 10% saturated fat	**Both groups** - ≥ 150 min of weighted PA and ≥ 5 sessions of at least moderate PA.wk^{-1} **Gym-Based RT group** - supervised program - 2-3 RT sessions.wk^{-1} for 12 wk (wk 7-18 of 52 wk intervention). Sessions of 5 min low intensity aerobic warm-up, 45 min high intensity RT, 5 min of stretching cool down. RT program focused on selected major muscle groups and was incremental **Home-based RT group** - unsupervised program - 2-3 RT sessions.wk^{-1} for 12 wk (wk 7-18 of 52 wk intervention). Selection of exercises and progressions using body weight exercises and convenient hand-held weights (e.g., cans of food). Wk 13-18, theraband and swiss ball exercises added - **Both groups** were advised to continue the regime from wk 19-52

Author, year and study name	Design	Participants	Intervention groups (n) Intervention Length Follow up	Description of dietary intervention	Description of exercise intervention
Authors Roumen et al 2008, (Corpeleijn et al 2006, Mensink et al 2003a, Mensink 2003b, Roumen et al 2011) **SN:** The SLIM study	RCT	high risk individuals for IGT n = 106[#] M: n = 75* F: n = 72* Age (mean ± SD) = INT 54.2 ± 5.8 years vs CON 58.4 ± 6.8 years	**Groups** lifestyle INT (n = 52) and CON (n = 54, brief general advice) **Intervention Length** 3 yr **Mode** individual face to face **Follow up** nil	- weight loss goal of 5-7% - diet comprising > 55% of total energy from carbohydrates, < 30-35% fat, < 10% saturated fat, 10-15% protein - fiber > 3 g.MJ[-1] - cholesterol < 33 mg.MJ[-1]	- 30 min PA.day[-1] for at least 5 days.wk[-1] - access to a supervised exercise program with aerobic and resistance activities for 1 hour.wk[-1]
Authors Villareal 2006, (Villareal et al 2008, Villareal 2006)	RCT	at risk for diabetes or IGT n = 24[#] M: n = 9* F: n = 18* Age (mean ± SD) = INT 71 ± 2 years vs CON 69 ± 1 years	**Groups** INT (n = 15) and CON (n = 9, instructed to maintain usual dietary and exercise patterns) **Intervention length** 26 wk **Mode** group face to face **Follow up** nil	- energy deficit of 750 kcal.day[-1] - weight loss goal of 10% - diet comprising approximately 50% carbohydrate, 30% fat and 20 % protein	- group exercise supervised training sessions, 3 non-consecutive days.wk[-1] - 90 min session comprising 15 min warm-up flexibility tasks, 30 min endurance exercise, 30 min strength training and 15 min balance exercises

Authors - Where multiple publications per study are present, the main outcomes paper is listed first, followed by the remaining relevant articles in alphabetical order
Participants – results shown are based on the number of participants reported on in the main outcomes paper (i.e., completed intervention and/or follow up). * Baseline sample (male and female), [#] sample that completed the intervention
CON - control group, **FPG** - Fasting Plasma Glucose, **IFG** - Impaired Fasting Glucose, **IGT** - Impaired Glucose Tolerance, **INT** - intervention group, **mg** - milligram, **MJ** - MegaJoule, **SN** - Study Name, **PA** - Physical Activity, **RCT** - Randomised Controlled Trial, **RT** - Resistance Training, **VLCD** - Very Low Calorie Diet, **wk** - week, **yr** – year

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Table 7 Risk of bias analysis for randomised studies

Author, year, Study Name (SN)	i) Did the study report a power calculation and was the study adequately powered to detect intervention effects?	ii) Was the randomisation procedure adequately described and carried out?	iii) Did the study include a control group? (randomised participants not a comparison group)	iv) Did the study present baseline characteristics separately for treatment groups?	v) Did the study analyses account for potential differences at baseline?	vi) Were the assessors blinded to treatment allocation at baseline and post-test?	vii) Did the study have a dropout of < 20% (< 6 month follow-up) or < 30% (> 6 month follow-up for the primary outcome of weight	vii) Did the study use an intention to treat analysis?	ix) Did the study report summary results for each group?	x) Did the study report precision estimates (eg 95% confidence interval) and/or effect sizes?	Total
Author											
Burtscher et al 2009	0	0	0	1	1	0	0	0	1	0	3
Authors											
Lindstrom et al 2003, (Eriksson et al 1999 (Laaksonen et al 2005, Lindstrom et al 2006, Lindstrom et al 2003b, Tuomilehto et al 2001, Uusitupa et al 2003, Uusitupa et al 2000) **SN:** Finnish DPS	0	1	1	1	1	0	1	1	1	1	8

Author, year, Study Name (SN)	i) Did the study report a power calculation and was the study adequately powered to detect intervention effects?	ii) Was the randomisation procedure adequately described and carried out?	iii) Did the study include a control group? (randomised participants not a comparison group)	iv) Did the study present baseline characteristics separately for treatment groups?	v) Did the study analyses account for potential differences at baseline?	vi) Were the assessors blinded to treatment allocation at baseline and post-test?	vii) Did the study have a dropout of < 20% (< 6 month follow-up) or < 30% (> 6 month follow-up for the primary outcome of weight	vii) Did the study use an intention to treat analysis?	ix) Did the study report summary results for each group?	x) Did the study report precision estimates (eg 95% confidence interval) and/or effect sizes?	Total
Author McAuley et al 2002, (Dale et al 2009)	0	1	1	1	1	1	1	1	1	1	9
Authors Page et al 1993 & Page et al 1992	0	1	1	1	0	0	1	0	1	0	5
Author Payne et al 2008	0	0	0	0	1	0	1	1	0	1	4
Authors Roumen et al 2008, (Corpeleijn et al 2006, Mensink et al 2003a, Mensink 2003b, Roumen et al 2011) **SN:** The SLIM study	1	1	1	1	1	1	1	1	1	1	10

Author, year, Study Name (SN)	i) Did the study report a power calculation and was the study adequately powered to detect intervention effects?	ii) Was the randomisation procedure adequately described and carried out?	iii) Did the study include a control group? (randomised participants not a comparison group)	iv) Did the study present baseline characteristics separately for treatment groups?	v) Did the study analyses account for potential differences at baseline?	vi) Were the assessors blinded to treatment allocation at baseline and post-test?	vii) Did the study have a dropout of < 20% (< 6 month follow-up) or < 30% (> 6 month follow-up for the primary outcome of weight	vii) Did the study use an intention to treat analysis?	ix) Did the study report summary results for each group?	x) Did the study report precision estimates (eg 95% confidence interval) and/or effect sizes?	Total
Authors Villareal 2006, (Villareal et al 2008, Villareal 2006)	0	1	1	1	1	1	1	1	1	1	9

2.3.4 Results of included studies

A summary of results is presented in Table 8. A brief description of results is presented below. Results are presented as change in mean from baseline to end of intervention or as pre-post intervention. Follow-up results (where available) are presented in Table 8.

2.3.4.1 Weight change

Seven of the eight studies reported a reduction in weight (kg) for the intervention group at the end of their respective interventions and four of the five RCTs reported significant weight loss for the intervention group compared to controls (Table 8). The largest weight loss (-8.2 ± 5.7 kg) was reported by Villareal et al [133-135] after 26 weeks of intervention. The Finnish DPS [41, 66, 88, 91, 146-149] and SLIM studies [140-144] reported a reduction in weight for the intervention compared to controls (INT -3.5 ± 5.1 vs CON -0.9 ± 5.4 kg, P < 0.001 and INT -1.08 ± 4.30 vs CON 0.16 ± 4.91 kg, P = 0.045, respectively) after three years, demonstrating that small-moderate long-term weight loss is achievable in this population.

Table 8 Results of included studies

Author, year Study Name (SN)	Analysis	Outcome measures	Results for weight and diabetes markers	Results on dietary and exercise outcomes	Retention
Author Bersoux et al 2010 **SN:** DEAL study	- Mann-Whitney test and Wilcoxon sign rank test for differences between unpaired continuous variables	- weight - FPG - OGTT	**Pre-post results at 6 months** - ↓ weight (pre 89.5 ± 17 kg – post 86.9 ± 16.8 kg, $P < 0.001$) - FPG did not change (pre 6.05 mmol.L^{-1} – post 6.11 mmol.L^{-1}, no SD, $P = 0.14$) - 2-h OGTT improved (pre 9.38 mmol.L^{-1} – post 8.44 mmol.L^{-1}, no SD, $P = 0.04$)	Not reported	- 47/92 (51%) completed 6 month intervention period
Author Burtscher et al 2009	- 2-way repeated measures ANOVA for between group differences - Post hoc paired t-test with bonferroni correction for within group differences	- weight - FPG - duration of PA/exercise - power output and METs	**Within group results counselling + supervised exercise at 1 yr** - ↓ weight (pre 86.9 ± 13.5 kg – post 84.3 ± 11.5 kg, $P < 0.05$) - ↓ FPG (pre 5.9 ± 0.4 mmol.L^{-1} – post 5.6 ± 0.4 mmol.L^{-1}, $P < 0.05$) **Within group results counselling only exercise at 1 yr** - no change in weight (pre 79.4 ± 12.3 kg – post 80.2 ± 12.0 kg, $P > 0.05$) - ↓ FPG (pre 6.0 ± 0.4 mmol.L^{-1} – post 5.5 ± 0.5 mmol.L^{-1}, $P < 0.05$) **Between group results at 1 yr** - ↓ weight ($P = 0.03$) - no difference FPG ($P = 0.19$)	**Within group results counselling + supervised exercise at 1 yr** no data on within group dietary changes **Exercise** - ↑ power output max (pre 133.5 ± 39.1 W – post 137.5 ± 40.3 W, $P < 0.05$) - ↑ METs$_{max}$ (pre 6.8 ± 1.2 METs$_{max}$ – post 7.1 ± 1.5 METs$_{max}$, $P = 0.01$) **Within group results counselling only exercise at 1 yr** No diet or exercise data **Between group results at 1 yr** **Diet** no data on between group dietary changes **Exercise** - ↑ power output max ($P = 0.04$) - ↑ METs$_{max}$ ($P = 0.01$) - approximately two-fold ↑ in PA/exercise (counselling + exercise 218 ± 105 min.wk^{-1} vs counselling only 111 ± 166 min.wk^{-1}, P value not shown)	- 36 of 131 (27%) participants completed 1 yr intervention period

Author, year Study Name (SN)	Analysis	Outcome measures	Results for weight and diabetes markers	Results on dietary and exercise outcomes	Retention
Authors Lindstrom et al 2003, (Eriksson et al 1999 (Laaksonen et al 2005, Lindstrom et al 2006, Lindstrom et al 2003b, Tuomilehto et al 2001, Uusitupa et al 2003, Uusitupa et al 2000) **SN:** Finnish DPS	- Student's *t*-test for differences at baseline and ANVCOVA adjusted for baseline value	- weight - FPG - OGTT - HBA1C - dietary composition - PA min.wk^{-1}	**Between group differences at 3 yr** - ↓ weight (INT -3.5 ± 5.1 kg vs CON - 0.9 ± 5.4 kg, P < 0.001) - no change in FPG (INT -0.0 ± 0.7 mmol.L^{-1} vs CON 0.1 ± 0.7 mmol.L^{-1}, P < 0.066) - no change in OGTT (INT -0.5 ± 2.4 mmol.L^{-1} vs CON -0.1 ± 2.2 mmol.L^{-1}, P < 0.066) - ↓ HbA$_{1C}$ (INT -0.2 ± 0.6 mmol.L^{-1} vs CON 0.0 ± 0.6 mmol.L^{-1}, P = 0.002)	**Between group differences at 3 yr Diet** - ↓ total energy intake (INT -853 ± 2044 kJ.day^{-1} vs CON -405 ± 1914 kJ.day^{-1}, P = 0.0067) - ↑ carbohydrate %E (INT 3.3 ± 8.0% vs CON 2.0 ± 7.6%, P = 0.007) - ↓ fat %E (INT -4.7 ± 7.7% vs CON -3.2 ± 7.5%, P < 0.001) - ↓ sat fat %E (INT -3.2 ± 4.5% vs CON -1.9 ± 4.9%, P < 0.001) - ↑ fibre (INT 2.4 ± 4.7 g.1000 kcal^{-1} vs CON -1.1 ± 4.1 g.1000 kcal^{-1}, P = 0.001) **Exercise** - No difference in total PA time (INT 50 min.wk^{-1} [-126 to 115 IQR] vs CON 23 min.wk^{-1} [-142 to 171 IQR], P = 0.2415) - ↑ moderate to vigorous leisure time PA (INT 61 min.wk^{-1} [-33 to 168 IQR] vs CON 6 min.wk^{-1} [-91 to 104 IQR], P = 0.0057)	- 434/522 (83%) competed 3 yr intervention period

Author, year Study Name (SN)	Analysis	Outcome measures	Results for weight and diabetes markers	Results on dietary and exercise outcomes	Retention
Author McAuley et al 2002, (Dale et al 2009)	- weight changes were assessed using ITT analysis using a mixed model with random effect for person - regression analysis with baseline measure as a covariate or ANCOVA used for other measures.	- weight - FPG - dietary composition - aerobic fitness by predicted VO_{2max}	**Between group results at 4 months** - → weight for both modest INT and intensive INT compared to control (adjusted differences: Modest INT -3.4 kg [-5.4, -1.3; 95% CI, Intensive INT - 4.7 kg [-6.9, -2.4; 95% CI], CON pre 102.8 ± 15.3 kg post 101.5 ± 15.1 kg, P = 0.002 and P < 0.001, respectively) - No changes in FPG (adjusted differences: Modest INT -0.1 mmol.L^{-1} [-0.3, 0.2; 95% CI, Intensive INT -4.7 mmol.L^{-1} [-0.4, 0.2; 95% CI], CON pre 5.2 ± 0.6 mmol.L^{-1} post 5.2 ± 0.5 mmol.L^{-1}, P = 0.61 and P = 0.47 respectively) **Between groups results at 2 years** - No differences	**Between group results at 4 months Diet** - → total energy intake for modest INT but not sig different for intensive INT (adjusted differences - Modest INT 1705 kJ.day^{-1} [523, 2884; 95% CI], Intensive INT -1012 kJ.day^{-1} [-2215, -192; 95% CI], CON pre 9564 kJ.day^{-1} [no SD or CI] post 8866 kJ.day^{-1} [no SD or CI], P = 0.005, P = 0.098, respectively) - ↑ carbohydrates %E for both INT groups (adjusted differences – Modest INT 7% [3, 11; 95% CI], Intensive INT 5% [1, 9; 95% CI] CON pre 47 ± 6 post 46 ± 8, P = 0.001, P = 0.02, respectively) - → total fat %E for both INT groups (adjusted differences - Modest INT 11% [-15, -7; 95% CI], Intensive INT -9% [-12, -5; 95% CI, CON pre 33 ± 6% post 35 ± 8%, P < 0.001 for both) - → sat fat %E for both INT groups (adjusted differences - Modest INT -7% [-10, -5; 95% CI], Intensive INT -7% [-9, -5; 95% CI], CON pre 14 ± 3% post 16 ± 5%, P < 0.001 for both) - ↑ protein %E for both INT groups (adjusted differences - Modest INT 4% [1, 6; 95% CI], Intensive INT 3% [1, 6; 95% CI], CON pre 17 ± 4% post 16 ± 3%, P = 0.002, P = 0.01 respectively) - ↑ fibre for intensive INT only (adjusted differences - Modest INT 5.4% [-0.4, 11.2; 95% CI], Intensive INT 8.9% [2.9, 14.9; 95% CI], CON pre 24.5 [no SD] post 21.7 [no SD], P = 0.07, P = 0.004, respectively)	- 77/79 (97 %) completed 4 month intervention period - 62/79 (78 %) completed 2 yr follow up measurements

Author, year Study Name (SN)	Analysis	Outcome measures	Results for weight and diabetes markers	Results on dietary and exercise outcomes	Retention
				Exercise - ↑ $VO2_{max}$ for intensive INT only (adjusted differences - Modest INT 0 $mL.min^{-1}.kg^{-1}$ [-3, 3; 95% CI, Intensive INT 4 $mL.min^{-1}.kg^{-1}$ [1, 7; 95% CI], CON pre 29 ± 6 $mL.min^{-1}.kg^{-1}$ post 32 ± 7 $mL.min^{-1}.kg^{-1}$, P = 0.94, respectively) **Between groups results at 2 years** - No differences	

Author, year Study Name (SN)	Analysis	Outcome measures	Results for weight and diabetes markers	Results on dietary and exercise outcomes	Retention
Authors Page et al 1993 & Page et al 1992	- paired and unpaired *t*-tests - Wilcoxon sign rank test NOTE: between groups results not reported for relevant outcomes to this review	- BMI/Weight - FPG - diet composition - aerobic fitness by VO_{2max}	**Within group results at 6 months** (n = 18) - non-sig reduction in BMI (INT pre 26 ± 4 kg.m^{-2} – post 25 ± 5 kg.m^{-2} vs CON pre 28 ± 4 kg.m^{-2} – 27 ± 4 kg.m^{-2}, P value not reported), weight (kg) not reported - no change in FPG (INT pre 5.6 ± 0.6 mmol.L^{-1} – post 5.6 ± 0.7 mmol.L^{-1} vs CON pre 5.8 ± 0.5 mmol.L^{-1} – 5.8 ± 0.5 mmol.L^{-1}, P value not reported) **Within group results at 2 yr** - no change in BMI (INT pre 26 ± 4 kg.m^{-2} – post 26 ± 4 kg.m^{-2} vs CON pre 28 ± 4 kg.m^{-2} – 28 ± 4 kg.m^{-2}, P value not reported) - ↑ FPG for intervention (INT pre 5.5 ± 0.6 mmol.L^{-1} – post 6.0 ± 1.2 mmol.L^{-1} vs CON pre 5.6 ± 0.5 mmol.L^{-1} – 6.0 ± 0.6 mmol.L^{-1}, P < 0.05 and P value not reported, respectively)	**Within group results at 6 months** **Diet** - ↓ total energy intake (INT pre 9455 ± 3925 kJ.day^{-1} – post 7382 ± 2855 kJ.day^{-1} vs CON pre 9288 ± 2370 kJ.day^{-1} – post 8072 ± 1860 kJ.day^{-1}, P < 0.01 and P value not reported, respectively) - no change in carbohydrate %E (INT pre 42.4 ± 6.3% – post 44.7 ± 6.7% vs CON pre 42.1 ± 5.8% – post 41.2 ± 4.7, P value not reported) - ↓ fat %E (INT pre 38.8 ± 6.5% – post 33.0 ± 5.4% vs CON pre 37.1 ± 8.4% – post 36.9 ± 8.0%, P < 0.05 and P value not reported, respectively) - ↑ protein %E (INT pre 15.7 ± 3.3% – post 18.5 ± 3.1% vs CON pre 15.6 ± 3.0% – post 16.7 ± 1.9%, P < 0.05 and P value not reported, respectively) - no change in fiber (INT pre 22.3 ± 8.3 g – post 25.9 ± 10.2 g vs CON pre 24.4 ± 7.3 g – post 22.3 ± 7.0 g, P value not reported) **Exercise** - ↑ VO_{2max} (INT pre 2.4 ± 0.6 L.min^{-1} – post 2.7 ± 0.7 L.min^{-1} vs CON pre 2.6 ± 0.6 L.min^{-1} – post 2.6 ± 0.6 L.min^{-1}, P < 0.05 and P value not reported, respectively) **Within group results at 2 yr** - diet and exercise not reported	- 25/31 (81 %) completed 6 month intervention period - 23/31 (74 %) completed 2 yr follow up

Author, year Study Name (SN)	Analysis	Outcome measures	Results for weight and diabetes markers	Results on dietary and exercise outcomes	Retention
Author Payne et al 2008	- ITT analysis - repeated measures ANOVA - independent samples *t*-test	- weight - FPG - OGTT - PA - diet composition	**Combined pre-post results at 1 year** - → Weight (-4.07 kg [-4.99, -3.15; 95% CI], P < 0.001) - → FPG (-0.15 mmol.L^{-1} [-0.23, -0.07; 95% CI], P < 0.001) - → 2-h OGTT (-0.34 mmol.L^{-1} [-0.60, -0.08; 95% CI], P < 0.011)	**Combined pre-post results at 1 year** **Diet** - → total energy intake (-1057 kJ.day^{-1} [-0.23, -0.07; 95% CI], P < 0.001) - → fat %E (-2.13 % [-2.96, -1.30; 95% CI], P < 0.001) - → saturated fat %E (-1.43% [-1.88, -0.97; 95% CI], P < 0.001) **Exercise** - ↑ PA (3.09 sessions.wk^{-1} [0.98, 5.19; 95% CI], P = 0.004) - ↑ weighted PA (81.88 min.wk^{-1} [22.93, 140.83; 95% CI], P = 0.007)	- 98/122 (80 %) completed 1 year intervention period
Authors Roumen et al 2008, (Corpeleijn et al 2006, Mensink et al 2003a, Mensink 2003b, Roumen et al 2011) **SN:** The SLIM study	- differences within groups tested by student *t*-test. - differences between groups assessed by repeated measures ANOVA for completers analysis and linear mixed models for ITT analysis.	- weight - FPG - OGTT - HBA1C - dietary composition - fitness - PA level	**Between group differences at 3 yr (ITT)** - → weight (INT -1.08 ± 4.30 kg vs CON 0.16 ± 4.91 kg, P = 0.045) - ↑ FPG however the INT was significantly lower (INT 0.32 ± 0.83 mmol.L^{-1} vs CON 0.55 ± 0.82 mmol.L^{-1}, P = 0.04) - Small → in 2-h OGTT for INT, though not sig (INT -0.05 ± 2.02 mmol.L^{-1} vs CON 0.89 ± 1.9 mmol.L^{-1}, P = 0.086) - no change in HbA$_{1C}$ (INT -0.09 ± 0.43% vs CON -0.10 ± 0.38%, P = 0.838)	**Between group differences at 3 yr** **Diet** - Non-significant → in total energy intake (INT -1100 ±1900 kJ.day^{-1} vs -300 ± 1800 kJ.day^{-1} - ↑ Carbohydrates %E (INT 4.8 ± 5.6% vs -CON 1.2 ± 5.4%, P = 0.001) - → fat %E (INT -4.7 ± 5.9% vs CON -0.5 ± 5.8%, P < 0.001) - → saturated fat %E (INT -2.9 ± 3.2% vs CON -0.7 ± 3.1%, P < 0.001) - ↑ fibre (INT 0.5 ± 0.6 g.MJ^{-1} vs CON 0.2 ± 0.8 g.MJ^{-1}, P = 0.05) **Exercise** - ↑ VO$_{2max}$ (INT 0.05 ± 0.35 L.min^{-1} vs CON -0.6 ± 0.21 L.min^{-1}, P = 0.009).	- 106 of 147 (72 %) participants completed 3 yr intervention period

Author, year Study Name (SN)	Analysis	Outcome measures	Results for weight and diabetes markers	Results on dietary and exercise outcomes	Retention
Authors Villareal 2006, (Villareal et al 2008, Villareal 2006)	- ITT analysis using last observation carried forward - between group differences assessed using ANOVA with baseline measures as covariates - within group differences assessed by t-test for paired samples	- weight - FPG - OGTT - physical performance test, VO_{2peak}, knee extension flexion strength, walking speed over 25 feet	**Between group differences at 26 wk** - ↓ weight (INT -8.2 ± 5.7 kg vs CON 0.7 ± 2.7 kg, P < 0.001) - ↓ FPG (INT -4.4 ± 4% vs CON 4 ± 2%, P < 0.05) - ↓ OGTT (INT -4 ± 12% vs CON 8 ± 4%, P < 0.05)	**Between group differences** **Diet** Not reported **Exercise** - ↑ physical performance test (INT 2.6 ± 2.5% vs CON 0.1 ± 1.0%, P = 0.001) - ↑ VO_{2peak} (INT 1.7 ± 1.6 $mL.min^{-1}.kg^{-1}$ vs CON 0.3 ± 1.1 $mL.min^{-1}.kg^{-1}$, P = 0.02) - ↑ knee extension strength (INT 12.9 ± 12.5% vs CON 4.3 ± 13.0%, P = 0.04) - ↑ Knee flexion strength (INT 25.5 ± 26.6% vs CON 1.1 ± 17.9%, P = 0.008) - ↑ walking speed (INT 7.6 ± 10.2% vs CON -1.9 ± 12.5%, P = 0.04)	- 24/27 (89 %) completed 24wk intervention period

Outcome measures – data for 1) weight (kg or BMI) 2) diabetic indices including FPG, OGTT, HbA$_{1C}$ 3) measure of dietary change including FPG, OGTT, HbA$_{1C}$ 3) measure of dietary change 5) measure of exercise change

Results - For RCTs where between group results are available they are presented. For other study designs within group results are presented. End of intervention and follow up results presented if available. In general for studies with no follow up, results for the last assessment time point are presented. Finnish DPS 3 year results paper is reported on in this table as the 4 year results are only presented as means from a small subset (one study site) of the total study. Page et al did not report between group differences for outcomes relevant to this review, therefore only within group results for relevant outcomes are presented.

CON - control group, **FPG** - Fasting Plasma Glucose, **IFG** - Impaired Fasting Glucose, **IGT** - Impaired Glucose Tolerance, **INT** - intervention group, **IQR** - interquartile range, **ITT** - Intention To Treat, **METs** - Metabolic Equivalents, **mg** - milligram, **sig** - significant, **SN** - Study Name, **PA** - Physical Activity, **RT** - Resistance Training, **VLCD** - Very Low Calorie Diet, **vs** - versus, **wk** - week, **yr** - year, **<** - less than, **>** - greater than, ↑ - increase, ↓ - decrease

2.3.4.2 Glucose regulation

FPG was reported in all eight studies (Table 8). Only two of the five RCTs reported significant differences between the intervention and control groups. Villareal et al [133-135] reported the intervention group had a reduction in FPG at 26 weeks whereas the control group increased (P < 0.05). In the SLIM study [140-144], FPG increased in both groups after three years relative to baseline, however the difference between groups was significant (P = 0.04). Payne et al [145] and Burtscher et al [139] reported significant within group pre-post reductions in FPG (P < 0.001 and P < 0.05, respectively) at 12 months. Two-hour OGTT was reported in five studies (Table 8). Villareal et al [133-135] reported a reduction in 2-h OGTT at 26 weeks for the intervention group whereas the control group increased (P < 0.05). Bersoux et al [136] and Payne et al [145] reported within group pre-post reductions (P = 0.04 and P = 0.011, respectively) at 6 and 12 months, respectively. HbA_{1C} was reported in two RCTs (Table 8). The Finnish DPS [41, 66, 88, 91, 146-149] intervention group had a significant reduction compared to controls (P = 0.002) at three years, whereas the SLIM study [140-144] reported no difference between groups (P = 0.838) at three years.

2.3.4.3 Exercise outcomes

Physical activity and/or physical fitness outcomes were questionnaire [41, 66, 88, 91, 133-135, 145-149] or exercise testing [133-135, 137-144, 150, 151] based (Table 8). Aerobic exercise outcomes were reported in five of the eight studies. McAuley et al [137] and Dale et al [138] predicted aerobic capacity (VO_{2max}) from performance in a sub-maximal walking test (modified Bruce protocol). The intensive intervention group improved compared to controls (P = 0.02) whereas the modest

intervention group did not (P = 0.94). In the SLIM study [140-144] aerobic capacity (VO_{2max}) was assessed using an incremental exhaustive cycle ergometer test. At three years, the intervention group improved their aerobic capacity compared to controls (P = 0.009). At 26 weeks, Villareal et al [133-135] reported the intervention group VO_{2peak} had improved compared to the controls (P = 0.02). Page et al [150, 151] measured aerobic capacity (VO_{2max}) using maximal cycle ergometry. The 'healthy living' intervention group improved aerobic capacity (P < 0.05) whereas the controls did not change (P value not reported) at six months. Burtscher et al [139] reported a pre-post increase in maximum metabolic equivalents ($METs_{max}$) for their 'counseling + supervised exercise' group after one year, which differed (P = 0.01) to the 'counseling only' group.

Only one of the eight studies measured improvements in muscular strength or performance (Table 8). Villareal et al [133-135] reported significant improvements in knee extension (P = 0.04) and knee flexion (P = 0.008) for the intervention group versus controls after 26 weeks.

No studies used objective measures (e.g., pedometers or accelerometers) to assess physical activity. Self-reported physical activity was presented in three studies (Table 8). The Finnish DPS [41, 66, 88, 91, 146-149] reported no difference in mean total leisure time physical activity (P = 0.2415), but moderate-vigorous leisure time physical activity increased in the intervention group compared with controls (P = 0.006) at three years (validated self-report questionnaire). Burtscher et al [139] reported that duration of physical activity (min.week^{-1} from log books) during the last three months of intervention in the supervised exercise

group was almost double that of the counselling only group (P value not reported). Payne et al [145] reported pre-post intervention increases in physical activity weighted min.wk^{-1} (P = 0.007) and sessions.wk^{-1} (P = 0.004) after one year (validated self-report questionnaire).

2.3.4.4 Dietary Outcomes

Dietary composition was assessed in six of the eight studies. Total energy intake (E) expressed as kilocalories (kcal) or kilojoules (kJ) per day was reported in five studies (Table 8). The Finnish DPS [41, 66, 88, 91, 146-149] reported reductions favouring intervention over controls at three years (P = 0.007). McAuley et al [137] and Dale et al [138] reported a reduction in energy intake for modest and intensive intervention groups at four months, however only the modest group (P = 0.005) was significantly different to controls. Significant within group pre-post reductions for energy intake were reported by Page et al [150, 151] (P < 0.01) at six months and Payne et al [145] (P < 0.001) at 12 months. Results for intervention effects on macronutrient composition are provided in Table 8.

2.3.4.5 Type 2 diabetes incidence

T2DM incidence was only reported in two studies. The Finnish DPS [41, 66, 88, 91, 146-149] reported the cumulative incidence of T2DM after four years was 58% lower in the intervention group than controls [41]. The SLIM study [41, 66, 88, 91, 133-135, 140-149] reported cumulative incidence for T2DM after three years of 18% (11/61) for intervention and 32% (19/60) for the controls (56% lower for the intervention compared to control).

2.3.5 Synthesis of results

Meta-analyses of RCTs with outcomes for weight and FPG were conducted. Funnel plots to assess publication bias were not generated as fewer than 10 interventions were included in the meta-analysis [129].

2.3.5.1 Weight change

In total, 325 intervention and 290 control participants (total 644) from four studies were included. The interventions were statistically heterogeneous (χ^2 = 18.04, d.f. = 3, P < 0.001, I^2 = 83%), so the random effects model was used. Meta-analysis (Figure 2) revealed a significant reduction in weight favoring the interventions over controls at the last reported assessment (WMD -3.79 kg [-6.13, -1.46; 95% CI], Z = 3.19, P = 0.001). The time frame of assessments varied from four to 36 months.

2.3.5.2 Fasting plasma glucose

In total, 331 intervention and 307 control participants (total 667) from five studies were included. The interventions were statistically homogenous (χ^2 = 3.01, d.f. = 4, P = 0.56, I^2 = 0%), so the fixed effects model was used. Meta-analysis (Figure 3) revealed a significant reduction in FPG favoring interventions over controls at the last reported assessment (WMD -0.13 mmol.L^{-1} [-0.24, -0.02; 95% CI], Z = 2.42, P = 0.02), with the time frame from four to 36 months.

Study or Subgroup	Intervention Mean [kg]	SD [kg]	Total	Control Mean [kg]	SD [kg]	Total	Weight	Mean Difference IV, Random, 95% CI [kg]	Mean Difference IV, Random, 95% CI [kg]
Lindstrom et al 2003	-3.5	5.1	231	-0.9	5.4	203	29.9%	-2.60 [-3.59, -1.61]	
Macauley et al 2002	-5.2	6	25	-1.3	1.7	23	23.4%	-3.90 [-6.35, -1.45]	
Roumen et al 2008	-1.08	4.3	52	0.16	4.91	54	26.8%	-1.24 [-3.00, 0.52]	
Villareal et al 2006	-8.2	5.7	17	0.7	2.7	10	19.9%	-8.90 [-12.08, -5.72]	
Total (95% CI)			**325**			**290**	**100.0%**	**-3.79 [-6.13, -1.46]**	

Heterogeneity: Tau^2 = 4.48; Chi^2 = 18.04, df = 3 (P = 0.0004); I^2 = 83%
Test for overall effect: Z = 3.19 (P = 0.001)

Favours intervention   Favours control

Meta-analysis forest plot comparison of weight loss (kg) in randomised controlled trials (intervention vs control) at the last reported assessment. **Tau²** – Tau square test; **Chi²** = Chi square test; **df** = degrees of freedom; **I²** = I-squared statistic; **IV** = inverse variance; **Z** = Z-test.

Figure 2 Forrest plot – weight loss (kg)

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Study or Subgroup	Intervention			Control			Weight	Mean Difference IV, Fixed, 95% CI [mmol/L]	Mean Difference IV, Fixed, 95% CI [mmol/L]
	Mean [mmol/L]	SD [mmol/L]	Total	Mean [mmol/L]	SD [mmol/L]	Total			
Lindstrom et al 2003	0	0.7	231	0.1	0.7	203	65.3%	-0.10 [-0.23, 0.03]	
Macauley et al 2002	-0.1	0.52	25	0	0.59	23	11.4%	-0.10 [-0.42, 0.22]	
Page et al 1993	0	0.46	6	0	0.58	17	5.4%	0.00 [-0.46, 0.46]	
Roumen et al 2008	0.32	0.83	52	0.55	0.82	54	11.5%	-0.23 [-0.54, 0.08]	
Villareal et al 2006	-0.22	0.39	17	0.22	0.61	10	6.4%	-0.44 [-0.86, -0.02]	
Total (95% CI)			331			307	100.0%	-0.13 [-0.24, -0.02]	

Heterogeneity: Chi² = 3.01, df = 4 (P = 0.56); I² = 0%
Test for overall effect: Z = 2.42 (P = 0.02)

Meta-analysis forest plot comparison of change in fasting plasma glucose in randomised controlled trials (intervention vs control) at the last reported assessment. **Chi²** = Chi square test; **df** = degrees of freedom; **I²** = I-squared statistic; **IV** = inverse variance; **Z** = Z-test.

Figure 3 Forrest plot – fasting plasma glucose (mmol.L^{-1})

2.4 Discussion

This systematic review found that multi-component lifestyle interventions incorporating diet + aerobic exercise + RT conducted in at risk or adults with prediabetes were efficacious for inducing modest weight loss and eliciting small improvements in glycaemic control, together with improvements in aerobic fitness and dietary intake. The impact of interventions on muscular fitness and physical activity were not consistently reported, making it difficult to determine the contributions of these components towards improvements in glucose regulation.

2.4.1 Weight change and glucose regulation

All interventions in this review and the meta-analysis found significant weight loss compared to controls. Importantly the DPP identified weight loss as the dominant predictor of their 58% reduction in T2DM incidence [48]. However, the effects on glucose regulation were less consistent. Meta-analysis found a small but significant reduction that would be of clinical importance in those with borderline prediabetes. The baseline FPG mean of the combined study population in the meta-analysis (5.6 mmol.L^{-1}) was at the lower limit of the prediabetes range (5.6 - 6.9 mmol.L^{-1}) [15]. This suggests that scope to improve further was limited in these cohorts, a circumstance which may be common amongst individuals with prediabetes who present in clinical settings. Furthermore, the small magnitude of change observed in the meta-analysis for FPG was heavily influenced by the results of the Finnish DPS, which received a 65% weighting due to its large sample size. The Finnish DPS excluded participants from the study after diagnosis of T2DM. As the majority of those

developing T2DM belonged to the control group, this introduces bias, which underestimates the FPG of the control group, leading to an attenuation of the difference between the groups.

2.4.2 Exercise programs and measurement of related outcomes

The reporting of exercise programs was inconsistent between studies and most studies provided only general descriptions of their exercise programs. For example, "The supervised exercise group has additionally been offered supervised, progressive, individually tailored aerobic exercise programs and circuit-type resistance training sessions for 1 hour twice a week" [139]. This makes it difficult to determine the specific modes of RT exercises that were performed (e.g., body weight, free weights, isometric exercises, isokinetic exercises, resistance band) and the volume (load, repetitions and sets) prescribed. Future studies are recommended to provide more comprehensive descriptions of the exercise programs. Most studies provided supervised individual or group exercise sessions; only one study included a home-based exercise component [145]. This has implications for the feasibility, practicalities and dissemination costs of these programs into community and health-care settings, as few health care systems can afford to provide supervision of exercise programs by qualified personnel.

Measurement of exercise-related outcomes was also inconsistent between studies. No studies used objective measures (e.g., pedometers or accelerometers) to assess physical activity, which is a major limitation in existing studies. Physical activity levels as measured by self-report improved in

intervention groups versus controls groups [41, 66, 88, 91, 146-149]. Aerobic exercise tests to measure or predict VO_{2max} were the most widely used fitness indicator, and improvements in aerobic fitness in intervention groups were generally observed [133-135, 137, 138, 140-144]. Only one study measured improvements in muscular strength [133-135], assessing only lower body limb strength using an isokinetic dynamometer. Without evaluation of muscular performance (including upper and lower body muscle groups) it is difficult to determine whether the RT program was adhered to or whether the addition of RT in multi-component programs contributes to improvements in muscular fitness and glycaemic control in prediabetes populations, as has been shown in adults with T2DM [152]. Future studies should provide comprehensive and objective evaluation of the impact on aerobic and muscular fitness.

2.4.3 Type 2 diabetes incidence

A reduction in T2DM incidence is the goal for all T2DM prevention programs. Of the studies reviewed, incidence of T2DM was only reported in the Finnish DPS and SLIM studies (up to 58% reduction in T2DM incidence). This finding is of great interest, particularly since the US DPP, which did not prescribe RT as part of their physical activity recommendations, also reported a 58% reduction in diabetes incidence (after 2.8 years) [40]. This suggests that multi-component T2DM prevention programs that include RT are effective, but whether RT provides benefits additional to dietary and aerobic components requires further investigation.

2.4.4 Features of effective interventions

Study design and intervention components were heterogeneous amongst the included studies, which may account for some of the variation observed in the outcomes assessed. Design characteristics of studies that achieved significant changes for weight loss and FPG [133-135, 138, 140-143, 145] included: face-to-face intervention delivery mode (individual and/or group), an average of eight contacts per month (including face to face sessions, emails and phone calls), and a minimum of six (preferably 12) months of follow up. Lifestyle intervention characteristics included: 150-210 minutes (3-5 sessions) of aerobic exercise per week; 60-120 minutes (1-3 sessions) of RT per week; recommendations for a specified macronutrient diet profile, energy restriction for weight loss and setting a weight loss goal of 5-10%.

2.4.5 Sex differences in lifestyle programs

Of the studies reviewed, 62% of participants were female. Since there is no reported global difference in gender distribution for diabetes [21], this may indicate that women are more likely to participate in diabetes prevention trials. None of the studies targeted a specific sex or reported their results by sex. Whether males and females benefit equally from these multi-component interventions is not known, but future studies should report their results by sex to reveal any differences that may exist. A recent systematic review [116] argued that sex-specific design features may be important influences on the effectiveness of lifestyle interventions.

2.4.6 Strengths and limitations

This is the first review to synthesise the evidence of multi-component interventions including diet, aerobic exercise and RT for the prevention of type 2 diabetes. It adhered to the PRISMA statement for the reporting of systematic reviews and meta-analyses; a comprehensive search strategy was performed across multiple databases with no date restrictions; high agreement levels for quality assessments were achieved; and detailed data extraction was performed to allow for comparisons between studies.

The review also has some limitations. Meta-analyses for weight and FPG were based on a small number of studies and the meta-analysis for weight was statistically heterogeneous. The sample for the meta-analyses consisted of 62% females, which introduces a sex bias. Furthermore the mean age of participants was 54.5 ± 9.7 years and only one study targeted older individuals (> 65) [133-135]. This limits the generalisability of the results particularly for older individuals and highlights the evidence gap in the field. Regular resistance training may result in gains or maintenance of muscle mass; consequently weight loss as an outcome by itself would be confounded by the inability to discriminate between loss of fat mass and gains in fat free mass. Future studies need to include more comprehensive assessments of body composition. For the aforementioned reasons results from the original studies and the synthesis of results presented here must be interpreted with caution. Finally, T2DM prevention studies that employed diet + aerobic exercise, but not RT were not eligible, including the highly successful US DPP.

2.4.7 Direction for future research

This review has highlighted the need for high quality long-term RCTs that assess multi-component lifestyle prevention programs for T2DM. Systematic investigation of the benefits of each additional component (diet, aerobic, RT, physical activity) of multi-component lifestyle interventions is also required to provide further support for the current recommendations for T2DM prevention. Future studies should report intervention component adherence and use objective measures to detect changes in muscular fitness, aerobic capacity and physical activity. More comprehensive measures of body composition (e.g., waist circumference, dual x-ray absorptiometry or bioimpedance analysis) should be utilised to determine changes in body composition as a result of multi-component T2DM prevention programs including RT. Studies exploring interventions tailored specifically for men or women are required to determine any impact on recruitment, retention and efficacy.

2.5 Conclusions

Multi-component lifestyle interventions to prevent T2DM, which include a dietary intervention and both aerobic and resistance exercise training, are modestly effective in inducing weight loss, improving impaired fasting glucose, improving glucose tolerance and improving dietary and exercise outcomes in at risk and prediabetes populations. These results support the current exercise guidelines for the inclusion of RT in T2DM prevention. Further research is required to determine the long-term efficacy of multi-component interventions on T2DM prevention and changes in biomarkers of risk e.g., (FPG, OGTT, HbA$_{1C}$, weight

and waist circumference) and the specific contributions of each intervention component to these outcomes.

Chapter 3 – The PULSE (Prevention Using LifeStyle Education) trial protocol: a randomised controlled trial of a type 2 diabetes prevention program for men

Preface:

This chapter presents a published peer-reviewed manuscript, which aligns with the *Primary Aim* of this thesis i.e., to evaluate the feasibility and efficacy of the *PULSE Program* for improving a range of risk factors strongly linked with type 2 diabetes mellitus development, including weight and glycaemic markers in men at high-risk for developing type 2 diabetes mellitus. This manuscript has been published in the journal *Contemporary Clinical Trials*.

Citation:

Aguiar EJ, Morgan PJ, Collins CE, Plotnikoff RC, Young MD, Callister R. The PULSE (Prevention Using LifeStyle Education) trial protocol: a randomised controlled trial of a Type 2 Diabetes Prevention programme for men. Contemp Clin Trials. 2014;39:132-144. doi:10.1016/j.cct.2014.07.008

Abstract

Intensive lifestyle interventions have been successful in reducing type 2 diabetes incidence. Whether intensive programs requiring face-to-face contact, trained staff and access to facilities are feasible on a larger scale has been debated. The aim of this trial is to determine the feasibility and efficacy of a lifestyle intervention for type 2 diabetes prevention in men using an assessor-blinded, parallel-group, randomised controlled trial. The '*Type 2 Diabetes PULSE (Prevention Using LifeStyle Education) Program for Men'* was a 6-month, self-administered, gender-tailored lifestyle intervention, with a multi-component approach (weight loss, dietary modification, aerobic exercise and resistance training). Eligible men were aged 18-65 years, overweight/obese (BMI 25-40 $kg.m^{-2}$) and at high-risk for type 2 diabetes (score ≥ 12, Australian diabetes risk tool). Men with diagnosed prediabetes were eligible, but those with type 1 and 2 diabetes were ineligible. Randomisation was stratified by age (< 50 or ≥ 50 years) and BMI category ($kg.m^{-2}$: 25-29.9; 30-34.9; 35-40) to the intervention or wait-list control group. Data were collected at study entry (baseline), 3 and 6 months. The primary outcome was weight change at 6 months. Secondary outcomes included: fasting plasma glucose, HbA_{1C}, waist circumference, body composition, blood pressure, diet quality, aerobic fitness, muscular fitness and physical activity. Linear mixed models (intention-to-treat) assessed outcomes for treatment (intervention vs. control), time (baseline, 3 and 6-months) and the treatment-by-time interaction. The results will determine the efficacy of a type 2 diabetes prevention program for men with potential for wide reach and dissemination.

3.1 Introduction

3.1.1 Background

Diabetes prevalence is rising globally [21]. Current estimates indicate the disease effected 382 million people (8.3%) worldwide in 2013 and is projected to rise to 592 million (10.1%) by 2035 [21]. Individuals with T2DM have a high risk of cardiovascular disease, retinopathy, nephropathy and neuropathy [27]. It is possible to prevent/delay progression to T2DM with lifestyle interventions (e.g., US Diabetes Prevention Program [DPP] [40]; Finnish Diabetes Prevention Study [DPS] [91]), which may increase life expectancy and quality of life, and reduce health care costs [27]. Whether these highly intensive lifestyle programs requiring face-to-face contact, trained staff and access to facilities are feasible on a larger scale has been questioned [93, 95]. For example, the DPP lifestyle intervention involved a minimum of 16 individual face-to-face curriculum sessions over 24 weeks and an additional two supervised group exercise classes per week [87]. The direct cost of the intervention was US$1399 per person over one year, with 54% (US$750) of the cost attributed to staffing [153]. There is a need for effective programs that are less time and resource intensive, allowing for greater reach, especially in regional, rural and remote areas.

A lifestyle intervention that is self-administered is a possible solution for reducing costs and enhancing wider implementation. This approach has been successful in achieving weight loss for men [103], however there is a paucity of information regarding the feasibility and efficacy of self-administered interventions for T2DM prevention and/or risk reduction. A self-administered lifestyle intervention would eliminate the need for highly skilled staff or facilities

and their associated costs, and could be practical, sustainable and economically viable [152], however efficacy needs to be established [97, 154]. Therefore rigorous trials investigating the feasibility and efficacy of self-administered multi-component (weight loss, dietary modification, exercise) lifestyle interventions for T2DM prevention are needed. Self-administered lifestyle interventions may also be particularly appealing to men who tend to favour programs that do not require regular face-to-face individual or group sessions [101]. Furthermore, the novel use of a gender-tailored tailored approach combined with the use of resistance training as a prescribed exercise choice may enhance the appeal of self-administered lifestyle interventions for men and result in greater program efficacy.

3.1.2 Objectives and hypothesis

The aim of this trial is to determine the feasibility and efficacy of the *"Type 2 Diabetes PULSE (Prevention Using LifeStyle Education) Program for Men"*, to improve T2DM risk biomarkers in overweight/obese men at risk of T2DM (including men already diagnosed with prediabetes). The *PULSE Program* was a 6-month, self-administered, gender-tailored, multi-component (weight loss, dietary modification and aerobic exercise + resistance training) lifestyle intervention. We hypothesise that the *PULSE Program* intervention group will achieve a significant and clinically meaningful reduction in weight (primary outcome) at 6 months post baseline (primary time point) compared to a wait-list control group. Secondary outcomes include glycosylated haemoglobin (HbA_{1C}), fasting plasma glucose (FPG), waist circumference, body composition, blood pressure, diet quality, aerobic fitness, muscular fitness and physical activity.

This trial addressed several evidence gaps in the field of T2DM prevention, including the feasibility and efficacy of: i) self-administered lifestyle interventions, ii) multi-component lifestyle interventions incorporating weight loss strategies, dietary modification, aerobic exercise and resistance training [98], and iii) home-based resistance training [152]. To our knowledge this was the first T2DM prevention trial gender-tailored for men.

3.2 Research Design and Methods

3.2.1 Study Design

This trial was an assessor-blinded, parallel-group randomised controlled trial (RCT) for overweight/obese men at high risk of T2DM. Eligible participants were stratified (age, BMI) and then randomised to either the 6-month *PULSE program* intervention or a wait-list control group. Figure 4 describes the study flow from recruitment through to baseline and assessments at 3 and 6 months (primary time point). The study was approved by the institution's Human Research Ethics Committee (Appendix 1). The study was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12612000721808 (Appendix 2). The design, conduct and reporting of this study adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [155, 156].
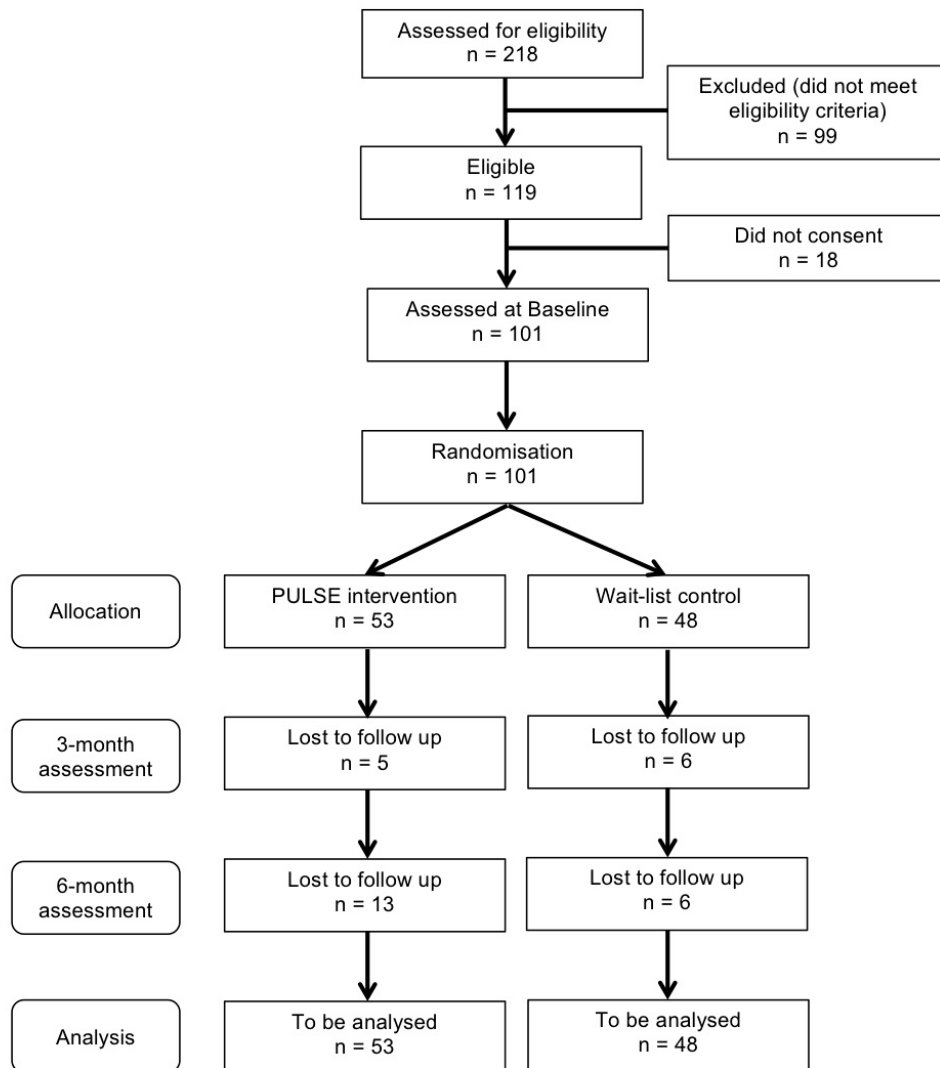
Figure 4 CONSORT flowchart describing the progress of participants through the study

3.2.2 Participants: eligibility, recruitment and screening

The trial recruited overweight/obese men at high risk for T2DM, including those already diagnosed with prediabetes. The eligibility and exclusion criteria are described in Table 9. High risk for T2DM was based on a score ≥12 on the Australian Diabetes risk tool (AUSDRISK) [17]. Individuals were not required to be

diagnosed with prediabetes prior to study entry or to have blood glucose values in the prediabetes range at the baseline time point.

Recruitment for the trial commenced in August 2012. Participants were recruited from the Hunter region, New South Wales, Australia, through advertisements on radio, television, newspapers, University website, emails to male dominated workplaces and via the Hunter Medical Research Institute volunteer register. Interested participants contacted the study team via phone or email and were then directed to an online screening questionnaire to assess eligibility (Table 9), which included the AUSDRISK tool (Appendix 3). Men were also required to pass an adult pre-exercise screening questionnaire [157]. The trial did not exclude men based on their current medication regimen unless a particular medication was known to effect or be affected by lifestyle changes and weight loss. All participants who were flagged as having medical issues from the pre-exercise screening questionnaire and those taking certain medications were additionally screened to determine eligibility by the chief investigator (RC), who is an exercise physiologist and registered pharmacist. Those who presented with medical issues identified through the screening process, as well as all men ≥ 45 years of age, were required to obtain clearance from their doctor to participate in the study. This process aimed to ensure that participants could safely participate in the diet and exercise program, and primarily excluded participants for whom it might be unsafe to exercise unsupervised. Eligible participants were then sent an information statement (Appendix 4) via email detailing the requirements of the study, the anticipated benefits and risks, the required commitment level, and a consent form (with

doctors' clearance form if required). All participants were required to provide written informed consent prior to enrolment (Appendix 4-5).

It is important to note that individuals with type 1 or 2 diabetes were not eligible for this trial. However, individuals with undiagnosed T2DM or who developed T2DM during the course of the trial remained eligible for the trial and will be included in statistical analyses at all stages. These individuals were advised to discuss their results with their general practitioner (medical doctor). This was considered an appropriate course of action since individuals with T2DM are advised to modify their lifestyle behaviours in a similar way as recommended for at risk or individuals with prediabetes (weight loss, diet and exercise).

Table 9 Eligibility criteria for the trial

Inclusion criteria
• Male
• 18-65 years of age
• Overweight or obese (BMI 25-40 kg.m^{-2})
• High risk for T2DM based on the AUSDRISK screening tool (≥ 12 points)
• Passed the pre-exercise screening assessment
Exclusion criteria
• Previously diagnosed with type 1 or 2 diabetes
• History of major medical problems such as heart disease or stroke in the last five years that would prevent them from exercising
• Medical conditions e.g. orthopaedic or joint problems that would be a barrier to physical activity
• Recently lost 5% or more of their body weight (previous 6 months)
• Currently taking medications that are affected by weight loss or had resulted in weight gain or loss in the last three months
• Currently participating in an alternative weight loss program
• Intending to participate in other weight loss programs during the study period
• Not available for assessment sessions
• Did not own a mobile phone

3.2.2.1 Rationale for men only

There appears to be little difference in the prevalence of T2DM among men and women globally [21]. T2DM prevention studies to date have largely included both men and women and reported the results collectively. Recent reports suggest that studies with weight loss as a targeted component may have greater appeal, retention, adherence, and ultimately be more effective if the programs are gender exclusive and gender-tailored [98, 110, 116, 158]. The use of gender-tailored health messages (Section 3.2.3.3) is an important strategy for engaging men and has been shown to be effective in weight loss programs for men [105, 106, 108, 110, 112-114]. Furthermore, a recent systematic review highlighted the limited

evidence regarding gender exclusive or gender-tailored lifestyle interventions for T2DM prevention [98]. The current trial aimed to address this evidence gap.

3.2.3 Intervention

3.2.3.1 Intervention study arm

The *PULSE Program* self-administered lifestyle intervention focused on improving dietary and exercise behaviours, with the goal of inducing moderate weight loss and improving glycaemic control and other risk factors for T2DM. The use of a self-administered approach with minimal face-to-face contact greatly reduced the costs associated with intervention delivery (e.g., dietary counselling, supervised exercise sessions, facility use and transport).

The *PULSE Program* intervention was informed by a series of resources including:

(i) The *International Diabetes Federation – 'Diabetes Education Modules'* (http://www.idf.org/diabetes-education-modules) [52]

(ii) The *American Diabetes Association* position statement – 'Nutrition recommendations and interventions for diabetes' [159]

(iii) Previous research from our group on the '*SHED-IT Weight Loss Program*' [103, 107, 108, 110, 119]

(iv) The '*Australian Guide to Healthy Eating*' (http://www.eatforhealth.gov.au/) [160]

(v) Current exercise guidelines for T2DM treatment and prevention [73, 86]

(vi) The *Diabetes Australia* website (www.diabetesaustralia.com.au)

Participants randomised to the intervention group received the *PULSE Program* resource pack after their baseline assessment. All resources and materials for

the *PULSE Program* intervention were provided at this time point with no further content provided at later time points. Each participant was given a standardised individual 15-minute orientation to the resource pack components and program structure. Otherwise the program was entirely self-administered, with no further face-to-face, telephone, SMS or email contact for intervention delivery or self-monitoring prompting. The authors believed that following this procedure would best reflect the real world application of the program and minimise any sense of accountability resulting from being part of a research trial.

The *PULSE Program* resource pack consisted of the following (Appendix 6-7).

a) The *'PULSE Type 2 Diabetes Prevention for Men'* provided key information under the headings "Type 2 Diabetes Prevention", "Eating to Beat Type 2 Diabetes" and "The Essential Exercises for Type 2 Diabetes Prevention". Each section provided examples and recommended behaviour change strategies to help men decrease their risk of T2DM. Based on current guidelines for healthy eating [160, 161] and T2DM management [52, 159], the underlying dietary recommendation targeted a macronutrient distribution (percentage of total energy intake, E%) of 45-60% carbohydrate [52, 160, 161]; 20-35% fat [52, 159-161]; 10-20% protein (0.8 $g.kg^{-1}$ body weight per day) [52, 160, 161]. Additional recommendations included limiting saturated fat intake (< 7% of total E%) [52], including monounsaturated fat (> 10% of E%) [52] and polyunsaturated fat (< 10% of E%) [52], consuming lean proteins, limiting salt intake to 1500-2300 $mg.day^{-1}$ [52, 160, 161], achieving a high fibre intake of 25-50 $g.day^{-1}$ [52, 161], and consuming a low glycaemic index (GI) diet [159-161]. Examples of foods that

would assist in achieving these dietary targets (e.g., low GI, high fibre foods) were provided in the handbook. In addition, the above dietary targets were tracked using the *Calorieking*[TM] self-monitoring tool.

b) The *'PULSE Exercise Support Book for Men'* and *Gymstick*[TM]: based on current exercise guidelines for T2DM treatment and prevention [73, 86], participants were advised to do a minimum 210 min of exercise per week (or 30 min a day), comprising 150 min of aerobic physical activity per week (e.g., 5 x 30 min sessions) and at least 60 min (2 x 30 min) of resistance training (RT) per week. Participants were asked to choose aerobic exercise(s) that they enjoyed such as walking, jogging, swimming or cycling. In order to facilitate RT in the home setting (unsupervised), participants were provided with a *Gymstick*[TM], a resistance band device with adjustable resistance loads and an accompanying RT program covering the major muscle groups of the body (Table 10). A range of dynamic and isometric exercises utilising the *Gymstick*[TM], as well as body weight exercises, were incorporated in the program, with instructions and pictures for the activities. Participants were asked to complete a minimum of two of the three provided sessions per week in order to meet the exercise guidelines for T2DM (approximately 30 min per session). The RT sessions were designed to be progressive throughout the intervention period by increasing the repetitions/duration of the exercises and the number of sets performed. After week 12 (mid program), participants were encouraged to design their own eight-exercise circuit to follow for the remainder of the intervention. This provided men with a greater level of autonomy. Participants were advised to perform a 5-minute warm up

and cool down, including a selection of post-workout stretching exercises. For some exercises, specific guidelines were provided regarding the safe performance of the activity. Participants were asked to record their exercise sessions in a log book section of the *'PULSE Exercise Support Book for Men'* and to return their support book to the investigators at each assessment for photocopying.

Table 10 *PULSE* exercise program

	Day 1	Reps or duration
A	BW Squat	10
B	BW Push Up	6
C	BW Prone Hold	20 s
D	GS Shoulder Press	6
E	BW Gluteal Bridge	20 s
F	GS Upright Row	6
G	GS Arm (Bicep) Curl	6
H	GS Lying Leg Extension	6/leg
	Day 2	**Reps or duration**
A	GS Squat	6
B	GS Kneeling Chest Press	6
C	BW Side Hold	15 s/side
D	GS Shoulder Press	6
E	GS Leg Extension	6/leg
F	GS Bent Over Row	6
G	GS Arm (Tricep) Extension	6
H	BW Split Squat	6/leg
	Day 3 (optional)	**Reps or duration**
A	GS Squat	6
B	BW Push Up	6
C	BW Flutter Kicks	10/leg
D	GS Front Raise	6
E	BW Gluteal Bridge	20 s
F	GS Upright Row	6
G	GS Arm (Bicep) Curl With Overhand Grip	6
H	GS Split Squat	6/leg

Participants were instructed to perform exercises A-H (1 round). During week 1, participants completed 2 rounds in total, with 30 s rest between the exercises and 2 min rest between rounds. Participants were instructed to select a resistance level (number of coils) for the Gymstick exercises so that they could just complete the indicated number of repetitions. BW – bodyweight, GS – gymstick, and reps – repetitions

4. The *SHED-IT Weight Loss Program* (Self-Help, Exercise and Diet using Internet Technology) philosophy is centred on making realistic and sustainable changes to eating and exercise behaviours that result in weight loss. The *SHED-IT Weight Loss Program* was a key component of the *PULSE Program,* as weight loss was the main predictor of reduced diabetes incidence in the US DPP [48]. The *SHED-IT Weight Loss Program* has been evaluated in previous studies and the intervention components are described extensively elsewhere [103, 119]. It should be noted that the original *SHED-IT Weight Loss Program* intervention duration was 3 months, but has been extended to 6 months for the *PULSE Program* intervention. The program consists of:

    i.   The *'SHED-IT Weight Loss DVD for Men'*

    ii. The '*SHED-IT Weight Loss Handbook for Men'*

    iii. The '*SHED-IT Weight Loss Log Book for Men*'

    iv. A tape measure

    v.   A pedometer

    vi. A user guide for the *Calorieking*[TM] self-monitoring tool

    vii. The *Calorieking*[TM] *'Calorie Fat and Carbohydrate Counter'* booklet

Participants were advised to set their own weight loss goals or weight target, aiming for 0.5-1 kg weight loss per week or roughly 10 kg over the 6-month program. A tape measure was provided to allow regular measurement of waist circumference and a pedometer was provided to track physical activity step counts. Self-monitored weight, waist circumference and pedometer step counts were recorded each week in

the '*SHED-IT Weight Loss Log Book for Men'*. Participants returned this log book to the investigators at each assessment for photocopying. Participants were encouraged to self-monitor their dietary intake and physical activity using the *Calorieking^(TM)* (www.calorieking.com.au) website in order to create a 2000 kilojoule (kJ) deficit on most days. Participants were provided with a *Calorieking^(TM)* user guide developed by our research team. This was supplemented with the *Calorieking^(TM) 'Calorie Fat and Carbohydrate Counter'* booklet [162]. Participants were advised to use the food and exercise diaries at least 4 days per week and record their weight online once a week. Please note – the trial did not provide individualised participant feedback during the intervention period. The process followed was similar to a recent version of the *SHED-IT Weight Loss Program* [120], but differed to an earlier version of the *SHED-IT Weight Loss Program* [104, 119], which provided individualised participant feedback to the online intervention group only.

3.2.3.2 Theoretical framework for behaviour change

In order to successfully engage men in the process of lifestyle behaviour change, the *PULSE Program* (and its constituent components) operationalised *Bandura's social cognitive theory* (SCT) [163, 164]. SCT defines a framework of key constructs based on the determinants of behaviour, the mechanisms of action and the optimal strategies for effecting positive health behaviour change. Perceived self-efficacy (i.e., the belief in ones own ability to successfully complete tasks and/or succeed in particular scenarios) is thought to be the most important construct of SCT and is suggested to directly effect health behaviour.

Other constructs include goal setting, outcome expectations (perceived physical, social and self-evaluative consequences of performing a behaviour) and socio-structural factors (environmental facilitators/impediments and social support) [164]. The operationalisation of SCT for the PULSE program components are summarised in Table 11 using the taxonomy for behaviour change techniques [165]. In addition to this, the operationalisation of SCT in the *SHED-IT Weight Loss Program has been described previously* [109, 119].

Table 11 Operationalisation of the Social Cognitive Theory within the PULSE Program

Intervention component	Additional detail	Behaviour change technique [165]	Social cognitive theory constructs targeted
The *'PULSE T2DM Prevention Handbook for Men'*	• Type 2 diabetes prevention • Eating to beat T2DM • The essential exercises for T2DM prevention	• Providing information about health consequences • Use of credible sources of information • Offering tips on behaviour substitution • Encouraging negative habit reversal • Encouraging positive habit formation • Prompt Goal setting (behaviour and outcome) • Action planning • Encouraging social support (unspecified)	• Building self-efficacy • Providing information to create positive outcome expectations • Encouraging goal setting and planning • Engaging social support • Encouraging self monitoring
The *'PULSE Exercise Support Book for Men*	• Getting started with aerobic exercise • Getting started with resistance training • Resistance training program • Exercise instructions • Exercise log	• Providing information about health consequences • Use of credible sources of information • Prompt Goal setting (behaviour and outcome) • Repetition of behaviour • Set graded tasks • Action planning • Provide instruction on how to perform a behaviour • Demonstration of a behaviour • Prompt self-monitoring of behaviour • Encourage social support (unspecified)	• Building self-efficacy • Providing information to create positive outcome expectations • Encouraging goal setting and planning • Engaging social support • Encouraging self-monitoring

3.2.3.3 Gender tailoring

The *PULSE program* was tailored for the target population by utilising surface and deep structure components [115]. The same approaches used in the development of the *SHED-IT Weight Loss Program* were used for the development of the novel components unique to the *PULSE Program*. Surface structures increase the receptivity and acceptability of health messages by

targeting superficial characteristics of the population. The *PULSE Program* materials included male-specific research findings, images of men, humour and male-oriented metaphors and anecdotes. For example, in order to describe a diet containing low GI foods, we included a metaphor of using premium fuel in a car - *"Low GI foods are like high-octane fuel, you'll get more kilometres and better performance from a tank full of low GI food compared with high GI foods".* And to encourage the habit of eating breakfast, we related this to using a lawn mower - *"Eating a good breakfast gives you the energy you require to power through the day. It's like priming a lawn mower, you need an injection of fuel first before the motor can kick over and start working."* Deep structure components draw on the psychological, cultural and social characteristics of the target population to influence health behaviours. Deep structure components embedded into the *PULSE Program* included the encouragement of individual choice in making changes to dietary and exercise behaviours [110]; the promotion of exercise (particularly RT) as an activity that improves fitness and body composition [166] and psychological well-being [167]; the use of a frank and realistic approach [168]; and a focus on the scientific-basis of the recommendations [168].

3.2.3.4 Inclusion of home-based resistance training

Current recommendations for T2DM prevention lifestyle programs include maintaining a healthy weight, consuming a healthy diet, and participation in exercise. Most T2DM prevention programs have recommended aerobic (cardio-respiratory) activities [73], with strong evidence supporting this approach. More recently, resistance training (RT) has been included in exercise guidelines for T2DM [73, 86] based on evidence established over the last decade, which

demonstrates benefits from RT on glucose regulation [74-78, 80-84] and the maintenance of fat free mass during energy restriction for weight loss [124, 125]. To date, there is very little evidence from high quality multi-component RCTs that have evaluated the efficacy of dietary modification in combination with both aerobic exercise and RT [98]. In addition, there is little evidence regarding the feasibility and efficacy of home-based RT programs for the treatment/prevention of T2DM [152]. The *PULSE Program* incorporated a multi-component behaviour change approach that included a home-based unsupervised exercise program (aerobic exercise and RT).

3.2.4 Wait-list control group

Participants randomised to the wait-list control group after baseline assessment were required to attend the 3 and 6 month assessment sessions, after which they were provided with the *PULSE Program* and offered a further optional assessment after completing the *PULSE Program* (12 months from baseline). This was a major strength in the design of our randomised controlled trial since it allowed us to investigate the unique impact of the *PULSE program* intervention over time. Following this procedure also ensured equitable treatment for all participants enrolled in the trial i.e., access to the lifestyle intervention rather than "usual" or "standard care". The data collected from the control group at 12 months (i.e., after completing the *PULSE program)* was not included in the primary analysis.

3.2.5 Study outcomes

Assessments were conducted at baseline, 3 months (mid-program) and 6 months (immediate post-program) in the Human Performance Laboratory at the University of Newcastle, Australia. All individuals were contacted by phone call, mobile phone SMS or email in order to arrange a time for these assessment sessions. The primary endpoint of the study was at 6-months (immediate post-test). Recruitment for the trial commenced in August 2012 and data collection commenced in September 2012. The same instruments were used for measurements at each time point. Assessors were trained prior to the assessments and followed a standardised protocol for all measures. Assessors were blinded to group allocation at all time points and participants were blinded to group allocation until after their baseline assessment.

3.2.5.1 Anthropometric measures

The primary outcome measure for the study is weight change (kg), as weight loss was the main predictor of reduced diabetes incidence in the US DPP [48]. Weight was measured in light clothing and without shoes on a calibrated digital scale to 0.01 kg (CH-150kp, A&D Mercury Pty Ltd., Seven Hills, NSW, Australia). Weight was measured twice, with acceptable values within 0.1 kg. If measurements were outside the acceptable range, a third measure was taken. The average of the two acceptable measures is reported. (Appendix 8)

Height (cm) was measured to 0.1 cm using the stretch stature method (without shoes) on a stadiometer (Harpenden portable stadiometer with high speed Veeder-Root counter, Holtain Ltd, Pembrokeshire, United Kingdom). Height was

measured twice, with accepted values within 0.3 cm. A third measure was taken if measurements were outside the acceptable range. The average of the two acceptable measures is reported. Height was measured at study entry only. Body mass index (BMI) was calculated using the equation (weight [kg]/height [m^2]).

Waist circumference (cm) was measured at two points: i) at the observable narrowest point between the lower costal border and iliac crest, and ii) level with the umbilicus. If the participant did not have an observable narrow point, the midpoint between the lower costal border and iliac crest was used. Two measures were taken at each site; with acceptable values within 0.5 cm. Further measures were taken if measurements were outside the acceptable range. The average of the two acceptable measures is reported. In order to improve the reliability of waist circumference measurements, a non-extensible steel tape was used (KDSF10-02, KDS Corporation, Osaka, Japan) and measurements were performed by an assessor with Level 1 anthropometry qualifications from the *International Society for the Advancement of Kinanthropometry*.

Body composition was assessed using bioimpedance analysis (InBody720, Biospace Co., Ltd, Seoul, Korea) to calculate fat mass (kg), fat free mass (kg), body fat (%), visceral fat area (cm^2) and skeletal muscle mass (kg). The InBody720 is a multi-frequency, 8-point tactile electrode system. Body composition assessment using this device has been shown to be valid and reliable [169].

3.2.5.2 Cardiovascular measures

Blood pressure and resting heart rate was measured using a manual inflation digital sphygmomanometer (NISSEI/DS-105E, Nihon Seimitsu Sokki Co. Ltd., Gunma, Japan) and a standardised procedure [170, 171]. Participants were seated for five min before the first measurement and given rest periods of two min between measures. Blood pressure was measured a minimum of three times, with acceptable values within the range of 10 mmHg for systolic pressure, 5 mmHg for diastolic pressure and 5 beats per minute (bpm) for resting heart rate. If the values were outside of these acceptable ranges, further measurements (up to a total of five measures) were obtained until three of the measures met the criteria. The mean of the two lowest systolic pressures (that are within 10 mmHg) and the diastolic pressures paired to them is reported. The mean of the two lowest resting heart rates (that are within 5 bpm) is reported.

3.2.5.3 Metabolic measures

Blood samples were collected after an overnight fast (minimum 8 h) by Hunter Area Pathology Service (HAPS) staff using a standardised procedure. Analysis was conducted using standard automated techniques by HAPS (National Association of Testing Authorities accredited pathology service). Samples were analysed for several blood biomarkers related to T2DM and cardiovascular disease markers including glucose regulation (FPG [$mmol.L^{-1}$], HbA_{1C} [%], insulin [$mIU.L^{-1}$]), lipid profile (cholesterol [$mmol.L^{-1}$], triglycerides [$mmol.L^{-1}$], LDL-cholesterol [$mmol.L^{-1}$], HDL-cholesterol [$mmol.L^{-1}$] and total/HDL ratio), an inflammatory marker (c-reactive protein [$mg.L^{-1}$]). The Homeostatic Model Assessment-2 (HOMA-IR 2) and Quantitative Insulin Sensitivity Check Index

(QUICKI) indices were calculated from the glucose and insulin values. Given individuals with T2DM commonly present with liver function abnormalities [172], a number of liver function assays were also conducted. These tests included total protein [g.L^{-1}], albumin [g.L^{-1}], calculated globulin [g.L^{-1}], total bilirubin [µmol^{-1}], gamma-glutamyl transferase [U.L^{-1}], alkaline phosphatase [U.L^{-1}], alanine aminotransferase [U.L^{-1}] and aspartate aminotransferase [U.L^{-1}]. Samples were also analysed for urate [mmol.L^{-1}], a clinical marker of gout, which is strongly associated with risk of T2DM and cardiovascular disease [173]. Extra blood samples were collected from participants at each assessment time-point for possible later analysis.

3.2.5.4 Fitness measures

Changes in aerobic fitness were assessed using a validated sub-maximal treadmill test (Ebbeling protocol) [174] to estimate aerobic fitness (VO_{2max}, mL.kg^{-1}.min^{-1}). Briefly, participants commenced the test on a treadmill (Powerjog Treadmill GM200, Expert Fitness UK Ltd, Mid Glamorgan, South Wales, United Kingdom) set to 4 km.h^{-1} and 0% gradient. The speed of the treadmill was increased by 1 km.h^{-1} every 30 s until the participant reached 55% of their predicted maximum heart rate (Polar FT1 heart rate monitor, Pursuit Performance Australia, Pty Ltd, Adelaide, SA, Australia). The participant then continued to exercise at this workload until 4 min had elapsed. At 4 min the treadmill gradient was raised to 5% and the participant continued to walk for a further 4 min. VO_{2max} was then calculated using the equation provided by Ebbeling et al [174].

Change in lower body muscular fitness was assessed using a weighted (10 kg plate) squat to box test (max repetitions to fatigue). The squat depth was standardised prior to the test by setting the box height so that knee angle was 90° when seated on the box. During the test participants were required to touch the box, but were not permitted to sit or rest on the box between repetitions. In order to reduce the effect of poor ankle range of motion on squat ability [175], participants stood (without shoes) on a 5° wedge, which elevated the heel and allowed a greater range of motion through the ankle joint. Prior to the test, participants were required to complete a familiarisation and warm-up procedure, completing 10 body weight repetitions, followed by a rest period of 30 s prior to the test. The tempo of the tests was governed by a metronome set at 40 bpm i.e., 20 repetitions per min. Participants who failed to maintain the tempo, or who displayed unsafe/poor form, were asked to stop. The number of successful repetitions (i.e., in time and full range of motion) is reported.

Change in upper body muscular fitness was assessed using a seated 25 kg barbell shoulder press (max repetitions to fatigue). Prior to the test, participants were required to complete a familiarisation and warm up procedure using a wooden dowel rod (10 repetitions), followed by a 10 kg barbell (5 repetitions) and were then allowed to rest for 1.5 min prior to the test. The tempo of the tests was governed by a metronome set at 40 bpm i.e., 20 repetitions per min. Participants who failed to maintain the tempo, or who were displaying unsafe/poor form, were asked to stop. The number of successful repetitions (i.e., in time and full range of motion) is reported.

3.2.5.5 Physical activity measures

Physical activity (step count) was objectively measured using Yamax Digi-Walker SW200 pedometers (Yamax Corporation, Kumamoto City, Japan) as described previously [119]. Participants were required to wear the device for seven days after their baseline, 3 and 6-month assessments. Participants were instructed on how to wear the device correctly, and requested to only remove the device while sleeping, when the device might get wet (e.g., showering or swimming) or if the device would get damaged (e.g., contact sports). Participants were instructed to keep to their normal routine during the seven-day period. A physical activity log sheet was provided (Appendix 11) and participants were asked to record the number of steps accumulated at the end of the day and to reset the device. Participants were requested to note down additional activities (e.g., swimming, cycling and contact sports) on the physical activity log sheet along with the duration of the activity. Non-wear time was also recorded on the physical activity log sheet. Physical activity step counts were included in the analysis if a minimum of four days was reported. The average of the reported values was imputed for participants who had three or less days of missing data [119]. The average step count per day is reported.

Self-report physical activity levels were assessed using a modified version [176] of the validated Godin Leisure-Time Exercise Questionnaire [177]. Briefly, participants were asked to indicate how many times in the past month they engaged in light, moderate, and vigorous intensity physical activities, in bouts of at least 10 min. Participants were also asked to estimate the average duration of sessions within each category. Frequency and duration responses were then

multiplied to provide a measure of the total time spent in light, moderate and vigorous physical activity in the previous month. (Appendix 9-10)

Sedentary behaviour was assessed using the Sitting Time Questionnaire [178], which is a valid and reliable measure of sitting time. Briefly, participants were asked to estimate the amount of time spent sitting per day in various settings (while travelling, at work, watching television, using a computer, leisure time) on both weekdays and weekends.

3.2.5.6 Dietary measures

Dietary intake was assessed using the validated Australian Eating Survey (AES) [179] in order to generate mean daily kJ intake and nutrient profile (including carbohydrate:fat:protein ratio, proportions of energy from saturated fat and alcohol and grams of fibre). The Australian recommended food score [180] was also calculated to provide an overall indication of diet quality. The AES is a 120-item semi-quantitative food frequency questionnaire (FFQ), with 15 supplementary questions regarding age, vitamin supplement use, food and sedentary behaviours. Portion sizes are calculated for individual food items from data purchased from the Australian Bureau of Statistics 1995 National Nutrition Survey [181], or using the "natural" serving size of specific food items (e.g., a slice of bread) where appropriate. Participants were asked to indicate the frequency of consumption of various food items or food types over the previous six months. Frequency options vary depending on the item e.g., 'Never' up to '4 or more times per day' for most food items and up to '7 or more glasses per day' for some beverages. The questionnaire groups food items based on common

'food groups' including main meals, fruit and vegetables, dairy foods, breads and cereals, drinks, sweets and snacks. Nineteen questions relate directly to intakes of vegetables and 11 for intakes of fruits. Seasonal variations of some fruits are accounted for in the nutrient calculations. Nutrient intakes are computed using the Australian AusNut 1999 database (All Foods) Revision 17 and AusFoods (Brands) Revision 5 (Australian Government Publishing Service, Canberra). Estimated mean individual daily intake for 20 macro- and micro-nutrients are calculated using FoodWorks (version 3.02.581, Xyris Software Australia, Highgate Hill, Queensland).

Portion size was assessed separately using the portion size section of the validated Dietary Questionnaire for Epidemiological Studies - Version 2 (DQES V2), Cancer Council Victoria [182, 183]. Portion size photographs of common foods (potatoes, vegetables, steak, and casserole) are used to determine whether, on average, a person eats median size serves (Portion Size Factor, PSF = 1), more than the median (PSF > 1), or less than the median (PSF < 1) serve sizes for main meals.

Alcohol consumption was measured using the 3-item Alcohol Use Disorders Identification Test (AUDIT-C) [184], a valid and reliable measurement tool for determining heavy drinking, alcohol abuse or alcohol dependence.

3.2.5.7 Quality of Life

General health and quality of life were assessed using the validated United Kingdom short form 12 (SF-12) [185], which covers both the physical and mental domains.

3.2.5.8 Demographic characteristics and additional self-report information

Sociodemographic data were collected by questionnaire at baseline. Items included date of birth, age, occupation, educational level, ethnic origin, primary language spoken, marital status, postal code, personal gross income and household gross income. Socioeconomic status (SES) was determined by postal code of residence using the *"Index of Relative Socioeconomic Advantage and Disadvantage"* from the Australian Bureau of Statistics census-based Socio-Economic Indexes for Areas (SEIFA) [186]. Additional self-report information was collected at each time-point including medication use and illness or injury over the past three months. Participants were also asked whether they had been diagnosed with prediabetes or T2DM since their last assessment session.

3.2.6 Process measures and feasibility assessment

Program feasibility is assessed by examining participant recruitment, retention, adherence and satisfaction. A program evaluation questionnaire was administered *at* 6 months to examine the participant's perceptions of the *PULSE Program* (Appendix 12-13). The questionnaire used scales, individual items and open-ended questions to obtain detailed information about the program, including participant's opinion of their allocated study group; their level

of engagement and satisfaction with the overall program; their engagement with individual components of the program; their impressions of the intervention resources; and their success in implementing specific health behaviours that are promoted in the resources. The participants were also asked to list the strengths and weaknesses of the program, to give suggestions for improvement and to indicate how much they would be willing to pay for the *PULSE Program*. A separate process evaluation was provided to the control group. Participants were asked to indicate their opinion of the allocated study group and whether they made any attempt to improve their health or lose weight during the control period. Both groups of men were asked to provide information regarding the diagnosis of any medical conditions post-study entry and if there were any changes in medication use, type or dose during the trial. Adherence to the *PULSE Program* is additionally assessed by examination of log book entries in the '*SHED-IT Weight Loss Log Book for Men'* and the *'PULSE Exercise Support Book for Men'*. These documents were photocopied after each assessment session and mailed back to the participant.

3.2.7 Participant reimbursement

Participants were reimbursed $10 per assessment session to cover travel and parking costs. Over the course of the study this entitled each participant to a maximum of $30. No additional payment or incentives were provided for completing the study or achieving milestones (e.g., weight loss goals) during the study.

3.2.8 Sample size

The sample size calculation was performed by a statistician independent to the research team. The calculation was based on the primary outcome of weight change at 6 months (primary time point). Using data from a previous trial [103], we assumed a standard deviation of weight at baseline of 14 kg and the correlation between baseline weight and weight at 6 months to be 0.9. Therefore, a total sample size of 74 (37 per group) at the analysis stage will give the study 80% power to find a difference in mean weight of 4kg between groups at 6 months using a significance level of 0.05 for two sided tests. To allow for 20% loss to follow-up we were required to enrol a minimum of 94 participants in the trial. This sample size was achieved (See CONSORT flow diagram, Figure 4).

3.2.9 Randomisation and allocation procedure

Participants were randomised at an individual level after their baseline assessment to the intervention or wait-list control group. Allocation was stratified by age (< 50 or ≥ 50) and BMI category (kg.m^{-2}: 25-29.9; 30-34.9; 35-40), resulting in a total of six strata. Following this stratification procedure created a greater likelihood of achieving similar baseline characteristics for the intervention and control groups, particularly for the primary outcome of weight. Furthermore, since T2DM risk is associated with advancing age [27], stratifying by this would asssist in achieving similar characteristics between groups. These strata were determined based on the distributions of age and BMI in a previous study of overweight/obese men [103]. The allocation sequence within each stratum was generated by a computer-based random number-producing algorithm in block lengths of six. The randomisation sequence within each of

the six strata was unique. The randomisation sequence was generated by an investigator not involved in the allocation of participants and was stored on a computer that was not accessible by those assessing participants. Group allocations were concealed in opaque envelopes and the envelopes were numbered in consecutive order within each stratum to ensure blinding was maintained.

A study investigator not involved in the assessment measures notified participants individually of their group assignment in a separate room. The participant's age and BMI were used to determine their stratum; then the next available envelope within that stratum was selected. Once the group allocation was revealed, the investigator recorded the participant's group allocation and then proceeded with a standardised explanation regarding the treatment condition. Participants allocated to the wait-list control group were informed about the conditions of their group and the requirements for further assessments. Participants allocated to the intervention group were provided with an explanation of the intervention resources, as described in Section 3.2.3.1.

3.2.10 Loss to follow-up

Individuals randomised into the trial were invited to return for an assessment session at the 3-month and 6-month time points by phone call, mobile phone SMS or email. As outlined in Section 3.2.8, it was anticipated that some individuals would be lost to follow-up during the trial. Participants who initially failed to book in for an assessment session were contacted on multiple

occasions via various contact methods (as above). Participants who failed to attend their assessment session were contacted to reschedule their appointment. It is important to note that participants were notified in the trial's information statement that they were free and able to withdraw at any stage of the trial without any repercussions. No additional incentives were provided to encourage participants to return for assessment sessions.

3.2.11 Data management, quality assurance and exclusion of bias

The data collection team were blinded to group allocation at all assessment time-points. One member of the research team (EJA) was aware of each participant's group allocation and undertook all contact where knowledge of group allocation was required or might have been revealed (e.g., booking in participants for appointments, organising assessment packs). All physical measures (anthropometry, blood pressure, fitness measures) were double entered. All variables were checked for missing values and plausibility checks were performed to identify unrealistic values.

3.2.12 Statistical methods

Statistical analyses was performed using IBM SPSS version 21. Data are presented as mean ± SD or mean [95% confidence interval] for continuous variables and counts (percentages) for categorical variables.

3.2.12.1 Baseline characteristics

Demographic and baseline characteristics of the intervention and control groups are reported for all measured variables. Mean AUSDRISK score as well as the

percentage of men who fell within the AUSDRISK risk level cut-points [17] (i.e.,

12-15, 16-19 and ≥ 20 points) is reported. The prevalence of prediabetes at

baseline is reported based on the clinical cut-points used by the American

Diabetes Association [15] for FPG (≥ 5.6 mmol.l^{-1}) and/or HbA$_{1C}$ (≥ 5.7%). Further

to this, the prevalence of metabolic syndrome (MetS) at the baseline time-point

is reported according to the International Diabetes Federation MetS worldwide

definition [187], which specifies that an individual must have central obesity (waist

circumference ≥ 94 cm or BMI ≥ 30 kg.m^{-2}) and two of the following four criteria:

raised triglycerides (≥ 1.7 mmol.L^{-1} or specific treatment for lipid abnormality),

reduced HDL-cholesterol (≤ 1.03 mmol.L^{-1} or specific treatment for lipid

abnormality), raised blood pressure (systolic ≥ 130 mmHg, diastolic ≥ 85

mmHg) and raised FPG (≥ 5.6 mmol.L^{-1}).

3.2.12.2 Program efficacy

Linear mixed models were used to assess the primary outcome of weight and

all other secondary outcomes for the impact of treatment (intervention vs.

control), time (treated as categorical with levels at baseline, 3 and 6 months)

and the treatment-by-time interaction, with these three terms forming the base

model. This ensures that the outcomes for participants who withdraw from the

trial prior to the 3 or 6-month time-points are retained in the analysis. This is

consistent with an 'intention-to-treat' approach. Age and SES are examined as

covariates to determine any significant interactions in the models. If a covariate

is significant, a term is added to the model to adjust for the effects. The

coefficient and P-value for the treatment-by-time interaction term is used to

determine the efficacy of the intervention at a significance level of P = 0.05. All secondary analyses are assessed using a significance level of P = 0.05.

In addition to this, the prevalence of prediabetes at baseline and the incidence of prediabetes and T2DM at the 3 and 6-month time-points are important secondary outcomes relating to the efficacy of the PULSE intervention and T2DM prevention. Prediabetes and T2DM are classified according to the clinical cut-points used by the American Diabetes Association [15]: prediabetes (FPG ≥ 5.6 mmol.L^{-1} and/or HbA$_{1C}$ ≥ 5.7%) and T2DM (FPG ≥ 7.0 mmol.L^{-1} and/or HbA$_{1C}$ ≥ 6.5%).

3.2.12.3 Secondary analyses

A per protocol analysis was also conducted and included men who complied with the program for at least 50% (12 weeks) of the 6 month (24 week) intervention. Compliance assessment was based on self-reported log book entries for: (i) weekly weigh-ins (n > 12 entries); and (ii) achievement of physical activity target of 210 min per week (n > 12 successful weeks). Results of the per-protocol group are compared with non-compliers i.e., those who did not meet the above adherence recommendations.

Additional exploratory analyses was conducted to determine the characteristics of men who lost a clinically important amount of weight (> 5%) and the associated changes in secondary health outcomes. Analysis was also conducted to determine the effect of the program for men in the prediabetes range for FPG (> 5.6 mmol.L^{-1}) and HbA$_{1C}$ (> 5.7% at baseline). Characteristics

of completers versus dropouts were tested using independent *t* tests for continuous variables and chi- squared (χ^2) tests for categorical variables. A significance level of P = 0.05 is used for these comparisons.

3.3 Discussion

Intensive T2DM prevention programs have shown reductions in T2DM incidence of up to 58% over 3 years using lifestyle interventions [40, 91]. However, the challenge remains in the translation of these highly intensive programs requiring face-to face contact, trained staff and access to facilities, as they might not be practical, achieve sufficient reach or remain effective within communities or health care systems. The aim of this trial is to determine the feasibility and efficacy of a self-administered lifestyle intervention for T2DM prevention targeting overweight/obese men at risk for T2DM. The *PULSE Program* was a gender-tailored lifestyle intervention, which utilised a multi-component health behaviour change approach (weight loss, dietary modification, aerobic exercise and resistance training). It built upon previous research from our group on the *SHED-IT Weight Loss Program* that successfully demonstrated clinically meaningful and statistically significant weight loss in men without regular face-to-face contact (between group difference intervention vs control: 4.2 kg; 95% CI 2.5, 5.9 kg, Cohen's *D = 0.96*) [103, 119]. The effects of the *SHED-IT Weight Loss Program* on T2DM or cardiovascular disease risk profile have not been evaluated.

A significant strength of the *PULSE Program* was the use of a multi-component approach that included RT. A recent systematic review [98] identified the limited

research regarding the efficacy of multi-component lifestyle interventions that include RT together with dietary modification + aerobic exercise, despite the inclusion RT in current guidelines [73, 86] for T2DM treatment and prevention. The same systemic review [98] also concluded that evaluation of the exercise/physical activity intervention components was poor in multi-component programs, with most studies failing to include objective physical activity and fitness measures, particularly regarding measures of muscular fitness. The current trial employed a number of tests to objectively measure its effects on aerobic and muscular fitness in addition to objective physical activity measures.

This trial had several other strengths including: an RCT design with a wait-list control group (as opposed to 'usual care'), a rigorous randomisation procedure to minimise bias, assessor blinding, and a detailed statistical analysis plan that followed an intention-to-treat principle. In addition to measuring weight, FPG and HbA_{1C}, we assessed a comprehensive range of secondary outcomes in order to capture the wider physiological and behavioural impacts of the program. Significant strengths of the *PULSE Program* intervention included the self-administered and gender-tailored approach, which addressed several evidence gaps in the field. The choice of a minimal face-to-face intervention delivery mode also has potential advantages for the widespread dissemination of the program, reducing patient-practitioner contact time and cost of transport and facility use. The *PULSE Program* has the potential to greatly inform future efforts in T2DM prevention.

3.4 Conclusion

Previous programs for T2DM prevention such as the US DPP and Finnish DPS remain a challenge to implement widely. The intensive nature of such interventions remains a significant barrier preventing widespread dissemination. A self-administered lifestyle intervention with minimal face-to-face contact, as per the *PULSE Program* in the current trial*,* has great potential for widespread dissemination into community and health care settings. Additional features of the *PULSE Program* including its gender-tailored approach and the inclusion of resistance training may also increase the appeal of the program for men, which in turn might improve the efficacy of the program.

Chapter 4 – Characteristics of men classified at high-risk for type 2 diabetes mellitus using the AUSDRISK screening tool

Preface:

This chapter presents a manuscript, which aligns with *Secondary Aim 2* of this thesis i.e., to describe the characteristics of men identified at high-risk for type 2 diabetes mellitus using the Australian Diabetes Risk Assessment (AUSDRISK) tool, and determine the ability of the tool to identify men with prediabetes and metabolic syndrome. This manuscript has been published in the journal *Diabetes Research and Clinical Practice*.

Citation:

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Abstract

Aims: The primary aim was to describe characteristics of men identified at high-risk for Type 2 Diabetes Mellitus (T2DM) using the Australian Diabetes Risk Assessment (AUSDRISK) tool. Secondary aims were to determine the prevalence of prediabetes and metabolic syndrome in these men.

Methods: Men (n = 209) completed the AUSDRISK tool, with 165 identified as high-risk for T2DM (score ≥ 12, maximum 38). Demographic, anthropometric, physiological and behavioural outcomes were assessed for 101 men. Comparisons (one-way ANOVA) among three AUSDRISK score groups (12-15, 16-19, ≥ 20) were performed (significance level, $P < 0.05$).

Results: Common risk factors (percentages) among high-risk men were waist circumference (> 90 cm; 93%), age (> 44 years; 79%), physical activity level (< 150 $min.wk^{-1}$; 59%), family history of diabetes (39%) and previously high blood glucose levels (32%). Men with AUSDRISK scores ≥ 20 had higher (mean ± SD) HbA_{1C} (6.0 ± 0.4% [42 ± 4.4 $mmol.mol^{-1}$], $P < 0.001$), FPG (5.3 ± 0.6 $mmol.L^{-1}$, $P = 0.001$) and waist circumference (113.2 ± 9.8 cm, $P = 0.026$) than men with scores of 12-15. Mean FPG for the sample was 5.0 ± 0.6 $mmol.L^{-1}$, whereas mean HbA_{1C} was 5.8 ± 0.5% [40 ± 5.5 $mmol.mol^{-1}$]. Prediabetes prevalence was 70% and metabolic syndrome prevalence was 62%.

Conclusions: The AUSDRISK tool identified men who were mostly older than 44, and had large waist circumferences and elevated HbA_{1C}. These findings provide evidence supporting the usefulness of the AUSDRISK screening tool for T2DM screening in clinical and research settings.

4.1 Introduction

4.1.1 Background

Diabetes is one of the most prevalent non-communicable diseases worldwide and is estimated to reach 592 million cases (10.1%) by 2035 [20]. Type 2 diabetes mellitus (T2DM) represents approximately 90% of all diabetes cases [21]. The early identification of individuals at high-risk for T2DM allows for targeted lifestyle intervention and/or drug treatment, which may prevent or delay disease progression. This is complicated however, as T2DM, and its precursor condition prediabetes [5], are often asymptomatic at early stages [188], making it difficult to identify individuals who would benefit from preventive approaches. Furthermore, diagnostic tests such as fasting plasma glucose (FPG), glycosylated haemoglobin (HbA$_{1C}$) and an oral glucose tolerance test (OGTT) are invasive and not justified for screening purposes in terms of cost and/or time [16, 189, 190]. Consequently, many individuals with T2DM and prediabetes remain untreated for several years prior to clinical diagnosis [5, 188].

The use of screening tools for early detection of T2DM risk is strongly supported in the literature [191-193]. Ideal screening tools require good sensitivity (i.e., probability that the test is positive for individuals that will develop T2DM in the future) and specificity (i.e., probability that the test is negative for individuals who will not develop T2DM in the future) [192]. A number of screening tools have been validated for T2DM risk assessment, including the Finnish Diabetes Risk Score (FINDRISC) [190] and the Australian Diabetes Risk Assessment (AUSDRISK) tool [16, 17]. AUSDRISK, released in 2008, was developed using data from the large population-based AUSDIAB study [18, 19]. The tool is

comprised of 10-items, assessing six modifiable and four non-modifiable risk factors. The AUSDRISK validation study [16] demonstrated good sensitivity (74%) and specificity (67.7%), with a positive T2DM predictive value of 12.7%, which is similar to the FINDRISC tool [190].

Despite the strong rationale for use, AUSDRISK is poorly used in clinical practice, predominantly due to lack of awareness of the tool [122] and of its potential usefulness. A small number of Australian studies have reported using it to assess T2DM risk in study cohorts [122, 194, 195] or as an eligibility criterion for T2DM prevention trials [196, 197]. However, no studies have reported the anthropometric and biomarker characteristics of participants identified as at high-risk for T2DM using AUSDRISK or its ability to identify individuals with elevated glycaemic markers. In addition, given the strong association between T2DM, cardiovascular disease, and several metabolic comorbidities, it is of interest to investigate the prevalence of Metabolic Syndrome (MetS) in individuals identified at high-risk for T2DM using AUSDRISK screening. Collectively, this information may provide further confidence in the usefulness of AUSDRISK screening to positively identify individuals with prediabetes and multiple risk factors for T2DM.

4.1.2 Aims

The primary aim is to profile the characteristics of a sample of Australian men identified as being at high-risk for T2DM using AUSDRISK screening (score ≥ 12 points). Secondary aims are to determine the ability of the AUSDRISK tool to: (a) identify existing prediabetes based on FPG and HbA_{1C} values; and (b)

identify the prevalence and associated characteristics of MetS in a population of men at high-risk for T2DM.

4.2 Subjects, materials and methods

4.2.1 Study design

This study is a cross-sectional investigation reporting the characteristics of Australian men (n = 101) identified with high-risk for T2DM using the AUSDRISK tool. These men were enrolled in the T2DM PULSE (Prevention Using LifeStyle Education) trial, a randomised controlled trial of a 6-month self-administered and gender-tailored lifestyle behavior change intervention (weight loss, diet modification, exercise) for men. The rationale and design of the trial are comprehensively described elsewhere [121]. AUSDRISK score was used as the primary eligibility criterion for the trial. At the baseline time point (study entry), a wide range of demographic, anthropometric, physiological and behavioural outcomes were collected. The characteristics of these men including the prevalence of prediabetes based on FPG and HbA_{1C} criteria [15], and the prevalence of MetS [187] were examined. Comparisons of the sample characteristics across three AUSDRISK score groups (12-15, 16-19 and ≥ 20 points) were investigated. This study was conducted at the *The University of Newcastle*, Australia and was approved by the institutions Human Research Ethics Committee (Appendix 1). The trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12612000721808 (Appendix 2).

4.2.2 Participants: recruitment, eligibility and screening

To be eligible for the T2DM PULSE trial, men were required to: be aged 18-65, have a BMI 25-40 kg.m^{-2} and be at high-risk for T2DM (AUSDRISK score $\geq$ 12 points; maximum score 38). Individuals were not required to have diagnosed prediabetes or markers of dysglycaemia (e.g., FPG or HbA$_{1C}$) in the prediabetes range at study entry. Individuals with diagnosed type 1 or type 2 diabetes mellitus were not eligible. Eligibility criteria did not exclude men based on their current medication regimen (e.g., medications for prediabetes, hypertension and dyslipidaemia) unless a particular medication was known to affect or be adversely affected by lifestyle changes and/or weight loss.

4.2.3 Study outcomes

Demographic information, medical history, and medication use for health conditions were obtained by an online questionnaire. In addition, several anthropometric, physiological and behavioural outcomes were assessed. Trained assessors conducted all measures following standardised protocols [121]. Repeated measurements were obtained for several outcomes (i.e., height, weight, waist circumference and blood pressure) for the purpose of accuracy (Appendix 8). For these measures, the average of the acceptable values (within accuracy tolerance ranges) are reported.

4.2.3.1 AUSDRISK score

Men completed the 10-item AUSDRISK screening tool [16, 17] prior to study entry (< 1 month) as part of an online eligibility-screening question for the T2DM PULSE trial (Appendix 3). The question items and scoring are presented in

Table 12, along with a summary of the participants' responses. According to the AUSDRISK report [17], 7% of individuals with scores between 12-15 points (out of a possible 38 points) will develop T2DM within five years, 14% of individuals with scores between 16-19 points will develop T2DM within five years, and 33% of individuals with scores greater than 20 points will develop T2DM within five years. Therefore, the number of men within these three AUSDRISK score groupings (12-15, 16-19 and ≥ 20 points) and their characteristics are reported.

4.2.3.2 Anthropometrics

Weight was measured to 0.01 kg on a calibrated digital scale (CH-150kp, A&D Mercury Pty Ltd., Seven Hills, NSW, Australia). Participants were weighed in light clothing and without shoes. Height (cm) was measured to 0.1 cm using the stretch stature method (without shoes) on a calibrated stadiometer (Harpenden portable stadiometer with high speed Veeder-Root counter, Holtain Ltd, Pembrokeshire, United Kingdom). Body mass index (BMI) was calculated using the equation (weight [kg]/height [m^2]) [198].

Waist circumference (cm) was measured to 0.1 cm using a non-extensible steel tape (KDSF10-02, KDS Corporation, Osaka, Japan). An assessor with Level 1 anthropometry qualifications from the *International Society for the Advancement of Kinanthropometry* conducted all measurements. Waist circumference was assessed in two places: i) at the observable narrowest point between the lower costal border and iliac crest, and ii) level with the umbilicus. Body composition was measured using bioimpedance analysis (InBody720, Biospace Co., Ltd,

Seoul, Korea) to calculate body fat (%) and visceral fat area (cm^2). This device is valid and reliable for the assessment of body composition [169].

4.2.3.3 Metabolic profile

A single blood sample was collected after an overnight fast and analysed using standardised procedures by staff from a *National Association of Testing Authorities* accredited pathology service. Blood sample assays included FPG ($mmol.L^{-1}$), HbA_{1C} (% and $mmol.mol^{-1}$), insulin ($mIU.L^{-1}$), triglycerides ($mmol.L^{-1}$) and cholesterols (total, HDL, LDL; $mmol.L^{-1}$). Homeostatic model of insulin resistance (HOMA-IR2) and Quantitative insulin sensitivity check index (QUICKI) were calculated from FPG and insulin values.

4.2.3.4 Cardiovascular parameters

Blood pressure was measured to 1 mmHg using a manual inflation digital sphygmomanometer (NISSEI/DS-105E, Nihon Seimitsu Sokki Co. Ltd., Gunma, Japan). A standardised procedure [170, 171] was followed requiring participants to be seated for five minutes before the first measurement, with two minutes between repeated measurements.

4.2.3.5 Physical activity

Physical activity ($steps.day^{-1}$) was objectively measured using pedometers (Yamax Digi-Walker SW200, Yamax Corporation, Kumamoto City, Japan). Participants were required to wear the device for seven days after their baseline assessments and to record the number of steps taken on a recording sheet at the end of each day (Appendix 11). The average step count per day is reported.

Self-report physical activity level (min.week^{-1}) was assessed using a modified version [176] of the validated Godin Leisure-Time Exercise Questionnaire [177]. Participants were asked to indicate the frequency and duration of light, moderate, and vigorous intensity physical activities sessions in the past month. The average total time per week (frequency x duration) spent in moderate-vigorous physical activity (MVPA) is reported.

4.2.3.6 Dietary quality

Dietary intake and quality were assessed using the validated Australian Eating Survey (AES) [179], a 120-item semi-quantitative food frequency questionnaire with 15 supplementary questions regarding age, vitamin supplement use, food and sedentary behaviours. The AES calculates mean daily kJ intake and nutrient composition. In addition, the AES generates an Australian recommended food score (ARFS) [180], which provides an overall indication of diet quality. The full description of the AES can be viewed elsewhere [179].

4.2.3.7 Prevalence of prediabetes and Metabolic syndrome

Objectively measured data were used to determine the prevalence of prediabetes and MetS. Prediabetes was defined using the American Diabetes Association (ADA) criteria [15] - FPG (5.6-6.9 mmol.l^{-1}) and HbA$_{1C}$ (5.7-6.4%, 39-46 mmol.mol^{-1}). MetS was defined using the International Diabetes Federation (IDF) definition [187]. To be classified with MetS an individual must have central obesity (waist circumference ≥ 94 cm or BMI ≥ 30 kg.m^{-2}) and two of the following four criteria: elevated triglycerides (≥ 1.7 mmol.L^{-1} or specific treatment for lipid abnormality), low HDL-cholesterol (≤ 1.03 mmol.L^{-1} or specific treatment

for lipid abnormality), elevated blood pressure (systolic ≥ 130 mmHg, diastolic ≥ 85 mmHg or treatment for hypertension) and elevated FPG (≥ 5.6 mmol.L^{-1}).

4.2.3.8 Statistical analyses

All statistical analyses were performed using IBM SPSS version 21. Participant responses (counts and percentages) to the AUDRISK tool are reported, as well as the number of men in each AUSDRISK score group [17] (i.e., 12-15, 16-19 and ≥ 20 points). The demographic, anthropometric, physiological and behavioural characteristics associated with each AUSDRISK group are presented as mean ± SD (primary aim). Statistical differences among the three AUSDRISK groups were tested using one-way analysis of variance (ANOVA) with post-hoc Games-Howell procedure for correction of unequal variances between groups (significance level, $P < 0.05$). The prevalence of prediabetes and MetS (counts and percentages) are reported based on the relevant prediabetes and MetS criteria outlined previously (secondary aims a and b). In addition, the characteristics (mean ± SD) of men with MetS are presented for each of the MetS criterion, along with the percentage of men within the subsample who achieved the criterion value.

4.3 Results

4.3.1 Participants and AUSDRISK screening tool responses

The AUSDRISK screening tool was completed by 209 men, of whom 166 (79%) were classified as at high-risk for T2DM. Table 12 reports the AUSDRISK responses of men with lower (< 12) and high-risk scores (≥ 12). The sample was predominately Caucasian and most men were born in Australia (92%). Men

were more likely to be classified in the high-risk group if they were: older (> 44 years), had a family history of diabetes, were taking blood pressure medication, and had a large waist circumference. All Aboriginal, Torres Straight Islander, Pacific Islander and Maori men; as well as all men who were smokers or who had previously high blood glucose levels were classified with high-risk for T2DM.

4.3.2 Characteristics of men at high-risk for type 2 diabetes mellitus

Of the 166 men who were screened with high-risk for T2DM, 101 met additional eligibility criteria for the T2DM PULSE trial. Demographic, anthropometric, physiological, behavioural outcomes were subsequently assessed for these men. The characteristics of men grouped by their AUSDRISK score (12-15, 16-19, ≥ 20) are summarised in Table 13 (primary aim). Forty per cent of men scored 12-15 points, 24% scored 16-19 points, and 37% scored ≥ 20 points. Strong associations were observed between higher AUSDRISK scores and T2DM risk factors. Post-hoc testing for between group differences revealed that men with AUSDRISK scores ≥ 20 points were significantly older in age ($P = 0.001$) and had larger waist circumference ($P = 0.026$), higher visceral fat area ($P = 0.013$), higher FPG ($P = 0.001$) and higher HbA_{1C} ($P < 0.001$) compared to men with lower scores (12-15). In addition, medication use for hypertension and dyslipidaemia was more commonly reported in men with AUSDRISK scores ≥ 20 (hypertension: 59%; and dyslipidaemia: 51%), compared to men with scores of 12-15 (18% and 25%, respectively) and men with scores of 16-19 (29% and 21%, respectively). No men reported the use of medication for hyperglycaemia.

Table 12 Frequency of responses for individual items of the AUSDRISK tool for men identified at high-risk (≥ 12) and those with lower risk (< 12) for type 2 diabetes mellitus

AUSDRISK question and associated score	Lower risk score (< 12) n = 43		High-risk score (≥ 12) n = 166		Total n = 209	
	n	%	n	%	n	%
Q1. Your age group						
Under 35 years (0 points)	18	42	13	8	31	15
35-44 years (2 points)	10	23	22	13	33	16
45-54 years (4 points)	6	14	48	29	54	26
55-64 years (6 points)	9	21	71	43	80	38
65 years or over (8 points)	0	0	11	7	11	5
Q2. Gender						
Male (3 points)	43	100	166	100	209	100
Q3. Ethnicity/country of birth						
a) Are you of Aboriginal, Torres Straight Islander, Pacific Islander or Maori descent?						
No (0 points)	43	100	158	95	202	97
Yes (2 points)	0	0	7	4	7	3
b) Where were you born?						
Australia (0 points)	40	93	151	91	192	92
Asia (including the Indian sub-continent), Middle East, North Africa, Southern Europe (2 points)	0	0	0	0	0	0
Other (0 points)	3	7	14	8	17	8
Q4. Have either of your parents, or any of your brothers or sisters been diagnosed with diabetes (type 1 or type 2)?						
No (0 points)	35	81	101	61	137	66
Yes (3 points)	8	19	64	39	72	34
Q5. Have you ever been found to have high blood glucose (sugar) (for example, in a health examination, during an illness)?						
No (0 points)	43	100	112	67	155	74
Yes (6 points)	0	0	53	32	54	26
6. Are you currently taking medication for high blood pressure?						
No (0 points)	41	95	105	63	147	70
Yes (2 points)	2	5	60	36	62	30

AUSDRISK question and associated score	Lower risk score (< 12) n = 43		High-risk score (≥ 12) n = 166		Total n = 209	
	n	%	n	%	n	%
Q7. Do you currently smoke cigarettes or any other tobacco products on a daily basis?						
No (0 points)	43	100	156	94	200	96
Yes (2 points)	0	0	9	5	9	4
Q8. How often do you eat vegetables or fruit?						
Every day (0 points)	27	63	101	61	129	62
Not every day (1 points)	16	37	64	39	80	38
Q9. On average, would you say you do at least 2.5 hours of physical activity per week (for example, 30 minutes a day on 5 or more days a week)?						
Yes (0 points)	25	58	67	40	93	44
No (2 points)	18	42	98	59	116	56
Q10. Your waist measurement taken below the ribs (usually at the level of the navel, and while standing)						
For men of Asian or Aboriginal or Torres Straight Islander descent						
Less than 90 cm (0 points)	0	0	0	0	0	0
90-100 cm (4 points)	0	0	2	1	2	1
More than 100 cm (7 points)	0	0	5	3	5	2
For all others						
Less than 102 cm (0 points)	27	63	10	6	38	18
102-110 (4 points)	15	35	77	46	92	44
More than 110 cm (7 points)	1	2	72	43	73	35

Table 13 Characteristics of men based on AUSDRISK score groups

Characteristics	AUSDRISK Score 12-15 (n = 40)		AUSDRISK Score 16-19 (n = 24)		AUSDRISK Score ≥ 20 (n = 37)		One-way ANOVA
	Mean	SD	Mean	SD	Mean	SD	P-value
Age (years)	47.5	10.7	55.0 *	6.7	55.8 *	8.2	< 0.001
Weight (kg)	102.20	12.0	99.25	12.71	106.37	14.00	0.101
BMI (kg.m^{-2}) [a]	32.2	3.3	31.8	3.4	33.0	3.5	0.414
Waist (umbilicus, cm) [b]	110.9	8.4	110.7	8.1	115.2	9.0	0.048
Waist (narrowest, cm) [b]	107.5	8.8	109.2	9.5	113.2 *	9.8	0.031
Fat mass (%) [c]	30.3	6.5	32.6	5.3	32.8	4.9	0.118
Visceral fat area (cm^2) [d]	165.7	29.8	177.1	27.4	185.9 *	30.9	0.014
Systolic BP (mmHg) [e]	124	11	128	12	129	13	0.101
Diastolic BP (mmHg) [e]	82	8	84	8	84	9	0.544
FPG (mmol.L^{-1}) [f]	4.8	0.6	5.0	0.6	5.3 *	0.6	0.001
HbA$_{1C}$ (%) [g]	5.6	0.4	5.8	0.5	6.0 *	0.4	< 0.001
HbA$_{1C}$ mmol.mol^{-1} [g]	38	4.4	40	5.5	42	4.4	< 0.001
Insulin (mIU.L^{-1})	8.8	6.1	7.9	3.3	11.4 [#]	7.1	0.066
HOMA-IR2 [h]	1.1	0.8	1.0	0.4	1.5 [#]	0.9	0.052
QUICKI [i]	0.36	0.04	0.36	0.03	0.34 *	0.03	0.020
Triglycerides (mmol.L^{-1}) [j]	2.5	4.2	2.0	1.2	2.0	1.2	0.687
Cholesterol (mmol.L^{-1}) [k]	5.0	1.0	5.0	1.2	4.8	0.9	0.705
LDL-Cholesterol (mmol.L^{-1}) [l]	3.1	0.8	3.1	0.8	2.9	0.8	0.362
HDL-Cholesterol (mmol.L^{-1}) [m]	1.0	0.2	1.0	0.3	1.1	0.2	0.577
Physical activity (steps.day^{-1}) [n]	6927	2794	5889	1982	6528	2757	0.335
MVPA (mins.week^{-1}) [o]	154	200	85	126	111	154	0.261
Total Energy intake (kj.day^{-1})	11192	3110	11197	3683	11672	3437	0.790
ARFS [p]	30.8	9.9	31.0	7.2	31.8	10.3	0.893
ARFS vegetables [q]	11.4	4.5	12.2	4.0	11.5	5.2	0.783
ARFS fruit [r]	4.2	3.2	3.6	2.7	4.4	2.5	0.541

* Significantly different to AUSDRISK score 12-15, P < 0.05 (post-hoc testing)
[#] Significantly different to AUSDRISK score 16-19, P < 0.05 (post-hoc testing)

The following reference ranges for anthropometric, physiological and behavioural outcomes are associated with increased risk for T2DM, cardiovascular disease and/or generally poor health. [a] Body Mass Index (BMI) > 25 kg.m^{-2} (overweight or obese) [198]. [b] Waist circumference ≥ 94 cm (central obesity) [187]. [c] Fat mass ≥ 27.8% (20th percentile, poor body composition, men aged 50-59 years) [199]. [d] Visceral fat area > 100 cm^2 (central obesity) [200]. [e] Systolic blood pressure (BP) ≥ 140 mmHg and diastolic blood pressure (BP) ≥ 90 mmHg (hypertension) [201]. [f] Fasting plasma glucose (FPG) ≥ 5.6 mmol.L^{-1} [15]. [g] Glycosylated haemoglobin (HbA$_{1C}$) ≥ 5.7% [39 mmol.mol^{-1}] (pre-diabetes) [15]. [h] Homeostatic Model Assessment (HOMA-IR2) > 1.85 [202] (insulin resistance). [i] Quantitative insulin sensitivity check index (QUICKI) < 0.30 (insulin sensitivity) [203]. [j] Triglycerides > 1.5 mmol.L^{-1} (dyslipidaemia) [204]. [k] Cholesterol > 4.0 mmol.L^{-1} (dyslipidaemia) [204]. [l] LDL-C > 2.0 mmol.L^{-1} (dyslipidaemia) [204]. [m] HDL-C < 1.0 mmol.L^{-1} (dyslipidaemia) [204]. [n] Physical activity < 7499 steps/day (low active) [205]. [o] Moderate-vigorous physical activity (MVPA) <150 min.wk^{-1} (low active) [86]. [p] Australian Recommended Food Score (ARFS) < 32 points (less than ideal diet quality) [180]. [q] ARFS vegetables max score 21. [r] ARFS fruit max score 12.

4.3.3 Identification of prediabetes

Mean ± SD FPG was 5.0 ± 0.6 mmol.L^{-1}, while mean HbA$_{1C}$ was 5.8 ± 0.5% (40 ± 5.5 mmol.mol^{-1}). The number of men with FPG, HbA$_{1C}$ or both FPG *and* HbA$_{1C}$ values above the respective ADA prediabetes cut-points are reported in Table 14. Seventy per cent of men (n = 71) had FPG and/or HbA$_{1C}$ values in the prediabetes range (secondary aim a). Only 20% of the sample had an FPG in the prediabetes range, whereas 65% had an HbA$_{1C}$ in the prediabetes range.

Table 14 Distribution of fasting plasma glucose and HbA$_{1C}$ values above and below the pre-diabetes range

Plasma glycaemia variables used for the diagnosis of pre-diabetes [a]	Total (n = 101)	
	n	%
FPG < 5.6 mmol.L^{-1}	81	80
FPG ≥ 5.6 mmol.L^{-1}	20	20
HbA$_{1C}$ < 5.7% (39 mmol.mol^{-1})	35	35
HbA$_{1C}$ ≥ 5.7% (39 mmol.mol^{-1})	66	65
HbA$_{1C}$ < 5.7% (39 mmol.mol^{-1}) & FPG < 5.6 mmol.L^{-1}	30	30
HbA$_{1C}$ < 5.7% (39 mmol.mol^{-1}) & FPG ≥ 5.6 mmol.L^{-1}	5	5
HbA$_{1C}$ ≥ 5.7% (39 mmol.mol^{-1}) & FPG < 5.6 mmol.L^{-1}	51	50
HbA$_{1C}$ ≥ 5.7% (39 mmol.mol^{-1}) & FPG ≥ 5.6 mmol.L^{-1}	15	15

FPG – Fasting Plasma Glucose, HbA$_{1C}$ – Glycosylated Haemoglobin

[a] Pre-diabetes is defined according to the ADA cut-points - FPG ≥ 5.6 mmol.L^{-1} or HbA$_{1C}$ ≥ 5.7% [39 mmol.mol^{-1}] (pre-diabetes) [15].

4.3.4 Metabolic syndrome

The prevalence of MetS in the sample of men was 62% (secondary aim b). Table 15 reports the mean ± SD of objectively assessed outcomes relevant to the five criteria used to define MetS. Interestingly, elevated FPG was the least frequently achieved MetS criteria.

Table 15 Characteristics of men classified with metabolic syndrome

Metabolic syndrome criterion [a]	Mean	SD	Percentage (%) of men who met the individual criteria [b]
Central obesity			
Waist circumference ≥ 94 cm	112	9	100
BMI ≥ 30 kg.m^{-2}	33	3	
Elevated triglycerides			
≥ 1.7 mmol.L^{-1}	2.9	3.3	75
or specific treatment for dyslipidemia			
Low HDL-cholesterol			
≤ 1.03 mmol.L^{-1}	0.97	0.23	68
or specific treatment for dyslipidemia			
Elevated blood pressure			
Systolic ≥ 130 mmHg	129	12	43
Diastolic ≥ 85 mmHg or treatment of previously diagnosed hypertension	85	7	60
Elevated FPG			
≥ 5.6 mmol.L^{-1}	5.2	0.7	29

[a] Metabolic Syndrome is defined by central obesity (waist circumference or BMI) plus any two of the remaining four criteria.
[b] n = 63

BMI – Body Mass Index, FPG – Fasting Plasma Glucose

4.4 Discussion

This study provides a comprehensive examination of the characteristics of Australian men identified as at high-risk for T2DM using AUSDRISK screening. These men were predominately Caucasian, > 44 years of age, non-smokers and had elevated waist circumference. Many characteristics were similar among men in three AUSDRISK score groups (12-15, 16-19 and ≥ 20 points) groups, however men scoring ≥ 20 points had significantly higher waist circumference, visceral fat area, FPG and HbA$_{1C}$ compared to men with scores of 12-15. Mean HbA$_{1C}$ (5.8%, 40 mmol.mol^{-1}) was above the ADA prediabetes cut-point (5.7%) [15], whereas mean FPG (5.0 mmol.L^{-1}) was substantially below the cut-point (5.6 mmol.L^{-1}). Furthermore, there was a large discrepancy in the classification of prediabetes based on HbA$_{1C}$ (65%) and FPG (20%). The prevalence of prediabetes was 70% based on FPG and HbA$_{1C}$ values and the prevalence of MetS was 62%. Of the five MetS criteria, elevated FPG had the lowest

frequency, with only 29% of men with MetS meeting the cut-point of 5.6 mmol.L^{-1}. Given the high prevalence of existing prediabetes in the current sample and the elevations in multiple risk factors, it is clear that the AUSDRISK tool has good ability to positively identify Caucasian men at high-risk for T2DM. These findings provide evidence supporting the usefulness of the AUSDRISK tool for T2DM screening for men in clinical practice and research settings.

The current study has assessed a wide range of demographic, anthropometric, physiological and behavioural outcomes in men identified at high-risk for T2DM using AUSDRISK screening. When comparing three AUDRISK score groups, we found that men with scores ≥ 20 had significantly higher BMI, waist circumference and visceral fat area than men with scores of 12-15. These men also had significantly higher mean HbA$_{1C}$ and FPG levels compared to men with scores of 12-15. This is consistent with previous research indicating the strong association between age [21], abdominal obesity [206] and hyperglycaemia. Furthermore, we found that mean HbA$_{1C}$ was above the prediabetes range only for men with AUSDRISK scores of ≥ 16 and that mean FPG was substantially lower than the prediabetes cut-point across all three AUSDRISK groups. This finding was particularly surprising given the aforementioned characteristics of men in the study and the fact that over a third of these men indicated on the AUSDRISK tool that they had previously had "high blood glucose", most likely FPG, values.

Surprisingly, physical activity and dietary behaviours were markedly similar across the three AUSDRISK groups. More than half of high-risk men (59%)

indicated they did not undertake the recommended level of physical activity of 150 mins.week^{-1}. No significant between group differences were observed for self-report estimates of MVPA. However, men with higher AUSDRISK scores (16-19 and ≥ 20 points) reported performing less than the recommended level of MVPA per week, whereas men with AUDRISK scores (12-15) did report achieving the recommended amount of MVPA per week. In addition, men in all three AUSDRISK groups were in the "low active" category [205] for objectively measured physical activity (pedometer steps.day^{-1}). These findings are important given the known effects of physical activity on blood glucose regulation over both acute (immediately post-exercise and up to 72 h) and chronic time frames [73, 207]. Regarding dietary quality, 39% of high-risk men indicated they did not eat any vegetables or fruit daily. Analysis of dietary quality indicated that men across all three AUSDRISK groups scored below the suggested ARFS minimum target of 32, which is indicative of moderate quality diet and representative of consumption of a reasonable variety of nutritious foods weekly, including vegetables, fruit, wholegrains, lean meat and reduced fat dairy, and more optimal nutrient intakes in terms of lower saturated fat and higher fibre intakes [180]. Notably, previous studies investigating vegetable/fruit intake and T2DM risk have reported mixed results. A meta-analysis by Carter and colleagues [55] reported no significant association between total vegetable or total fruit intake and incidence of T2DM. In contrast, an 11-year cohort study by Cooper and colleagues [56] did report a significant association between total vegetable intake and T2DM incidence. Interestingly, both studies reported significant associations between high consumption of green leafy vegetables and reduced T2DM [55, 56]. In addition, Mursu et al [208] reported a significant

association between high berry consumption and reduced T2DM risk. Further detailed analysis of dietary intake with respect to AUSDRISK score is warranted.

The characteristics of men summarised above are comparable to individuals from the AUSDIAB study, from which the AUSDRISK tool was developed. In a sub-analysis, Magliano and colleagues [19] reported the baseline characteristics of a sub-sample of individuals who developed T2DM in the following five years. Of those who returned for follow-up, 224 individuals (4%) developed T2DM. These individuals were aged (mean ± SD) 55.8 ± 12 years, with a waist circumference of 104.1 ± 11.6 cm (male value reported) and BMI of 29.3 ± 0.4 $kg.m^{-2}$. In addition, the sample was (percentages) male (51%), insufficiently active (< 150 $min.wk^{-1}$ physical activity, 59%), hypertensive (55%) and had a family history of diabetes (30%). Mean HbA_{1C} was 5.5% (5.2-5.7, 25th-75th percentile; 37 $mmol.mol^{-1}$, 33-39) and mean FPG was 6.0 $mmol.L^{-1}$ (5.5-6.4). The characteristics of men in the current study are similar, with the exception of FPG, to the AUSDIAB sub-sample. This comparison further confirms the high-risk classification of men in the current study.

A secondary aim of this study was to report the ability of AUSDRISK to identify men with existing prediabetes. Analysis of fasting blood samples revealed a prevalence of prediabetes of 70% based on FPG and/or HbA_{1C} values. Mean HbA_{1C} was above the ADA prediabetes cut-point of 5.7% (39 $mmol.mol^{-1}$), whereas mean FPG was below the prediabetes cut-point of 5.6 $mmol.L^{-1}$. There was a large discrepancy in classification of prediabetes between HbA_{1C} and

FPG measures. The marked observed difference may be partly explained by the different pathophysiologies involved in early stage T2DM and prediabetes i.e., impaired fasting glucose (IFG) or impaired glucose tolerance (IGT). Furthermore, FPG, an acute marker of glycaemia, is subject to substantial variation secondary to physical activity and/or a period of fasting prior to testing, whereas HbA_{1C} is a longer-term marker of glycaemia and is subject to less intra-individual daily variation [191]. Notably, numerous studies have demonstrated discrepancies in diagnosis of prediabetes/T2DM using HbA_{1C}, FPG and OGTT in various populations [209-211]. This reiterates the importance of assessing HbA_{1C} in conjunction with FPG and OGTT to minimise misclassification of individuals. In summary, these findings suggest the AUSDRISK tool is sensitive in identifying individuals with elevated glycaemic markers, in particular $HbA_{1C,}$ at least in Caucasian men.

The AUSDRISK tool, in addition to identifying a sample with a high prevalence of prediabetes, was also successful in identifying a group of men with multiple risk factors for cardiovascular disease. Using the IDF definition [187], there was a high prevalence (62%) of MetS in the current sample of men. This was almost double the MetS prevalence (34.4%) observed for men in the population-based AUSDIAB study [117]. In those with MetS, mean waist circumference and triglyceride levels were substantially elevated above the MetS cut-point, whereas mean blood pressure was similar to the MetS cut-point. It is noteworthy that the current study sample included men who were taking medications for dyslipidaemia (19%) and hypertension (37%) and therefore the mean values for those classified with MetS must be interpreted with this in

mind. In contrast to these findings, mean FPG (5.2 mmol.L^{-1}) in this sub-sample was considerably lower than the MetS cut-point (5.6 mmol.L^{-1}). This value is particularly surprising given that all men had central obesity, a risk factor strongly linked to hyperglycaemia [206].

This study has several strengths. The comprehensive set of demographic, anthropometric, physiological and behavioural outcomes has allowed for a detailed risk-profile analysis to be conducted. In particular, the inclusion of clinical biomarkers for the classification of prediabetes and MetS is a particular strength. This study also has some limitations. Classification of prediabetes was based on a single blood sample collected at the baseline time point of the T2DM PULSE trial. It was not feasible/practical to confirm blood test results using repeat measures for diagnostic purposes. Individuals with previously unknown T2DM, but who were subsequently revealed to have FPG and/or HbA$_{1C}$ values in the T2DM range on assessment were included in all analyses presented here. Only one participant (1%) had an FPG in the T2DM range ($\geq$ 7.0 mmol.L^{-1}) and 7 participants (7%) were found to have HbA$_{1C}$ values in the T2DM range ($\geq$ 6.5%, 48 mmol.mol^{-1}). Furthermore, this study was conducted in a regional city in Australia, which has less ethnic diversity than the larger metropolitan cities. Consequently, the vast majority of the men were Caucasian and born in Australia. The limitations outlined above may influence the generalisability of the results reported in this study, however we believe these findings are important and will inform the practise of T2DM screening in clinical and research settings.

Screening for T2DM risk using AUSDRISK identified a population of men with several T2DM and MetS risk factors. Men with AUSDRISK scores ≥ 20 had higher mean waist circumference, visceral fat area, FPG levels and HbA$_{1C}$ levels. Blood testing confirmed a high prevalence of prediabetes, with significantly more men in the prediabetes range for HbA$_{1C}$ than FPG. In addition to risk for T2DM, the high prevalence of MetS indicates significant risk for cardiovascular disease and other obesity related co-morbidities. We conclude that the AUSDRISK screening tool is effective for the early identification of Caucasian men at high-risk for T2DM and recommend its use in clinical practice and research settings.

Chapter 5 – Efficacy of the type 2 diabetes PULSE Program randomised controlled trial

Preface:

This chapter presents a manuscript, which aligns with *Primary Aim* of this thesis i.e., to evaluate the feasibility and efficacy of the *PULSE Program* for improving a range of risk factors strongly linked with type 2 diabetes mellitus development, including weight and glycaemic markers in men at high-risk for developing type 2 diabetes mellitus. This manuscript has been accepted for publication in the *American Journal of Preventive Medicine*.

Citation:

Aguiar EJ, Morgan PJ, Collins CE, Plotnikoff RC, Young MD, Callister R. Efficacy of the type 2 diabetes PULSE Program randomized controlled trial. Am J Prev Med. 2015 (in press)

Abstract

Introduction: Self-administered lifestyle interventions have been suggested as an alternative to face-face delivery modes, though their efficacy remains uncertain. The aim was to evaluate the efficacy of the type 2 diabetes mellitus PULSE (Prevention Using LifeStyle Education) Program*,* a self-administered and gender-tailored lifestyle intervention for men at high-risk for developing type 2 diabetes mellitus.

Design/setting: A 6-month, assessor-blinded, parallel-group, randomised controlled trial was conducted at the University of Newcastle, Australia in 2012-2013.

Participants: Men (18-65 years, BMI 25-40 kg.m^{-2}, high-risk for developing type 2 diabetes mellitus) were stratified by age (< 50, > 50 years) and BMI category (25.0-29.9, 30.0-35.9, 35.0-40 kg.m^{-2}) and individually randomised (1:1 ratio) to the intervention (n = 53) or wait-list control groups (n = 48).

Intervention: The intervention group received the *PULSE Program*, which contained print and video resources on weight loss (*SHED-IT Weight Loss Program*), diet modification and exercise for type 2 diabetes mellitus prevention. The wait-list control group received no information until six months.

Main outcome measures: Data were collected from September 2012 to September 2013 and analysed in 2014-2015. Linear mixed models (intention-to-treat) were used to determine group-by-time interactions (differences between groups in changes over time) at six months for the primary outcome (weight), HbA$_{1C}$ and several secondary outcomes (significance level, $P < 0.05$).

Results: Differences between groups in mean changes from baseline to six months (group-by-time interaction; mean [95% CI]) favoured the intervention

over control group for weight loss (-5.50 kg [95% CI: -7.40, -3.61], P < 0.001, Cohen's d = 1.15), HbA$_{1C}$ (-0.2% [95% CI: -0.3, -0.1], P = 0.002, d = 0.64), and BMI, waist circumference, body fat percentage, aerobic fitness and lower body muscular fitness (all P < 0.05). No group-by-time effects were observed for fasting plasma glucose, upper body muscular fitness, physical activity or energy intake.

Conclusions: The *PULSE Program* improved several type 2 diabetes mellitus risk factors in men, including weight and HbA$_{1C}$. These findings provide evidence for a self-administered and gender-tailored lifestyle intervention, which has potential for dissemination in community settings.

5.1 Introduction

The prevalence of diabetes is rising globally, with current estimates indicating that 592 million people (10.1% of the world's population) will be affected by 2035 [20]. Type 2 diabetes mellitus (T2DM) prevention trials, such as the US Diabetes Prevention Program [40] and Finnish Diabetes Prevention Study [41], have demonstrated that lifestyle intervention can reduce T2DM incidence by up to 58%. Despite their demonstrated efficacy, there is debate about the associated costs and sustainability of lifestyle interventions [93]. Most lifestyle interventions involve an intensive period of individual or group-based face-face lifestyle education and supervised exercise, which requires a substantial time commitment from participants (several hours of contact with providers), as well as significant resourcing from the provider (professional staffing and facility use). Effective programs that are less resource and time intensive are required [93].

Self-administered (self-directed) lifestyle interventions have potential to address these concerns and improve reach to regional communities. Self-administered interventions may also be more appealing to men who tend to favour programs with minimal or no face-face contact [101, 110]. In addition, the gender-tailoring [110, 115] of lifestyle behaviour change interventions may improve the acceptability of the program, as has been demonstrated for weight loss interventions for men [103-105, 107-111, 114]. To the authors' knowledge, there is currently no evidence from randomised controlled trials regarding the efficacy of self-administered [97] and gender-tailored [98] lifestyle interventions for T2DM prevention for men.

The aim of the current study was to determine the efficacy of the "Type 2 diabetes mellitus *PULSE* (Prevention Using LifeStyle Education) *Program*", a self-administered and gender-tailored lifestyle intervention, to achieve improvements in T2DM risk factors for men at high risk for developing the disease. We hypothesised that the *PULSE Program* intervention group would achieve statistically significant and clinically meaningful reductions in weight (primary outcome) and a range of secondary outcomes (including glycosylated hemoglobin [HbA_{1C}] and fasting plasma glucose [FPG]) at six months post-baseline (immediate post-intervention and primary time point) compared with a wait-list control group.

5.2 Research Design and Methods

5.2.1 Trial design

The T2DM *PULSE Program* randomised controlled trial (RCT) protocol is described in detail elsewhere [121]. The trial was an assessor-blinded, parallel-group RCT. Eligible participants were stratified (age, BMI) and individually randomised to either the 6-month *PULSE Program* intervention or a wait-list control group. The trial was conducted at The University of Newcastle, Australia and approved by its Human Research Ethics Committee. The trial is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12612000721808. The design, conduct and reporting adheres to the Consolidated Standards of Reporting Trials guidelines (CONSORT guidelines) [155].

5.2.2 Participants: eligibility, recruitment and screening

Men (n = 101) from the Hunter region, New South Wales, Australia were recruited from August 2012 to March 2013, using a variety of strategies (newspaper, radio, recruitment flyers, work place emails and social media). Inclusion criteria included males, 18-65 years of age, BMI 25-40 kg.m^{-2}, and at high risk for developing T2DM (Australian Diabetes risk tool, AUSDRISK; score ≥ 12; self-report) [16]. Men were not required to have prediabetes at trial entry. Men with diagnosed type 1 or 2 diabetes were excluded. There were no racial, ethnic, or cultural selection criteria. Men completed an online eligibility questionnaire, which included a pre-exercise screening questionnaire [157]. All men provided free and informed consent. In addition, men ≥ 45 years of age and those with medical issues identified through screening were required to

obtain a medical practitioner's clearance for participation in a lifestyle behaviour change program. Exclusion criteria included recent weight loss > 5% in the previous six months, or taking medication that could affect or be affected by lifestyle behaviour changes.

5.2.3 Sample size calculation

The primary outcome was weight change at six months. The power calculation assumed a 14 kg standard deviation in baseline weight and a 0.9 correlation between baseline and six month weight [103]. As such, a sample size of 74 (37 per group) was required to give the trial 80% power to detect a 4 kg difference in mean weight change between groups at six months (P < 0.05; two-sided test). To allow for 20% loss to follow-up at six months, a minimum of 94 participants were required at baseline.

5.2.4 Randomisation

Participants were individually randomised to the intervention or control group after baseline assessments. Allocation was stratified by age (< 50 or ≥ 50 years) and BMI category (25-29.9; 30-34.9; 35-40 kg.m^{-2}). Allocation sequences were generated by an investigator not involved in the allocation process using a computer-based random number-producing algorithm with a randomisation ratio of 1:1 in block lengths of six. The same investigator concealed group allocations in opaque envelopes, which were numbered in consecutive order within each stratum. A separate investigator carried out the randomisation of participants to groups. This investigator was not involved in assessments at any time point. Participants were given the next available envelope in their strata category,

which contained their group allocation. The investigator then proceeded with a standardised explanation of the respective study arm. To ensure assessor blinding was maintained throughout the trial, group allocations were not accessible to assessors at any time point.

5.2.5 Intervention

2.5.5.1 Intervention group

After baseline assessments, participants randomised to the intervention group received the *PULSE Program* resource pack. Each participant received a standardised individual 15 min orientation to the intervention resources. Aside from this initial briefing, no further contact was made for intervention delivery or self-monitoring prompting.

The *PULSE Program* was a 6-month, self-administered (self-directed), multi-component lifestyle intervention, which aimed to assist men achieve moderate weight loss (> 5% of initial body weight) and improvements in secondary outcomes (including glycaemic markers) through changes in diet and exercise behaviours. The *PULSE Program* built on previous research from the authors' group by including the self-administered and gender-tailored *SHED-IT Weight Loss Program for men* [103, 107-111, 119, 120], and providing additional intervention components to bring the overall intervention in line with current dietary [159] and exercise guidelines [73, 86] for T2DM prevention. The intervention resources were based on Bandura's Social Cognitive Theory [163]. The key constructs of the theory (e.g., self-efficacy, outcome expectations, goal setting, social support)

were operationalised in the program resources [121]. The resource pack contained:

a) The *'SHED-IT Weight Loss Program'* (Self-Help, Exercise and Diet using Internet Technology)

The *'SHED-IT Weight Loss Program'* components are described in detail elsewhere [119] and the program has been extensively evaluated [103, 107-111]. The program consists of the *'SHED-IT Weight Loss DVD for Men'*, the *'SHED-IT Weight Loss Handbook for Men'*, the *'SHED-IT Weight Loss Log Book for Men'*, a tape measure, a pedometer, a user guide for the web-based version of the Calorieking™ self-monitoring tool, and the Calorieking™ 'Calorie Fat and Carbohydrate Counter' booklet. Men were encouraged to create a 477 kcal (2000 kilojoule) energy deficit on most days to elicit weight loss and to monitor dietary and exercise behaviours using Calorieking™. Men also self-monitored weight loss, waist circumference and physical activity; and completed goal setting and social support tasks in the *'SHED-IT Weight Loss Log Book for Men'*. Participants were asked to return this document for assessment of program compliance.

b) The *'PULSE Type 2 Diabetes Prevention Handbook for Men'*

This document contained three sections: "Type 2 Diabetes Prevention", "Eating to Beat Type 2 Diabetes", and "The Essential Exercises for Type 2 Diabetes Prevention". Examples of the dietary and exercise messages included: creating a colourful plate, i.e., including more vegetables and fruit in meals; consuming five vegetable and two fruit servings per day; choosing low glycaemic

index foods; choosing healthy versus unhealthy fats; choosing lean proteins; increasing fibre intake; avoiding skipping meals; being active everyday; and moving after meals. The specific macro- and micronutrient targets that aligned with these program messages can be viewed elsewhere [121].

c) The *'PULSE Exercise Support Book for Men'*

Based on current exercise guidelines for T2DM [73, 86], men were prescribed an exercise program consisting of at least 150 min (5 x 30 min) of aerobic exercise and 60 min (2 x 30 min) of resistance training (total of 210 min) per week [121]. The program was home-based and unsupervised. Participants were encouraged to choose aerobic exercises they enjoyed (e.g., walking, swimming, cycling). This booklet also provided participants with a Gymstick[TM] (resistance band device) and a bodyweight exercise program, which included both dynamic and isometric exercises covering all major muscle groups. The *'PULSE Exercise Support Book for Men'* contained a logbook section to encourage self-monitoring of exercise sessions. Participants were asked to return this document for assessment of exercise compliance.

5.2.5.2 Gender-tailoring of the intervention

The novel components of the *PULSE Program* were gender-tailored to appeal to the preferences/needs of the target population, and to increase the receptivity and acceptability of the program [115]. For example, the intervention resources featured images of men performing healthy behaviours; used male-

oriented language, humour and anecdotes; used a frank and realistic approach [168]; provided men with flexible options [110]; and promoted 'masculine' exercise choices (i.e., resistance training) with an emphasis on the health and fitness benefits of exercise [166]. A more detailed description of the gender tailoring can be found elsewhere [121].

5.2.6 Wait-list control group

Participants allocated to the wait-list control group received the *PULSE Program* after their 6-month control period.

5.2.7 Trial outcomes

Outcome measures are described briefly here and more comprehensively in the trial protocol [121]. Data collection was conducted at baseline, three months (mid-program) and six months (immediate post-program) at the Human Performance Laboratory, The University of Newcastle, from September 2012 to September 2013. Assessors were trained and followed standardised protocols. Assessors were blinded to group allocation at all time points and participants were blinded to group allocation until after their baseline assessment.

5.2.7.1 Anthropometrics

Weight (*kg*, primary outcome) was measured on a calibrated digital scale (CH-150kp, A&D Mercury Pty Ltd., Seven Hills, NSW, Australia). *Height (cm)* was assessed at baseline on a calibrated stadiometer (Harpenden stadiometer, Holtain Ltd., Pembrokeshire, United Kingdom). *BMI* was calculated using the equation *(weight [kg]/height [m^2])*. *Waist circumference (cm)* was measured

using a non-extensible steel tape (KDSF10-02, KDS Corporation, Osaka, Japan) in two places: (i) at the observable narrowest point between the lower costal border and iliac crest, and (ii) level with the umbilicus. Body composition was assessed using a valid and reliable [169] bioimpedance device (InBody720, Biospace Co., Ltd, Seoul, Korea) to calculate *fat mass (kg), fat free mass (kg), body fat (%), skeletal muscle mass (kg) and visceral fat area (cm^2)*. To ensure good hydration for bioimpedance measurement, participants were instructed to drink water on the day prior, and the morning of, their assessment session.

5.2.7.2 Metabolic profile and cardiovascular measures

A blood sample was collected after an overnight fast and analysed using standardised procedures in an accredited pathology laboratory. Blood sample assays included*: FPG (mmol.L^{-1}), HbA$_{1C}$ (%, mmol.mol^{-1}) and insulin (mIU.L^{-1}). Homeostatic Model of Insulin Resistance (HOMA-IR2)* and *Quantitative Insulin Sensitivity Check Index (QUICKI)* were calculated from glucose and insulin values. *Blood pressure (mmHg)* was measured using a manual inflation digital sphygmomanometer (NISSEI/DS-105E, Nihon Seimitsu Sokki Co. Ltd., Gunma, Japan) following a standardised procedure.

5.2.7.3 Fitness and Physical activity

Aerobic fitness (VO$_{2max}$, mL.kg^{-1}.min^{-1}) was assessed using the validated sub-maximal treadmill test (Ebbeling protocol) and associated estimation equation [174]. *Upper body muscular fitness* was assessed using a 25 kg barbell seated shoulder press *(max repetitions). Lower body muscular fitness* was assessed using a 10 kg plate squat to box test *(max repetitions).*

Physical activity (pedometer steps.day^{-1}) was self-reported using an objective measure (Yamax Digi-Walker SW200 pedometer, Yamax Corporation, Kumamoto City, Japan). Self-report *moderate-vigorous physical activity (MVPA, min.week^{-1})* was assessed using a modified version of the validated Godin Leisure-Time Exercise Questionnaire (GODIN LTEQ) [176].

5.2.7.4 Dietary Intake

Total energy intake (kcal.day^{-1}) was assessed using the Australian Eating Survey (AES) [179], a validated 120-item semi-quantitative food frequency questionnaire. Men were required to report the frequency of intake of food over the previous three months.

5.2.7.5 Quality of life

General health and quality of life were assessed using the validated United Kingdom *Short Form 12 (SF-12 physical and mental domains)* [185].

5.2.7.6 Prevalence of prediabetes and metabolic syndrome

Objectively measured data were used to determine the prevalence of *prediabetes* and *metabolic syndrome (MetS)*. *Prediabetes* was defined using the American Diabetes Association criteria [15] and *MetS* was defined using the International Diabetes Federation definition [187].

5.2.7.7 Demographic characteristics and additional self-report information

An online questionnaire was used to obtain demographic and additional information, including age, ethnicity, education level and socio-economic status.

5.2.8 Statistical analyses

Detailed descriptions of statistical analyses are reported elsewhere [121]. Statistical analyses were performed in 2014-15 using SPSS version 21, IBM, St Leonards, NSW, Australia. Data are presented as means ± SDs or means [95% confidence interval] for continuous variables and as counts (percentages) for categorical variables. Demographic and baseline characteristics for the intervention and control group are reported. Characteristics of completers versus non-completers are compared using independent *t* tests for continuous variables and chi-squared (X^2) tests for categorical variables (significance level, $P < 0.05$).

Linear mixed models (intention-to-treat), fitted with an unstructured covariance matrix, were used to assess intervention efficacy. The primary outcome (weight) and secondary outcomes were assessed for the impact of treatment (intervention versus control), time (treated as a categorical variable; baseline, three and six months) and group-by-time interaction. The primary time point was six months (immediate post-program). Age and socio-economic status (specified a-priori) were examined as covariates to determine any interactions in the models. Where a covariate was significant, the model was adjusted. The coefficient and P-value testing the difference between groups in changes from baseline to six months were used to determine the effect of the intervention on

outcomes (significance level, P < 0.05). Missing data, assumed to be missing at random, were statistically modelled using a likelihood-based analysis that included all available data [212, 213]. Effect sizes were calculated using the equation: Cohen's $d = (M_{1 \text{ change score}} - M_{2 \text{ change score}}) / SD_{\text{pooled [change scores]}}$ [214].

A number of secondary analyses were also conducted using linear mixed models. A completers analysis was performed using data from all men who returned for assessments at six months. A per protocol analysis, defined a priori [121], included men who achieved 50% compliance over six months based on self-report logbook entries for: (i) recording of weekly weight (n ≥ 12 entries), and (ii) recording and achievement of the physical activity target of 210 min per week (n ≥ 12 successful weeks). The impact of the intervention for men who were in the prediabetes range for FPG (≥5.6 mmol.L^{-1}) or HbA$_{1C}$ (≥5.7%, 39 mmol.mol^{-1}) at baseline was also explored.

5.3 Results

5.3.1 Participants

Figure 5 describes the flow of participants through the trial from eligibility screening to completion. In total, 119 of the 218 men who completed the online eligibility questionnaire met the inclusion criteria. Of this group, 101 consented and were randomised (intervention n= 53, control n = 48). Participant retention was 89% at three months (mid-program) and 81% at six months with no significant between group differences in retention at three (X^2 = 0.244 df = 1, P = 0.621) or six months (X^2 = 2.386, df = 1, P = 0.122). Participants lost to follow

up at six months reported lower total energy intakes (P = 0.032) at baseline than those who completed the trial.

5.3.2 Baseline characteristics

The characteristics of men in the intervention and control groups were similar at baseline (Table 16). Mean age (range) was 52.3 (20-65) years. Most men were born in Australia (89%). Mean ± SD weight was 103.03 ± 13.10 kg and mean waist circumference was 112.4 ± 13.10 cm. Mean FPG was 5.0 ± 0.6 mmol.L^{-1}, which is lower than the prediabetes cut-point of 5.6 mmol.L-1 [15]. Mean HbA$_{1C}$ was 5.8 ± 0.5% (40 ± 5.5 mmol.mol^{-1}), which is above the prediabetes cut-point of 5.7% (39 mmol.mol^{-1}) [15]. In total, 70% of men were above the respective prediabetes cut-points for HbA1C or FPG at the baseline time point.
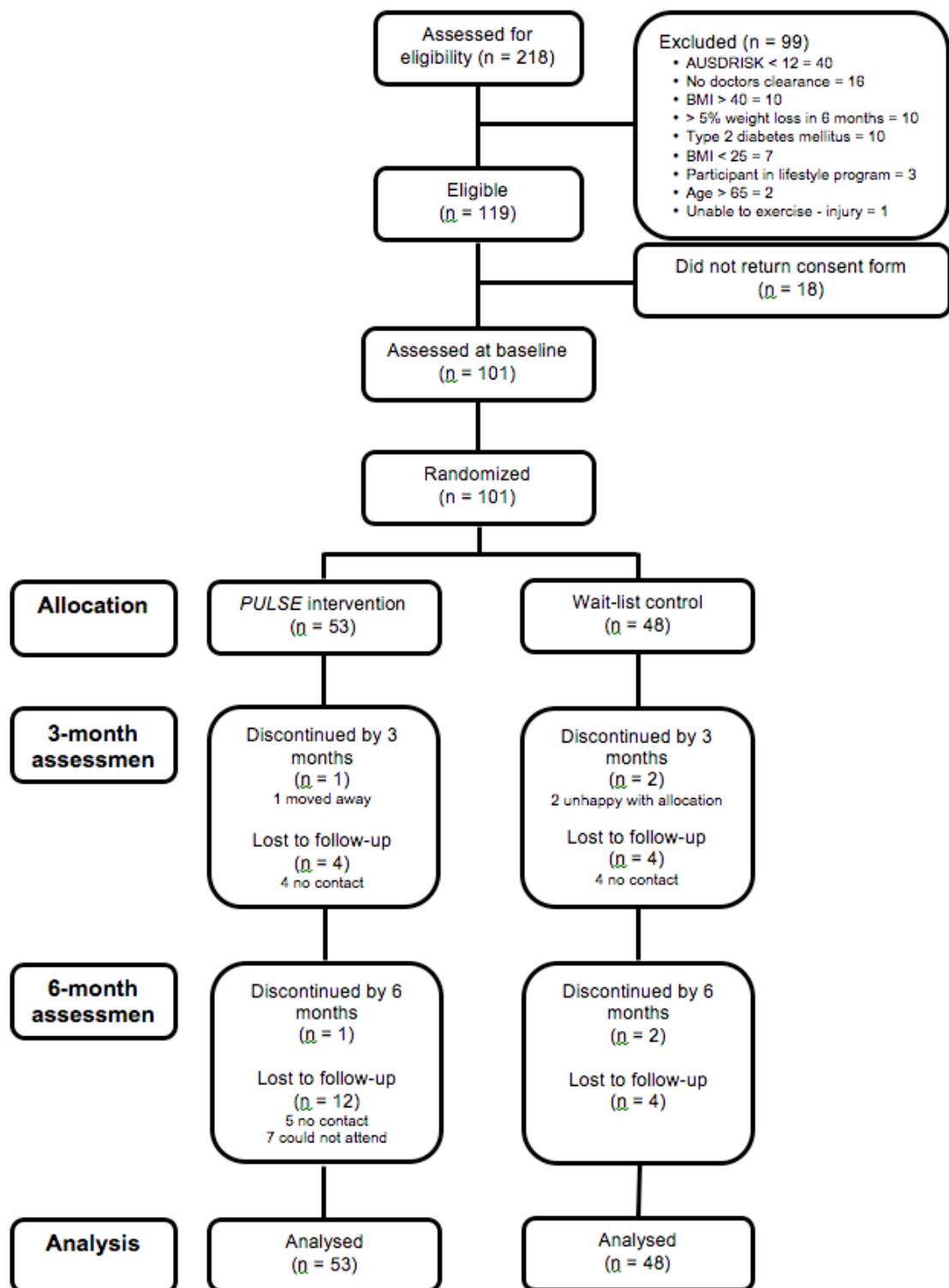
Figure 5 CONSORT diagram describing study design and flow of participants through the trial

Table 16 Baseline characteristics of men randomised to the control and intervention groups

Characteristics	Control (n = 48)		Intervention (n = 53)		Total (n = 101)	
	Mean	SD	Mean	SD	Mean	SD
AUSDRISK score [a]	18	5	18	5	18	5
Age (years)	52.2	10.1	52.5	9.5	52.3	9.7
Height (cm)	177.8	6.9	178.5	6.6	178.2	6.7
Weight (kg)	103.33	12.68	102.75	13.58	103.03	13.10
BMI (kg.m^{-2})	32.6	3.3	32.2	3.5	32.4	3.4
Waist (umbilicus) (cm)	112.9	8.5	112.0	9.0	112.4	8.7
Waist (narrowest) (cm)	110.1	9.7	109.9	9.64	110.0	9.6
Fat mass (kg)	34.6	8.4	31.9	8.4	33.2	8.5
Fat mass (%)	33.0	5.7	30.6	5.6	31.8	5.8
Fat free mass (kg)	69.3	8.2	71.4	8.7	70.4	8.5
Skeletal muscle mass (kg)	39.3	4.9	40.5	5.3	39.9	5.1
Visceral fat area (cm^2)	179.9	30.5	172.1	30.7	175.8	30.7
Systolic blood pressure (mmHg)	126	10	127	14	127	12
Diastolic blood pressure (mmHg)	84	8	82	8	83	8
FPG (mmol.L^{-1})	5.1	0.6	5.0	0.7	5.0	0.6
HbA$_{1C}$ (%)	5.8	0.4	5.8	0.5	5.8	0.5
HbA$_{1C}$ (mmol.mol^{-1})	40	4.4	40	5.5	40	5.5
Insulin (mIU.L^{-1})	8.6	4.0	10.4	7.6	9.5	6.1
HOMA-IR2	1.1	0.5	1.3	1.0	1.2	0.8
QUICKI	0.35	0.03	0.35	0.04	0.35	0.04
Aerobic fitness (mL.kg^{-1}.min^{-1}) [b]	38.0	6.7	37.5	6.7	37.7	6.7
Squat to box (reps)	43	24	44	23	43	23
Seated shoulder press (reps)	13	6	13	5	13	5
Physical activity (pedometer steps.day^{-1})	6368	2643	6699	2613	6544	2618
MVPA (min.week^{-1})	107	139	136	193	122	169
Total energy intake (kcal.day^{-1})	2809	848	2630	751	2715	799
SF12 mental score	50.8	8.7	49.6	9.8	50.12	9.3
SF12 physical score	45.2	7.7	47.4	9.6	46.3	8.8
	n	%	n	%	n	%
AUSDRISK score						
12-15	20	42	20	38	40	40
16-19	10	21	14	26	24	24
≥ 20	18	38	19	36	37	37
BMI Category						
Overweight (25.0 - 29.9 kg.m^{-2})	11	23	15	28	26	26
Obese class 1 (30.0 - 34.9 kg.m^{-2})	26	54	26	49	52	51
Obese class 2 (35.0 – 40.0 kg.m^{-2})	11	23	12	23	23	23
Glucose biomarkers (prediabetes cut-point)						
FPG < 5.6 mmol.L^{-1}	38	79	43	81	81	80
FPG ≥ 5.6 mmol.L^{-1}	10	21	10	19	20	20

Characteristics	Control (n = 48)		Intervention (n = 53)		Total (n = 101)	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
	n	%	n	%	n	%
HbA$_{1C}$ < 5.7%	16	33	19	36	35	35
HbA$_{1C}$ ≥ 5.7%	32	67	34	64	66	65
HbA$_{1C}$ < 5.7% & FPG < 5.6 mmol.L^{-1}	13	27	17	32	30	30
HbA$_{1C}$ < 5.7% & FPG ≥ 5.6 mmol.L^{-1}	3	6	2	4	5	5
HbA$_{1C}$ ≥ 5.7% & FPG < 5.6 mmol.L^{-1}	25	52	26	49	51	50
HbA$_{1C}$ ≥ 5.7% & FPG ≥ 5.6 mmol.L^{-1}	7	15	8	15	15	15
GODIN LTEQ						
< 150 min/week	34	71	36	68	70	69
150 – 209 min/week	4	8	3	6	7	7
≥ 210 min/week	10	21	14	26	24	24
Socio-economic status [c]						
1-2 (lowest)	1	2	2	4	3	3
3-4	15	31	13	25	28	28
5-6	26	54	23	43	49	49
7-8	2	4	12	23	14	14
9-10 (highest)	4	8	3	6	7	7
Highest qualification completed						
No formal qualifications	1	2	3	6	4	4
Higher school certificate (year 12 or equivalent)	7	14	5	10	12	12
Trade/Apprenticeship, diploma (e.g., carpenter, chef, plumber, tiler, accountant)	26	54	28	53	54	54
University degree (e.g., Bachelor, Master, PhD)	14	29	17	32	31	31
Country of birth						
Australia	42	88	48	91	90	89
United Kingdom	2	4	2	4	4	4
Other	4	8	3	6	7	7

AUSDRISK – Australian diabetes risk assessment tool, BMI – body mass index, FPG – fasting plasma glucose, GODIN LTEQ – Godin leisure time exercise questionnaire (modified), HbA$_{1C}$ – glycosylated haemoglobin, HOMA-IR2 – homeostatic model assessment of insulin resistance, QUICKI – quantitative insulin sensitivity check index, SD – standard deviation, SF12 – UK short form 12-item health survey

[a] AUSDRISK high-risk score ≥ 12 points [b] Aerobic fitness was estimated using the Ebbeling sub-maximal treadmill protocol [c] Socio-economic status by population decile for SEIFA Index of Relative Socioeconomic Advantage and Disadvantage [186]

5.3.3 Change in primary and secondary outcomes

Table 17 presents the results of the intention-to-treat analysis for differences between the intervention and control groups in changes from baseline to six months for the primary and secondary outcomes. A significant difference favouring the intervention over control group at six months was observed for change in the primary outcome of weight (-5.50 kg [95% CI: -7.40, -3.61], P < 0.001, Cohen's d = 1.15). In addition, significant group-by-time effects were observed for HbA$_{1C}$ (-0.2% [95% CI: -0.3, -0.1, P = 0.002, d = 0.64) and several secondary outcomes, including: BMI (P < 0.001, d = 1.14), waist circumference narrowest (P < 0.001, d = 0.98), fat mass (P < 0.001, d = 0.87), body fat percentage (P = 0.002, d = 0.65), visceral fat area (P < 0.001, d = 0.72), insulin (P = 0.002, d = 0.64), HOMA-IR2 (P = 0.002, d = 0.63), QUICKI (P = 0.006, d = 0.56), aerobic fitness (P = 0.013, d = 0.50) and lower body muscular fitness (squat repetitions) (P < 0.001, d = 0.87). No significant group-by-time effects were observed for fasting glucose, blood pressure, upper body muscular fitness, physical activity, quality of life (SF-12 physical) or energy intake.

5.3.4 Secondary analyses

A completers analysis (pre-specified) was performed using data from all men who returned for their 6-month assessment (intervention n = 40; control n = 42). The same pattern of significant effects was observed, but these effects were slightly larger in magnitude than the intention-to-treat population. The group-by-time interaction for weight change at six months favoured the intervention group (-5.7 kg [95% CI: -7.75, -3.72], P < 0.001). A significantly higher proportion of

completers in the intervention group achieved > 5% weight loss compared to controls (42.1% versus 4.8%, respectively; X^2 = 15.96 df = 1, P < 0.001).

A per-protocol analysis (pre-specified) was planned for men who met the a priori defined criteria. Of the 53 men randomised to the intervention group, 13 withdrew or were lost to follow-up at six months and nine did not return their *SHED-IT Weight Loss Log Book for Men* and *PULSE Exercise Support Book for Men* at six months. Self-monitoring (log book) compliance for the remaining 31 men (78%) was poor, with only 13% (n = 4) of men meeting compliance criteria over the 6-month intervention and hence insufficient to justify the per-protocol analysis.

Linear mixed models were also used to assess group-by-time effects for men with prediabetes at baseline (intervention n = 36 [68%]; control n = 35 [73%]). Similar changes were observed in comparison with the intention-to-treat analysis. Significant group-by-time differences favoured the intervention group versus controls for weight (-4.65 kg [95% CI: -6.57, -2.74], P < 0.001), HbA$_{1C}$ (-0.2% [95% CI: -0.4, -0.1], P < 0.001), insulin (-3.6 mIU.L^{-1} [95% CI: -5.5, -1.7], P<0.001) and HOMA-IR2 (-0.52 [95% CI: -0.79, -0.26], P < 0.001) compared with controls. No group-by-time effect was observed for FPG (-0.25 [95% CI: -0.60, -0.10], P = 0.153). At 6-months, n = 14 (38%) men in the intervention group and n = 18 (44%) remained above the prediabetes cut point, representing an absolute reduction in the prevalence of prediabetes of 30% and 29%, respectively.

Table 17 Mean change in outcomes from baseline to three and baseline to six months within in each treatment group and the group-by-time difference at six months (intention-to-treat population)

| Outcomes | Month | Treatment group Mean change from baseline (95% CI) [a] | | Mean difference between groups (95% CI) [b] | P-value | Effect Size (Cohen's *d*) |
		Control n = 48	Intervention n = 53			
Weight (kg) [c]	3	- 0.06 (- 0.95, 1.07)	- 3.84 (- 4.79, - 2.90) *	- 5.50 (- 7.40, - 3.61)	**< 0.001**	1.15
	6	0.52 (- 0.84, 1.89)	- 4.98 (- 6.29, - 3.67) *			
Weight (%)	3	- 0.06 (- 0.92, 1.04)	- 3.74 (- 4.66, - 2.82) *	- 5.34 (- 7.18, - 3.50)	**< 0.001**	1.18
	6	0.50 (- 0.81, 1.83)	- 4.85 (- 6.12, - 3.57) *			
BMI (kg.m^{-2}) [c, d]	3	- 0.0 (- 0.3, 0.3)	- 1.1 (- 1.4, - 0.8) *	- 1.8 (- 2.4, 1.2)	**< 0.001**	1.14
	6	0.2 (- 0.3, 0.6)	- 1.6 (- 2.0, - 1.2) *			
Waist umbilicus (cm)	3	0.00 (- 1.08, 1.08)	- 3.89 (- 4.91, - 2.87) *	- 5.35 (- 7.35, - 3.36)	**< 0.001**	1.06
	6	0.44 (- 0.98, 1.86)	- 4.92 (- 6.32, - 3.52) *			
Waist narrowest (cm)	3	0.89 (- 0.60, 2.38)	- 4.00 (- 5.40, - 2.60) *	- 6.22 (- 8.72, - 3.71)	**< 0.001**	0.98
	6	1.91 (0.13, 3.69) *	- 4.31 (- 6.07, - 2.55) *			
Fat mass (kg) [d]	3	- 0.57 (-1.52, 0.37)	- 2.59 (- 3.48, - 1.69) *	- 3.82 (- 5.62, - 2.02)	**< 0.001**	0.87
	6	0.47 (- 0.82, 1.76)	- 3.35 (- 4.61, - 2.09) *			
Body fat (%) [d]	3	- 0.61 (- 1.35, 0.14)	- 1.51 (- 2.21, - 0.80) *	- 2.32 (- 3.73, - 0.91)	**0.002**	0.65
	6	0.24 (- 0.76, 1.24)	- 2.08 (- 3.07, - 1.09) *			
Fat free mass (kg) [c]	3	0.56 (0.04, 1.07) *	- 1.21 (- 1.70, 0.72) *	- 1.54 (- 2.24, - 0.84)	**< 0.001**	0.83
	6	-0.07 (- 0.56, 0.43)	- 1.60 (- 2.10, - 1.11) *			

Outcomes	Month	Treatment group Mean change from baseline (95% CI) [a] Control n = 48	Intervention n = 53	Mean difference between groups (95% CI) [b]	P-value	Effect Size (Cohen's d)
Skeletal muscle mass (kg) [c]	3	0.37 (0.06, 0.67) *	- 0.70 (-0.99, - 0.41) *	- 0.90 (- 1.51, - 0.49)	**< 0.001**	0.87
	6	- 0.05 (- 0.33, 0.24)	- 0.95 (- 1.24, - 0.66) *			
Visceral fat area (cm^2) [c]	3	0.10 (- 3.53, 3.74)	- 6.27 (- 9.72, -2.81) *	- 11.85 (- 18.34, - 5.36)	**< 0.001**	0.72
	6	4.06 (- 0.57, 8.69)	- 7.79 (- 12.34, - 3.23) *			
Systolic blood pressure (mmHg)	3	- 1 (- 4, 2)	- 5 (- 7, - 2) *	- 3 (- 8, 1)	0.161	0.28
	6	2 (- 1, 5)	- 1 (- 4, 2)			
Diastolic blood pressure (mmHg)	3	- 2 (- 4, 1)	- 1 (- 3, 1)	0 (- 3, 3)	0.842	0.04
	6	1 (- 1, 2)	1 (- 1, 3)			
FPG (mmol.L^{-1})	3	- 0.01 (- 0.20, 0.18)	- 0.02 (- 0.20, 0.16)	- 0.05 (- 0.32, 0.23)	0.742	0.07
	6	- 0.03 (- 0.22, 0.16)	- 0.08 (-0.28, 0.13)			
HbA$_{1C}$ (%) [c]	3	- 0.1 (- 0.2, - 0.0) *	- 0.2 (- 0.2, - 0.1) *	- 0.2 (- 0.3, - 0.1)	**0.002**	0.64
	6	- 0.2 (- 0.2, - 0.1) *	- 0.4 (- 0.4, - 0.3) *			
Insulin (mIU.L^{-1}) [d]	3	1.0 (- 0.5, 2.5)	- 1.6 (- 3.0, - 0.1) *	- 3.0 (- 4.8, - 1.1)	**0.002**	0.64
	6	1.2 (- 0.1, 2.5)	- 1.8 (- 3.1, - 0.5) *			
HOMA-IR2 [d]	3	0.08 (- 0.10, 0.26)	- 0.20 (- 0.38, - 0.3) *	- 0.40 (- 0.66, - 0.15)	**0.002**	0.63
	6	0.17 (- 0.1, 0.35)	- 0.24 (- 0.42, - 0.05) *			
QUICKI [c, d]	3	0.00 (- 0.01, 0.01)	0.01 (0.00, 0.02) **	0.02 (0.01, 0.03)	**0.006**	0.56
	6	- 0.09 (- 0.1, - 0.08) *	- 0.07 (- 0.08, - 0.06) *			

| Outcomes | Month | Treatment group Mean change from baseline (95% CI) [a] | | Mean difference between groups (95% CI) [b] | P-value | Effect Size (Cohen's *d*) |
		Control n = 48	Intervention n = 53			
Aerobic fitness (ml.kg^{-1}.min^{-1}) [c, d]	3	- 0.10 (- 1.71, 1.52)	2.81 (1.27, 4.35)	3.43 (0.73, 6.13)	**0.013**	0.50
	6	0.18 (- 1.74, 2.10)	3.61 (1.71, 5.51) *			
Lower body muscular fitness Squat to box (reps) [c]	3	- 4 (- 9, 2)	6 (2, 10) *	17 (9, 25)	**< 0.001**	0.87
	6	- 4 (- 10, 2)	13 (8, 19) *			
Upper body muscular fitness Seated shoulder press (reps) [c]	3	- 1 (- 2, - 0) *	0 (- 1, 1)	1 (- 1, 3)	0.413	0.16
	6	- 1 (- 2, 0)	0 (- 2, 1)			
Physical activity (pedometer steps.day^{-1}) [c, d]	3	- 347 (- 1042, 348)	1641 (955, 2326) *	796 (- 238, 1830)	0.129	0.30
	6	134 (- 572, 839)	930 (174, 1686) *			
GODIN LTEQ MVPA (mins.week^{-1})	3	19 (- 36, 74)	114 (62, 166) *	81 (- 1, 162)	0.052	0.39
	6	- 5 (- 63, 52)	75 (17, 133) *			
Total Energy intake (kcal.day^{-1})	3	- 220 (- 422, - 19) *	- 348 (- 539, - 158) *	- 307 (- 653, 39)	0.082	0.35
	6	- 70 (- 314, 174)	- 377 (- 622, - 131) *			
SF12 physical score	3	0.42 (- 1.66, 2.51)	1.06 (- 0.89, 3.02)	2.50 (- 0.47, 5.47)	0.098	0.33
	6	- 0.0 (- 2.12, 2.11)	2.50 (0.41, 4.58) *			
SF12 mental score	3	- 0.41 (- 2.97, 2.15)	0.89 (- 1.52, 3.30)	- 4.28 (- 8.14, - 0.41)	**0.030**	0.44
	6	- 5.36 (- 8.12, - 2.60) *	- 9.64 (- 12.34, - 6.94) *			

Outcomes	Month	Treatment group Mean change from baseline (95% CI) [a]		Mean difference between groups (95% CI) [b]	P-value	Effect Size (Cohen's *d*)
		Control n = 48	Intervention n = 53			

BMI – body mass index, CI – confidence interval, FPG – fasting plasma glucose, GODIN LTEQ – Godin leisure time exercise questionnaire (modified), HbA$_{1c}$ – glycosylated haemoglobin, HOMA-IR2 – homeostatic model assessment of insulin resistance, QUICKI – quantitative insulin sensitivity check index, SF12 – UK short form 12-item health survey

Bold face indicates statistical significance. * The mean within group change is significant, P < 0.05
[a] Time differences were calculated as (3 months minus baseline) and (6 months minus baseline)
[b] Between group differences at 6 months (intervention minus control)
[c] Adjusted for age
[d] Adjusted for socioeconomic status

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5.4 Discussion

To the authors' knowledge, this was the first randomised controlled trial of a self-administered, gender-tailored lifestyle intervention for T2DM prevention for men. After six months, the *PULSE Program* intervention group demonstrated significant reductions in anthropometric markers including weight (primary outcome; -5.50 kg [95% CI: -7.40, -3.61]), waist circumference, body fat percentage and visceral fat area, compared with the control group. Significant improvements favouring the intervention group were also observed for markers of glycaemic control including HbA_{1C}, insulin, HOMA-IR2 and QUICKI. The prevalence of prediabetes in the intervention group was reduced by 30%, though a similar reduction was also observed in the control group. Collectively, these findings demonstrate that the *PULSE Program* was efficacious in achieving improvements in diabetes risk factors, at least in the short term.

Given the novel approaches used in the *PULSE Program* (i.e., self-administered and gender-tailored)*,* it is of interest to compare the current study to previous T2DM prevention trials. Weight loss for the *PULSE Program* intervention group (-4.98 kg [95% CI: -6.29, -3.67]) was lower than the US Diabetes Prevention Program (DPP) intensive lifestyle intervention group at six months (approximately -7 kg) [40], but the PULSE Program was able to elicit a greater within intervention group reduction in mean HbA_{1C} (-0.4% [-0.4, -0.3]) compared with the DPP intensive lifestyle group at six months (approximately -0.1%). This comparison is of particular interest given the DPP's far more intensive intervention approach. In addition, weight loss in the current study was greater than that reported by Dunkley and colleagues in a recent meta-analysis of

pragmatic ("real world") T2DM prevention lifestyle interventions (direct pairwise meta-analysis: -2.12 kg [-2.61 -1.63] [95] and comparable to that observed by Ma and colleagues in the E-LITE DPP translation trial (self-directed group weight loss at six months: -4.3 ± 0.8 (SE) kg [215]. Notably, Ma and colleagues reported no significant differences between their coach-led versus self-directed intervention groups, supporting the use of self-administered interventions for men. Further, weight loss in the current study was also comparable to a meta-analysis of male-only weight loss programs (mean between group difference of -5.66 kg [-6.34, -4.97] at last reported assessment) [158]. Regarding changes in glycaemic control, moderate-large (Cohen's *d),* and clinically important effects were observed for changes in HbA_{1C}, insulin, HOMA-IR2 and QUICKI, however no changes were observed for FPG. This was not surprising given that baseline FPG levels were substantially below the prediabetes cut point of 5.6 $mmol.L^{-1}$ [15], thereby limiting the capacity for change. This may have also limited changes in HOMA-IR2 and QUICKI, as they rely on the input of FPG for their respective calculations. Overall, the changes in weight and glycaemic markers observed here highlights the potential for self-administered lifestyle intervention in achieving clinically important improvements in T2DM risk factors, at least in the short term.

In addition to changes in anthropometric and glycaemic outcomes, significant group-by-time effects for objectively measured aerobic fitness and lower body muscular fitness were also observed. In contrast, group-by-time effects for self-report MVPA, objectively measured physical activity and energy intake failed to reach statistical significance, despite significant within intervention group

changes. This was not surprising given the trial was not powered to detect changes in these secondary outcomes. A comprehensive investigation of physical activity, dietary outcomes and program compliance is warranted, but beyond the scope of the current manuscript. Poor compliance with self-monitoring behaviours, in particular self-monitoring of exercise, may explain some of these negative findings. Only 13% of men reported achieving the recommended level of physical activity, despite the observed improvements in objectively measured aerobic fitness and lower body muscular fitness. This suggests that men may have performed the behaviours, but not self-reported them. It is likely that self-monitoring compliance was poor due to the multiple self-monitoring options provided (Calorieking™, *SHED-IT Weight Loss Log Book for Men* and *PULSE Exercise Support Book for Men*). Unfortunately, we did not request access to Calorieking™ records and therefore we were unable to factor it in for self-monitoring compliance. Furthermore, overall program compliance may have been negatively impacted by intervention message overload (*SHED-IT Weight Loss Program + PULSE Program*). Future trials will need a more streamlined program and focus on a single self-monitoring option.

This trial had several strengths including a randomised controlled design, rigorous randomisation procedure with stratification by age and BMI, assessor blinding, intention-to-treat analysis and a comprehensive set of outcome measures. The retention rate was high, with 81% of participants retained at six months. Notably, aside from a $10 reimbursement per assessment to cover travel and parking costs, no additional incentives were provided to encourage participants to return for assessments. The current trial also had some

weaknesses. The short duration of this trial limits the interpretation of these findings. Future versions of the *PULSE Program* could include longer follow-up (> 1 year) to assess longer-term effects and to allow direct comparisons with previous successful T2DM prevention trials. In addition, due to the gender-targeted approach used in the *PULSE Program,* the results presented here are relevant for men only. Furthermore, the men in the trial were predominately older (mean age 52.3 ± 9.7 years), Australian-born Caucasian men, which limits the generalisability of the results. A future large-scale, community-based trial might help to establish the generalisability of the program for men from varying ethnic/cultural backgrounds, education levels and socio-economic positions.

5.5 Conclusions

This trial has demonstrated the efficacy of a 6-month self-administered and gender-tailored lifestyle intervention for improving T2DM risk factors including weight and HbA_{1C}. The magnitudes of changes were similar or greater than previous T2DM lifestyle prevention programs that have involved intensive face-face delivery modes. This is an important finding, as self-administered programs have the potential to reduce delivery costs and participant burden, and to facilitate dissemination in community settings (e.g., medical practices, pharmacies, male workplaces) and in rural and remote areas. This study also adds to the growing body of literature regarding the importance of gender tailoring to improve the acceptability and efficacy of behavioural interventions for men. Future trials should involve larger samples sizes, and investigate the long-term effectiveness, sustainability and cost-effectiveness of self-administered and gender-tailored T2DM lifestyle prevention programs.

Chapter 6 – Process evaluation of a 6-month self-administered and gender-tailored lifestyle prevention program for men: The type 2 diabetes mellitus PULSE Program

Preface:

This chapter presents an unpublished manuscript, which aligns with *Secondary Aim 3* of this thesis, i.e., to conduct a process evaluation of the *PULSE Program* randomised controlled trial to examine the trial's design and its intervention program (Chapter 6)

Abstract

Background: Self-administered lifestyle interventions for type 2 diabetes mellitus prevention have been suggested as an alternative to face-to-face programs, though their feasibility and efficacy is uncertain. The aim was to conduct a process evaluation of the type 2 diabetes *PULSE (Prevention Using LifeStyle Education) Program* for men to examine the trial's design and the intervention program.

Methods: An assessor-blinded, parallel-group, randomised controlled trial was conducted. Men (18-65 years of age, BMI 25-40 $kg.m^{-2}$, high-risk for type 2 diabetes) were randomised to intervention (n = 53) or wait-list control groups (n = 48). The intervention group received the *PULSE Program*, a 6-month self-administered, gender-tailored, multi-component intervention, which incorporated the *SHED-IT Weight Loss Program* and novel diet and exercise components for

type 2 diabetes prevention. Process evaluation was conducted at six months using a questionnaire (quantitative and qualitative data), recruitment and retention rates, and self-monitoring compliance (log book) data. Aspects of trial design that were evaluated included: the wait-list control group design, randomisation and stratification procedures, recruitment and retention, length of trial, and appropriateness of primary and secondary outcomes. Men's perceptions, engagement, adherence and satisfaction with the intervention were also examined. Associations between self-monitoring compliance and weight loss, change in HbA_{1C} and other selected outcomes were assessed using Spearman's rank correlation (significance level, $P < 0.05$).

Results: Overall, the design of the trial was feasible. Control participants considered the 6-month wait-list control period acceptable. Recruitment procedures were effective, with the required sample size achieved at baseline and retained at six months (81%). The high prevalence of prediabetes (70%) indicated the recruitment and selection procedures to identify men at high-risk of type 2 diabetes were suitable. The randomisation and stratification procedures effectively achieved two groups with similar characteristics at baseline. The intervention length was appropriate to observe the effects of the program on the primary (weight) and several secondary outcomes (e.g., HbA_{1C}, insulin, waist), however interpretation of the trial's findings was limited by the short duration. Significant group-by-time effects favouring the intervention group for changes in aerobic fitness and lower-body muscular fitness were observed, however changes in physical activity (objectively measured and self-report) and dietary (energy intake) behaviours failed to reach statistical significance, despite significant within group intervention effects. Intervention participants reported

high levels of engagement and satisfaction with the program. Adherence to self-monitoring was not optimal, with only 13% of men meeting the requisite criteria. Despite this, significant associations were observed for self-monitoring of weekly weight and change in weight (r_s = -0.471, P = 0.004), waist circumference (r_s = -0.376, P = 0.026) and fat mass (r_s = -0.463, P = 0.006); while self-monitoring of daily exercise was significantly associated with changes in waist circumference (r_s = -0.369, P = 0.038) and objectively measured physical activity (r_s = 0.406, P = 0.032).

Conclusions: This evaluation has provided a more comprehensive understanding of the feasibility and limitations of the *PULSE Program* RCT. Future studies should investigate strategies to improve adherence to self-monitoring of exercise behaviours and consider alternative outcomes to assess dietary and exercise behaviours.

6.1 Introduction

Diabetes is a global health concern. Recent reports have consistently projected further increases in diabetes prevalence over the next 20 years in both the developed and developing world [20, 216, 217]. A number of seminal randomised controlled trials (RCTs) have demonstrated the benefits of lifestyle behaviour change for reductions in type 2 diabetes mellitus (T2DM) incidence over the medium (3-6 year) [40, 41, 89] and long term (10-20 year) [42-44]. Although these and several other lifestyle interventions have demonstrated strong efficacy for T2DM prevention [46, 218-220], concerns remain about the cost of delivery, sustainability and scalability of programs when translated into community settings [93, 94]. Traditional diabetes prevention programs have involved an intensive approach with multiple individual or group-based face-face sessions per week. This creates substantial participant burden (time and travel), as well as significant resource requirements (staffing and facility use). Effective programs that employ less time and resource intensive approaches, and are therefore scalable and sustainable, are needed [93-95].

Self-administered online or print-based delivery modes have been suggested as alternatives to intensive face-face approaches, as they have great potential to overcome the aforementioned concerns [95, 97]. In addition, engaging men in lifestyle interventions remains a significant challenge, with men commonly under-represented in diabetes prevention [100] and weight loss [101] studies. Research suggests men may prefer lifestyle programs that are self-administered [101], flexible and less time-consuming [110]. Further, the gender-targeting [110, 115] of lifestyle interventions may improve recruitment and

engagement with such interventions for men with prediabetes, as has been demonstrated for weight loss interventions for men [102-110, 113, 114, 221]. To the authors' knowledge, few trials have investigated self-administered lifestyle interventions for T2DM prevention [97] and none have evaluated gender-tailored interventions for men [98]. Process evaluation of trials exploring these novel approaches could provide valuable insights to inform future research. Process evaluation may include the evaluation of trial design (e.g., recruitment and retention) and the intervention program (e.g., adherence and satisfaction) [109, 222-226]. When paired with outcome data, process information may provide a more comprehensive understanding of lifestyle intervention trials [108, 222-224].

We recently conducted a 6-month RCT of the T2DM *PULSE (Prevention Using LifeStyle Education) Program* [121], a self-administered, gender-tailored, multi-component lifestyle intervention for men at high-risk of developing T2DM (Chapter 5). We undertook this process evaluation to examine the design of the trial and its intervention components. In combination with previously published efficacy data, these additional insights will provide valuable information about the trial and contribute to the currently limited evidence base for self-administered and gender-tailored T2DM prevention programs for men. The objectives of the current analysis were to examine:

1. The trial's design, including: its 6-month wait-list control period; randomisation and stratification procedures; recruitment and selection process; retention; duration of the trial; and appropriateness of primary and secondary outcomes; and

2. The intervention program, including the perceptions, engagement, adherence and satisfaction of men who completed the intervention.

6.2 Methods

6.2.1 Trial description

The T2DM *PULSE Program* trial has been described previously [121]. The trial was a 6-month assessor-blinded, parallel-group RCT. The aim was to assess the feasibility and efficacy of the *PULSE Program* to achieve improvements in the primary outcome (weight) and several secondary outcomes (anthropometric, metabolic, dietary and physical activity outcomes). Participants were individually randomised (stratified by age and BMI) to either the *PULSE Program* intervention or wait-list control groups immediately after their baseline assessment session. Assessment sessions were conducted at baseline, three (mid-program) and six months (immediate post-program and primary time point) at The University of Newcastle, Australia. In terms of efficacy, significant ($P < 0.05$) group-by-time interactions at six months favouring men in the intervention group were observed for changes in weight, HbA_{1C}, aerobic fitness and lower body muscular fitness compared to men in the control group (Chapter 5). No group-by-time differences were observed for physical activity, upper body muscular fitness or energy intake. The trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12612000721808 (Appendix 2), and was approved by The University of Newcastle's Human Research Ethics Committee (Appendix 1). The design, procedures and reporting of the trial [121] adhered to the CONSORT statement for parallel group RCTs [155, 156] to ensure transparency of reporting and methodological quality.

6.2.2 Process evaluation design

Process evaluation data were collected at six months (immediate post-program) to evaluate the design of the trial and the intervention materials. Separate process evaluation questionnaires were administered to the intervention and control groups to capture both quantitative and qualitative data regarding the trials' design and its intervention components (Appendix 12-13). The questionnaires used scales (five point Likert-type, strongly disagree to strongly agree), individual items and open-ended questions to obtain a range of information about the trial. Other quantitative data included participant flow data (recruitment and retention) and log book compliance (intervention adherence). Process data are reported as mean ± SD and as percentages where appropriate. Representative quotes from men are provided to highlight the perceptions of men regarding specific aspects of the trial. All statistical analyses described below were performed using IBM SPSS version 21.

6.2.3 Evaluation of trial design (Objective 1)

6.2.3.1 Wait-list control group design

A 6-month parallel group, assessor-blinded randomised control trial design was chosen for this trial. We opted for a wait-list control group design, rather than a usual care control group, to minimise any changes that may be observed secondary to minimal intervention. The control group received the intervention program immediately after the 6-month waiting period, including assessment follow-up of a further six months. To evaluate the feasibility of this design, we asked control participants to indicate their initial reaction to being randomised to the control group, and to comment on the duration of the waiting period.

6.2.3.2 Randomisation

A rigorous randomisation procedure was implemented to minimise randomisation bias between the groups, thereby achieving two groups with similar characteristics at the baseline time point [121]. Briefly, after baseline assessments participants were individually randomised, stratified by age (< 50 and ≥ 50 years) and BMI category (25.0-29.9, 30.0-34.9, 35.0-40.0 kg.m^{-2}) to either the intervention or control groups. Allocation sequences for each of the six strata (i.e., age x BMI groups) were generated using a computer-based random number producing algorithm with an allocation ratio of 1:1 in block lengths of six. To evaluate the performance of this procedure, we examined the characteristics of men in both groups at the baseline time point.

6.2.3.3 Participant recruitment, selection, and retention

The target population was men 18-65 years of age, with a BMI 25-40 kg.m^{-2} and at high-risk for T2DM (Australian Diabetes risk tool, AUSDRISK; score ≥ 12) [16]. Men with prediabetes were eligible, however men with type 1 or 2 diabetes were not eligible. We chose this protocol as it was considered to be more practical and cost-effective than using diagnostic blood tests to screen for prediabetes prior to study entry. Full details of the trial's eligibility criteria and screening can be viewed elsewhere [121]. Based on our sample size calculation [121] we required 74 men (37 per group) at the analysis stage to give the trial 80% power to detect a 4 kg difference in mean weight change (primary outcome) between groups at six months (immediate post-program and primary time point; $P < 0.05$ for two sided tests). The retention target was set at 80% at six months, a level commonly used to assess the methodological quality of RCTs [98, 158, 227].

To allow for loss to follow-up at six months, a minimum of 94 participants was required at baseline.

Men from the Hunter region, New South Wales, Australia were recruited from August 2012 to March 2013 in four recruitment waves. A variety of recruitment methods were employed including newspaper ads, radio interviews and ads, print flyers, targeted work place emails and social media. The general pitch of the recruitment materials/media interviews was "Are you a man who wants to get fit and lose a few kilos?" Recruitment materials and media interviews also emphasised that the trial was investigating T2DM prevention for men, was tailored for men, was university-based, and involved minimal face-face contact.

To assess the feasibility and appropriateness of recruitment for the trial, we examined the flow of men through the recruitment and selection process, and whether the aforementioned recruitment target was achieved. Men were asked to comment on how they heard about the trial and which aspects of the study appealed to them. The characteristics of men for selected outcomes at baseline (means ± SDs for continuous variables and counts and percentages for categorical variables) were examined to assess whether the recruitment and selection process was successful in identifying the target population of men at high-risk for T2DM.

Participant retention was examined at three (mid-program) and six months (immediate post-program and primary time point). Reasons for withdrawal and loss to follow-up are provided. Differences between completers and dropouts

were assessed using independent samples t tests for continuous variables and chi-squared (X^2) tests for categorical variables (significance level, P < 0.05) (Chapter 5).

6.2.3.4 Selection of primary and secondary outcomes and duration of trial

A detailed description of outcomes and assessment procedures are reported elsewhere [121]. *Weight (kg)* was selected as the primary outcome based on its strong association with T2DM development [27, 40]. Secondary outcomes included height (cm), BMI ($kg.m^{-2}$), waist circumference (narrowest point and umbilicus, cm), fat mass (%), fasting plasma glucose (FPG, $mmol.L^{-1}$), glycosylated haemoglobin (HbA_{1C}, %; $mmol.mol^{-1}$) and insulin ($mIU.L^{-1}$), aerobic fitness (VO_{2max}, $mL.kg^{-1}.min^{-1}$), upper body muscular fitness (max repetitions), lower body muscular fitness (max repetitions), objectively measured physical activity ($steps.day^{-1}$), self-report physical activity (moderate-vigorous [MVPA] $min.week^{-1}$) and total energy intake ($kJ.day^{-1}$). An online questionnaire was administered at baseline to obtain demographic information, including AUSDRISK score.

Based on the T2DM prevention literature [40, 41, 137, 138, 150, 151], the duration of the intervention was set at six months, as this was expected to be the most appropriate time frame over which the effects of the program on both weight (primary outcome) and glycaemic markers (key secondary outcomes) might be observed. The suitability of the selected primary and secondary outcomes and the duration of the trial can be evaluated by examining group-by-time interactions for changes in outcomes after six months (Chapter 5).

6.2.4 Evaluation of intervention program: men's perceptions, engagement, adherence and satisfaction (Objective 2)

The PULSE Program intervention provided men with recommendations and strategies to assist them to lose weight and improve their diet and exercise behaviours. Men received the *SHED-IT Weight Loss Program*, a self-administered and gender-tailored weight loss intervention for men developed by our group [102, 103, 107-111, 118-120]. The additional novel intervention components of the current study (outlined below) were designed to align the overall intervention with current diet and physical activity guidelines for the prevention and management of T2DM [52, 73, 86, 159]. To facilitate and optimise lifestyle behaviour change, the intervention resources were grounded in Bandura's Social Cognitive Theory [163, 164] and were also gender-tailored [103, 110, 115, 120]. The operationalisation of Social Cognitive Theory and the gender-tailoring of the intervention have been previously reported [121]. For brevity, we will henceforth refer to the intervention collectively as the PULSE Program.

The *PULSE Program* intervention (outlined below) was presented as a resource pack to intervention participants after their baseline appointment. Each participant received a standardised 15 min orientation to the program resources. No further contact was made for intervention delivery or self-monitoring prompting over the following six months. A detailed description of the *PULSE Program* resources is reported elsewhere [121]. Briefly, the pack consisted of (Appendix 6-7):

a) The *SHED-IT Weight Loss Program* (Self-Help, Exercise and Diet using Internet Technology)

The *SHED-IT Weight Loss Program* is considered the key component of the overall *PULSE Program* resource pack, as weight loss is known to be the dominant predictor of reduced diabetes incidence [48]. The *SHED-IT Weight Loss Program* intervention components are described in detail elsewhere [119, 120]. The program consists of: 1) The *SHED-IT Weight Loss DVD for Men*, 2) The *SHED-IT Weight Loss Handbook for Men*, 3) The *SHED-IT Weight Loss Log Book* for Men, 4) a tape measure, 5) a pedometer, 6) a user guide for the Calorieking[TM] self-monitoring tool, and 7) the Calorieking[TM] 'Calorie Fat and Carbohydrate Counter' booklet. Men were encouraged to self-monitor their weight (and several other program tasks) in the *SHED-IT Weight Loss Log Book* for men. Participants were asked to return this document after six months (immediate post-program) for assessment of program compliance.

b) The *PULSE Type 2 Diabetes Prevention Handbook for Men*

This document was developed as a supplement to the *SHED-IT Weight Loss Program for Men*. The information provided complied with current T2DM prevention/management dietary and exercise guidelines [52, 73, 86, 159]. The document contained three main sections: "Type 2 Diabetes Prevention", "Eating to Beat Type 2 Diabetes", "The Essential Exercises for Type 2 Diabetes Prevention". Examples of the dietary and exercise messages included: creating a colourful plate i.e., include more vegetables and fruit in meals; consuming five vegetable and two fruit serves per day; choosing low GI foods; choosing healthy versus unhealthy fats; choosing lean proteins; increasing fibre intake; avoiding skipping meals; being active everyday; and moving after meals. The

specific macro- and micronutrient targets that aligned with these program messages are reported elsewhere [121].

c) The *PULSE Exercise Support Book for Men*

This document contained the prescribed exercise program, which was developed to comply with current exercise guidelines for T2DM prevention and management [73, 86]. The program advised men to perform at least 150 min (5 x 30 min) of aerobic exercise and 60 min (2 x 30 min) of home-based resistance training (total of 210 min per week). The *PULSE Exercise Support Book for Men* contained a logbook section to encourage self-monitoring of exercise sessions. Participants were asked to return this document after six months (immediate post-program) for assessment of program compliance.

Intervention participants were asked a series of questions to determine their perceptions, engagement and satisfaction with the program. Quantitative and qualitative data were generated from the process evaluation questionnaire and from log books. Men were specifically asked to comment on their implementation of the program's weight loss, dietary and exercise messages. Most of the questions related to the novel components of the *PULSE Program* resources, as the *SHED-IT Weight Loss Program* has previously been evaluated [109]. Men were also asked to list the strengths and weaknesses of the program and to give suggestions for improvement of the *PULSE Program.*

Adherence to the intervention was assessed using self-monitoring compliance data for weekly weight in the *SHED-IT Weight Loss Log Book for Men* and

weekly exercise in the *PULSE Exercise Support Book for Men*. Log book compliance was set apriori [121] at 50% (12 week) of the 6-month (24 week) intervention for: (i) recording of weight (n ≥ 12 weekly weigh-in entries); and (ii) recording and achieving the physical activity goal (n ≥ 12 weeks achieving 210 minutes per week). In addition, the associations between change in selected outcomes and log book compliance for self-monitoring (number of weekly entries for weight and daily entries for exercise over six months) were assessed using Spearman rank correlations (rs; significance level, P < 0.05).

6.3 Results and discussion

6.3.1 Process data

One hundred and one men were randomised into the trial (Figure 6), with 53 allocated to the intervention group and 48 to the control group. A total of 81 men completed the process evaluation questionnaires at six months, comprising 40 men from the intervention group (100% of completers) and 41 men from the control group (97% of completers).
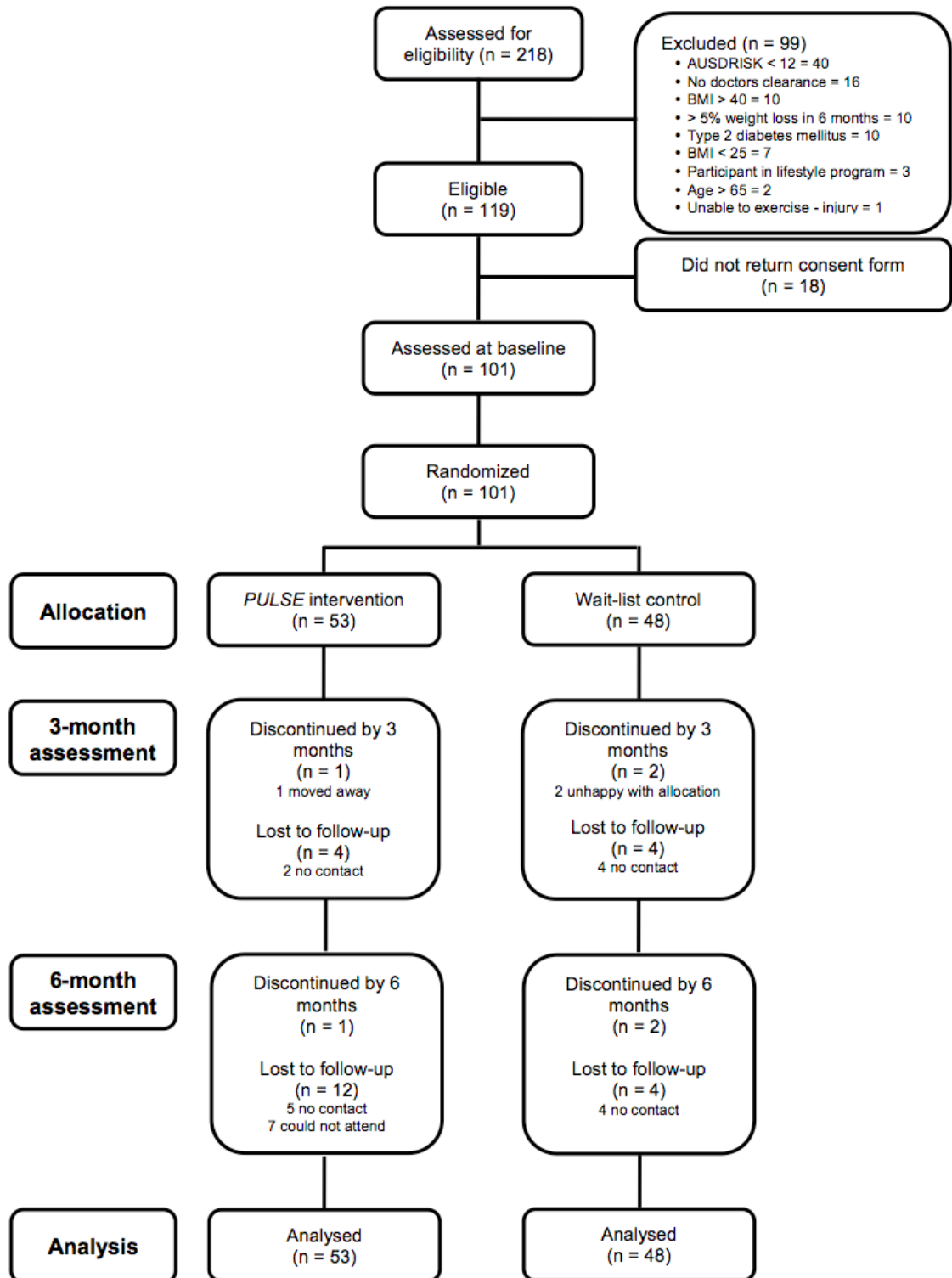
Figure 6 Flow of participants through the trial including reasons for exclusion and loss to follow up

6.3.2 Evaluation of trial design

6.3.2.1 Waist-list control group design

We chose a rigorous, parallel group, assessor-blinded RCT design, with a wait-list control group. This design has been implemented by a number lifestyle intervention studies [106, 228-230], including a previous evaluation of the *SHED-IT Weight Loss Program* [103, 119]. This design is purported to have an advantage over usual care and minimal intervention control designs, where the control group's change may be substantial, therefore reducing statistical power to detect significant between group differences or requiring a much larger initial sample size [231]. A concern with this design is the dissatisfaction of control group participants, which may lead to non-compliance with the treatment condition, or withdrawal from the trial. To evaluate the feasibility of a wait-list control group design, we surveyed participants from the control group (n = 41) regarding initial reactions to their group allocation. Forty one per cent of these men indicated that they did not mind being allocated to the wait-list control group; 37% were disappointed with their group allocation, but understood the importance of a control group in research; and 22% were disappointed with their group allocation and would have preferred to start straight away. Further, the majority of men (88%) indicated that six months was an acceptable amount of time to wait for the *PULSE Program.* This design may not be appropriate for longer duration trials (≥ 1 year) or for trials involving individuals with diagnosed T2DM, where it would be considered unethical to withhold treatment from individuals for an extended period of time.

6.3.2.2 Randomisation

The randomisation and stratification procedure based on age and BMI was effective in achieving two groups of men with similar characteristics at baseline (Table 18). Importantly, the groups were very similar for the primary outcome (weight) and several key secondary outcomes (HbA$_{1C}$, FPG, insulin).

Table 18 Baseline characteristics of men enrolled in the *PULSE Program*

Characteristics	Control (n = 48)		Intervention (n = 53)		Total (n = 101)	
	Mean	SD	Mean	SD	Mean	SD
Age (years)	52.2	10.1	52.5	9.5	52.3	9.7
AUSDRISK score	18	5	18	5	18	5
Weight (kg)	103.33	12.68	102.75	13.58	103.03	13.10
Height (cm)	177.8	6.9	178.5	6.6	178.2	6.7
BMI (kg.m^{-2})	32.6	3.3	32.2	3.5	32.4	3.4
Waist (narrowest) (cm)	110.1	9.7	109.9	9.64	110.0	9.6
Waist (umbilicus) (cm)	112.9	8.5	112.0	9.0	112.4	8.7
Fat mass (kg)	34.6	8.4	31.9	8.4	33.2	8.5
Fat mass (%)	33.0 *	5.7	30.6 *	5.6	31.8	5.8
FPG (mmol.L^{-1})	5.1	0.6	5.0	0.7	5.0	0.6
HbA$_{1C}$ (%)	5.8	0.4	5.8	0.5	5.8	0.5
HbA$_{1C}$ (mmol.mol^{-1})	40	4.4	40	5.5	40	5.5
Insulin (mIU.L^{-1})	8.6	4.0	10.4	7.6	9.5	6.1
Aerobic fitness (mL.kg^{-1}.min^{-1})	38.0	6.7	37.5	6.7	37.7	6.7
Squat to box (reps)	43	24	44	23	43	23
Shoulder press (reps)	13	6	13	5	13	5
Physical activity (pedometer steps.day^{-1})	6368	2643	6699	2613	6544	2618
Total Energy intake (kj.day^{-1})	2809	848	2630	751	11369	3346

AUSDRISK – Australian Diabetes Risk assessment tool, Reps – repetitions

* Significant difference between control and intervention groups (P < 0.05)

BMI – Body Mass Index; FPG – Fasting Plasma Glucose; HbA$_{1C}$; reps – repetitions; SD – standard deviation

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6.3.2.3 Participant recruitment, selection, and retention

We examined the flow of participants through the trial and their characteristics to assess the feasibility and appropriateness of the recruitment and selection procedures. More than 250 men expressed interest in the trial. Of these, 87% completed an online eligibility-screening questionnaire, and 55% were eligible for the trial (Figure 6). The trial recruitment target (> 94 men at baseline) was achieved, with 101 men randomised into the trial. However, recruitment was considerably slower than anticipated, requiring four recruitment waves over a 7-month period to achieve the target sample size. Ineligibility was most commonly due to an AUSDRISK score < 12 points (40% of men) (Figure 6). The specific nature of the eligibility criteria meant that just under half of those who enquired were ineligible. Despite this, we believe the recruitment process was feasible and appropriate, particularly given the characteristics of the sample of men at baseline. Mean (± SD) AUSDRISK score was 18 ± 5 points (high-risk cut point ≥ 12). Men were obese with a weight of 101.03 ± 13.10 kg, BMI of 32.4 ± 3.4 kg.m^{-2} and waist circumference (narrowest) of 110 ± 9.6 cm (Table 18). Mean FPG was 5.0 ± 0.6 mmol.L^{-1}, while mean HbA$_{1C}$ was 5.8 ± 0.5% (40 ± 5.5 mmol.mol^{-1}). In total, 70% of men were above the pre-diabetes cut-points [15] for FPG or HbA$_{1C}$. These anthropometric and metabolic characteristics indicate substantial risk for T2DM. As noted by Plotnikoff and colleagues [232, 233], it is important to consider that the study sample may be biased and not entirely representative of men, as those who enquired and subsequently enrolled are more likely to be motivated to improve their health than men who did not respond i.e., a self-selection bias. This may limit the generalisability of the trial to self-motivated men.

To gain insight into the optimal recruitment strategies, we asked men (n = 218) where and how they heard about the trial. The most effective strategies were newspaper advertisements (29% of men), word of mouth (family and friends) (26%) and radio interviews (24%). Recruitment flyers (16%), targeted workplace emails (12%) and social media (4%) were less effective. To gain insight into why men enrolled for the trial, we asked participants (n = 81) to indicate which aspects of the recruitment messages and trial information influenced their decision. Men reported the trial was appealing because it mentioned: weight loss (76% of men), T2DM prevention (65%) and getting fit (48%). This is consistent with a previous finding from Hankey and colleagues, who reported men seek weight loss primarily because of its association with improvements in health and fitness [166]. Men were also interested because the trial: sounded 'do-able' (35%), was gender-exclusive and tailored for men (31%), and was university-based (27%). This information supports previous studies that suggest that men prefer programs that are self-administered [101, 110] and gender-targeted [110], and value credible sources of information [168].

The participant retention target (> 80% at six months) for the trial was achieved. Retention at three months (mid-program) was 89% and 81% at six months. Reasons for withdrawal and loss to follow-up are reported in Figure 6. There were no significant between group differences in retention rates at three months (X^2 = 0.244 df = 1, P = 0.621) or six months (X^2 = 2.386, df = 1, P = 0.122). Participants who withdrew or were lost to follow-up by six months reported a lower total energy intake (kJ.day^{-1}, P = 0.032) at baseline than those who completed the trial. Notably, aside from a $10 reimbursement per assessment

to cover travel and parking costs, no additional financial incentives were provided to encourage participants to return for assessments [121]. This information provides further support for the feasibility of our wait-list control group study design in this population.

6.3.2.4 Selection of primary and secondary outcomes and duration of trial

We opted for a trial duration of six months based on the minimum time expected to observe changes in both the primary and secondary outcomes, particular HbA_{1C} which reflects the previous three months of glycaemic control [14]. We chose body weight as the primary outcome based on its strong association with T2DM development [27, 40]. In the US Diabetes Prevention Program, weight loss over a 3.2 year period was the strongest predictor of reduced diabetes incidence [40]. It was estimated that for every kilogram of weight loss there was a 16% reduction in risk for the development of T2DM [40].

The duration was appropriate, as evidenced by the significant group-by-time interactions observed at six months for several key anthropometric, metabolic and behavioural outcomes including changes in the primary outcome of weight (-5.50 kg [95% CI: -7.40, -3.61], P < 0.001, Cohen's d = 0.42) (Chapter 5). Given the trial's focus on T2DM prevention, changes in glycaemic markers were also of key interest. Significant group-by-time interactions favouring the intervention versus control group were observed for HbA_{1C} (-0.2% [95% CI: -0.3, -0.1], P = 0.002, d = 0.41), insulin (-3.0 mIU.L^{-1} [95% CI: -4.8, -1.1], P = 0.002, d = 0.49), HOMA-IR2 (0.40 [95% CI: -0.66, -0.15], P = 0.002, d = 0.51) and QUICKI (-0.02 [95% CI: -0.01, 0.03], P = 0.006, d = 0.56). Arguably, FPG or

HbA_{1C} may have been chosen as the primary outcome, however we could not be certain these glycaemic biomarkers would be elevated in this population at baseline, thereby limiting the capacity of the intervention to induce statistically significant changes. For example, mean FPG (5.0 ± 0.6) was considerably lower than the prediabetes cut-point of 5.6 mmol.L^{-1} [15] at baseline and indeed remained virtually unchanged after six months (-0.05 mmol.L^{-1} [95% CI: -0.32, 0.23], P = 0.742, *d* = 0.08). This further affirms our decision to select weight as the primary outcome. Ideally, we might have also included a 75 gram two hour OGTT, but the cost and time burden of the test rendered it impractical for evaluation in the current trial. Further, assessment of T2DM incidence, a common primary outcome in previous large-scale T2DM prevention trials [87, 88] was not feasible due to the short duration of the current trial. Future studies should consider implementing a 6-month intervention, followed by long term follow-up at one year (minimum), and preferably two or three years, to allow comparison with previous T2DM prevention trials [40, 41, 143].

Given the moderate weight loss and changes observed for glycaemic outcomes, it is reasonable to have expected changes in diet and exercise outcomes as well, however this was not consistently the case. Significant group-by-time interactions favouring the intervention over the control group were observed for aerobic fitness (-3.43 mL.kg^{-1}.min^{-1} [95% CI: 0.73, 6.13], P = 0.013, *d* = 0.51) and lower body muscular fitness (squat to box, 17 repetitions [95% CI: 9, 25], P < 0.001, *d* = 0.74). No between group differences were observed for upper body muscular fitness (shoulder press, 1 repetition [95% CI: -1, 3], P = 0.413 *d* = 0.19), objectively measured physical activity (pedometers,

697 steps.day^{-1} [95% CI: -321, 1715], P = 0.177 *d* = 0.27), self-reported physical activity (81 min MVPA min.week^{-1} [95% CI: -1, 162], P = 0.052, *d* = 0.48) or energy intake (-1285 kj.day^{-1} [95% CI: -2734, 165], P = 0.082 *d* = 0.38). Notably, significant within group changes for the intervention group were observed for objectively measured physical activity (865 steps.day^{-1} [95% CI: -120, 1610], P = 0.023), self-report physical activity (78 min.week^{-1} [95% CI: 17, 133], P = 0.011) and energy intake (-1578 kj.day^{-1} [95% CI: -2606, -550], P = 0.003). A number of reasons might account for these findings. First, it is possible that the study was statistically underpowered for several of the secondary physical activity and diet outcomes. Second, to comply with the Exercise and Sports Science Australia guidelines for T2DM/prediabetes [86], we adopted a multi-component aerobic exercise and resistance training approach (150 min aerobic + 60 min resistance training). It is possible that the combination of aerobic exercise and resistance training compromised overall physical activity levels, as participants may have felt over-burdened. This may have implications for the design of future programs, for example providing a staged exercise program that begins with aerobic exercise and progresses to a combination of aerobic exercise and resistance training. Third, physical activity outcomes (daily step count and minutes of MVPA per week) may have been confounded by the non-ambulatory resistance training physical activity performed, as these physical activity measures used may not be sensitive measures of resistance training adherence. This is supported by changes observed for lower body muscular fitness. Future studies should consider alternative objective outcome measures or biomarkers for the assessment of physical activity and energy intake.

6.3.3 Evaluation of intervention delivery, engagement, adherence and satisfaction

Men's perceptions, engagement and satisfaction with the *PULSE Program* intervention resources are reported in Table 19 (*Objective 2*). The majority of men in the intervention group highly valued the program, with 52% of men agreeing and 31% strongly agreeing that their participation had decreased their risk of T2DM.

> "The program was truly life-changing…My overall fitness has improved immeasurably…My overall well-being and self-esteem has improved greatly!"
>
> (Age 62, Weight loss -6.2%, HbA$_{1C}$ change -0.7%)

> "The program information reinforced the need to develop a 7 day routine of daily walking and body mass, resistance training and healthier eating. I have continued to lose weight, feel stronger and healthier and enjoy the routine."
>
> (Age 63, Weight loss -4.1%, HbA$_{1C}$ change 0.1%)

Men reported high levels of engagement and enjoyment with the self-administered and gender-tailored lifestyle education components of the intervention. Men read the *PULSE Type 2 Diabetes Prevention Handbook for Men* 2.6 ± 0.7 times (once: 48%, twice: 41%, three or more times: 12%) and mostly agreed (64% of men) or strongly agreed (26%) that the document increased their understanding of T2DM (Table 19). Men reported that the

document length was 'about right' (95%), with very few men thinking the document was 'too long' (5%). Men mostly agreed (69%) or strongly agreed (10%) that the document was enjoyable to read. Men read the *SHED-IT Weight Loss Handbook for Men* 2.6 ± 0.6 times (once: 45%, twice: 50%, three or more times: 5%), mostly agreed (69%) or strongly agreed (12%) that the document was enjoyable to read, and mostly agreed (60%) or strongly agreed (26%) that the program provided them with the information required to assist them to lose weight. Men watched The *SHED-IT Weight Loss DVD for Men* 2.6 ± 0.7 times (once: 50%, twice: 38%, three or more times: 12%); and agreed (74%) or strongly agreed (17%) that the DVD was enjoyable to watch. These findings are consistent with previously published process evaluations of the *SHED-IT Weight Loss Program* [108-110]. While difficult to assess, it is likely that the gender-tailoring of the intervention improved the reception and engagement with the intervention resources.

"The information packs were well presented and made really easy to understand." (Age 38, Weight loss -0.2%, HbA_{1C} change -0.1%)

"It was directed at blokes and has an easy to follow and laid back approach."

(Age 59, Weight loss -7.0%, HbA_{1C} change -0.2%)

Table 19 Men's perceptions of the *PULSE Program*

Item	Item Score Mean ± SD
The PULSE Type 2 Diabetes Prevention Handbook for Men	
a) The PULSE 'Type 2 Diabetes Prevention for Blokes' handbook increased my understanding of type 2 diabetes	4.1 ± 0.6
b) The 'Type 2 Diabetes Prevention for Blokes' handbook was enjoyable to read	3.9 ± 0.6
The PULSE Exercise Support Book for Men	
The PULSE 'Exercise Support Book for Blokes' was useful.	4.0 ± 0.5
I found the PULSE pedometer useful.	3.7 ± 1.0
I found the body weight exercises useful.	3.5 ± 0.8
I found the Gymstick™ useful.	3.4 ± 0.9
I feel that my endurance fitness has improved since commencing the PULSE study (i.e., in the last 6 months).	3.6 ± 0.9
I feel that I have gotten stronger since commencing the PULSE study (i.e., in the last 6 months).	3.5 ± 0.8
The SHED-IT Weight Loss Program	
The SHED-IT Weight Loss Program provided me with the information I needed to help me lose weight	4.1 ± 0.6
The SHED-IT Weight Loss Program improved my understanding of physical activity, nutrition and weight loss.	4.2 ± 0.6
The SHED-IT Weight Loss Handbook for men was enjoyable to read	3.9 ± 0.6
The SHED-IT Weight Loss DVD for men was enjoyable to watch.	4.1 ± 0.5
The Calorieking™ website was easy to use.	3.6 ± 1.1
Using the Calorieking™ website to record my food and exercise was time consuming.	3.7 ± 0.8
The Calorieking™ website was a valuable tool to help me understand how to lose weight.	3.8 ± 0.7
The Calorieking™ user guide was useful.	3.8 ± 0.6
Effects of the PULSE program on self and on others	
I believe that my participation in the PULSE study has decreased my risk of type 2 diabetes.	4.0 ± 0.9
As a result of my participation in the PULSE study other members of my family have started to make healthier food choices.	3.4 ± 0.9

As a result of my participation in the PULSE study other members of my family have become more active.	3.3 ± 0.8
As a result of my participation in the PULSE study other members of my family have lost weight.	3.0 ± 0.8
As a result of my participation in the PULSE study one or more of my friends have lost weight.	2.8 ± 0.8
I have had conversations with friends, co-workers and/or relatives about the PULSE study and the strategies I have learned to reduce my risk for type 2 diabetes.	3.8 ± 0.7
I would recommend the PULSE study to my friends.	4.4 ± 0.5
Additional Feedback	
Being part of a research study has helped me to stick to the program? (i.e., health eating, exercise and weight loss)	3.8 ± 1.0
Knowing that I was accountable (i.e., being followed up by the PULSE team) motivated me to stick to the program (i.e., healthy eating, exercise and weight loss).	3.6 ± 1.1
There was too much reading to do for the PULSE study.	2.6 ± 0.8
I would prefer a program that had more regular face-to-face contact than the PULSE study.	3.5 ± 1.0

Data are reported as mean ± standard deviation of participant responses (n = 40) to the above statements.

1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree.

Men valued the Calorieking^{TM} online diet and exercise self-monitoring tool, with most men agreeing (58%) or strongly agreeing (13%) that the website helped them to understand how to lose weight (Table 19). When asked about which aspects of the program they liked, men commented:

"Recording food and exercise in the Calorie King website"

(Age 47, Weight loss -7.70 kg, HbA$_{1C}$ change -0.9%)

"Visual of energy input and energy output bar chart from calorieking"

(Age 61, Weight loss -15.5 kg, HbA$_{1C}$ change -0.7%)

Just over half the men agreed (33%) or strongly agreed (25%) that the website was easy to use, the remainder either disagreed (25%) or held a neutral position (17%). Dissatisfaction was likely due to the time it took to record diet and exercise behaviours, with most men agreeing (54%) or strongly agreeing (13%) that using the website for self-monitoring was time consuming.

"Tried the online system but found it frustrating"

(Age 61, Weight loss -0.3%, HbA$_{1C}$ change -0.2%)

"Didn't like the calorie king website - time to record was an issue"

(Age 38, Weight loss -13%, HbA$_{1C}$ change -0.6%)

Based on this feedback, future versions of the *PULSE Program* might consider alternative diet and exercise self-monitoring tools, such as mobile phone applications that integrate with physical activity monitors. This would reduce the time burden of self-monitoring of physical activity.

The program's dietary and physical activity messages were generally well implemented, indicating good engagement with the intervention (Table 4). Men indicated that they tried more often to: "create a colourful plate" (agree: 52% of men, strongly agree: 21%), eat more low glycaemic index foods (agree: 60%, strongly agree: 24%), include more 'healthy' monounsaturated and polyunsaturated fats (agree: 64%, strongly agree: 24%) and limit 'unhealthy' saturated fats (agree: 48%, strongly agree: 29%). In addition, we asked men which of the nine *SHED-IT Weight Loss Program* tips they used [103]. The most

commonly implemented tips were "Read food labels" (69%), "Reduce your portion size" (62%) and "Every step counts" (60%). The authors acknowledge that the interpretation of these data is limited by the lack of pre-post comparisons and the social desirability of responses. Nevertheless these findings support the previously published efficacy data (Chapter 5).

Table 20 Engagement with diet and physical activity messages

Item	Item Score Mean ± SD
a) I now try to 'create a colourful plate' by including a greater variety of foods (e.g. vegetables and fruit) in a meal.	3.9 ± 0.8
b) I now try to eat more low GI foods e.g., fruits and vegetables, wholegrain breads and cereals, low fat milk, low fat yoghurt and nuts.	4.0 ± 0.8
c) I now try to include more healthy (monounsaturated and polyunsaturated) fats in my diet e.g., nuts, oily fish, healthy oils.	4.1 ± 0.7
d) I know try to avoid or limit unhealthy (saturated) fats in my diet, e.g., butter, cream, full cream milk, full fat cheese, fatty cuts of meat.	3.9 ± 1.0
e) I now try to include lean cuts of meat and other sources of protein in my diet.	4.0 ± 0.8
f) I now try to include more fibre in my diet, e.g., wholegrain bread and cereals, lentils, beans, fruits and vegetables.	4.1 ± 0.8
g) I now try to 'move after meals'	3.5 ± 0.9
h) I usually do 30 min (or more) of aerobic exercise (walk, jog, swim, cycle)	3.2 ± 1.2
i) I usually do 30 min (or more) of resistance training (body weight, Gymstick^{TM}, free or machine weights)	1.8 ± 0.8
j) I now eat five serves of vegetables	3.2 ± 1.0
k) I now eat two serves of fruit	3.2 ± 1.1
l) I now skip meals	1.6 ± 0.9
m) I now eat breakfast	4.6 ± 0.7
n) I now pack my lunch or choose healthy options if I have to buy lunch	3.4 ± 1.3
o) I now avoid eating meals or snacking late at night	3.2 ± 1.4

Data are reported as mean ± standard deviation of participant responses (n = 40) to the above statements.

Questions a-j 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree. Questions h-o 1 = zero days per week, 2 = one-two days per week, 3 = three-four days per week, 4 = five-six days per week, 5 = 7 days per week

GI - Glycaemic Index

We included a number of self-monitoring components (paper-based and online) to encourage engagement and adherence to the intervention. Self-monitoring is considered a key component of successful behaviour change [164] as it increases an individual's awareness of their behaviours [234, 235], provides direct feedback with respect to achievement of lifestyle behaviour goals [234], and is associated with improvements in health outcomes [234, 236, 237]. Carels and colleagues reported that higher compliance with self-monitoring of exercise over six months was associated with greater weight loss (r = 0.44, P < 0.05), with those consistently self-monitoring losing an average of 10.5 kg versus those inconsistently self-monitoring losing 5.5 kg [235]. In the current study, paper-based self-monitoring compliance was poor, a phenomenon previously reported in the literature [238].

Of the 40 men in the intervention group assessed at six months, 10 did not return their *SHED-IT Weight Loss Log Book for Men* or *PULSE Exercise Support Book for Men*. Log book self-monitoring compliance analysis was therefore based on these 30 (75%) men. Men achieved better compliance (criteria met for 50% of weeks) in recording their weight in the *SHED-IT Weight Loss Log Book for Men* at three months (68%, n = 27) and six months (58%, n = 18), compared to recording and achieving the weekly exercise goal (210 min.week^{-1}) in the *PULSE Exercise Support Book for Men* at three months (16%, n = 6) and six months (13%, n = 4). Unfortunately we did not obtain access to Calorieking^{TM} data, so we cannot report compliance with online self-monitoring. The provision of multiple self-monitoring components *(SHED-IT Weight Loss Handbook for Men, PULSE Exercise Support Book for Men,*

Calorieking[TM] online) may have contributed to poor paper-based self-monitoring compliance. Future studies should consider a more streamlined approach for self-monitoring, e.g., mobile phone self-monitoring apps.

Despite this poor paper-based self-monitoring compliance, moderate inverse correlations were observed for self-monitoring and changes in outcomes. Table 21 describes the associations between self-monitoring compliance (weekly weight records and daily exercise records over six months) and changes in anthropometric, glycaemic, fitness and dietary outcomes. Self-monitoring of weekly weight was significantly associated with changes in weight (r_s = -0.471, P = 0.004), waist circumference umbilicus (r_s = -0.376, P = 0.026) and fat mass (r_s = -0.463, P = 0.006), while self-monitoring of daily exercise was significantly associated with waist circumference umbilicus (r_s = -0.369, P = 0.038) and physical activity (r_s = 0.406, P = 0.032). No associations were observed for changes in glycaemic biomarkers.

Table 21 Associations between self-monitoring compliance and changes in outcomes

Outcome measure	No. SHED-IT weekly weight records [a]	No. PULSE daily exercise records [a]
Weight (kg)	-0.47**	-0.29
Waist circumference narrowest (cm)	-0.18	-0.32
Waist circumference umbilicus (cm)	-0.38*	-0.37*
Fat mass (kg)	0.46**	-0.30
HbA$_{1C}$ (%)	-0.05	-0.19
FPG (mmol.L^{-1})	0.18	0.07
Insulin (mIU.L^{-1})	-0.22	0.06
Aerobic fitness (mL.kg^{-1}.min^{-1})	0.3	0.25
Lower body muscular fitness (reps)	0.11	-0.0
Upper body muscular fitness (reps)	-0.12	-0.07
Physical activity (steps.day^{-1})	-0.02	0.41*
Energy intake (kJ.day^{-1})	0.15	0.21

[a] Number of SHED-IT weekly weight records and PULSE daily exercise records from men (n = 30) over the 6-month intervention

*$P < 0.05$, **$P < 0.01$

FPG – fasting plasma glucose, HbA$_{1C}$ – glycosylated haemoglobin, reps – repetitions

Regarding suggestions for improvement of the *PULSE Program*, slightly more than half of the men in the intervention group reported that they would have preferred more face-face contact (Table 3, agree: 38%; strongly agree: 17%). This is an interesting, although slightly perplexing finding, given that a key aspect of the program's appeal for men was its "do-able" self-administered delivery mode (Section 6.3.2.3); and given that men reported high satisfaction levels, and achieved significant weight loss and improvements in HbA$_{1C}$ at six months. This finding is consistent with previous process evaluations of the *SHED-IT Weight Loss Program* [108-110]. Several men commented that they struggled with motivation without regular contact:

"I found it hard to motivate myself."

(Age 36, Weight loss -7.0%, HbA$_{1C}$ change -0.5%)

A common suggestion from men was to include more face-face and non-face-face contact (e.g., email, SMS, phone or video message) in order to maintain participant engagement, motivation and accountability. Men also suggested we explore avenues to increase social support within the program itself.

"Maybe have monthly communication either face to face or over the phone"

(Age 47, Weight loss -6.5%, HbA$_{1C}$ change -0.9%)

"Monthly appointments, weekly check-ups (phone, email), have other participants join in as a group to support each other"

(Age 43, Weight loss -0.8%, HbA$_{1C}$ change -0.3%)

"I think pairing people off, either for verbal support or for an exercise buddy to make sure each other is staying on track"

(Age 36, Weight loss -7.0%, HbA$_{1C}$ change -0.5%)

We are uncertain whether additional face-face or non-face-face contact would have substantially improved the efficacy of the program. Previous findings from the *SHED-IT Weight Loss Program* [103] suggests there may not be a large effect, if any at all*,* given that men in the *SHED-IT* online intervention group (who received individualised feedback on dietary and exercise behaviours) lost a

similar amount of weight to those who received the standard *SHED-IT* intervention without feedback.

6.4 Conclusions

The purpose of this process evaluation analysis of the *PULSE Program* RCT was to provide additional insights regarding the trial's design and to examine the men's perceptions, engagement, adherence and satisfaction with the intervention program. The 6-month wait-list control period was considered acceptable. The trial was successful in recruiting the target sample of men who were at high-risk for developing T2DM. This was clearly demonstrated by the characteristics of the men, in particular, the high prevalence of prediabetes. The trial achieved the required sample size at baseline and retention at six months was greater than the 80% target. The duration of the trial was appropriate to determine the effects of the intervention on the main outcome (weight) and several secondary outcomes including glycaemic markers (HbA$_{1C}$, insulin, HOMA, QUICKI). Changes in physical activity outcomes were inconsistent, perhaps the result of under-powering of the trial, poor compliance with the exercise program due to participant burden, or confounding by non-ambulatory physical activity. Overall, men enjoyed the *PULSE Program* intervention and believed their health was improved as a result of their participation. The program's diet and physical activity messages were generally well implemented, however compliance with paper-based self-monitoring components was poor, with men reporting that self-monitoring tasks were time-consuming.

A limitation of this study is that adherence and process data were only collected from men who returned for follow up at six months and therefore may not be representative of those who did not complete the study. Furthermore, log book compliance for exercise behaviours was poor, and limits the interpretation of associations between self-monitoring compliance and change in outcomes. A significant limitation of this study was that men's engagement and perceptions of the intervention were acquired using questionnaires that included Likert-type scale items and open-ended questions. The study could have been considerably strengthened by inclusion of face-face interviews, focus group discussions or semi-structured telephone interviews. Unfortunately, this additional data collection and analysis were not feasible given time and budgetary constraints. Overall, these findings provide valuable information regarding the *PULSE Program* RCT and will inform future self-administered and gender-tailored T2DM prevention programs.

Chapter 7 – Thesis Discussion

7.1 Overview

The central focus of this thesis was the development and evaluation of the T2DM *PULSE* (Prevention Using LifeStyle Education) *Program* (Chapters 3, 5, 6). This thesis was presented as a series of studies (Chapters 2-6). The findings have been described and discussed in detail in the earlier chapters. This chapter will focus on addressing the over-arching aims of this thesis, synthesising the body of work in relation to the development and evaluation of the *PULSE Program,* and discussing this thesis within the context of the T2DM prevention literature*.* The strengths and limitations of each study, as well as recommendations for future research and clinical practice, are provided within each of the respective sections below. This chapter is organised in the order of presentation of this thesis, and thus commences by addressing *Secondary Aims 1* and *2*, before addressing the *Primary Aim* and *Secondary Aim 3.*

7.2 Secondary Aim 1

Secondary Aim 1 - To systematically review and meta-analyse the current evidence regarding multi-component lifestyle interventions (diet, aerobic exercise and resistance training) for type 2 diabetes mellitus prevention in adults at high-risk or with prediabetes.

7.2.1 Chapter 2 – summary and discussion of findings

Current guidelines for T2DM prevention recommend the modification of diet [52, 53] and physical activity behaviours [73, 86], including both aerobic and resistance training. A systematic review was conducted to synthesise the evidence from

T2DM prevention lifestyle interventions that had combined diet modification, aerobic exercise and resistance training (henceforth referred to as multi-component lifestyle interventions). Eight trials that matched the selection criteria were identified. The methodological quality of trials was mixed, with four trials classified as having a high risk of bias. The results of meta-analyses for changes in weight and FPG were similar to previous systematic reviews of lifestyle interventions for T2DM prevention [100, 239]. Relative to controls, changes in dietary and physical activity outcomes generally favoured the intervention groups. Multi-component T2DM prevention lifestyle interventions were effective for achieving modest weight loss, small improvements in glycaemic control, and some improvements in dietary and exercise outcomes in individuals at high-risk for developing T2DM or with prediabetes.

This review highlighted two major limitations in the T2DM prevention literature to date. Firstly, all the included trials employed face-face (individual or group-based) intervention delivery modes. Further, most of these trials provided supervised individual or group-based exercise sessions. While this approach is likely to improve engagement and adherence, and may enhance changes in health outcomes, it is also associated with significant resource (facility use and staffing) and participant burden (time and travel costs). The community translation of lifestyle interventions requiring face-face delivery modes remains a considerable challenge [95, 97], particularly for regional, rural and remote areas. Research evaluating lifestyle interventions that are pragmatic (less time and resource intensive) and therefore likely to be scalable and sustainable, is urgently required [95, 97].

Secondly, of the 1050 participants included in this review, only 38% were males. This finding is consistent with other systematic reviews of T2DM prevention trials [100, 240] and weight loss trials in general [241, 242]. None of the trials included in this review were gender-targeted and none reported sex-specific data, therefore we were unable to draw any conclusions regarding the sex-specific effects of multi-component lifestyle interventions. Notably, a recently published systematic review of seven T2DM prevention RCTs reported no sex-specific differences in T2DM incidence or changes in health outcomes following lifestyle intervention [100]. Given the interventions of trials that include both men and women are likely to be gender-neutral, this is not surprising. As noted by studies in the weight loss literature [103, 107, 108, 110, 113, 114, 119], the gender-targeting of lifestyle interventions may enhance engagement and adherence to lifestyle intervention, and are likely to improve changes in health outcomes. This highlighted the need for gender-targeted lifestyle interventions, particularly for men, who are an under-represented population in the T2DM prevention literature.

7.2.2 Strengths and limitations

This review had a number of strengths. The conduct and reporting of this systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement [92]. Further, this review employed a rigorous and comprehensive search strategy and conducted detailed data extraction to allow comparison of key T2DM prevention outcomes including weight loss, glycaemic markers and dietary and physical activity outcomes. This review also had some limitations. Due to the search criteria

used, lifestyle interventions that only employed diet and physical activity/aerobic exercise were excluded. We were therefore unable to compare the efficacy of lifestyle interventions incorporating diet and aerobic exercise versus diet, aerobic exercise and RT. In addition, limitations of the included studies impact the generalisability of the findings from this study. These include: the small number of eligible trials, the poor methodological quality of several of the trials, a bias towards women who accounted for 62% of the sample, and a bias towards older adults (mean age 54.5 ± 9.7). These limitations in the existing literature provided further rationale for the inclusion of a multi-component approach for the *PULSE Program* RCT.

7.2.3 Implications and future considerations for research

Overall, this review highlighted the efficacy of multi-component approaches for T2DM prevention. However, changes in weight and glycaemic markers were modest at best, suggesting further research is required to optimise intervention delivery and improve changes in health outcomes. This study also highlighted a number of limitations in the included trials and evidence gaps in the wider T2DM literature, which formed part of the rationale for the *PULSE Program* RCT. The following points summarise these limitations and evidence gaps.

- The evidence-base for multi-component lifestyle interventions, both in terms of quantity and quality, was limited. High-quality, rigorous RCTs that are informed by the CONSORT guidelines [155, 156] are required.

- All interventions included in this review involved a face-face delivery mode, and none were gender-targeted or reported data by sex. Based on the purported advantages of self-administered and gender-tailored

approaches (outlined above and in Chapter 1), future studies investigating alternative delivery modes (e.g., online or paper based) and gender-targeted interventions are urgently required.

- Evaluation of changes in diet and physical activity are important indicators of adherence to lifestyle interventions. Of the reviewed trials, muscular fitness was only assessed by one trial and none objectively measured physical activity. The absence of rigorous evaluation of changes in muscular fitness and physical activity limits the interpretation of trial findings. Future trials should consider comprehensive objective assessment of dietary and physical activity behaviours.

- The extent to which lifestyle interventions were described varied greatly between the included trials. In particular, the reporting of physical activity recommendations and exercise programs was inconsistent, with the majority of trials providing brief and generic descriptions. This makes it difficult to interpret the specific dose (intensity, duration, frequency) and types of physical activity that were recommended to achieve improvements in T2DM risk factors. For transparency, future lifestyle trials should comprehensively describe intervention components, including diet and exercise prescriptions.

- Due to the search criteria employed, a comparison of the efficacy of T2DM prevention lifestyle interventions with and without RT could not be made. Future studies should investigate this area to determine whether the addition of RT enhances the efficacy of lifestyle intervention for improving T2DM risk factors.

7.2.4 Implications for practice

This review demonstrated that multi-component lifestyle interventions have the potential to induce modest changes in weight and small changes in glycaemic markers. Thus, a multi-component approach (diet, aerobic exercise and resistance training) for T2DM prevention was supported. As per current recommendations for T2DM prevention [52, 53, 73, 86], individuals at risk for T2DM or with prediabetes should aim to lose weight/maintain healthy body weight [52, 53], improve diet quality (e.g., consume more vegetables and fruits, reduce saturated fat intake, improve fibre intake, replace high GI foods with low GI options [52, 53] and perform sufficient physical activity (210 min per week including 150 min aerobic and 60 min RT) [73, 86].

7.3 Secondary Aim 2

Secondary Aim 2 - To describe the characteristics of men identified at high-risk for developing type 2 diabetes mellitus using the Australian Diabetes Risk Assessment (AUSDRISK) tool, and determine the ability of the tool to identify men with prediabetes and metabolic syndrome

7.3.1 Chapter 4 - summary and discussion of findings

During the development of the *PULSE Program RCT,* one consideration was whether to recruit men at high-risk for developing T2DM or those with diagnosed prediabetes (IFG, IGT, glycosylated haemoglobin). Given the trial's focus on T2DM prevention, we might have targeted a population of men with previously diagnosed prediabetes, or screened men for prediabetes using diagnostic blood testing prior to trial entry. This was not considered feasible for

two reasons. First, we anticipated difficultly in recruiting men with known prediabetes, as individuals may be asymptomatic and therefore remain undiagnosed for several years prior to clinical diagnosis [188]. In an analysis of the United States population-based NHANES study (2009-10), the *Centers for Disease Control and Prevention* reported that only 11% of individuals with prediabetes (n = 2603) were aware they had the condition [243]. This is likely to be similar within the Australian context.

Second, diagnostic blood testing is not considered cost-effective as a first line approach for prediabetes screening [191, 192]. A number of questionnaire-based T2DM screening tools have been developed to aid in the identification of individuals at high-risk for developing T2DM. One such example, the AUSDRISK screening tool [16, 17], was used as the primary eligibility criteria for the *PULSE Program* RCT. When combined with confirmatory diagnostic blood testing, screening tools are considered the optimal approach for identifying individuals with prediabetes [191].

Chapter 4 presented a study describing the characteristics of men identified as at high-risk for developing T2DM using the AUSDRISK tool. The anthropometric, metabolic and behavioural characteristics of men at baseline were consistent with substantial risk for T2DM. Although mean FPG was substantially lower than the prediabetes cut-point [15], mean HbA_{1C} was slightly above the prediabetes cut-point [15]. Notably, 70% of men displayed elevations in the prediabetes range for FPG or HbA_{1C} at baseline, with 50% of men displaying elevations for HbA_{1C} only, 5% for FPG only and 15% for both HbA_{1C}

and FPG. Discrepancies in glycaemic markers are not uncommon, with previous studies reporting similar findings in various populations with prediabetes [209-211]. The marked differences observed may be partly explained by the varied pathophysiology of prediabetes i.e., IFG or IGT. This study supported the usefulness of the AUSDRISK tool for prediabetes screening in Australian men.

7.3.2 Strengths and limitations

This study had a number of strengths, as well as some limitations to acknowledge. A comprehensive range of demographic, anthropometric, physiological, and behavioural outcomes were assessed. This allowed for a detailed risk-profile analysis of men screened at high-risk for developing T2DM using the AUSDRISK tool. However, men who were screened as being at low or moderate risk for T2DM were not eligible to participate further, and therefore comparisons of the characteristics of low/moderate risk men with those at high-risk for developing T2DM could not be made. This comparison could have strengthened this analysis. Further, based on the demographic characteristics of men, these results may only be generalisable for Australian born, Caucasian men older than 44 years of age.

7.3.3 Implications and future considerations for research

These analyses demonstrated that screening tools are an effective approach to identify men at high-risk for developing T2DM. Based on the findings of this study, the following recommendations for future research are made:

- In the current study, a large discrepancy for prediabetes classification was observed between FPG and HbA_{1C}. The use of a single diagnostic test would have misclassified numerous individuals who would otherwise test positive with additional screening. A limitation of this study is that it did not include 2 h OGTT to assess IGT, as this test was not considered feasible based on time and cost. The inclusion of this test may have identified an additional sample of men with IGT. Future trials should ideally aim to assess FPG (IFG), HbA_{1C} (glycosylated haemoglobin) and if possible 2 h OGTT (IGT), as each of these tests assess unique pathophysiological mechanisms for prediabetes/T2DM.

- The *PULSE Program* trial used the AUSDRISK tool as its primary eligibility criteria, with men required to be at high-risk for developing T2DM (score ≥ 12 points). Future T2DM prevention trials might consider a similar approach or use the tool as a first line of screening prior to diagnostic testing. This could assist in streamlining the process of identifying individuals with prediabetes and reduce the financial and time burden associated with diagnostic testing.

- This study reported the characteristics of men classified at high-risk for T2DM using the AUSDRISK tool. Future studies might explore the characteristics of men classified with low/moderate risk for developing T2DM. In particular, the assessment of glycaemic status in these men might provide further confidence in the sensitivity and specificity of the tool to identify individuals with and without immediate risk of developing T2DM.

7.3.4 Implications for practice

According to Wong and colleagues, use of the AUSDRISK tool in clinical practice is low [122]. This study has demonstrated the good ability of the AUSDRISK tool to identify Australian men at high-risk for prediabetes and provides support for the usefulness of the AUSDRISK tool in clinical practice. The ease of use and brevity of the tool makes it accessible to lay audiences and for implementation using a variety of methods, including web-based delivery. Individuals who suspect they may be at risk for developing T2DM should be encouraged to complete the tool and discuss the results with their general practitioner.

7.4 Primary aim and secondary aim 3

Primary Aim - to evaluate the feasibility and efficacy of the PULSE Program for improving a range of risk factors strongly linked with type 2 diabetes mellitus development, including weight and glycaemic markers in men at high-risk for developing type 2 diabetes mellitus

7.4.1 Chapter 5 - summary and discussion of findings

The central focus of this thesis was the development and evaluation of the *PULSE Program.* To my knowledge, this was the first self-administered, gender-tailored lifestyle intervention for T2DM prevention for men. The primary hypothesis was that men who received the *PULSE Program* would experience greater weight loss (primary outcome) and improvements in glycaemic markers after six months (immediate post-program and primary time point) compared to men who received no intervention (wait-list control group).

Chapter 5 presented the main outcomes of the trial. Group-by-time differences favoured the intervention versus controls for weight (primary outcome) and HbA_{1C}. In comparison to the gold-standard US DPP at six months, the magnitude of intervention group weight loss in the current trial was approximately 2 kg less, whereas changes in HbA_{1C} were approximately 0.3% greater [40]. This is an important comparison, particularly given the highly intensive individual face-face intervention delivery mode employed by the US DPP, which involved 16 individual face-face curriculum sessions over the first six months and additional supervised weekly exercise sessions [40]. Another important difference between the current trial and the DPP, was the inclusion of RT in the current study, which may have contributed to the maintenance of muscle mass and greater changes in HbA_{1C}. In the current study, no group-by-time effect was observed for changes in FPG, however baseline levels were substantially below the prediabetes cut-point, thereby acting as a ceiling effect and limiting the capacity for the intervention to induce changes. Overall, these findings support the primary hypothesis of this thesis.

Significant group-by-time changes favouring the intervention group were also observed for a number of secondary outcomes, including BMI, waist circumference, body fat percentage, aerobic fitness and lower body muscular fitness. However, changes in self-report dietary intake and physical activity (objectively measured and self-report) failed to reach statistical significance, despite within intervention group effects. A number of reasons might explain these particular null findings. First, the study may have been under-powered to detect changes in these secondary outcomes, particularly as the magnitudes of

changes were modest to small. Second, along with ambulatory physical activity, the *PULSE Program* advised men to perform non-ambulatory exercise (i.e., RT). It is possible that the combination of aerobic and resistance training may have negatively affected overall physical activity levels, as participants may have felt over-burdened by the high volume of exercise recommended. It is also possible that the objective (pedometers) and self-report (Godin leisure time physical activity questionnaire) physical activity measures were not sensitive to changes in non-ambulatory physical activity. This is supported by the significant group-by-time increase in lower body muscular fitness (squat to box repetitions) for the intervention group compared to controls. Further, comprehensive evaluation of dietary and exercise behaviours is required. Overall, these findings highlight the potential for self-administered lifestyle intervention in achieving clinically important improvements in T2DM risk factors, at least in the short term.

7.4.2 Chapter 6 - summary and discussion of findings

Secondary Aim 3 - to conduct a process evaluation of the PULSE Program randomised controlled trial to examine the trial's design and its intervention program.

Chapter 6 presented the findings of a process evaluation examining the design of the *PULSE Program* RCT, and participants' perception, engagement, adherence and satisfaction with the intervention program. Overall, the trial's design was considered to be feasible. The 6-month wait-list control period was considered acceptable by control group participants. Recruitment procedures

were effective, with the required sample size achieved at baseline and retained at six months (81%). Notably, the recruitment process took considerably longer than anticipated (seven months). Intervention participants reported high levels of engagement and satisfaction, however adherence to self-monitoring was not optimal, with only 13% of men meeting the requisite criteria for self-monitoring of weekly weight, as well as for self-monitoring and achieving the weekly physical activity target. Despite this, significant associations were observed for self-monitoring of weekly weight and change in weight, waist circumference and fat mass; with self-monitoring of daily exercise significantly associated with changes in waist circumference and physical activity.

7.4.3 Strengths and limitations

To our knowledge, the *PULSE Program* RCT was the first trial to investigate the feasibility and efficacy of a self-administered, gender-tailored, multi-component T2DM lifestyle prevention program for men. This trial had several strengths. It employed a methodologically high-quality RCT design using a wait-list control group, a rigorous randomisation procedure, was assessor blinded, had high retention rates at six months and used an intention-to-treat statistical analysis. Further, the design, conduct and reporting of the trial were informed by the CONSORT statement for parallel-group RCTs [155, 156]. A wide range of anthropometric, metabolic and behavioural (diet and physical activity) outcomes were assessed to evaluate the effects of the program and also conducted a comprehensive process evaluation to examine the trials design and participants engagement, adherence and satisfaction with intervention components. This trial also had a number of limitations. Based on the demographics of the men,

who were predominately older, Australian-born Caucasian men; the findings may not be generalisable for ethnic and younger males. The analyses presented in Chapters 5 and 6 have focused on anthropometric and glycaemic outcomes, and examined the effects of the *PULSE Program* on physical activity and dietary outcomes in a limited fashion. Comprehensive analyses of dietary and physical activity outcomes will be the focus of further studies arising from this trial. A significant limitation of the study was the absence of long-term follow-up, which limited the ability to assess the longer term effects of the program, such as the maintenance of weight loss, changes in glycaemic control and incidence of T2DM. Finally, a cost-effectiveness analysis was not undertaken, as this was not within the scope and budget of this trial. Further investigations of the current trial and future versions of the *PULSE Program* will address these limitations.

7.4.4 Implications and future considerations for research

This thesis has demonstrated the feasibility and efficacy of a self-administered, gender-tailored and multi-component lifestyle intervention for improving T2DM risk factors in men at high-risk of developing the disease. Based on the findings presented in Chapter 5, the process evaluation in Chapter 6, and the experience gained during the implementation of the trial, several changes and recommendations for future research are outlined below. A subsection containing specific recommendations for the *PULSE Program* follows. These recommendations may also be important considerations for other trials.

- To my knowledge, this was the first self-administered, gender-tailored T2DM prevention lifestyle intervention for men. Further trials evaluating

the efficacy of this approach for T2DM prevention are required. Future studies should consider a longer duration of follow-up e.g., intervention period of 6-months and long-term follow-up at 1, 2, or preferably 3 years to allow of the effects of the intervention on T2DM incidence to be observed. Furthermore, the assessment of the cost-effectiveness of a self-administered approach for T2DM prevention is strongly encouraged.

- Following additional efficacy studies, trials investigating the community translation of self-administered and gender-tailored programs are required. This might include dissemination of programs in community health clinics, pharmacies, or workplaces. Long-term follow-up and cost-effectiveness analysis of these studies would be important to demonstrate the effectiveness of such programs.

- To establish whether self-administered approaches are as effective as face-face delivery modes for T2DM prevention, trials comparing the efficacy of self-administered lifestyle interventions versus individual/group-based face-face delivery modes are encouraged. Similarly, trials comparing the efficacy of gender-tailored versus gender-neutral lifestyle interventions for T2DM prevention are also required.

- In the current trial, the effects of the intervention on changes in 2 h OGTT were not assessed. Future trials should consider a comprehensive assessment of glycaemic markers, i.e., FPG, HbA_{1C} and 2 h OGTT.

- In the current study, no changes in overall physical activity or upper body muscular fitness were observed. Further consideration of the assessment of physical activity and muscular fitness outcomes is

required, particularly for interventions that encourage non-ambulatory physical activity.

7.4.4.1 Future directions for the *PULSE Program*

- The *PULSE Program* included a Gymstick™ and body weight RT program. Anecdotally, the large age range and the variety of pre-existing injuries and mobility issues meant that for some individuals the exercise program, particularly the Gymstick™, was difficult to undertake. Future versions of the *PULSE Program* might feature an instructional DVD outlining the technique for Gymstick™ and body weight exercises, as well as safety considerations and modifications to exercises to cater for common injuries. Alternatively, future versions of *PULSE Program* may implement an initial period of supervised exercise with an exercise physiologist. This would allow for personalisation of the exercise program to cater for injury and mobility issues. While this would reduce the scalability of the intervention, it may be necessary to improve adherence to the RT exercise component.

- The current study incorporated the *SHED-IT Weight Loss Program* and two novel components regarding diet and exercise specific for T2DM prevention. The provision of several information resource documents and self-monitoring components may have contributed to a perception of intervention overload by some participants. Future trials might consider a more streamlined approach amalgamating these two programs.

- Compliance with self-monitoring tasks was less than ideal. Again, this may have been negatively influenced by the provision of multiple self-

monitoring components from the *SHED-IT Weight Loss Program* and *PULSE Program.* User feedback regarding the Calorieking^{TM} website indicated that although valuable, the website was difficult to use and time-consuming. Given the wide adoption of smart phone and tablet technology, a self-monitoring program that offers web and mobile app platforms might be a good alternative. Further, self-monitoring programs that offer integration with wearable tech-gadgets (Fitbit®, Jawbone®) may be particularly suitable, as this feature would reduce the necessity for manual entry of physical activity.

- A common suggestion from men was to include face-face contact, or alternatively, SMS/phone support between follow-up visits. Further, several men suggested stronger integration of social support within the program, e.g., teaming up individuals or creating small groups. These additions would be valuable improvements for future versions of the *PULSE Program*.

- Given that similar lifestyle behaviour changes are recommended for men with T2DM, future trials might evaluate the efficacy of the *PULSE Program* for T2DM management.

7.4.5 Implications for practice

This thesis has demonstrated that a self-administered, gender-tailored, and multi-component (diet, aerobic training, resistance training) lifestyle T2DM prevention program can be effective for improving T2DM risk factors in men. Programs that are self-administered and gender-targeted have great potential to improve the health of Australian men, who are at high-risk for developing

T2DM due to the high prevalence of obesity and other risk-factors. Self-administered programs may be particularly suitable for delivery through health clinics, pharmacies, community centres and workplaces, particularly in regional, rural and remote areas, where access to preventative health care is limited. The addition of phone/SMS/online support may further strengthen self-administered approaches. Programs that are gender-targeted (and tailored) for men are also encouraged, as they are likely to be more acceptable and adhered to by men.

7.5 Concluding remarks

T2DM prevention is a global health priority. Australian men are at increased risk of developing T2DM due to their high prevalence of overweight/obesity and prediabetes. To date, men are under-represented in the T2DM prevention literature. Further, the current evidence for T2DM prevention is largely based on intensive face-face interventions, which are difficult to translate in real-world settings. There is urgent need for effective, scalable, gender-targeted interventions for T2DM prevention in men. This thesis has developed and evaluated the *PULSE Program,* and in turn contributed towards the currently limited evidence base for self-administered, gender-tailored, and multi-component lifestyle interventions for T2DM prevention. Further research examining the efficacy of self-administered and gender-tailored lifestyle interventions for T2DM prevention are encouraged. Based on the findings of this thesis, there is potential to further improve the *PULSE Program* intervention and to implement a large-scale community translation trial.

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8. Appendices

Appendix 1 – Ethics approval

HUMAN RESEARCH ETHICS COMMITTEE

THE UNIVERSITY OF
NEWCASTLE
AUSTRALIA

Notification of Expedited Approval

To Chief Investigator or Project Supervisor:	**Professor Robin Callister**
Cc Co-investigators / Research Students:	**Professor Philip Morgan**
	Professor Clare Collins
	Professor Ronald Plotnikoff
	Mr Simon Harries
	Mr Myles Young
	Miss Ashlee Dunn
	Mr Elroy Aguiar
Re Protocol:	**The Type 2 Diabetes PULSE study: a randomised controlled trial to determine the feasibility and efficacy of a multi-component prevention program for men at high risk of Type 2 Diabetes**
Date:	**09-Aug-2012**
Reference No:	**H-2012-0232**
Date of Initial Approval:	**09-Aug-2012**

Thank you for your **Response to Conditional Approval** submission to the Human Research Ethics Committee (HREC) seeking approval in relation to the above protocol.

Your submission was considered under **Expedited** review by the Chair/Deputy Chair.

I am pleased to advise that the decision on your submission is **Approved** effective **09-Aug-2012**.

In approving this protocol, the Human Research Ethics Committee (HREC) is of the opinion that the project complies with the provisions contained in the National Statement on Ethical Conduct in Human Research, 2007, and the requirements within this University relating to human research.

Approval will remain valid subject to the submission, and satisfactory assessment, of annual progress reports. *If the approval of an External HREC has been "noted" the approval period is as determined by that HREC.*

The full Committee will be asked to ratify this decision at its next scheduled meeting. A formal *Certificate of Approval* will be available upon request. Your approval number is **H-2012-0232**.

If the research requires the use of an Information Statement, ensure this number is inserted at the relevant point in the Complaints paragraph prior to distribution to potential participants You may then proceed with the research.

Conditions of Approval

This approval has been granted subject to you complying with the requirements for *Monitoring of Progress, Reporting of Adverse Events*, and *Variations to the Approved Protocol* as detailed below.

PLEASE NOTE:
In the case where the HREC has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's HREC.

- ***Monitoring of Progress***

Other than above, the University is obliged to monitor the progress of research projects involving human participants to ensure that they are conducted according to the protocol as approved by the HREC. A progress report is required on an annual basis. Continuation of your HREC approval for this project is conditional upon receipt, and satisfactory assessment, of annual progress reports. You will be advised when a report is due.

- ***Reporting of Adverse Events***

1. It is the responsibility of the person **first named on this Approval Advice** to report adverse events.
2. Adverse events, however minor, must be recorded by the investigator as observed by the investigator or as volunteered by a participant in the research. Full details are to be documented, whether or not the investigator, or his/her deputies, consider the event to be related to the research substance or procedure.
3. Serious or unforeseen adverse events that occur during the research or within six (6) months of completion of the research, must be reported by the person first named on the Approval Advice to the (HREC) by way of the Adverse Event Report form within 72 hours of the occurrence of the event or the investigator receiving advice of the event.
4. Serious adverse events are defined as:
    - Causing death, life threatening or serious disability.
    - Causing or prolonging hospitalisation.
    - Overdoses, cancers, congenital abnormalities, tissue damage, whether or not they are judged to be caused by the investigational agent or procedure.
    - Causing psycho-social and/or financial harm. This covers everything from perceived invasion of privacy, breach of confidentiality, or the diminution of social reputation, to the creation of psychological fears and trauma.
    - Any other event which might affect the continued ethical acceptability of the project.

5. Reports of adverse events must include:
    - Participant's study identification number;
    - date of birth;
    - date of entry into the study;
    - treatment arm (if applicable);
    - date of event;
    - details of event;
    - the investigator's opinion as to whether the event is related to the research procedures; and
    - action taken in response to the event.

6. Adverse events which do not fall within the definition of serious or unexpected, including those reported from other sites involved in the research, are to be reported in detail at the time of the annual progress report to the HREC.

- **Variations to approved protocol**

If you wish to change, or deviate from, the approved protocol, you will need to submit an *Application for Variation to Approved Human Research*. Variations may include, but are not limited to, changes or additions to investigators, study design, study population, number of participants, methods of recruitment, or participant information/consent documentation. **Variations must be approved by the (HREC) before they are implemented** except when Registering an approval of a variation from an external HREC which has been designated the lead HREC, in which case you may proceed as soon as you receive an acknowledgement of your Registration.

Linkage of ethics approval to a new Grant

HREC approvals cannot be assigned to a new grant or award (ie those that were not identified on the application for ethics approval) without confirmation of the approval from the Human Research Ethics Officer on behalf of the HREC.

Best wishes for a successful project.

Professor Allyson Holbrook
Chair, Human Research Ethics Committee

For communications and enquiries:
Human Research Ethics Administration

Research Services
Research Integrity Unit
HA148, Hunter Building
The University of Newcastle
Callaghan NSW 2308
T +61 2 492 18999
F +61 2 492 17164
Human-Ethics@newcastle.edu.au

Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref
Hunter Medical Research Institute/Project Grant(**)	Feasibility and efficacy of a diet and exercise prevention program for men at high risk of Type 2 Diabetes	Callister Robin,	G1200815

Appendix 2 – ANZCTR approval

Your ACTRN (registration number): ACTRN12612000721808

info@actr.org.au

Sent: Thursday, 5 July 2012 2:48 PM

To: Elroy Aguiar

Dear Elroy,

Re: The Type 2 Diabetes PULSE study: a randomised controlled trial to determine the feasibility and efficacy of a multi-component prevention program for men at high risk of Type 2 Diabetes

Thank you for submitting the above trial for inclusion in the Australian New Zealand Clinical Trials Registry (ANZCTR).

Your trial has now been successfully registered and allocated the ACTRN: ACTRN12612000721808

Web address of your trial: http://www.ANZCTR.org.au/ACTRN12612000721808.aspx
Date submitted: 4/07/2012 9:34:38 AM
Date registered: 5/07/2012 2:48:06 PM
Registered by: Elroy Aguiar

If you have already obtained Ethics approval for your trial, could you please send the ANZCTR a copy of at least one Ethics Committee approval letter? A copy of the letter can be sent to info@actr.org.au (by email) OR (61 2) 9565 1863, attention to ANZCTR (by fax).

Please be reminded that the quality and accuracy of the trial information submitted for registration is the responsibility of the trial's Primary Sponsor or their representative (the Registrant). The ANZCTR allows you to update trial data, but please note that the original data lodged at the time of trial registration and the tracked history of any changes made will remain publicly available.

The ANZCTR is recognised as an ICMJE acceptable registry (http://www.icmje.org/faq.pdf) and a Primary Registry in the WHO registry network (http://www.who.int/ictrp/network/primary/en/index.html).

If you have any enquiries please send a message to info@actr.org.au or telephone +61 2 9562 5333.

Kind regards,
ANZCTR Staff
T: +61 2 9562 5333
F: +61 2 9565 1863
E: info@actr.org.au
W: www.ANZCTR.org.au

Appendix 3 – Eligibility screening questionnaire

PULSE Pre-Program Screening Questionnaire

1. Introduction

Thank you for your interest in the PULSE study.

The PULSE study consists of a 6 month diet and exercise (aerobic exercise and resistance training) program designed specifically for men. It aims to teach you the skills you need to lose weight and reduce your risk of type 2 diabetes – without having to completely give up your favourite foods and drinks. The program does not include any regular face-to-face commitments, so it will fit in with your lifestyle with out any hassle.

The study will commence recruitment September 2012 - March 2013. Because this is a research study there will be two groups of men - one of the groups will start the program straight away; and the second group will start in 6 months time (both programs are exactly the same). You won't be able to choose which group you're in because we have to do it randomly – like drawing names out of a hat.

We need to take some measurements on you to see how you change as a result of being on the program. These measurement (or assessment) sessions will be held at the University of Newcastle, Australia, on weekdays in the morning between 7-11am. The assessment will take approximately 1.5 hours and you will be able to choose a time that suits. They will involve some physical measures (e.g., height, weight, waist circumference, blood pressure, a blood test and fitness testing) as well as filling in some surveys about what you eat, how active you are and your health status. We will also ask you to wear a pedometer for 7 days (including two weekend days) to see how physically active you are.

If you are interested in taking part in this research trial, please continue on to the next page and complete the pre-program screening questionnaire. This will help us determine whether our study is suitable for you. After you have completed the questionnaire we will contact you as soon as possible to let you know if you are eligible. *If we are experiencing high demand, this might take up to a week. We appreciate your patience.

Thank you again for your interest in the PULSE study.

2. PULSE Eligibility Screener

Please complete all questions.

٭1. What is your FIRST name?

[   ]

٭2. What is your FAMILY name?

[   ]

PULSE Pre-Program Screening Questionnaire

＊3. How did you hear about the PULSE study? (tick all that apply)

☐ Newcastle University Website

☐ Recruitment Flyer

☐ Newspaper

☐ Radio

☐ Email

☐ Text Message

☐ Facebook

☐ Twitter

☐ A Friend

☐ A Family Member

☐ Other (please describe)

_____

3. PULSE Eligibility Screener

Please complete all questions.

＊4. Are you a male?

◌ No

◌ Yes

＊5. What is your age?

_____

＊6. What is your date of birth?

	DD	MM	YYYY
DD/MM/YYYY	___ /	___ /	_____

＊7. What is your current height, to the nearest cm? (number only)

_____

＊8. What is your current weight, to the nearest kg? (number only)

_____

9. PLEASE LEAVE THIS BOX BLANK - office use only

_____

＊10. Do you have readily available access to the internet?

◌ No (note: this is required for the study)

◌ Yes

*11. Do you have a mobile phone that you can use whilst in the study?

○ No (note: you will need a mobile phone to be involved in the study)

○ Yes

*12. Do you have an e-mail account that you can use whilst in the study?

○ No (note: you will need an email to be involved in the study)

○ Yes

*13. Are you currently involved in any weight loss programs?

○ No

○ Yes (please provide detail)

*14. Do you currently do MORE than 150 minutes per week of physical activity or exercise?
e.g., walking, jogging, running, swimming, cycling, other sports

○ No

○ Yes (please provide detail)

*15. Do you currently do any resistance training e.g., lifting weights?

○ No

○ Yes (please provide detail)

*16. If you are accepted into the study, do you agree not to participate in any other specific weight loss programs until after your last assessment session at the University (September 2013)?

○ No

○ Yes

*17. Assessment sessions will be held in March, June and September 2013. You will be able to choose a time between 7-11 (Monday-Friday) that is convenient for you. Will you be available to attend all of the assessments, which will be held at the University of Newcastle, Australia? (you will be reminded about the dates).

- ○ No
- ○ Yes

*18. Have you lost any weight in the last six months? (number only e.g., 10)

- ○ No
- ○ Yes (please estimate how much weight to the nearest kg)

[   ]

*19. Do you have Type 1 or Type 2 Diabetes? (not including pre-diabetes)

- ○ No
- ○ Yes

*20. We need to work out if you are taking any medications that could affect your ability to lose weight (or if losing weight might not be recommended for people taking your medication). Are you currently taking any medications?

- ○ No
- ○ Yes (please specify)

[   ]

4. Diabetes Risk

This section of the survey will assess your diabetes risk. Some of the questions are similar to before, please complete all questions.

*21. What is your age group?

- ○ Under 35 years
- ○ 35-44 years
- ○ 45-54 years
- ○ 55-64 years
- ○ 65 years or over

22. PLEASE LEAVE THIS BOX BLANK - office use only

[   ]

✱23. Are you of Aboriginal, Torres Strait Islander, Pacific Islander or Maori descent?

○ No

○ Yes

✱24. Where were you born?

○ Australia

○ Asia (including the Indian sub-continent), Middle East, North Africa, Southern Europe

○ Other (please provide detail)

[   ]

✱25. Have either of your parents, or any of your brothers or sisters been diagnosed with diabetes (type 1 or 2)?

○ No

○ Yes

✱26. Have you ever been found to have high blood glucose (sugar) (for example in a health examination or during an illness)?

○ No

○ Yes

✱27. Are you currently taking medication for high blood pressure?

○ No

○ Yes

✱28. Do you currently smoke cigarettes or any other tobacco products on a daily basis?

○ No

○ Yes

✱29. How often do you eat fruits or vegetables?

○ Every day

○ Not every day

✱30. On average would you say you do at least 2.5 hours of physical activity per week (for example, 30 minutes a day on 5 or more days a week)?

○ No

○ Yes

*31. Is your waist measurement (taken below the ribs, usually at the level of the navel, and while standing)

☐ Less than 102 cm

☐ 102 - 110 cm

☐ More than 110 cm

32. PLEASE LEAVE THIS BOX BLANK - office use only

5. Adult Pre-Exercise Screener

*33. Please choose one response for each question.

	Yes	No
1. Has your doctor ever told you that you have a heart condition or have you ever suffered a stroke?	○	○
2. Do you ever experience unexplained pains in your chest at rest or during physical activity/exercise?	○	○
3. Do you ever feel faint or have spells of dizziness during physical activity/exercise that cause you to lose balance?	○	○
4. Have you had an asthma attack requiring immediate medical attention at any time over the last 12 months?	○	○
5. If you have diabetes (type 1 or type 2) have you had trouble controlling your blood glucose in the last 3 months? (if you do not have diabetes, click no)	○	○
6. Do you have any diagnosed muscle, bone or joint problems that you have been told could be made worse by participating in physical activity/exercise?	○	○
7. Do you have any other medical condition(s) that may make it dangerous for you to participate in physical activity/exercise?	○	○

*34. Do you have any other medical conditions (including muscular or joint problems) that could limit your ability to exercise? (specifically to stand up / lie on the floor, perform resistance-training exercise)

○ No

○ Yes (please provide detail)

35. If there is anything from the above questions that you wish to clarify with additional detail, please do so below.

6. Contact Information

36. PLEASE LEAVE THIS BOX BLANK - office use only

PULSE Pre-Program Screening Questionnaire

37. PLEASE LEAVE THIS BOX BLANK - office use only

*38. What is your address?

Address 1:

Address 2:

City/Town:

State:

Post Code:

Country:

39. What is your home phone number?

*40. What is your mobile phone number?

*41. What is your email address?

*42. What is the best time to call you?

○ Before 9am

○ 9am - 5pm

○ After 5pm

○ Any time

○ Other (please specify)

＊43. We are interested in the advertising method or materials that led you to contact us about the PULSE Study. We are also interested in the different types of men who apply for this research project.

If you allow us to retain the information you have given us today, this information would be entered into a database and your name permanently removed. You will not be identified in any reports arising from the study as individual information will never be used in the analysis and reporting of this information.
The results of the research will be reported at national and international conferences and in scientific publications.

Regardless of your entry status into the study, do you give permission for us to retain the information you have provided?

○ No

○ Yes

7. Thank you

Thank you for completing the PULSE pre-program screening survey. A member of our research team will review your records as soon as possible and we will be in contact with you shortly (up to a week) to let you know if our study suits you.

Cheers
The PULSE research team

Appendix 4 – Information statement

Prof Robin Callister
Priority Research Centre in Physical Activity and Nutrition
School of Biomedical Sciences & Pharmacy
Faculty of Health
The University of Newcastle
Callaghan NSW 2308
4921 5650 (PH)
4921 2084 (Fax)
Robin.Callister@newcastle.edu.au

PULSE
Type 2 Diabetes Prevention Using LifeStyle Education

Information Statement for the Research Project:
The Type 2 Diabetes PULSE study: a randomised controlled trial to determine the feasibility and efficacy of a multi-component prevention program for men at high risk of Type 2 Diabetes
Version 3 16/08/2012

You are invited to participate in the research project identified above which is being conducted by Professor Robin Callister, Professor Philip Morgan, Professor Clare Collins and Professor Ronald Plotnikoff from the Priority Research Centre for Physical Activity and Nutrition at the University of Newcastle.

The research is part of Mr Elroy Aguiar's PhD studies, supervised by Professor Robin Callister from the School of Biomedical Sciences and Pharmacy, The University of Newcastle. The project is funded by grants from the Hunter Medical Research Institute and QR National.

Why is the research being done?
Type 2 Diabetes (T2D) is the fastest growing chronic disease in Australia, with approximately 275 Australians developing T2D each day and more than 1 million cases already existing. Australian men are at particularly high risk due to high rates of overweight/obesity and lack of awareness of their risk. Men are often reluctant to engage in preventative health programs as most programs fail to engage them or fit into their busy lifestyles. There is an urgent need for a diabetes prevention program specifically designed for these Australian men.

The proposed study will use a diet-and-exercise resource package combined with a home-based exercise program to form a comprehensive, but low-cost T2D prevention intervention. The study will provide men at risk of T2D with a program that provides them with the knowledge and skills needed to lead a healthy lifestyle and reduce their risk of developing T2D.

Who can participate in the research?
You can participate in this project if you are:
- aged 18-65 years
- overweight or obese with a body mass index (BMI) between 25 and 40 kg/m^2
- at high risk of Type 2 Diabetes based on an AUSDRISK (Australian Diabetes Risk tool) score of >12
- able to participate in a diet and exercise program (doctors certificate may be required)
- agree to not participate in other weight loss programs during the study
- pass a health-screening questionnaire
- available for assessment sessions
- able to obtain access to a computer with e-mail and Internet facilities

You cannot participate in this project if you:
- have a history of major medical problems such as heart disease or diabetes
- have orthopaedic or joint problems that would be a barrier to physical activity such as walking, jogging and resistance training
- recently lost 4.5 kg or more in weight
- are taking medications that might be affected by weight loss or affect weight loss or glucose tolerance/insulin sensitivity

What choice do you have?

Participation in this research project is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you. If you do decide to participate, you may withdraw from the project at any time without giving a reason and have the option of withdrawing any data that identifies you.

What would you be asked to do?

Once written consent is obtained, you will be required to attend a baseline measurement session. Following this, participants will be randomly assigned to one of two groups: diet + aerobic exercise + resistance training, or a control group. You will have an equal chance of being allocated to each of the two groups. The intervention consists of a 6 month:

- Self-administered dietary program (with energy restriction) aimed to induce weight loss, improve dietary quality and improve Type 2 Diabetes/cardiovascular biomarker profile.
- A self-administered (home-based), progressive structured exercise program involving moderate intensity aerobic exercise (walking/jogging 5 x 30 min sessions per week) and resistance band (Gymstick) exercises (2 x 30 min sessions per week) aimed to induce weight loss, improve aerobic/muscular fitness and improve Type 2 Diabetes/Cardiovascular biomarker profile.

After 3 and 6 months, follow up measurements will be conducted on both groups. The control group will commence the *diet + aerobic exercise + resistance training* program after the 6 month follow up assessment and a further follow up session at 12 months will be conducted for this group only. In total there are 3 assessment sessions for the group getting the exercise program first, and 4 sessions for the control group.

Each assessment session will include the following measurements:
Anthropometry and body composition:

- Height
- Weight
- Body mass index (BMI) – calculated from height and weight (kg/m^2)
- Waist circumference - measured using a non-extensible steel tape
- Abdominal height – measured with a device to measure stomach height when you are lying down
- Fat mass and fat free mass – determined using bioimpedance analysis to assess total body water, extracellular and intracellular fluids. Fat mass and fat free mass are subsequently calculated from these values.

Biomarker indicators of health status:

- Blood pressure - systolic and diastolic blood pressure measured using an automated blood pressure monitor under standardised conditions
- Arterial stiffness – measured by pulse wave analysis and pulse wave velocity (and associated index measures) using the Sphygmocor CPV device
- Blood sample analysis - blood will be collected after an overnight fast and analysed using standard automated techniques at a National Association of Testing Authorities accredited pathology service. The blood will be analysed for metabolic health markers including glucose and insulin, HbA_{1C}, fructosamine, HOMA and QUICKI indices, blood lipids (total cholesterol, LDLs, HDLs, and triglycerides), C-reactive protein, leptin, grehlin, obestatin and grehlin/obestatin ratio, Omega 3 index and uric acid. Together, these measures provide a comprehensive indication of metabolic health.

Dietary intake:

- Food Frequency Questionnaire - Australian Eating Survey (AES)
- Portion Size – measured using the Dietary Questionnaire for Epidemiological Studies from the Cancer Council Victoria
- Online diet diary (Calorie King)

Physical activity:

- Pedometers – these are small devices that clip onto the belt or waistband and are used to calculate the total amount of steps you do each day. They will be worn for 7 days around each assessment period
- Online physical activity diaries (Calorie King)
- A moderate intensity (walk/jog) treadmill exercise test
- Muscular fitness testing

Other Questionnaire based data:

- Demographic information (age, ethinicity, education, marital status etc.)
- General Health - measured using the SF-12 health survey consisting of 12 questions regarding functional health and well-being
- Alcohol Consumption – measured using the Australian Government Department of Veteran Affairs, Alcohol Use Disorders Identification Test (AUDIT) 2009
- Physical Activity – measured using the GODIN Leisure Time Physical Activity Questionnaire.
- A sitting time questionnaire
- Other illness or medications – additional information on illness and medication use.

A program evaluation questionnaire will be distributed after participants have completed the diet and exercise program.

NOTE – Many of these questionnaires will be administered online to reduce the time burden during the assessment sessions at the university.

NOTE – For the purpose of promotion of the study, some participants maybe be asked if photographs could be taken of themselves while performing assessment measures such as blood pressure and exercise testing. You will have the option to decline this request at time you are asked.

Assessment sessions will be conducted at the Callaghan Campus of the University of Newcastle. You will be required to attend the University of Newcastle campus on 3 occasions (5 for wait list control), **at the beginning of the study (February/early March 2013), after 3-months (May/early June 2013), after 6-months (August/early September 2013)** to allow a range of health and wellness measurements to be taken. The first assessment sessions will be held February, after the consent form has been returned.

All measurements will be taken by members of the research team including Professors Robin Callister, Phil Morgan, Clare Collins and Ronald Plotnikoff, PhD candidate Mr Elroy Aguiar or other experienced research assistants.

Please note, for each assessment session you attend, you will be reimbursed $10 (provided via a shopping voucher at the end of the study) to cover any travel or parking costs.

Please note, you will be asked to provide the research team with access to the study website (CalorieKing), so that the researchers can monitor your use of the study website.

How much time will it take?
The assessment sessions should take approximately 1.5 hours to complete on each occasion. You will be able to select a day and time that suits your schedule.

Study Timetable

Date	Event	Venue
February/Early March 2013	Baseline assessment	HPE2.8 HPE Building, Callaghan Campus
May/Early June 2013	3-month assessment	HPE2.8 HPE Building, Callaghan Campus
August/ Early March 2013	6-month assessment	HPE2.8 HPE Building, Callaghan Campus

*What are the risks and benefits of participating***?**
- The purpose of this study is to help you lose weight and improve your health and wellbeing through developing skills and knowledge to increase levels of physical activity and improve food choices.
- As a result of blood collection, some individuals may feel light-headed or experience some bruising at the sight of blood collection.
- There may be some muscle soreness associated with commencing an exercise program.

How will your privacy be protected?
Some information will be gathered via questionnaires. The questionnaires will be completed either in paper form or via the Internet. The internet-based questionnaires will be completed via Survey Monkey,

which is a reputable data collection company frequently used in research. Data collected by Survey Monkey is stored securely and only accessible by the research team using a password. Initially, all raw data will be stored in a locked filing cabinet in the chief investigator's office to ensure its security and the confidentiality of any identified data. Only the research assistants and the chief investigators will have access to the raw data. There is a need to be able to identify individual data due to multiple data collection times, but your name will be removed and replaced with a code. A research assistant will then enter the data into an electronic spreadsheet, using the code number. Data used for analysis will be de-identified before entry into a statistical program. Once the information is entered on the data file and checked, all raw data will be shredded and no person will be identifiable in the data files or published report. The results of the study will be published in general terms and will not allow the identification of individuals. The data will be kept for a minimum of five years beyond the completion of the project but no person will be identifiable in the data files or published reports.

How will the information collected be used?
The results of the research will be reported and disseminated via national and international conferences and scientific publications. The results will form part of the PhD thesis of Mr Elroy Aguiar. You will not be identified in any reports arising from the study. At the conclusion of the study, you will receive an email from the research team summarising your results (including anthropometry, blood tests, blood pressure and exercise test scores) and the combined results of the study.

*What do you need to do to participate***?**
Please read this Information Statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, contact one of the researchers.

If you would like to participate, please complete and return the attached consent form (and associated documentation if required) in the reply paid envelope provided, or scan and email the documents to PULSE-study@newcastle.edu.au. This will be taken as your informed consent to participate. You may also be required to obtain a doctor's certificate, which indicates you are able to participate in a diet and exercise program. Following this you will be contacted to arrange a time for the baseline assessment session.

Further information

If you would like further information please contact our research team on (02) 4985 4975 or by email PULSE-study@newcastle.edu.au. Alternatively you could contact Mr Elroy Aguiar (Elroy.Aguiar@newcastle.edu.au) or Professor Robin Callister (Robin.Callister@newcastle.edu.au).

Thank you for considering this invitation.

_____

Professor Robin Callister
Project Chief Investigator

_____

Mr Elroy Aguiar
Student researcher

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2012-0232. Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au.

Appendix 5 – Consent form

Professor Robin Callister
Priority Research Centre in Physical Activity and Nutrition
School of Biomedical Sciences & Pharmacy
Faculty of Health
The University of Newcastle
Callaghan NSW 2308
4921 5650 (PH)
4921 2084 (Fax)
Robin.Callister@newcastle.edu.au

PULSE

Type 2 Diabetes Prevention Using LifeStyle Education

Consent Form for the Research Project:

The Type 2 Diabetes PULSE study: a randomised controlled trial to determine the feasibility and efficacy of a multi-component prevention program for men at high risk of Type 2 Diabetes

Version 3 16/08/2012

I agree to participate in the above research project and give my consent freely.

I understand that the project will be conducted as described in the Information Statement, a copy of which I have retained. I understand I can withdraw from the project at any time and do not have to give any reason for withdrawing.

I consent to

- Attending required assessment sessions over 6-12 months, depending on the group I am allocated to
- Participating in a 6-month diet and exercise intervention
- Having my height, weight, waist circumference, body fat, and blood pressure measured
- Participating in exercise testing (moderate intensity treadmill test and muscular fitness)
- Completing a set of questionnaires including: diet, portion size, demographic information, general health alcohol consumption, physical activity, sitting time and information about other illness or medications and a program evaluation.
- Providing blood samples (3 for intervention group and 4 for control group) to evaluate my health status at each assessment
- Wearing a pedometer for a week at each assessment session

- The researchers accessing details of my use of the study website over the study period. Yes / No

- Photographs being taken of myself while performing assessment measures such as, blood pressure and exercise testing   Yes/ No

Please indicate (circle) whether you would like a copy of your blood test results   Yes / No
Would you like your results sent to you by email or post   Email / Post

Please indicate (circle) your preferred dates and times to attend the first assessment session. These will be conducted in February/early March:

M T W T F

7.15am 8.00am 8.45am

I understand that my personal information will remain confidential to the researchers.
I have had the opportunity to have questions answered to my satisfaction.

Print Name: _____

Contact Details: _____ (e-mail) _____ (phone)

Signature: _____ **Date:** _____

Appendix 6 – The PULSE Type 2 Diabetes Prevention Handbook for Men (sample)

PULSE

Type 2 Diabetes Prevention Using LifeStyle Education

TYPE 2 DIABETES

PREVENTION

for

BLOKES*

THE UNIVERSITY OF
NEWCASTLE
AUSTRALIA

HMRI
Hunter Medical Research Institute

QR NATIONAL

* PLEASE NOTE
This handbook will self-destruct in the hands of a woman!

THE UNIVERSITY OF
NEWCASTLE
AUSTRALIA

QR NATIONAL

HMRI
Hunter Medical Research Institute

PRIORITY RESEARCH CENTRE FOR
PHYSICAL ACTIVITY AND NUTRITION

Table of Contents

Introduction

CONGRATULATIONS on taking a huge step to improving your health. The PULSE program - a lifestyle program for type 2 diabetes prevention - is designed help you lose weight, improve your eating and exercise behaviours, and ultimately steer clear of type 2 diabetes. Experts in type 2 diabetes, weight loss, exercise physiology, physical activity, nutrition and men's health have developed this program and covered all the bases to ensure you have the best chance of success.

The program understands that you still need to enjoy some of life's luxuries, like having a beer now and then (Phew!). And don't worry, the program won't ask you to drink soup for the rest of your life or run a marathon in record time. It will however ask you to make some changes to the way you eat and exercise. The program won't tell you specifically what to eat, but will give you the knowledge to choose food and drink options that are good for your health and will help you lose weight. The program will also give you some great information about the types of exercise (and how much) you should be doing to help you with your weight loss and to prevent type 2 diabetes.

SO, ARE YOU READY?

The PULSE research team

Dr. Robin Callister (BPharm, MSc, PhD)

Robin is a Professor in Biomedical Sciences and Pharmacy at the University of Newcastle. Dr. Callister is an exercise physiologist with over 20 years of research experience and a pharmacist registered in NSW. She is passionate about the role of exercise for health.

Dr. Philip Morgan (BEd HPE (Hons) PhD)

Phil is a Professor in Education at the University of Newcastle. He is passionate about promoting good eating and physical activity behaviours for all men. Phil has won national and international awards for his research into weight loss programs for men.

Dr. Clare Collins (PhD, BSc, Dip Nutr&Diet, Dip Clin Epi)

Clare is a Professor in Nutrition and Dietetics at the University of Newcastle. She is a Fellow of the Dietitians Association of Australia and is the nutrition consultant to the TV program The Biggest Loser. She is passionate about translating nutrition research into healthy eating messages that help families enjoy food and achieve a healthy weight.

Dr. Ron Plotnikoff (BAEd (PE) PhD)

Ron is a Professor in Education at the University of Newcastle. He is also the Director of Newcastle's *Priority Research Centre in Physical Activity and Nutrition*. Professor Plotnikoff is an internationally regarded researcher in population health, diabetes and physical activity research.

Mr. Elroy Aguiar (BBiomed Sci (Hons))

Elroy is the project manager of the PULSE study. He has completed a Bachelor of Biomedical Science at the University of Newcastle in 2008 and is now at the mid-candidature stage of his PhD. Elroy has extensive experience in body composition and fitness testing.

1. Type 2 Diabetes Prevention

You are at risk for type 2 diabetes

You have been selected for this study because you are carrying excess weight and are at risk for type 2 diabetes. You might be thinking "Who Me? At risk for type 2 diabetes?...Really?...Where did that come from…?" Let's start by learning a bit more about type 2 diabetes and the risk factors for it.

What is type 2 diabetes?

Type 2 Diabetes is a condition where excessive amounts of glucose (sugar) build up in the blood. To explain how this occurs, we have to take a few steps back to where the process begins.

When you eat food, your body breaks it down in order to provide fuel (e.g., glucose) for the body. When glucose is detected in the blood of a healthy individual, a hormone called insulin is released. The role of insulin is to encourage the uptake of glucose into energy requiring parts of the body such as your muscles.

In type 2 diabetes, these energy requiring parts of the body become insulin resistant, that is, they do not recognise (or are less responsive to) insulin in the blood. This means that they are unable to absorb all of the glucose, leaving it floating around in the blood. In order to deal with this, the pancreas increases its insulin release, but eventually it cannot release enough insulin to match the level of glucose in the blood. The result is the build up of dangerously high levels of glucose in the blood, which can damage organs and blood vessels.

Type 2 Diabetes in Australia
- Estimated to affect nearly 2 million Australians
- 275 develop the disease every day
- Australia's fastest growing chronic disease
- Total number of Australians with Type 2 Diabetes and Pre-Diabetes estimated at 3.2 million

What is pre-diabetes?

Pre-diabetes is a medically recognised transition stage between normal glucose regulation and type 2 diabetes. Individuals with pre-diabetes have the ability to reverse their condition by improving their lifestyle i.e., their diet and exercise behaviours. Your doctor might have mentioned that you are on the borderline of pre-diabetes, or have insulin resistance, impaired glucose tolerance or impaired fasting glucose. All of these conditions are associated with pre-diabetes.

What are the consequences of type 2 diabetes?

Individuals with type 2 diabetes have a high risk of heart disease, stroke, eye disease, kidney disease, nerve damage, limb amputation and even erectile dysfunction! And that's just naming a few. In fact, as many as 50% of people living with diabetes will die from cardiovascular-related diseases, showing the strong link between the two conditions. With all these associated health conditions its not surprising that type 2 diabetes is estimated to shorten your life by approximately 12–14 years.

What are the risk factors for type 2 diabetes?

Type 2 diabetes is a condition that is a result of your genetics and your lifestyle. These risk factors can be split up into non-modifiable and modifiable factors. For example:

Non-modifiable risk factors
- Age, especially older adults
- Gender, especially males
- Ethnic background
- Family history

Modifiable risk factors
- Being overweight or obese
- A large waist circumference
- High blood glucose
- High blood pressure
- Smoking
- Poor diet
- Lack of exercise

What can you do about it?

The good news is that type 2 diabetes is a largely preventable disease. Now is the time to make a change. By targeting the modifiable risk factors (e.g., poor diet, lack of exercise, obesity, high blood pressure), you can avoid these nasty health problems.

Remember - if you have already been diagnosed with pre-diabetes you can reverse your health situation by making changes to your lifestyle.

What is type 2 diabetes prevention?

Type 2 diabetes prevention is aimed at improving the health of *at risk* individuals and reducing their risk of type 2 diabetes. There are 3 main areas that health professionals and researchers target for type 2 diabetes prevention. These are:

- Weight loss
- Healthy eating
- Regular exercise

This is where the PULSE program can help you.

The PULSE program

PULSE teaches you the information you need to know to get your health back on track. By following this program you will become empowered with the skills and knowledge to make successful life-long improvements in your health.

The PULSE program contains three main focus areas:

- The PULSE type 2 diabetes prevention for blokes handbook (what you are reading now)
- The SHED-IT weight loss program for blokes handbook and the SHED-IT weight loss (and associated materials)
- The PULSE exercise support book and gymstick DVD

This handbook is the main document of the PULSE program. It provides you with the key information to improve your lifestyle (diet and exercise behaviours) and reduce your risk of type 2 diabetes.

Throughout the handbook, you will see references to the other resources included in your PULSE program pack. This tells you that there is information or an activity that you need to complete in one of the other books.

PULSE EXERCISE SUPPORT BOOK FOR BLOKES
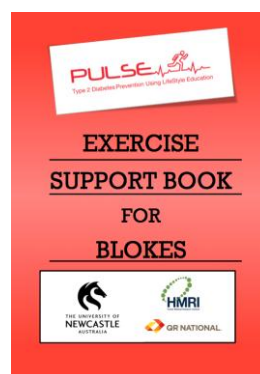
THE SHED-IT WEIGHT LOSS HANDBOOK AND DVD FOR BLOKES
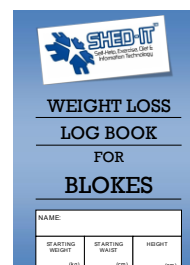
The CALORIEKING CALORIE FAT & CARBOHYDRATE COUNTER and the SHED-IT CALORIEKING WEBSITE USER GUIDE FOR BLOKES
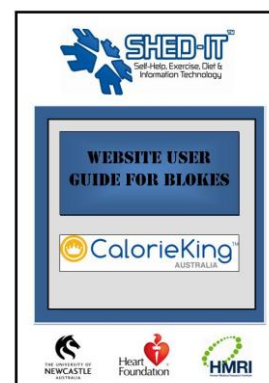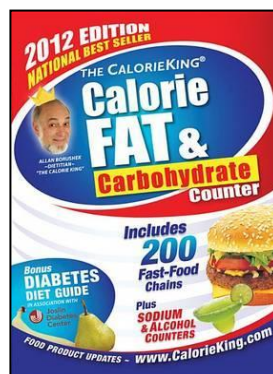
2. The SHED-IT Weight Loss Program for Blokes

The SHED-IT weight loss program for blokes

As part of the PULSE program you have been provided with 'The SHED-IT weight loss program for blokes', an evidence-based and thoroughly evaluated weight loss program. The SHED-IT philosophy is centered around making small, positive and sustainable changes to your eating and exercise behaviours that ultimately result in big changes in your weight.

Before you go any further, watch the SHED-IT DVD and read the SHED-IT weight loss handbook for blokes.

WEIGHT LOSS
HANDBOOK
FOR
BLOKES*

The SHED-IT weight loss program for blokes

Dr Philip Morgan, PhD. Professor of Health and Physical Education, The University of Newcastle

"The SHED-IT program will teach you the secrets of weight loss and dispel many of the myths about how to lose weight. You will also be provided with 9 weight loss tips designed specifically for blokes.

From our previous research on the SHED-IT program, we know that men who implement these tips into their lifestyle lose weight the right way."

Why is weight loss so important?

You may want to lose weight so that you look better (in your budgie smugglers) and feel better, but what you might not realise is that losing weight could actually save your life. All of those extra kilos increase your likelihood of developing type 2 diabetes, heart disease and a host of other conditions. Weight loss is a key factor in preventing type 2 diabetes. Research studies have shown that as little as 5% weight loss can vastly improve your health (e.g., if a 100 kg bloke loses 5kg, that's 5%). Reducing your weight by just 5% can decrease your risk of developing type 2 diabetes by up to 60% (a twelve-fold return!).

What if you are not losing weight?

Once you understand the mathematics of weight loss (outlined in the SHED-IT resources) you will know that weight loss occurs when kJ OUT is greater than kJ IN, i.e., you need to burn more kilojoules (normal body function + exercise) than you consume (through foods and drinks). This is referred to as achieving a negative energy balance (see figure below). If you are not losing weight, then it is possible that your calculations of kJ IN are an underestimate of what you are actually consuming, or your calculations of kJ OUT are an overestimate of what you are actually burning. You might need to make some further small adjustments to ensure you are burning more energy than you are consuming.

Positive energy balance

kJ IN > kJ OUT = weight gain

kJ IN → ← kJ OUT

Negative energy balance

kJ in < kJ out = weight loss

kJ IN → ← kJ OUT

3. Eating To Beat Type 2 Diabetes

In addition to the dietary tips that you have read about in the SHED-IT handbook, there are some additional dietary messages that are crucially important for men at risk of type 2 diabetes. For example, it is important to balance your diet between carbs, healthy fats, protein, and fibre rich foods.

Our Aussie diet is typically full of high kilojoule, high saturated fat, sugary and salty foods; a recipe that has resulted in bigger, unhealthier blokes. The foods and drinks that you choose have major consequences for your health, putting you at risk for a range of health conditions, with type 2 diabetes right at the top of the hit list. It's time to change course and swap to healthy and nutritious foods.

Below is a reference guide for your daily nutrient targets. Don't worry, this will all make sense once you read the rest of the information in this section.

Eating for Type 2 Diabetes

Dr Clare Collins, PhD. Professor of Nutrition and Dietetics, The University of Newcastle

"Eating nutritious, healthy foods that taste great will help you feel better and fuel your body for the fight against type 2 diabetes.

The PULSE program gives you all the information you need to make smart and healthy choices about what you eat. By choosing the right foods you will help your body to maintain blood glucose levels in the healthy range."

Food group / dietary item	Recommendation
Carbohydrates	45-60% *(3915 - 5220 kJ/day)
Dietary Fibre	25-50g/day
Fats	20-35% *(1740 – 3045 kJ/day)
Saturated	<7%
Polyunsaturated	$\leq$10%
Monounsaturated	>10%
Protein	10-20% (0.8g/kg/day) *(870 – 1470 kJ/day)
Sodium (salt)	1500-2300 mg/day

kJ/day amounts estimated based on an average intake of 8700 kJ/day.

* Adapted from the International Diabetes Federation education module – nutrition therapy

Table 1. Nutrient reference table

4. The Essential Exercises for Type 2 Diabetes Prevention

In addition to the physical activity tips that you read about in the SHED-IT handbook, there are some additional exercise messages that are crucially important for men at risk of type 2 diabetes.

Why is exercise so important?

Human beings were designed to move. From an evolutionary perspective, men were designed to be lean, mean hunting machines. But in the current obesity-promoting environment, we don't have to hunt to survive and this brings a whole set of health consequences.

Even if you don't lose any weight, it is well established that getting regular exercise makes you healthier, improves your quality of life and reduces your risk of type 2 diabetes and cardiovascular disease. In fact, research tells us that a single session of exercise helps your body control your blood glucose for up to 48 hours post-exercise.

One of the most successful type 2 diabetes prevention research studies even showed that exercise was better than medicine when it came to blood glucose control.

This section gives you the knowledge and skills you need to be more active and prevent type 2 diabetes. You will learn the key bits of information and find out some great tips that will give you the edge.

Aim to implement each of these essential exercise instructions**.** You should be using all of these in your day-to-day life.

Essential Exercise Tips

1. Be active *every* day
2. Move after meals
3. Turbocharge your muscles

Why is exercise so important?

Dr Robin Callister, PhD. Professor of Exercise Physiology, The University of Newcastle

"We all know that exercise is important for maintaining a healthy body weight and improving your general health. But did you know that for Type 2 Diabetes prevention, exercise takes on another important role, that is, in regulating your blood glucose levels. By exercising for at least 30 minutes each day, you are helping your body to use up the excess glucose in your blood and also increasing the storage of glucose in your muscles.

Think of all activity as an opportunity to exercise – not as an inconvenience."

5. What do you do next?

You have now:

- Read the PULSE handbook
- Watched the SHED-IT DVD
- Read the SHED-IT handbook
- Found out all the secrets to weight loss and reducing your risk for type 2 diabetes

What you need to do now:

- Complete all the sections in the SHED-IT WEIGHT LOSS LOG BOOK i.e., calculating your RMR, Weigh-in-Wednesday (Weight and Waist Charts), S.M.A.R.T. Goals, pedometer chart and your social support strategies
- Sign up for your CalorieKing account
- Read the PULSE exercise support book
- Watch the Gymstick exercise DVD

Now it's up to YOU
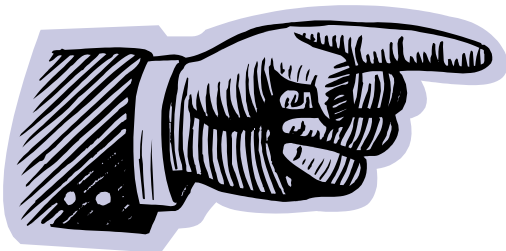
Over the next 6 months you need to:

- Update your SHED-IT Weight Loss Support Book each week to track your weight loss and waist circumference
- Use the CALORIEKING website to track your energy intake and energy output
- Refer to your CALORIE FAT AND CARBOHYDRATE COUNTER BOOK
- Complete at least 210 minutes of exercise each week, including 150 minutes of aerobic exercise and 60 minutes of resistance training
- Use your pedometer and update your SHED-IT weight loss support book
- Update your PULSE Exercise Support Book each day.

Standing at a cross road

You are now at a cross-road. Which way you go is up to you – but choose correctly and you will be well on your way to losing weight and preventing type 2 diabetes.
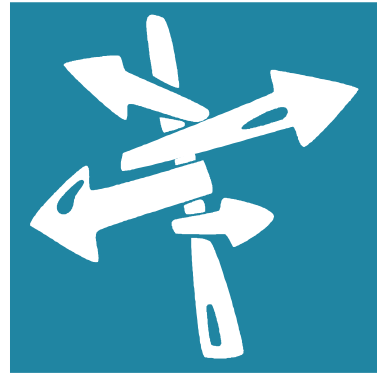
All the best,

The PULSE Research Team

PULSE
Type 2 Diabetes Prevention Using LifeStyle Education

Appendix 7 – PULSE Exercise Support Book for Men (sample)

PULSE

Type 2 Diabetes Prevention Using LifeStyle Education

EXERCISE

SUPPORT BOOK

FOR

BLOKES

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HMRI
Hunter Medical Research Institute

PRIORITY RESEARCH CENTRE FOR
PHYSICAL ACTIVITY AND NUTRITION
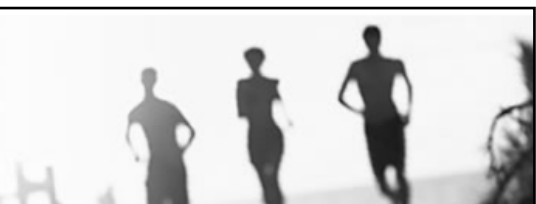
PLEASE REMEMBER TO BRING THIS LOG BOOK TO YOUR 3-MONTH ASSESSMENT AT THE UNIVERSITY

Type 2 Diabetes Prevention Using LifeStyle Education

INTRODUCTION

In the 'PULSE type 2 diabetes prevention for blokes' handbook you learned that exercise is an important component in the prevention of type 2 diabetes and improving your health. The PULSE exercise support book for blokes is where you will find out about the exercises you need to do to lose weight, get fit and improve your health. There is also space in this support book where you need to log (record) the exercise sessions you do.

WE CAN'T EMPHASISE ENOUGH HOW IMPORTANT

LOGGING YOUR EXERCISE SESSIONS ARE.

Fact - we know that men who read this support book, do the exercise and fill in the exercise logs will lose the most weight and will be much fitter in 6 months time.

It might seem painful at first, but it will get easier as you go. It's only for 6 months and it will provide you feedback along the way that will allow you to track your improvement in fitness.

There are 4 main sections to this support book:

1. Getting started with aerobic exercise
2. Getting started with resistance training
3. PULSE Resistance training session program
4. Bodyweight (BW) exercise instructions
5. Gymstick (GS) exercise instructions
6. PULSE exercise log

Don't be discouraged if you are not currently very physically active, that's part of the reason why you signed up for the PULSE study. The time is right to make a change -

WILL YOU RISE TO THE CHALLENGE...OR COME UP WITH EXCUSES?

If you stick to the PULSE exercise program over the next 6 months you will be fitter, strong and healthier.

The PULSE Research Team

1. Getting started with aerobic exercise

This type of exercise includes jogging, running, swimming, cycling. It's the type of exercise that causes you to sweat and be slightly short of breath. Aerobic exercise typically burns a lot of energy and is fantastic for blood glucose control and improving your cardiovascular health.

How much aerobic exercise do I need to do?
The current Australian exercise guidelines for type 2 diabetes prevention recommend you that you

> **Do at least 150 minutes per week of moderate intensity aerobic exercise**
>
> **(e.g., 5 x 30 min sessions per week)**

Moderate intensity exercise causes you to sweat and be slightly short of breath.

Start slow and build up
Walking is the most accessible form of aerobic exercise and the best place to start for beginners. You could walk the dog, walk to work, walk during your lunch break, walk to the bus stop or walk your kids to school. Start walking at a moderate or fast pace. As you get fitter, you can progress to jogging or running.

Warm up and cool down
It is important to warm up before each aerobic exercise session. Begin each session with a 5 minute walk, starting at normal pace and increasing your speed gradually. To cool down, slow your pace down over 3-5 minutes and then perform some stretching (page 32).

Get some variety
You can add some variety to your exercise routine by including some other types of exercise such as swimming and cycling. They are both low impact forms of exercise, an ideal choice if you have any pre-existing joint injuries. Jump in the backyard pool or at your local public swimming pool and get some laps in. Cycling is also a great mode of alternate transport. Cycling to work, uni or the shops is an easy way to fit in your recommended daily amount of exercise. Try some hills on the bike for an extra challenge.

TIP - make sure you are wearing your PULSE pedometer to track how many steps you are taking.

Buddy up
Achieving your physical activity goals is much easier if you can enlist the support of others. Planning to exercise with a friend, partner or kids is an excellent way to make sure you don't slacken. You wouldn't leave your mate stranded at the park at 6am would you?

Exercise safely
It is important to know how far you can push yourself. There's no use trying to run a half marathon in the first month of your 6 month health kick; you will more than likely do more harm than good. Listen to your body when you exercise, if you are feeling faint or dizzy during exercise, STOP. If your breathing becomes uncomfortable, slow down or sit down and take a break. If you have a pre-existing injury, make sure you take this into consideration and choose safe exercise options.

Getting started with resistance training

Resistance training (weights or strength training) focuses on forceful muscular contractions, with either your bodyweight or an external load applied to make things harder for your muscles. The increased activity of your muscles rebuilding after exercise will keep your body's fat burning rate up all day and your blood glucose levels in check. Other benefits include increased muscular fitness, increased muscle mass, reduced body fat and improvements in chronic musculoskeletal injuries.

How much resistance training do I need to do?
The Australian exercise guidelines for type 2 diabetes prevention recommend you that you

> **Do at least 60 minutes per week of resistance training**
>
> **(e.g., 2 x 30 min sessions per week)**

Warm up and cool down
It is important to warm up before each resistance training session. Begin with a 5-minute walk, starting at normal pace and increasing your speed gradually. As you are walking, swing your arms around so that you are warming up your upper body muscles. At the end of each session cool down by performing a 5-minute walk and some stretching (page 32).

Exercise safely
Starting resistance training can be daunting. It is vital that resistance training is performed using the correct technique to maximise results and avoid injury. Work to a tempo of 2 seconds e.g., pushing upwards over a count of 2 seconds, then returning to the start position over a count of 2 seconds.

What if I can't perform some of the exercises?
Some of the exercises in the 'PULSE Resistance Training Program' might be difficult for you to perform initially. Substitute the exercises that you *can do* for those that you *can't* do. As you become fitter, you can go back and try to perform the harder exercises.

You might find that you can't complete all of the repetitions or rounds of exercises that are recommended. Listen to your body when you exercise. If you are feeling faint or dizzy during exercise, STOP. If your breathing becomes uncomfortable, slow down or sit down and take a break. If you have a pre-existing injury, make sure you consider this and choose safe exercise options.

Make sure you breathe
When you are exercising, don't hold your breath. For dynamic exercise (those which involve movement of limbs/joints, contraction/relaxation), breathe out as you begin the muscular contraction and breathe in as you begin to relax back to the starting position. For static exercises (those which involve holding a certain position/posture), make sure you breathe in and out during the static hold. This is particularly important if you have high blood pressure.

Muscle soreness is normal
It is common when starting out with resistance training to have sore muscles. This usually occurs 24-48 hours after exercise and is referred to as Delayed Onset Muscle Soreness (DOMS). Be assured, DOMS is a good thing. It's your muscles response to challenging exercise and actually stimulates your muscles to grow bigger and stronger. It is important however to distinguish between DOMS and pain/injury. Pain that lasts for longer than 3 days, severe pain, or a pain that feels deeper in a joint might indicate that you have an injury. Consult your GP or physiotherapist for a diagnosis if pain persists.

PULSE Resistance Training Program – Weeks 1 and 2

	Day 1	Reps or duration	Instructions	GS Resistance (coils)
A	BW Squat	10	For Gymstick (GS) exercises, choose a resistance (number of coils) for each exercise so that you can comfortably complete all reps. Perform exercises A-H (1 round). **Complete 2 rounds in total**. Rest 30 sec between exercises and 2 mins between rounds.	
B	BW Push Up (Beginner or Advanced)	6		
C	BW Prone Hold (Beginner or Advanced)	20 sec		
D	GS Shoulder Press	6		
E	BW Gluteal Bridge	20 sec		
F	GS Upright Row	6		
G	GS Arm (Bicep) Curl	6		
H	GS Lying Leg Extension	6/leg		
	Day 2	Reps or duration	Instructions	GS Resistance (coils)
A	GS Squat	6	For Gymstick (GS) exercises, choose a resistance (number of coils) for each exercise so that you can comfortably complete all reps. Perform exercises A-H (1 round). **Complete 2 rounds in total**. Rest 30 sec between exercises and 2 mins between rounds.	
B	GS Kneeling Chest Press	6		
C	BW Side Hold (Beginner or Advanced)	15 sec/side		
D	GS Shoulder Press	6		
E	GS Leg Extension	6/leg		
F	GS Bent Over Row	6		
G	GS Arm (Tricep) Extension	6		
H	BW Split Squat	6/leg		
	Day 3 (optional)	Reps or duration	Instructions	GS Resistance (coils)
A	GS Squat	6	For Gymstick (GS) exercises, choose a resistance (number of coils) for each exercise so that you can comfortably complete all reps. Perform exercises A-H (1 round). **Complete 2 rounds in total**. Rest 30 sec between exercises and 2 mins between rounds.	
B	BW Push Up (Beginner or Advanced)	6		
C	BW Flutter Kicks	10/leg		
D	GS Front Raise	6		
E	BW Gluteal Bridge	20 sec		
F	GS Upright Row	6		
G	GS Arm (Bicep) Curl With Overhand Grip	6		
H	GS Split Squat	6/leg		

PULSE Resistance Training Program – Weeks 11 and 12

	Day 1	Reps or duration	Instructions	GS Resistance (coils)
A	BW Squat	20		
B	BW Push Up (Beginner or Advanced)	10	**Increase resistance** (1 more coil) for each GS exercise. Perform exercises A-H (1 round). **Complete 3 rounds**. Rest 30 sec between exercises and 2 min between rounds.	
C	BW Prone Hold (Beginner or Advanced)	20 sec		
D	GS Shoulder Press	10		
E	BW Gluteal Bridge	30 sec		
F	GS Upright Row	10		
G	GS Arm (Bicep) Curl	10		
H	GS Lying Leg Extension	10/leg		
	Day 2	**Reps or duration**	**Instructions**	**GS Resistance (coils)**
A	GS Squat	10		
B	GS Kneeling Chest Press	10	**Increase resistance** (1 more coil) for each GS exercise. Perform exercises A-H (1 round). **Complete 3 rounds**. Rest 30 sec between exercises and 2 min between rounds.	
C	BW Side Hold (Beginner or Advanced)	20 sec/side		
D	GS Shoulder Press	10		
E	GS Leg Extension	10/leg		
F	GS Bent Over Row	10		
G	GS Arm (Tricep) Extension	10		
H	BW Split Squat	10/leg		
	Day 3 (optional)	**Reps or duration**	**Instructions**	**GS Resistance (coils)**
A	GS Squat	10		
B	BW Push Up (Beginner or Advanced)	10	**Increase resistance** (1 more coil) for each GS exercise. Perform exercises A-H (1 round). **Complete 3 rounds**. Rest 30 sec between exercises and 2 min between rounds.	
C	BW Flutter Kicks	15/leg		
D	GS Front Raise	10		
E	BW Gluteal Bridge	30 sec		
F	GS Upright Row	10		
G	GS Arm (Bicep) Curl With Overhand Grip	10		
H	GS Split Squat	10/leg		

Body Weight (BW) Exercises

The following section outlines exercises that you can do with your body weight as part of the **PULSE Resistance training program**. Make sure you read through the exercise descriptions carefully and look at the associated photos. Performing the exercise correctly maximises your fitness gains and reduces the risk of injuring yourself.

*Refer to the **PULSE Resistance training program** for the number of repetitions of dynamic exercises and the duration of static exercises. It also gives you the number of rounds that you should aim to complete for each session and the rest breaks you should take between exercises.*

BW Squat

Instructions

1. Stand with your feet shoulder width apart and with a straight back, arms held out parallel to the ground.
2. Squat down by bending the hips and knees, making sure you keep your heels flat on the floor. Push your bottom out keeping your back straight and head up. Squat down till your thighs are just above parallel to the floor. Remember to breathe in as you squat down and count to 2.
3. Return slowly to the starting position. Remember to breathe out as you squat down and count to 2.
4. Repeat until you have completed the allocated number of repetitions.
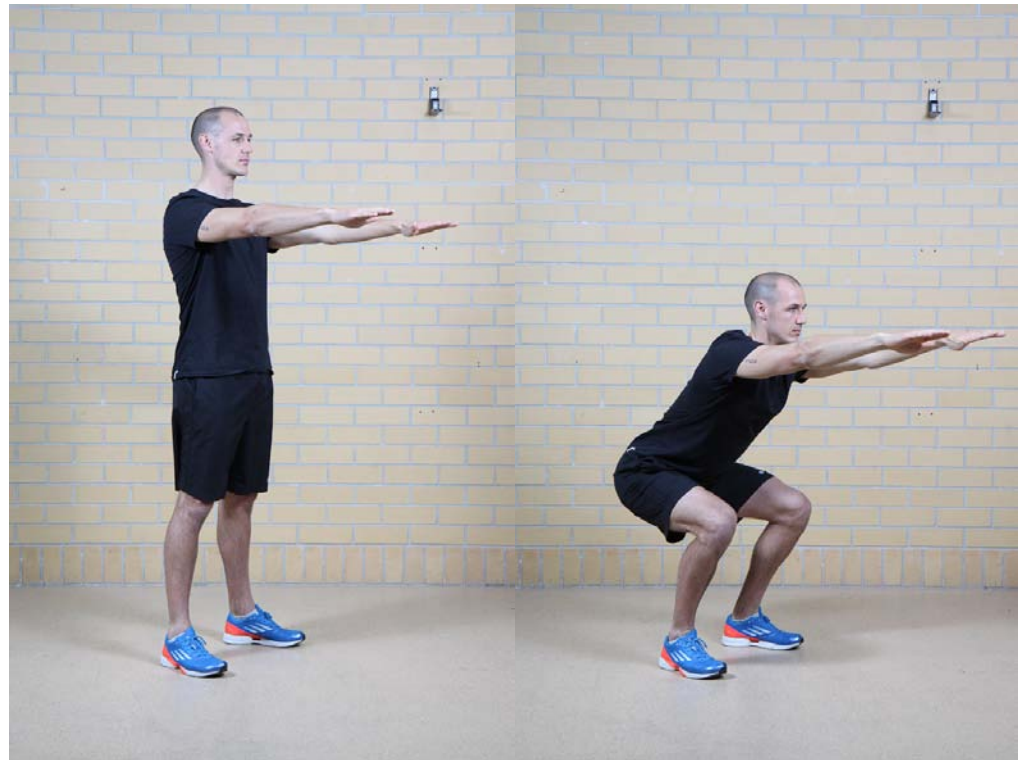
NOTE – this is a difficult exercise that not everyone can perform. Place a 3-5 cm thick piece of timber (or similar hard object) under your heels. This should make the movement easier to perform. As you get fitter, you might find that you can perform the squat without the heel wedge.

BW Push Up

Beginner Instructions

1. Start with your feet, knees and hands on the ground. Feet and knees close together. Arms fully extended and slightly wider than shoulder width apart.
2. Keeping your upper legs and back in a straight line, and your knees on the ground, lower your body towards the ground till your face is roughly 5-10 cm from the ground. Remember to breathe in as you lower yourself down and count to 2.
3. Push up and straighten your elbows, returning slowly to the starting position. Remember to breathe out as you lower return to the starting position and count to 2.
4. Repeat until you have completed the allocated number of repetitions.

Advanced Instructions

1. Repeat the above activity, but this time keep your legs and back straight, and your knees off the ground.

NOTE – this is a difficult exercise that not everyone can perform. If you can't do this exercise, swap it for a GS kneeling chest press instead. As you get fitter, you might find that you can progress to a beginner push up and then an advanced push up.

BW Prone Hold

Beginner Instructions

1. Start with your knees and elbows on the ground, hands together, knees close together and elbows directly below your shoulders.
2. Keep your upper legs and back in a straight line.
3. Hold this position for the allocated time (20 or 30 sec), breathing in and out as you do so.

Advanced Instructions

1. Start with your feet and elbows on the ground, hands together. Feet close together and elbows directly below your shoulders.
2. Keep you your legs and back in a straight line.
3. Hold this position for the allocated time (20 or 30 sec), breathing in and out as you do so.

NOTE – this is a difficult exercise that not everyone can perform. If you can't do this exercise, swap it for BW flutter kicks. As you get fitter, you might find that you can progress to a beginner prone hold and then an advanced prone hold.

BW Gluteal Bridge

Instructions

1. Lie flat on the ground or mat with your hand by your sides, palm facing down.
2. Bend your knees so they are at a 90° angle and keep your feet flat on the floor.
3. Raise your hips up so that your legs and trunk form a straight line.
4. Hold this position for the allocated time (20 or 30 sec), breathing in and out as you do so.

BW Side Bridge

Beginner Instructions

1. Start by lying in a side on position, with your knees, hips and elbow contacting the ground. Your other arm should rest on your hip and you should bend your knees at 90° behind your body.
2. Raise your hips up so that your upper legs and trunk form a straight line.
3. Hold this position for the allocated time (15 or 20 sec), remembering to breathe in and out as you do so.
4. Swap sides and repeat steps 1-3.

Advanced Instructions

1. Start by lying in a side on position, with your feet, knees, hips and elbow contacting the ground. Your other arm should rest on your hip.
2. Raise your hips and knees up so that your legs and trunk form a straight line.
3. Hold this position for the allocated time (15 or 20 sec), remembering to breathe in and out as you do so.
4. Swap sides and repeat steps 1-3

BW Split Squat

Instructions

1. Stand with your feet shoulder width apart and with a straight back, hands on hips.
2. Take an exaggerated step forward with your right leg.
3. Squat down by bending your left knee close to the ground, but do not touch the ground. Remember to breathe in and count to 2 as you squat down.
4. Return slowly to the starting position. Remember to breathe out and count to 2 as you return to the start position.
5. Repeat until you have completed the allocated number of repetitions.
6. Swap legs and repeat steps 2-5.

BW Flutter Kicks

Instructions

1. Lie flat on the ground or mat with your hands under your bottom, palms facing down.
2. Raise both of your legs 15-20 cm off the ground.
3. Raise your left leg a further 20 cm higher, while maintaining your right leg in the first position.
4. Return your left leg to the starting position.
5. Next raise your right leg a further 20 cm higher, while maintain your left leg in the first position.
6. Continue to alternate between right and left legs until you have completed the allocated number of repetitions per leg (10 or 15 per leg).

Gymstick (GS) Exercises

The following section outlines exercises that you can do with your Gymstick as part of the **PULSE Resistance training program.** Make sure you read through the exercise descriptions carefully and look at the associated photos. Performing the exercise correctly maximises your fitness gains and reduces the risk of injuring yourself. For all of the exercises you need to connect the Gymstick to your feet using the foot loops. As you get stronger, you can add resistance by rotating the bar (adding coils on the bar). This will increase the difficulty of the exercise.

*Refer to the **PULSE Resistance training program** for the number of repetitions of dynamic exercises and the duration of static exercises. It also gives you the number of rounds that you should aim to complete for each session and the rest breaks you should take between exercises.*

GS Shoulder Press

Instructions

1. Stand with your feet shoulder width apart and with a straight back.
2. Hold the Gymstick on your chest using an overhand grip (fingers facing away from your body). Your hands should be slightly wider than shoulder width apart.
3. Slowly push up (press) with your arms, extending at the elbows, so that the Gymstick moves above your head. Remember to breathe out as you push up and count to 2.
4. Return slowly to the starting position. Remember to breathe in as you return to the starting position and count to 2.
5. Repeat until you have completed the allocated number of repetitions.

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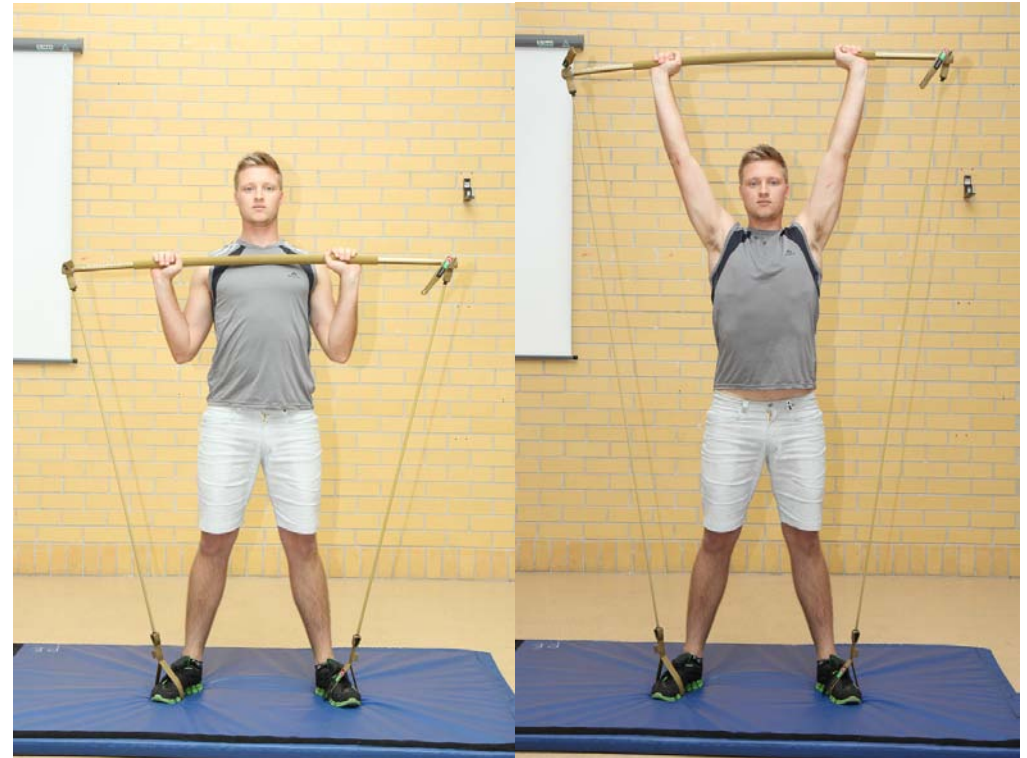
GS Upright Row

Instructions

1. Stand with your feet shoulder width apart and with a straight back.
2. Grip the Gymstick just below your waist using an overhand grip (back of your hand facing away from your body). Your hands should be shoulder width apart. You may need to rotate the bar (add coils) to get the bar in this position.
3. Pull up (row) with your arms, bending your elbows out as you pull up. Remember to breathe out as you pull up and count to 2.
4. Return slowly to the starting position. Remember to breathe in as you return to the starting position and count to 2.
5. Repeat until you have completed the allocated number of repetitions.
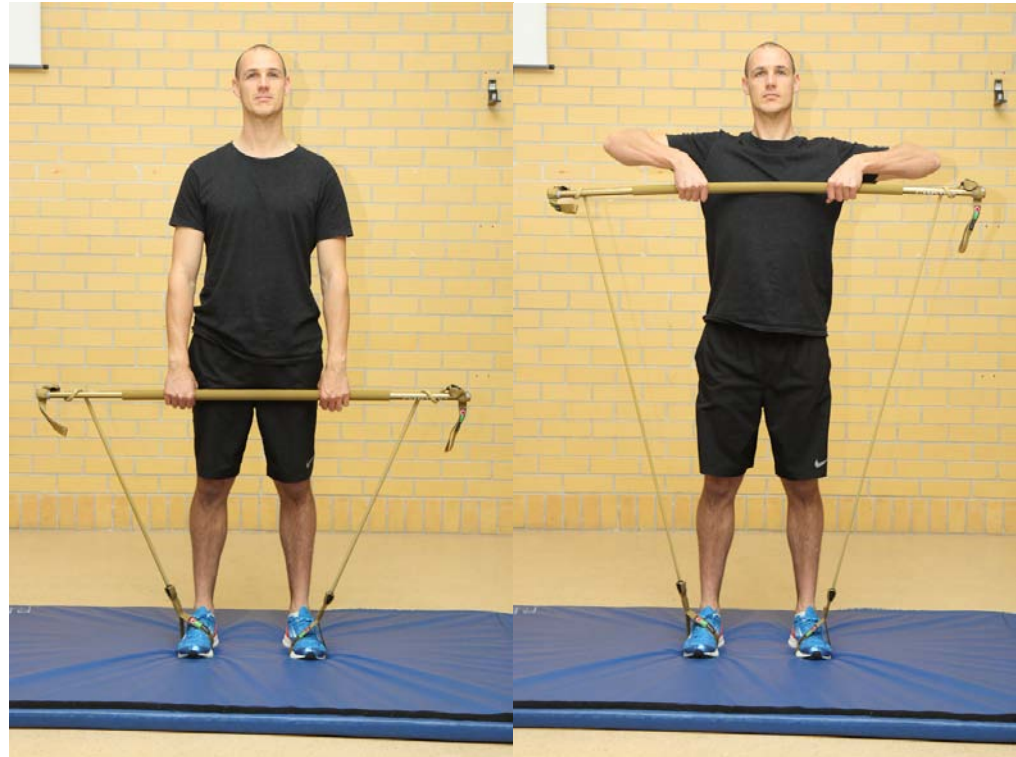
GS Arm (Bicep) Curl

Instructions

1. Stand with your feet shoulder width apart and with a straight back.
2. Grip the Gymstick at just below your waist using an underhand grip (fingers facing away from your body). Your hands should be shoulder width apart. You may need to rotate the bar (add coils) to get the bar in this position.
3. Curl the Gymstick up towards you chest, bending your elbows up. Do not support your elbows on your body. Remember to breathe out as you curl up and count to 2.
4. Return slowly to the starting position. Remember to breathe in as you return to the starting position and count to 2.
5. Repeat until you have completed the allocated number of repetitions.
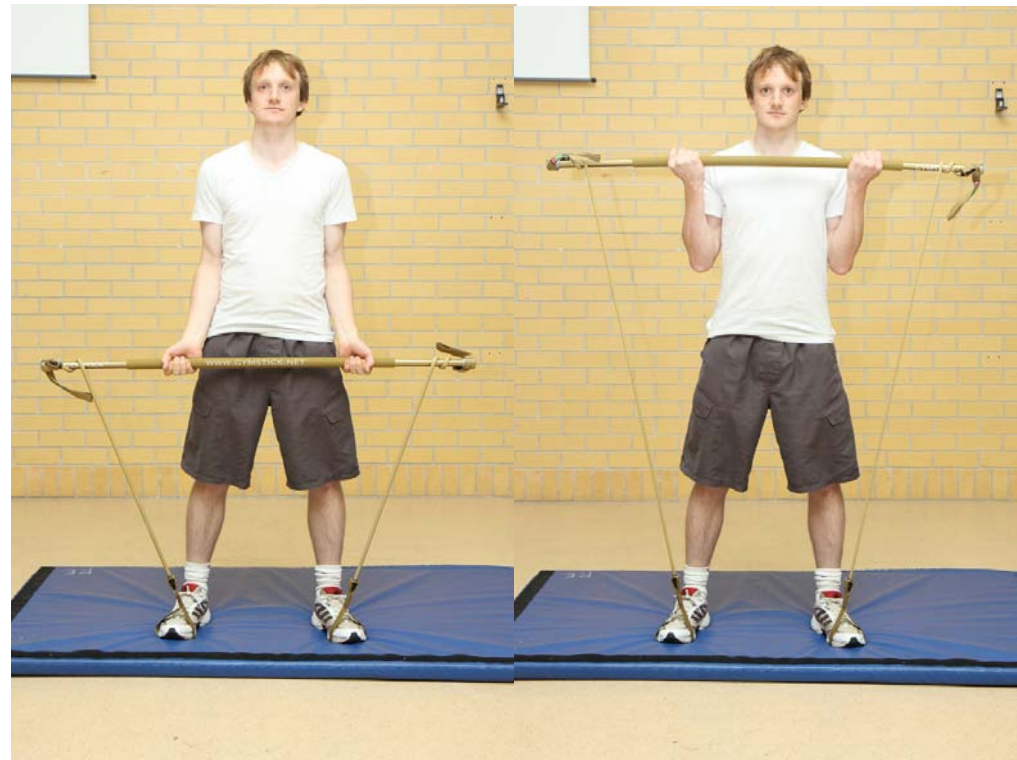
GS Lying Leg Extension

Instructions

1. Lie on the floor (or mat) and raise your legs so your hips and knees are bent at roughly 90°.
2. Grip the Gymstick at your chest using an overhand grip (fingers of your hand facing away from your body). Your hands should be slightly wider than shoulder width apart.
3. Extend your right leg out, keeping your core tight. Remember to breathe out as you extend your right leg and count to 2.
4. Return slowly to the starting position. Remember to breathe in as you return to the start position and count to 2
5. Extend your left leg out, keeping your core tight. Remember to breathe out as you extend your left leg and count to 2.
6. Return slowly to the starting position. Remember to breathe in as you return to the start position and count to 2
7. Repeat until you have completed the allocated number of repetitions.

GS Squat

Instructions

1. Stand with your feet shoulder width apart and with a straight back.
2. Position the Gymstick on the back of your shoulders using an overhand grip. Your hands should be slightly wider than shoulder width apart.
3. Squat down by bending the hips and knees, making sure you keep your heels flat on the floor. Push your bottom out keeping your back straight and head up. Squat down till your thighs are just above parallel to the floor. Remember to breathe in as you squat down and count to 2.
4. Return slowly to the starting position. Remember to breathe out and count to 2.
5. Repeat until you have completed the allocated number of repetitions.
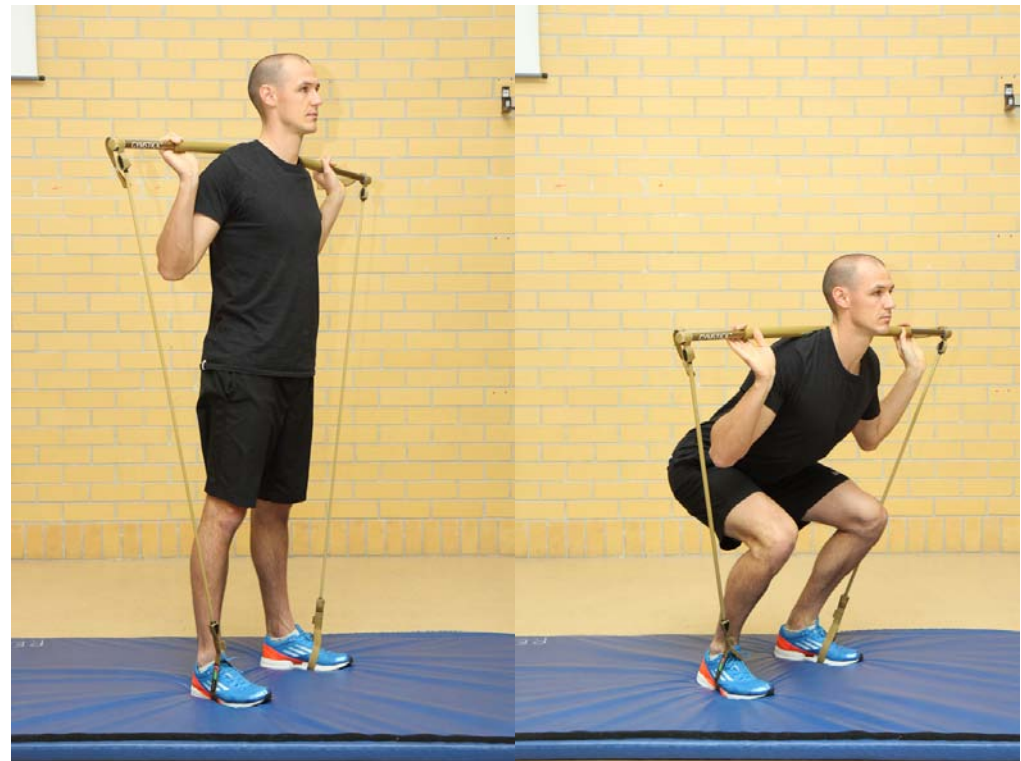
GS Kneeling Chest Press

Instructions

1. Kneel on the floor (or mat) with your knees shoulder width apart and with a straight back.
2. Grip the Gymstick at your chest with an underhand grip (fingers facing away from your body). Your hands should be slightly wider than shoulder width apart.
3. Slowly press (push) your arms away from your body and slightly upward, extending at the elbows, so that the Gymstick moves out. Remember to breathe out as you press the Gymstick and count to 2.
4. Return slowly to the starting position. Remember to breathe in and count to 2.
5. Repeat until you have completed the allocated number of repetitions.
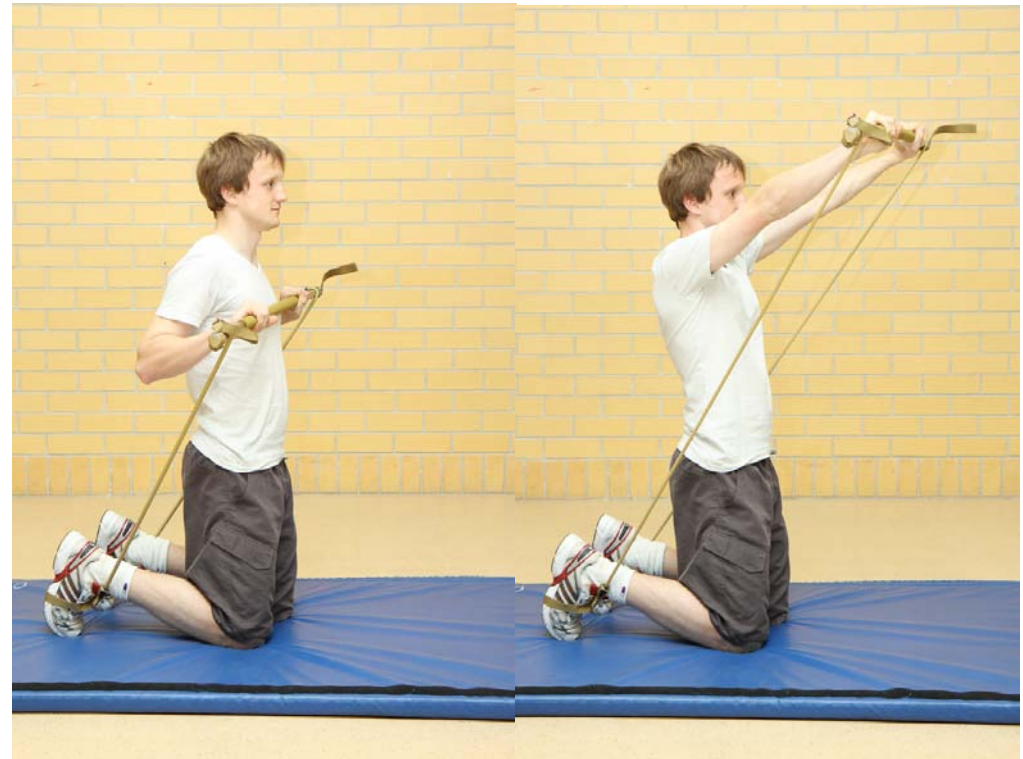
GS Leg Extension

Instructions

1. Kneel on all fours with your knees and arms shoulder width apart, with your back straight.
2. Place the Gymstick under your hands.
3. Engage your core then extend your right leg out behind so it is parallel to the floor. Remember to breathe out as you extend your leg and count to 2.
4. Return slowly to the starting position. Remember to breathe in and count to 2.
5. Repeat until you have completed the allocated number of repetitions.
6. Swap legs and repeat steps 3-5.
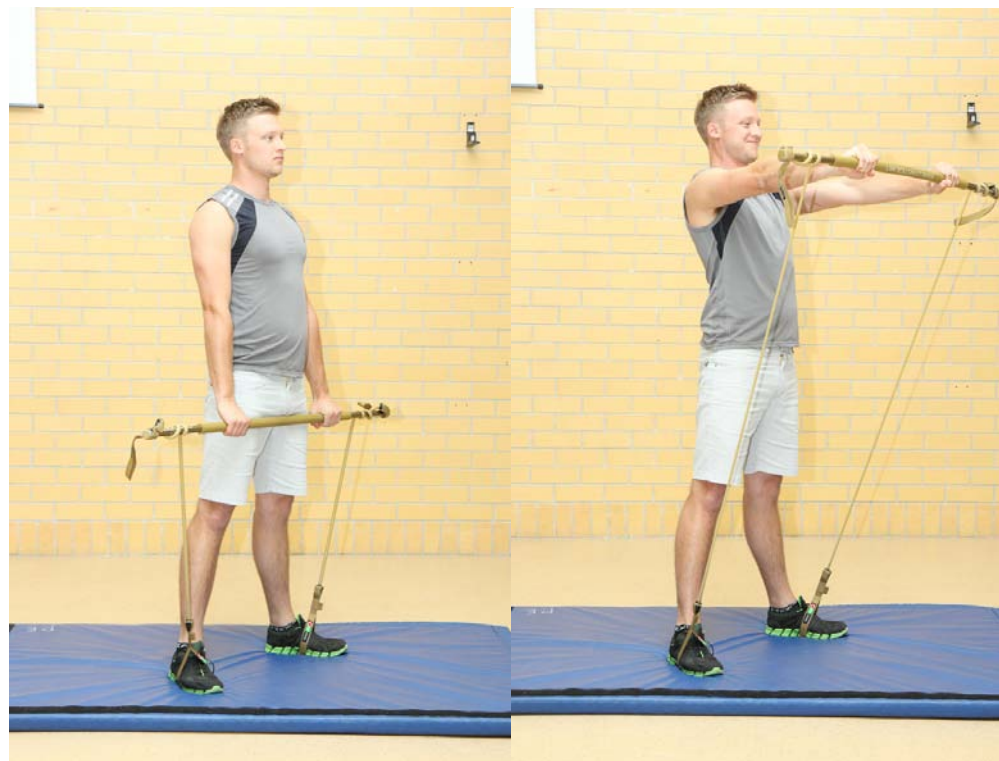7. Repeat until you have completed the allocated number of repetitions.
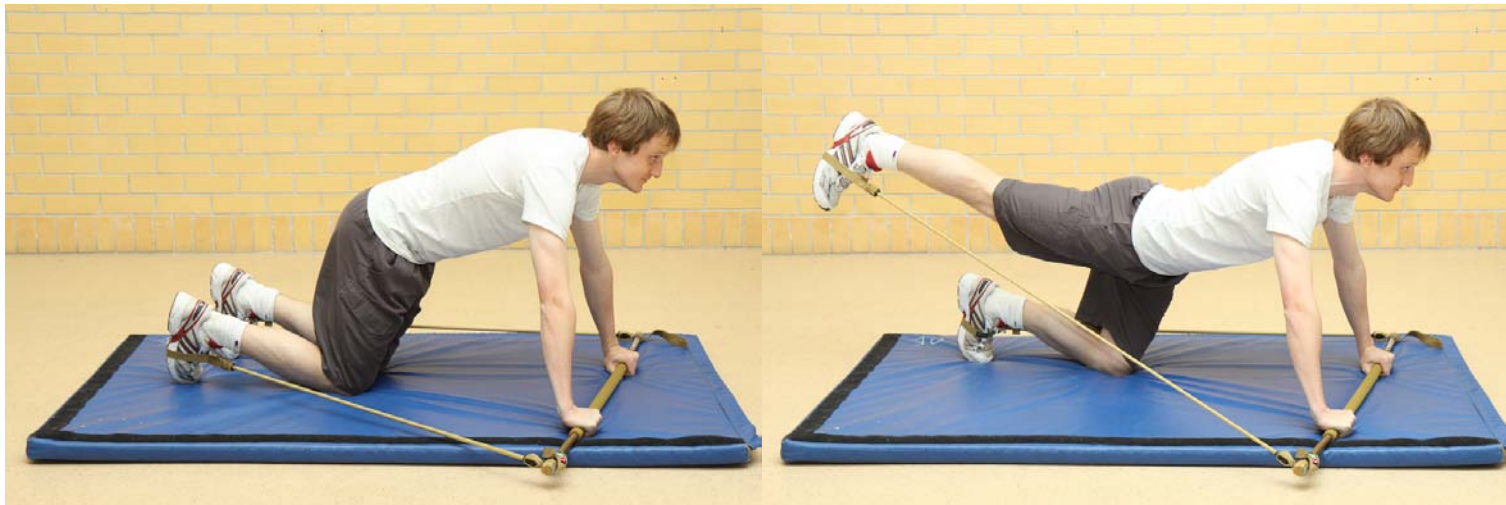
GS Bent Over Row

Instructions

1. Stand with your feet shoulder width apart and with your knees slightly bent. Lean forward keeping your back straight back.
2. Grip the Gymstick at your knees using an overhand grip (back of your hand facing away from your body). Your hands should be slightly wider than shoulder width apart. You will need to add some resistance (coils) by rotating the bar to get the Gymstick in this position.
3. Pull up (row) with your arms towards your hips, pulling your elbows back and squeezing your shoulders blades together as you pull up. Remember to breathe out as you pull up and count to 2.
4. Return slowly to the starting position. Remember to breathe in and count to 2.
5. Repeat until you have completed the allocated number of repetitions.
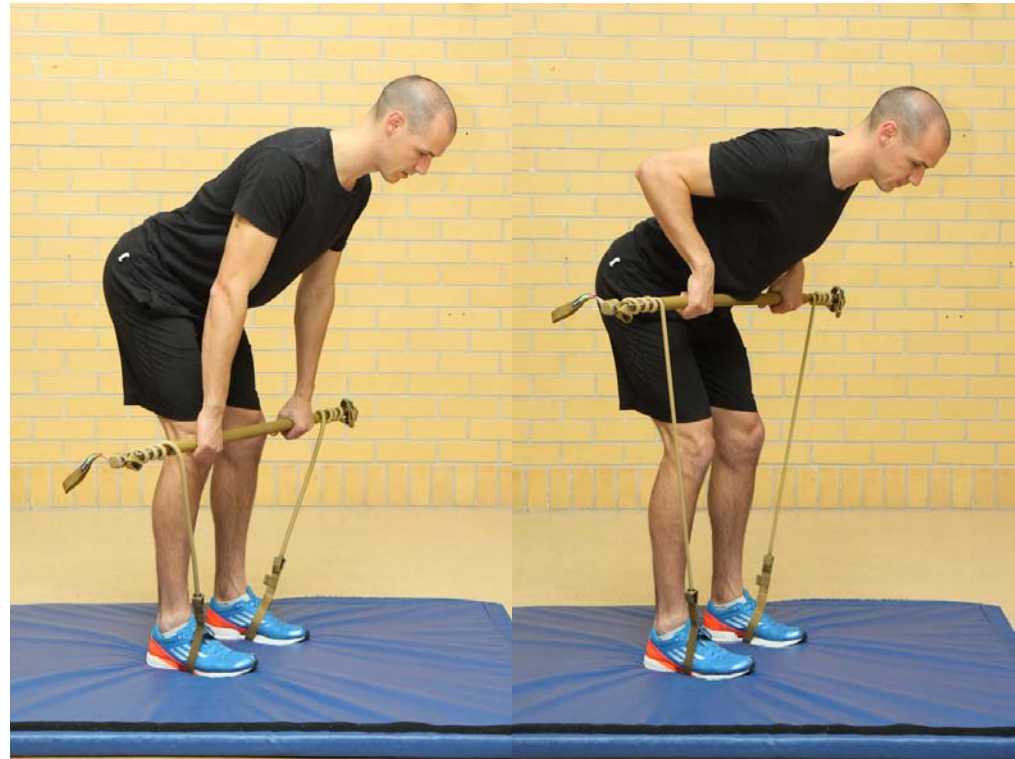
GS Arm (Tricep) Extension

Beginner Instructions
1. Kneel on the floor (or mat) with your knees shoulder width apart and with a straight back
2. Grip the Gymstick behind your head using an overhand grip (palm of your hand facing up). Your hands should be less than shoulder width apart.
3. Slowly extend your arms above your head, straightening you arms. Remember to breathe out as you extend your arms up and count to 2.
4. Return slowly to the starting position. Remember to breathe in and count to 2.
5. Repeat until you have completed the allocated number of repetitions.
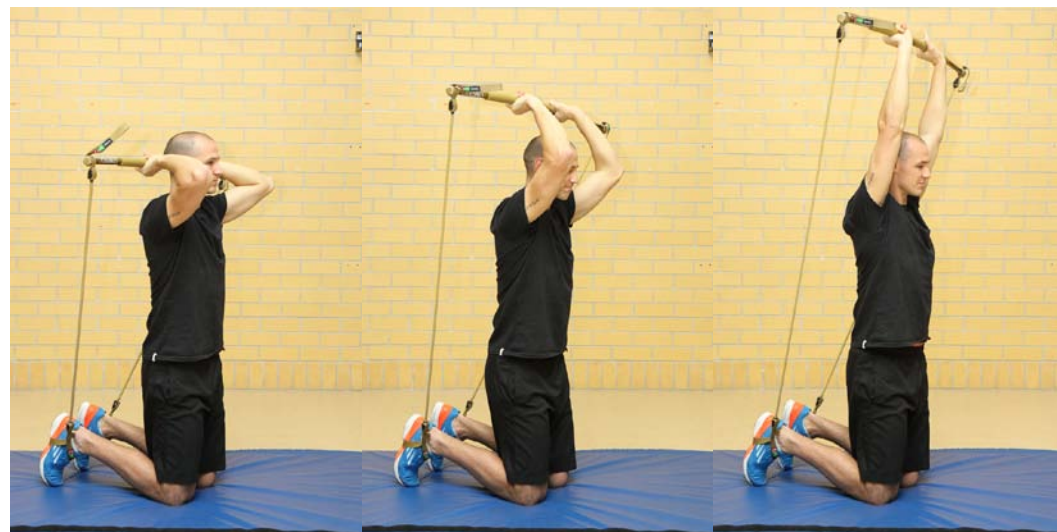
Advanced Instructions
1. Stand with your feet shoulder width apart and with a straight back.
2. Repeat steps 2 -5 from above.
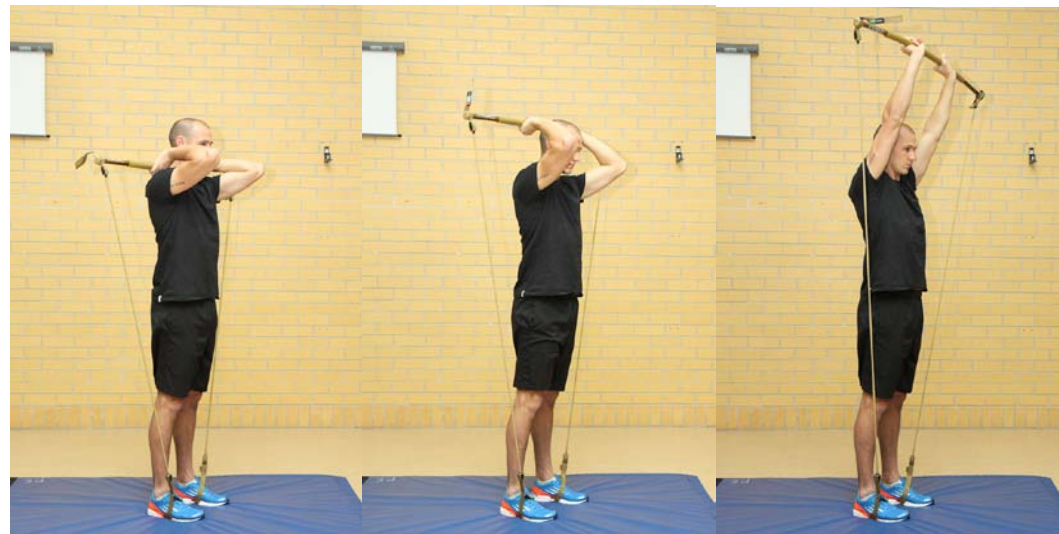
GS Front Arm Raise

Instructions

1. Stand with your feet shoulder width apart and with a straight back.
2. Grip the Gymstick slightly below your waist using an overhand grip (back of your hand facing away from your body). Your hands should be slightly wider than shoulder width. You will need to add some resistance (coils) by rotating the bar to get the Gymstick in this position.
3. Keeping your arms straight, raise the Gymstick up to shoulder height. Remember to breathe out as you raise the Gymstick and count to 2.
4. Return slowly to the starting position. Remember to breathe in and count to 2.
5. Repeat until you have completed the allocated number of repetitions.

GS Arm (Bicep) Curl Overhand Grip

Instructions

1. Stand with your feet shoulder width apart and with a straight back.
2. Grip the Gymstick below your waist using an overhand grip (back of your hand facing away from your body). Your hands should be shoulder width apart. You will need to add some resistance (coils) by rotating the bar to get the Gymstick in this position.
3. Curl the Gymstick up towards your chest, bending your arms at the elbows up. Do not support your elbows on your body. Remember to breathe out as you curl up and count to 2.
4. Return slowly to the starting position. Remember to breathe in and count to 2.
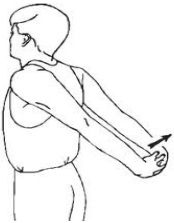5. Repeat until you have completed the allocated number of repetitions.
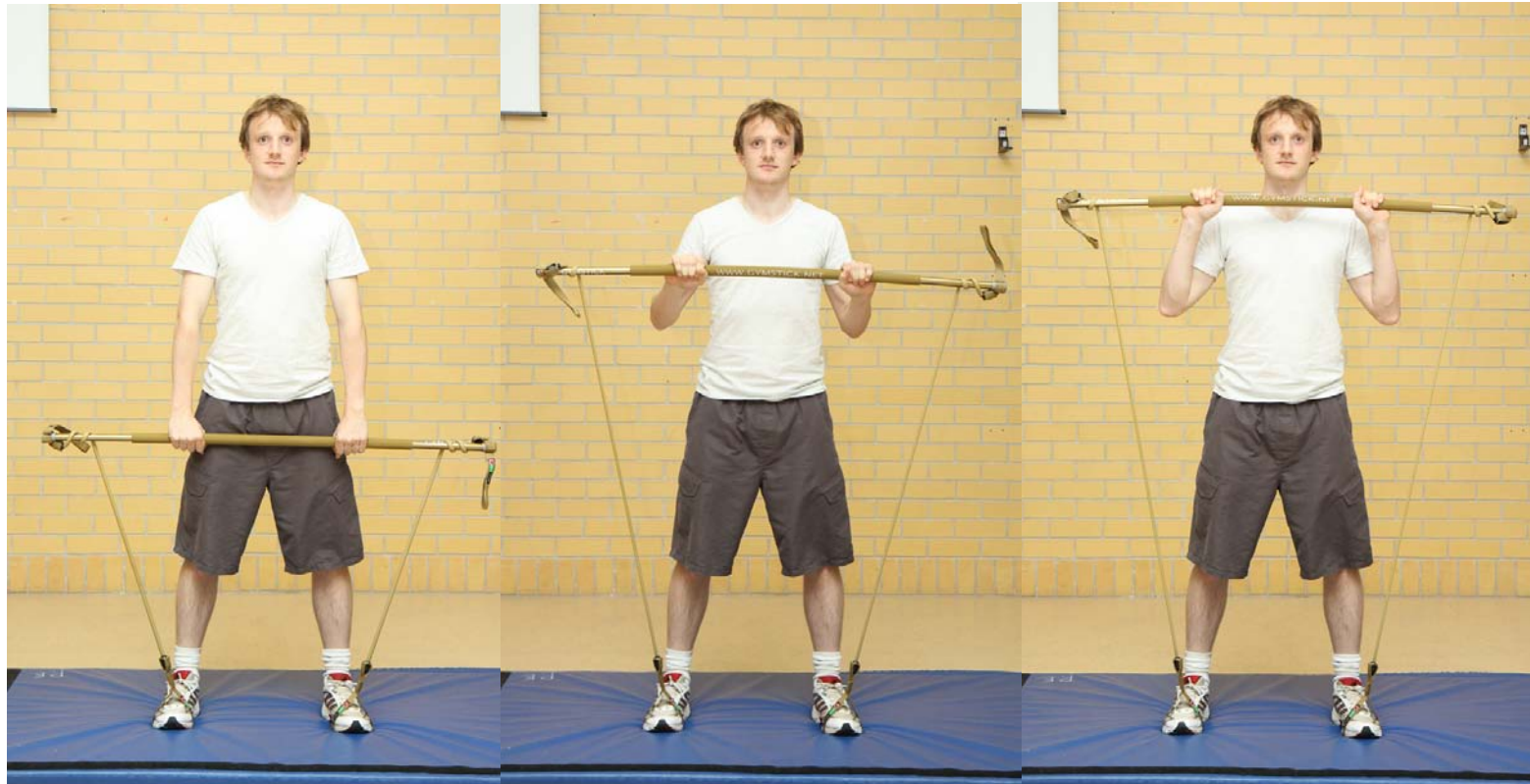
GS Split Squat

Instructions

1. Stand with your feet shoulder width apart and with a straight back.
2. Position the Gymstick on the back of your shoulders using an overhand grip (back of your hand facing away from your body). Your hands should be slightly wider than shoulder width apart.
3. Take an exaggerated step forward with your left leg.
4. Squat down by bending your right knee close to the ground, but do not touch the ground. Remember to breathe in as you squat down and count to 2.
5. Return to the starting position. Remember to breathe in and count to 2.
6. Repeat until you have completed the allocated number of repetitions.
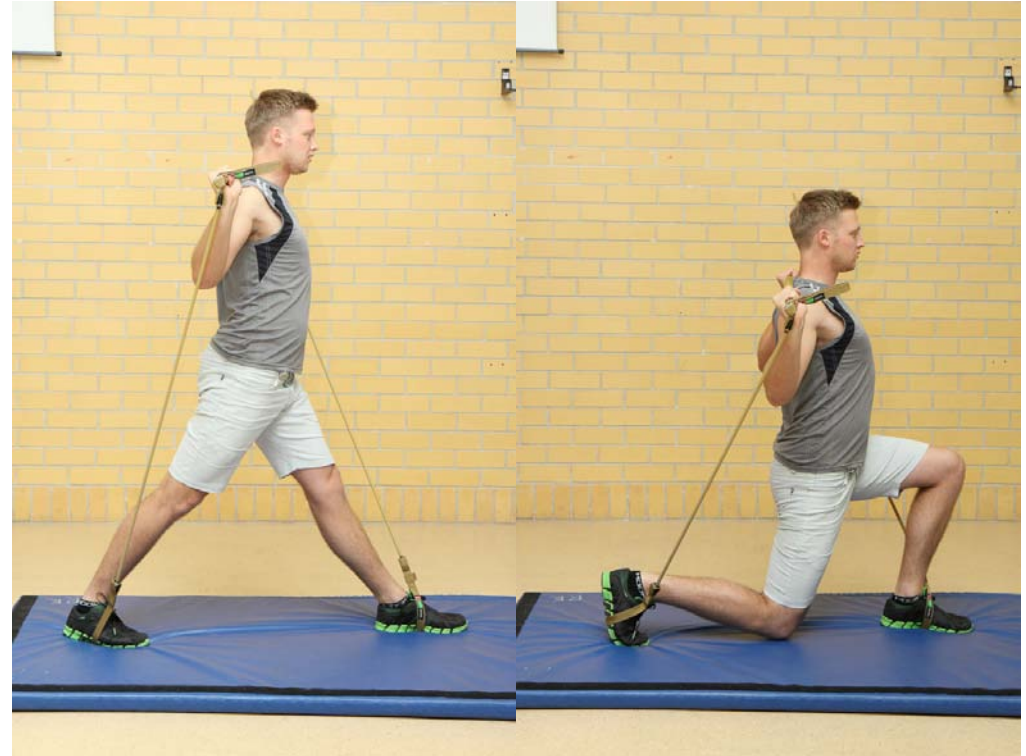
Stretching

	Back and Hips	Sit on the floor and fully extend both legs. Bend your left leg and cross it over your right leg. Place your left foot on the outer-side of your right knee. Keeping your buttocks on the floor, turn your upper body to the left. Use your right elbow to press against the outside of your left leg. Hold this position for 30 seconds.
	Front of Thigh	Stand near a stationary object and place your right hand on that object at shoulder level for support. Lift your left heel toward your buttocks and grasp your foot with your left hand. Hold for 30 seconds. Switch legs and repeat.
	Chest and Shoulders	Stand and keep your knees slightly bent. Bring your arms behind your back, clasping your hands together and slowly lift upward. As you become more flexible, bend forward at the waist and raise the arms higher. Hold for 30 seconds.
	Back of Thigh	Sit on the floor and cross your left leg so the bottom of your left foot touches your inner right thigh. Keep your right leg fully extended. Bend forward from your hips keeping your back straight. Reach with your hands towards your toes. Taking slow deep breaths, hold for 30 seconds. Switch legs and repeat.
	Calves	Stand facing a wall that is slightly beyond your reach (as pictured). Place both hands on the wall at shoulder height. Bring your left foot closer to the base of the wall and step back with your right leg. Keeping your right leg straight and your heel on the floor, press your hips forward toward the wall until your feel a stretch along the back of your lower leg. Hold for 30 seconds. Next, slowly bend your right knee and slide your hips back as if preparing to sit down. Again, hold for 30 seconds. Switch legs and repeat.
	Upper Back and Shoulder	Stand and keep your knees slightly bent. Bring your arms in front of you, clasping your hands, as pictured. Hold for 30 seconds.
	Back of Arm, Upper & Middle Back and Shoulder	Stand and raise both arms above your head. Drop your left hand behind your head. With your right hand, reach down to your left elbow and press towards the centre of your body. Hold for 30 seconds.
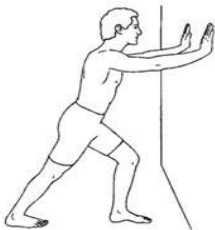
PULSE Exercise Log

To succeed with exercise for weight loss and type 2 diabetes prevention, you need to track your levels of exercise. Keeping an exercise log is a powerful technique to keep yourself accountable and make sure you are achieving the recommended amounts of exercise.

Do at least 150 minutes per week of moderate intensity aerobic exercise

(e.g., 5 x 30 min sessions per week).

AND

Do at least 60 minutes per week of resistance training

(e.g., 2 x 30 min sessions per week).

The PULSE exercise log on the next page is where you can record the activity you do in your exercise sessions. Make sure you fill in the exercise log each day. Write down the duration of the exercise (e.g., 30 min) and use the acronyms "AEx" for aerobic exercise and "RT" for resistance training to indicate what type of session you did.

Remember – you need to 'Be active *every* day', but don't stress if you miss an exercise session, just do a little extra exercise the following day. For example, if you can't exercise on a particular Friday night, you can do 30 min of aerobic exercise and 30 minutes of resistance training on Saturday morning (total 60 min). If you need to catch up on your exercise, try to limit your session to around 60 minutes.

Day	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total (min)
Wk 1	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	
Wk 2	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	
Wk 3	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	
Wk 4	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	Duration (min) Type	

Appendix 8 – Assessment recording sheet

PULSE

Type 2 Diabetes Prevention Using LifeStyle Education

PULSE BASELINE ASSESSMENT RECORDING SHEET

Name: **Participant ID**

DOB: **Age:_____**

Clothing: _____

Measurements	1	2	3	4	Assessor
Height - Record to 0.1 cm - 2 readings within 0.3 cm					
Height (cm)					
Weight - Record to 0. 01 kg - 2 readings within 0.1 kg					
Weight (kg)					
BMI (kg/m^2)					
InBody BIA					
	Weight (kg)		**Body Fat Mass (kg)**		
Waist Circumference - Record to .1cm - 2 readings within 0.5 cm					
Umbilicus (cm)					
Waist (cm)					
Resting Blood Pressure - **3 readings within Systolic 10mmHg - Diastolic 5mm Hg - HR 5 bpm**					
Cuff Size: Colour: Arm:					
Blood Pressure (mmHg) (Sys/Dias)	/	/	/	/	
Resting Heart Rate (bpm)					
Arterial Stiffness - Sphygmocor PWA - operator index must be > 80 % with no red numbers					
Arm:	BP Used /	Aortic PP	Aug Pres (mmHg)	Buckberg Ratio (%)	

Blood Test - Yes / No **- Fasting sample**   Yes / No **-** Right arm / Left arm

Fitness Testing - please number the order in the circles					
Muscular Fitness **Both tests @ 40 BPM**	Shoulder Press Endu ◯		Squat end ◯		
	Reps	Time	Box Height	Reps	Time
Aerobic Fitness - Ebbeling Protocol ◯	TM Speed	55% HRmax	End HR	VO2max	

Checklist:
☐ All physical measurements completed
☐ Online Questionnaire completed
☐ Food Frequency Questionnaire completed (check all pages for incomplete)

Appendix 9 – Baseline assessment questionnaire

PULSE - Baseline Questionnaire

1. Introduction

Thank you for participating in the PULSE study.

PRIOR to attending your baseline assessment session we would like you to complete this questionnaire. It will take about 15-20 minutes to complete.

The questionnaire contains the following sections:

o Identification
o Background Information
o General health
o Portion size
o Physical activity behaviours
o Sitting time
o Alcohol intake
o Medical history and medications

IMPORTANT - We want to know what your behaviours were before joining the PULSE study.
PLEASE answer all questions honestly and in terms of how you have felt over the PAST 3 MONTHS (unless another time-frame is indicated).

o To protect your privacy, your questionnaire data will be de-identified once your participant number has been assigned and answers to the questionnaire will be kept confidential.

If you have any concerns regarding this questionnaire, please contact Mr Elroy Aguiar
Ph: (02) 4985 4975 E: PULSE-study@newcastle.edu.au

Thanks again for your participation.

Cheers

The PULSE research team

THE UNIVERSITY OF
NEWCASTLE
AUSTRALIA

2. Identification

*1. What is your first name?

[   ]

*2. What is your last name?

[   ]

3. Participant number (Office Use Only - Please leave this box blank).

3. The PULSE study

The PULSE study is a diet and exercise program designed to prevent men from developing Type 2 Diabetes

*4. Which of the following strategies do you think you will be most interested in using over the next 3 months? (you can select more than one option)

☐ Changing your diet

☐ Doing some aerobic exercise (e.g., walking, jogging, swimming, cycling)

☐ Doing some resistance training (e.g., weight lifting)

4. Background Information

The following questions are about you:

*5. What is your date of birth?

           DD   MM   YYYY

Date of Birth   ☐ / ☐ / ☐

*6. What is your age?

*7. What is your occupation?

*8. What is the highest qualification you have completed?

○ No formal qualifications

○ School certificate (Year 10 or equivalent)

○ Higher school certificate (Year 12 or equivalent)

○ Trade/Apprenticeship (e.g. carpenter, chef, plumber, tiler)

○ Certificate/Diploma (e.g. accounting, technician, bricklayer, business, IT)

○ University Degree (e.g. Bachelor)

○ Higher University Degree (e.g. Grad Dip, Masters, PhD)

*9. Are you of Aboriginal or Torres Strait Islander origin?

☐ No

☐ Aboriginal

☐ Torres Strait Islander

*10. In which country were you born?

○ Australia

○ United Kingdom

○ Italy

○ Greece

○ Vietnam

○ Other

Other (please specify)

[   ]

*11. What language do you usually speak at home?

○ English

○ Italian

○ Greek

○ Cantonese

○ Mandarin

○ German

○ Arabic

Other (please specify)

[   ]

*12. What is your PRESENT marital status?

○ Married

○ De facto

○ Separated

○ Divorced

○ Widowed

○ Never married

*13. What is your postcode?

[   ]

*14. What is your average gross (before tax) income?

○ No income

○ $1 - $6,000 annually ($1 - $115 per week)

○ $6001 - $16,000 annually ($116 - $307 per week)

○ $16001 - $37,000 annually ($308 - $711 per week)

○ $37,001 - $60,000 annually ($712 - $1153 per week)

○ $60,001 - $80,000 annually ($1154 - $1538 per week)

○ $80001 - $140,000 ($1539 - $2692 per week)

○ $140,000 - $180,000 ($2693 - $3461 per week)

○ $180,001 and over annually ($3462 or more per week)

○ Don't know

○ Don't want to answer

*15. What is the average gross (before tax) income of your household (e.g. you and your partner, or you and your parents sharing a house)?

○ No income

○ $1 - $6,000 annually ($1 - $115 per week)

○ $6001 - $16,000 annually ($116 - $307 per week)

○ $16001 - $37,000 annually ($308 - $711 per week)

○ $37,001 - $60,000 annually ($712 - $1153 per week)

○ $60,001 - $80,000 annually ($1154 - $1538 per week)

○ $80001 - $140,000 ($1539 - $2692 per week)

○ $140,000 - $180,000 ($2693 - $3461 per week)

○ $180,001 and over annually ($3462 or more per week)

○ Don't know

○ Don't want to answer

○ I live alone

5. General Health

The following questions ask for your views about your health, how you feel and how well you are able to do your usual activities. If you are unsure about how to answer any questions please give the best answer you can. Do not spend too much time answering as your immediate response is likely to be the most accurate.

*16. In general would you say your health is:

○ Excellent

○ Very Good

○ Good

○ Fair

○ Poor

6. General Health (continued)

HEALTH AND DAILY ACTIVITIES

The following questions are about activities you might do during a typical day.

For Q16 and 17 - Does your health now limit you in these activities? If so, how much?

*17. Moderate activities, such as moving a table, pushing a vacuum, bowling or playing golf.

○ Yes, limited a lot

○ Yes, limited a little

○ No, not limited at all

*18. Climbing several flights of stairs

○ Yes, limited a lot

○ Yes, limited a little

○ No, not limited at all

7. General Health (continued)

For Q18 and Q19 - 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?

*19. Accomplished less than you would like

○ Yes

○ No

*20. Were limited in the kind of work or other activities

○ Yes

○ No

8. General Health (continued)

PULSE - Baseline Questionnaire

For Q20 and Q21 - During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

*21. Accomplished less than you would like

○ Yes

○ No

*22. Didn't do work or other activities as carefully as usual

○ Yes

○ No

9. General Health (continued)

*23. During the past 4 weeks how much did pain interfere with your normal work? (Including work both outside the home and housework)

○ Not at all

○ A little bit

○ Moderately

○ Quite a bit

○ Extremely

YOUR FEELINGS

These questions are about how you feel and how things have been with you during the past four weeks. For each questions, please indicate the one answer that comes closest to the way you have been feeling.

For Q23-Q25 - How much of the time during the past 4 weeks

*24. Have you felt calm and peaceful?

○ 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

*25. Did you have a lot of energy?

○ 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

*26. Have you felt downhearted and blue?

○ 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

10. General Health (continued)

*27. During the past 4 weeks, how much of the time has your physical health or emotiona interfered with your social activities (like visiting friends/close relatives)?

○ All of the time

○ Most of the time

○ Some of the time

○ A little of the time

○ None of the time

11. Portion Sizes

For each food shown on this page, indicate how much on average you would usually have eaten at main meals during the past 12 months.
When answering each question, think of the amount of food you usually ate, even though you may rarely have eaten the food on its own.
If you usually ate more than one helping, choose the answer for the serving size closest to the total amount you ate.
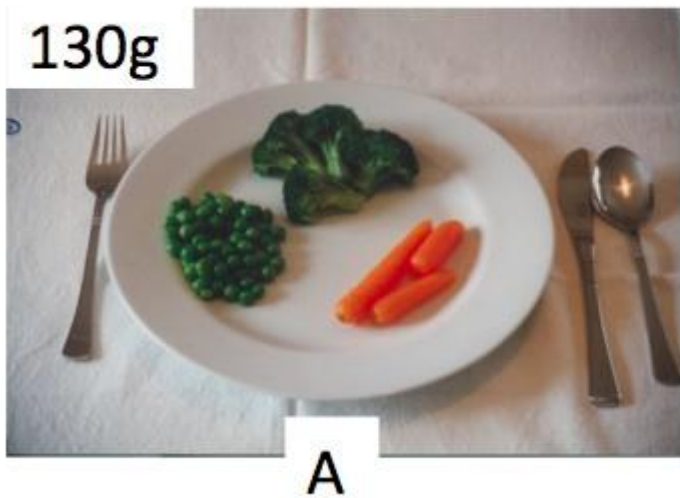
Portion Size of Potato

60g A

100g

*28. For the following question refer to the above images of potato serving sizes. When you ate potato, did you usually eat:

○ I never ate potato

○ Less than A

○ A

○ Between A & B

○ B

○ Between B & C
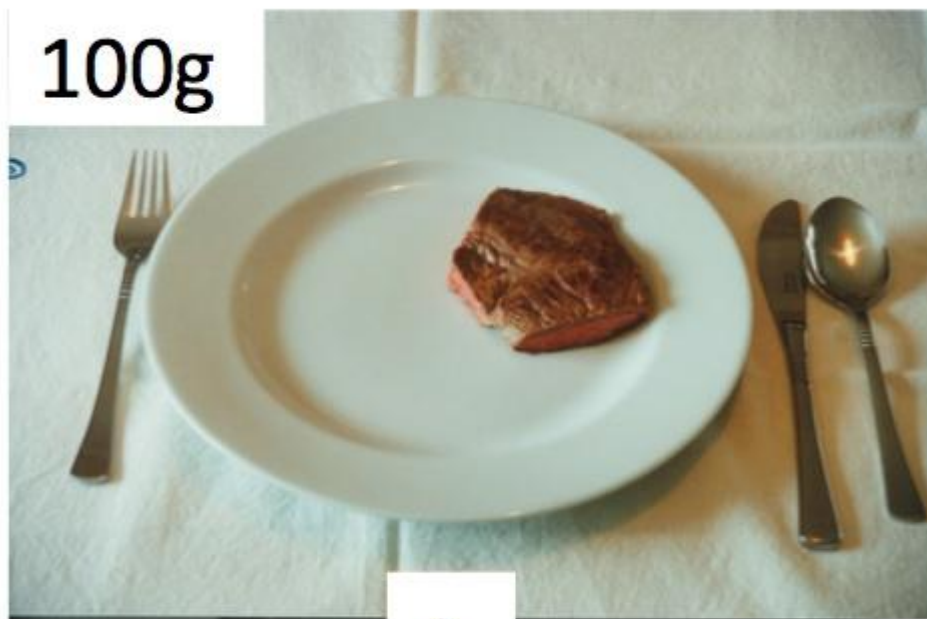
○ C

○ More than C

Portion Size of Vegetables

*29. For the following question refer to the above images of vegetable serving sizes. When you ate vegetables, did you usually eat:
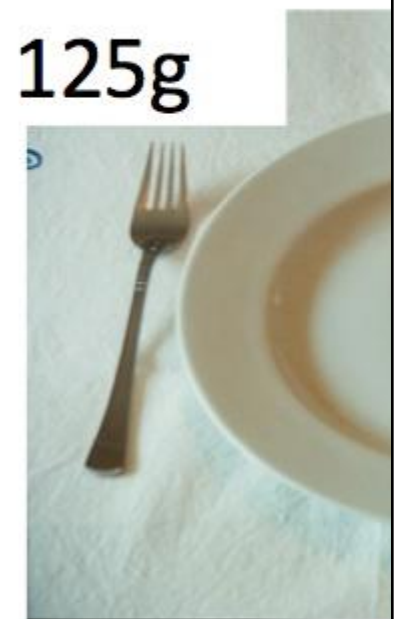
- ○ I never ate vegetables
- ○ Less than A
- ○ A
- ○ Between A & B
- ○ B
- ○ Between B & C
- ○ C
- ○ More than C

Portion Sizes of Steak

100g

A

125g

*30. For the following question refer to the above images of steak serving sizes. When you ate steak, did you usually eat:
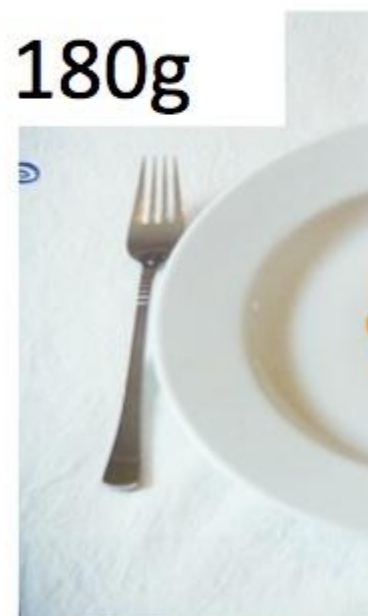
○ I never ate steak

○ Less than A

○ A

○ Between A & B

○ B

○ Between B & C

○ C

○ More than C

Portions Sizes for Casserole

100g 180g

A

＊31. For the following question refer to the above images of casserole serving sizes. When you ate meat or vegetable cassorole, did you usually eat:

○ I never ate casserole

○ Less than A

○ A

○ Between A & B

○ B

○ Between B & C

○ C

○ More than C

12. Section G - Physical Activity Behaviours

For the following questions (Q31-Q35) we would like you to recall your average WEEKLY participation in physical activity OVER THE PAST MONTH.
How many TIMES PER WEEK on average did you do the following kinds of physical activity during your free time OVER THE PAST MONTH?

When answering these questions please:
* Consider your average amount of activity over the past month.
* Only count physical activity sessions that lasted 10 minutes or longer in duration.
* Do not count physical activity that was done as part of your employment or household chores.

* Note that the main difference between the three catergories below is the intensity of the physical activity.
* Please answer with the average amount of times per week as well as the average time per session for each question - STRENUOUS, MODERATE and MILD PHYSICAL ACTIVITY.

*32. Strenuous physical activity (heart beats rapidly, sweating)

(Eg. Running, jogging, hockey, soccer, squash, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling, vigorous aerobic dance classes, heavy weight training)

Times per week	
Average time per session (minutes)	

*33. Moderate physical activity (not exhausting, light perspiration)

(eg. fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)

Times per week	
Average time per session (minutes)	

*34. Mild physical activity (minimal effort, no perspiration)

(Eg. easy walking, yoga, archery, fishing, bowling, lawn bowling, shuffleboard, horseshoes, golf, snowmobiling)

Times per week	
Average time per session (minutes)	

*35. During a typical 7-Day period (a week), in your leisure time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)?

○ Often   ○ Sometimes   ○ Never/Rarely

*36. Is the amount of activity you did in the past month less, more, or about the same as your usual physical activity habits?

○ I am now much less active

○ I am now less active

○ I am now about the same

○ I am now more active

○ I am now much more active

13. Sitting Time

Please estimate how much time you spend SITTING EACH DAY in the following situations. Select an hour and minute option from the drop-down list (click on the arrows next to the box)

PULSE - Baseline Questionnaire

For example
if you spend 1 hour sitting at work each day during the week, select 1 (for hours) and 0 (for minutes)
If you spend 2 hour and a half hours sitting watching television on a weekend, select 2 (for hours) and 30 (for minutes)

If you are not currently working, please select NA for Question 2: Sitting time while at work (weekday and weekend)

If you do not have an answer for a particular box, PLEASE select 'O'(zero).

*37. Please estimate how much time you spend sitting for the following situations. Please answer in HOURS and MINUTES. PLEASE place an ANSWER in EACH BOX, even if it is ZERO (0)

	WEEKDAY (HOUR)	WEEKDAY (MIN)	WEEKEND (HOUR)	WEEKEND (MIN)
While traveling to and from places				
While at work				
While watching television				
While using a computer at home				
In your leisure time, NOT including television (i.e., visiting friends, movies, dining out etc.)				

14. Alcohol Consumption

Try to answer these questions in terms of 'standard drinks' as described in the diagram below.

Please select the responses that best fits your drinking pattern over the past 3 months.

Full Strength Beer 285ml 4.8% Alcohol	Low Strength Beer 425ml 2.7% Alcohol	Pre-mix Spirits 330ml 5% Alcohol	Wine 100ml 11.5% Alcohol	Spirits 30ml 40% Alcoh

*38. How often do you have a drink containing alcohol?

- ○ Never
- ○ Monthly or less
- ○ 2-4 times a month
- ○ 2-3 times a week
- ○ 4 or more times a week

15. Alcohol Consumption

*39. How many standard drinks do you have on a typical day when you are drinking?

- ○ 1 or 2
- ○ 3 or 4
- ○ 5 or 6
- ○ 7 to 9
- ○ 10 or more

*40. How often do you have six or more standard drinks on one occasion?

- ○ Never
- ○ Less than monthly
- ○ Monthly
- ○ Weekly
- ○ Daily or almost daily

16. Medical History and Medications

*41. Have you ever been diagnosed with

- ☐ Type 2 Diabetes
- ☐ Pre-Diabetes
- ☐ Impaired Glucose Tolerance
- ☐ Impaired Fasting Glucose
- ☐ High blood sugar
- ☐ None of the above

*42. Do you have any illness or injuries, which could affect your capacity to adhere to the diet and exercise program in this study? YES/NO (please list)

*43. Do you take any medications (prescribed by a doctor or purchased over the counter)? YES/NO (please list)

*44. Do you take any vitamin/nutrient supplements? YES/NO (please list)

17. Well done, you're finished!

THANK YOU FOR COMPLETING ALL QUESTIONS. YOUR CO-OPERATION IS GREATLY APPRECIATED.

Appendix 10 – 6-month assessment questionnaire

PULSE - 6 month Questionnaire

1. Introduction

Thank you for participating in the PULSE study.

PRIOR to attending your 6-month assessment session we would like you to complete this questionnaire, which will take about 15-20 minutes.

The questionnaire contains the following sections:

o Identification
o General health
o Portion size
o Physical activity behaviours
o Sitting time
o Alcohol intake
o Medical history and medications

IMPORTANT - We want to know what your behaviours were over the past 3 months since your last assessment session.

PLEASE answer all questions honestly and in terms of how you have felt over the PAST 3 MONTHS (unless another time-frame is indicated).

To protect your privacy, your questionnaire data will be de-identified once your participant number has been assigned and answers to the questionnaire will be kept confidential.

If you have any concerns regarding this questionnaire, please contact Mr Elroy Aguiar
Ph: (02) 4985 4975 E: PULSE-study@newcastle.edu.au

Thanks again for your participation.

Cheers

The PULSE research team

THE UNIVERSITY OF
NEWCASTLE
AUSTRALIA

2. Identification

*1. What is your first name?

*2. What is your last name?

3. Participant number (Office Use Only - Please leave this box blank).

3. The PULSE study

The PULSE study is a diet and exercise program designed to prevent men from developing Type 2 Diabetes

4. GROUP 1 PARTICIPANTS ONLY -
Which of the following strategies have you used consistently over the past 3 months? (you can select more than one option)

☐ Changed your diet (eating habits)

☐ Performed aerobic exercise (e.g., walking, jogging, swimming, cycling)

☐ Performed resistance training (e.g., gymstick and body weight exercises)

5. GROUP 2 PARTICIPANTS ONLY -
Which of the following strategies do you think you will be most interested in using when you begin the program in the next week? (you can select more than one option)

☐ Changing your diet (eating habits)

☐ Doing some aerobic exercise (e.g., walking, jogging, swimming, cycling)

☐ Doing some resistance training (e.g., weight lifting)

4. General Health

PLEASE ANSWER THESE QUESTIONS WITH THE PAST 3 MONTHS IN MIND (SINCE YOUR LAST ASSESSMENT SESSION AT THE UNIVERSITY)

The following questions ask for your views about your health, how you feel and how well you are able to do your usual activities. If you are unsure about how to answer any questions please give the best answer you can. Do not spend too much time answering as your immediate response is likely to be the most accurate.

*6. In general would you say your health is:

○ Excellent

○ Very Good

○ Good

○ Fair

○ Poor

5. General Health (continued)

HEALTH AND DAILY ACTIVITIES

The following questions are about activities you might do during a typical day.

For Q7 and 8 - Does your health now limit you in these activities? If so, how much?

*7. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf.

○ Yes, limited a lot

○ Yes, limited a little

○ No, not limited at all

*8. Climbing several flights of stairs

○ Yes, limited a lot

○ Yes, limited a little

○ No, not limited at all

6. General Health (continued)

For Q9 and Q10 - During the past 3 months, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

*9. Accomplished less than you would like

○ Yes

○ No

*10. Were limited in the kind of work or other activities

○ Yes

○ No

7. General Health (continued)

For Q11 and Q12 - During the past 3 months, have you had any of the following problems with your work or other regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

*11. Accomplished less than you would like

○ Yes

○ No

*12. Didn't do work or other activities as carefully as usual

○ Yes

○ No

8. General Health (continued)

*13. During the past 3 months how much did pain interfere with your normal work? (Including work both outside the home and housework)

- ○ Not at all
- ○ A little bit
- ○ Moderately
- ○ Quite a bit
- ○ Extremely

YOUR FEELINGS

These questions are about how you feel and how things have been for you during the past 3 months. For each question, please indicate the one answer that comes closest to the way you have been feeling.

For Q14-Q16 - How much of the time during the past 3 months

*14. Have you felt calm and peaceful?

- ○ 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

*15. Did you have a lot of energy?

- ○ 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

*16. Have you felt downhearted and blue?

- ○ 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

9. General Health (continued)

＊17. During the past 3 months, how much of the time has your physical health or emotion interfered with your social activities (like visiting friends/close relatives)?

○ All of the time

○ Most of the time

○ Some of the time

○ A little of the time

○ None of the time

10. Portion Sizes

PLEASE ANSWER THESE QUESTIONS WITH THE PAST 3 MONTHS IN MIND (SINCE YOUR LAST ASSESSMENT SESSION AT THE UNIVERSITY)

For each food shown below, indicate how much on average you would usually have eaten at main meals during the past 3 months.
When answering each question, think of the amount of food you usually ate, even though you may rarely have eaten the food on its own.
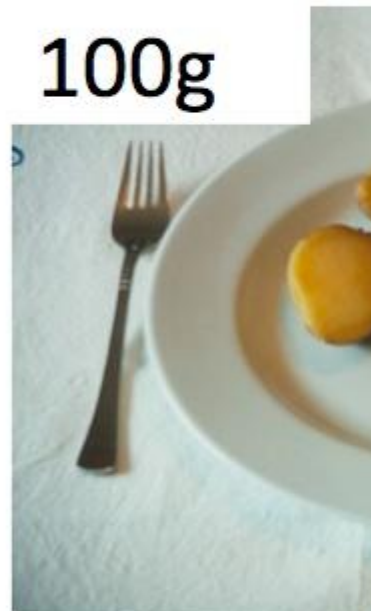If you usually ate more than one helping, choose the answer for the serving size closest to the total amount you ate.
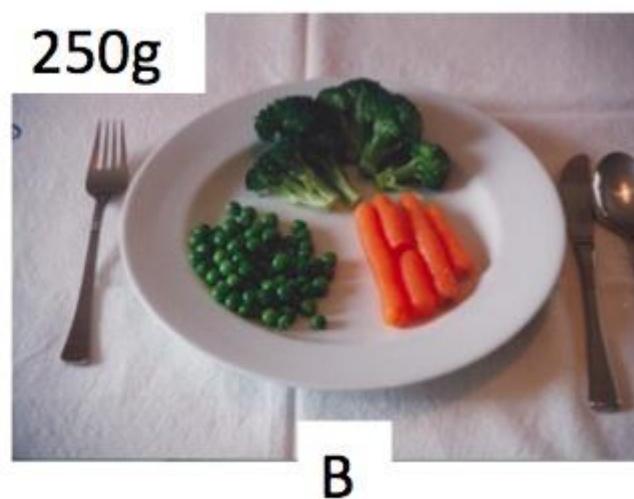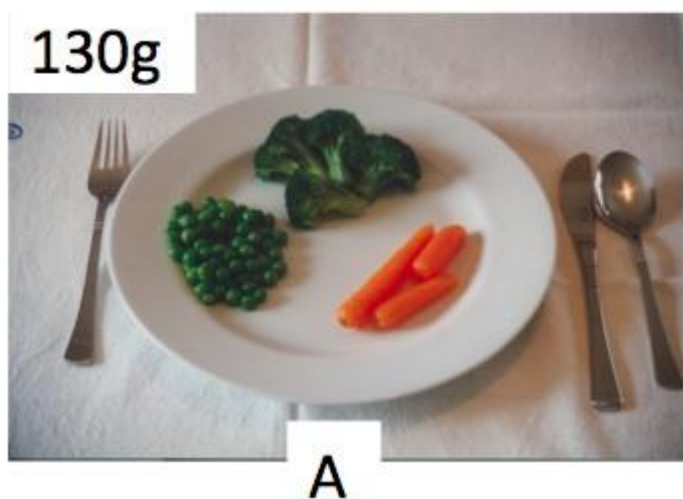
Portion Size of Potato

*18. For the following question refer to the above images of potato serving sizes. When you ate potato, did you usually eat:

- ○ I never ate potato
- ○ Less than A
- ○ A
- ○ Between A & B
- ○ B
- ○ Between B & C
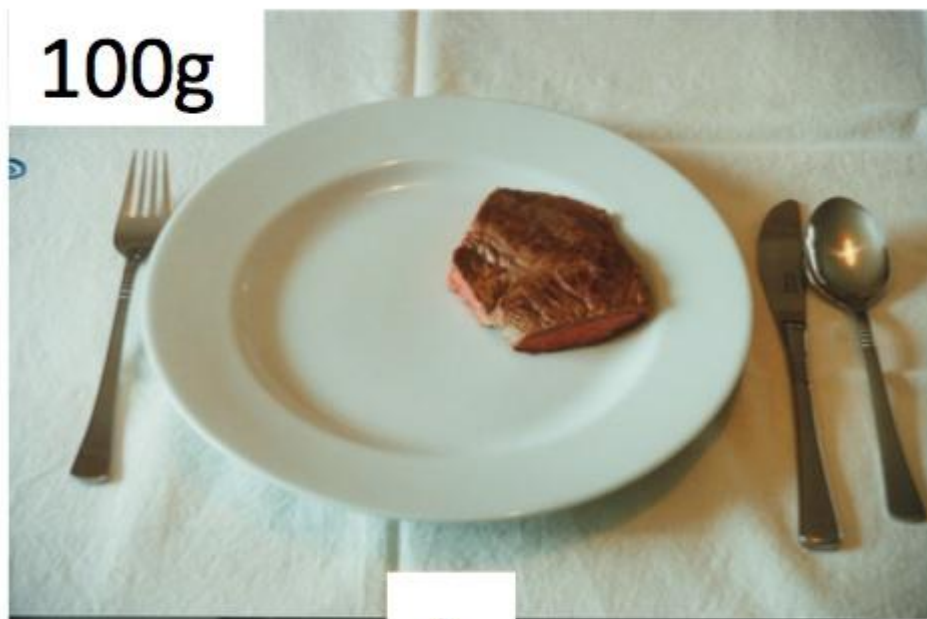- ○ C
- ○ More than C

Portion Size of Vegetables

*19. For the following question refer to the above images of vegetable serving sizes. When you ate vegetables, did you usually eat:

- ○ I never ate vegetables
- ○ Less than A
- ○ A
- ○ Between A & B
- ○ B
- ○ Between B & C
- ○ C
- ○ More than C

Portion Sizes of Steak

100g

A

125g
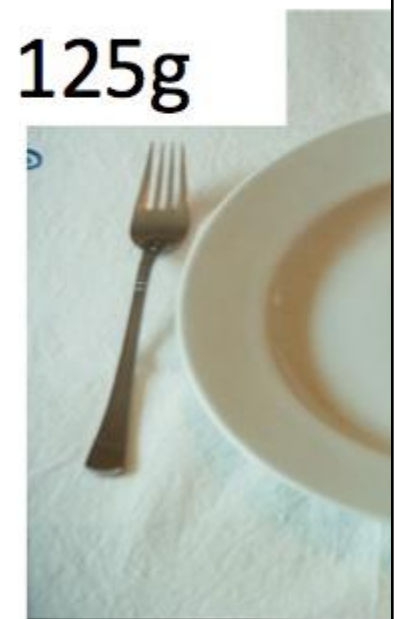
*20. For the following question refer to the above images of steak serving sizes. When you ate steak, did you usually eat:

○ I never ate steak

○ Less than A

○ A

○ Between A & B

○ B

○ Between B & C

○ C

○ More than C

Portions Sizes for Casserole

100g ... 180g

A

*21. For the following question refer to the above images of casserole serving sizes. When you ate meat or vegetable cassorole, did you usually eat:

○ I never ate casserole

○ Less than A

○ A

○ Between A & B

○ B

○ Between B & C

○ C

○ More than C

11. Section G - Physical Activity Behaviours

PLEASE ANSWER THESE QUESTIONS WITH THE PAST 3 MONTHS IN MIND (SINCE YOUR LAST ASSESSMENT SESSION AT THE UNIVERSITY)

For the following questions (Q22-Q26) we would like you to recall your average WEEKLY participation in physical activity OVER THE PAST 3 MONTHS.
How many TIMES PER WEEK on average did you do the following kinds of physical activity during your free time OVER THE PAST 3 MONTHS?

When answering these questions please:

* Consider your average amount of activity over the past 3 months.
* Only count physical activity sessions that lasted 10 minutes or longer in duration.
* Do not count physical activity that was done as part of your employment or household chores.
* Note that the main difference between the three catergories below is the intensity of the physical activity.
* Please answer with the average amount of times per week as well as the average time per session for each question - STRENUOUS, MODERATE and MILD PHYSICAL ACTIVITY.

*22. Strenuous physical activity (heart beats rapidly, sweating)
(Eg. Running, jogging, hockey, soccer, squash, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling, vigorous aerobic dance classes, heavy weight training)

Times per week	
Average time per session (minutes)	

*23. Moderate physical activity (not exhausting, light perspiration)
(eg. fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)

Times per week	
Average time per session (minutes)	

*24. Mild physical activity (minimal effort, no perspiration)
(Eg. easy walking, yoga, archery, fishing, bowling, lawn bowling, shuffleboard, horseshoes, golf, snowmobiling)

Times per week	
Average time per session (minutes)	

*25. During a typical 7-Day period (a week), in your leisure time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)?

○ Often   ○ Sometimes   ○ Never/Rarely

*26. Is the amount of activity you did in the past 3 months less, more, or about the same as your usual physical activity habits?

○ I am now much less active

○ I am now less active

○ I am now about the same

○ I am now more active

○ I am now much more active

12. Sitting Time

PLEASE ANSWER THESE QUESTIONS WITH THE PAST 3 MONTHS IN MIND (SINCE YOUR LAST ASSESSMENT SESSION AT THE UNIVERSITY)

Please estimate how much time you spend SITTING EACH DAY in the following situations. Select an hour and minute option from the drop-down list (click on the arrows next to the box)

For example
if you spend 1 hour sitting at work each day during the week, select 1 (for hours) and 0 (for minutes)
If you spend 2 hour and a half hours sitting watching television on a weekend, select 2 (for hours) and 30 (for minutes)

If you are not currently working, please select NA for Question 2: Sitting time while at work (weekday and weekend)

If you do not have an answer for a particular box, PLEASE select 'O'(zero).

*27. Please estimate how much time you spend sitting for the following situations. Please answer in HOURS and MINUTES. PLEASE place an ANSWER in EACH BOX, even if it is ZERO (N/A or 0)

	WEEKDAY (HOUR)	WEEKDAY (MIN)	WEEKEND (HOUR)	WEEKEND (MIN)
While traveling to and from places				
While at work				
While watching television				
While using a computer at home				
In your leisure time, NOT including television (i.e., visiting friends, movies, dining out etc.)				

13. Alcohol Consumption

PULSE - 6 month Questionnaire

PLEASE ANSWER THESE QUESTIONS WITH THE PAST 3 MONTHS IN MIND (SINCE YOUR LAST ASSESSMENT SESSION AT THE UNIVERSITY)

Try to answer these questions in terms of 'standard drinks' as described in the diagram below.

Please select the responses that best fits your drinking pattern over the past 3 months.

Full Strength Beer 285ml 4.8% Alcohol	Low Strength Beer 425ml 2.7% Alcohol	Pre-mix Spirits 330ml 5% Alcohol	Wine 100ml 11.5% Alcohol	Spirits 30ml 40% Alcoh

*28. How often do you have a drink containing alcohol?

- ○ Never
- ○ Monthly or less
- ○ 2-4 times a month
- ○ 2-3 times a week
- ○ 4 or more times a week

14. Alcohol Consumption

*29. How many standard drinks do you have on a typical day when you are drinking?

- ○ 1 or 2
- ○ 3 or 4
- ○ 5 or 6
- ○ 7 to 9
- ○ 10 or more

*30. How often do you have six or more standard drinks on one occasion?

○ Never

○ Less than monthly

○ Monthly

○ Weekly

○ Daily or almost daily

15. Medical History and Medications

PLEASE ANSWER THESE QUESTIONS WITH THE PAST 3 MONTHS IN MIND (SINCE YOUR LAST ASSESSMENT SESSION AT THE UNIVERSITY)
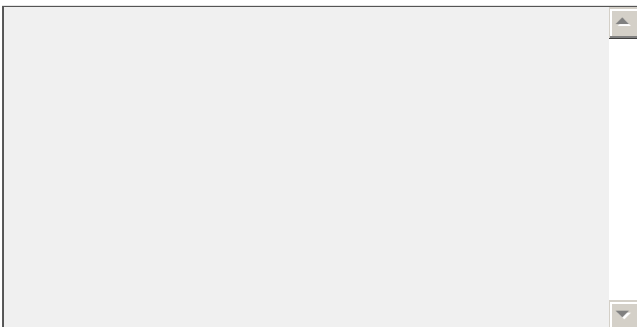
*31. Since your last assessment session have you been diagnosed with (*you can select more than one option)

☐ Type 2 Diabetes

☐ Pre-Diabetes

☐ Impaired Glucose Tolerance

☐ Impaired Fasting Glucose

☐ High blood sugar

☐ None of the above

☐ Have not visited a doctor

*32. Do you have any illness or injuries, which could affect your capacity to adhere to the diet and exercise program in this study?

○ Yes

○ no

If yes, please provide details
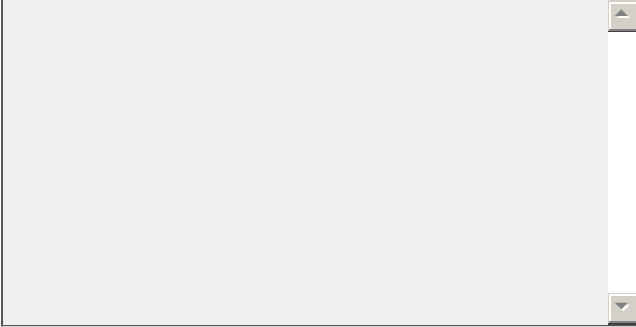
∗33. Are you currently taking any medications (prescribed by a doctor or purchased over the counter)?

○ Yes

○ No

If yes, please provide details (drug name and dose if you remember it)
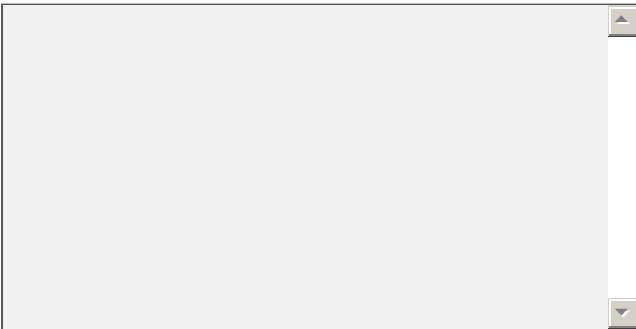
16.

34. Since your last assessment session has your doctor changed the dose or taken you off any of your medications?

○ Yes

○ No

If yes, please provide details of change in dose and/or whether you were taken off a medication
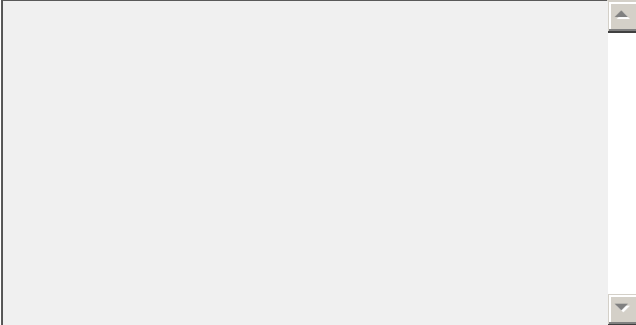
*35. Do you take any vitamin/nutrient supplements?

○ Yes

○ No

If yes, please provide details

17. Well done, you're finished!

THANK YOU FOR COMPLETING ALL QUESTIONS. YOUR CO-OPERATION IS GREATLY APPRECIATED.

Appendix 11 – Pedometer recording sheet

Type 2 Diabetes Prevention Using LifeStyle Education

Dear PULSE participant

Thank you for your interest in the University of Newcastle's PULSE study.

Please find attached the instructions for using the enclosed Pedometer. We would like you to wear the pedometer for **7-days** after your assessment session at the university.

VERY IMPORTANT!!! You need to complete your

7-day pedometer record using the **black** pedometer. PLEASE NOTE - this is NOT a test to see who can be the most active – we want to capture how active you are in a USUAL day/week. Please don't change your behaviour because you are wearing a pedometer. Just do what you would normally do.

IN FACT, TRY TO FORGET YOU ARE EVEN WEARING IT!!

Once you have completed the 7-day pedometer record, please return the pedometer and accompanying log sheet using the reply paid envelope. Please place the pedometer and record sheet inside the sealed plastic bag.

If you have any questions about how to use your pedometer, please give us a call on: 4985 4975 or email at: PULSE-study@newcastle.edu.au

Cheers

The PULSE team

How to use your Pedometer

1) The pedometer should be clipped onto your belt/pants directly in line with the middle of your right or left knee. Ensure that it sits in an upright position and does not lean forward or sideways.

2) Attach the safety leash to your pants/belt loop to prevent losing the pedometer.
3) Once the pedometer is attached, you can open it by pushing the tab on the top of the pedometer away from your body. Press the yellow/grey button to reset the device.
4) Put your pedometer on when you get out of bed in the morning and wear it all day. Only take it off if you are playing contact sports or when it might get wet.
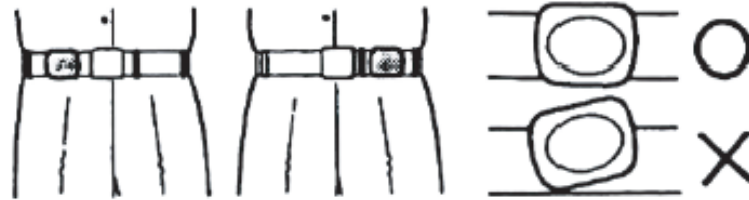5) Try to avoid looking at the pedometer throughout the day.
6) Before bed, take the pedometer off and record the number of steps for the relevant day in the table provided (pg 3). **If you did an activity like cycling, swimming, contact sports or another activity that does not involve stepping, please include details (type of activity and duration) in the "Additional Activity" section for that day.**
7) **If you forgot to wear your pedometer please indicate how long it was removed in the "Additional Activity" section for that day.**
8) Wear the pedometer for 7 days in total. If you miss a day, you can catch up this day in the following week. Eg if you miss Wednesday, wait till the following Wednesday to complete that day.
9) Once you have worn the pedometer for 7 days and completed the table, return the pedometer and this sheet in the enclosed reply paid envelope, or bring it to your assessment session. Please place the pedometer and record sheet inside the sealed plastic bag.

REMEMBER: DON'T CHANGE YOUR ACTIVITY LEVEL BECAUSE YOU ARE WEARING THE PEDOMETER, JUST DO WHAT YOU WOULD NORMALLY DO OVER THE WEEK YOU ARE WEARING IT. TRY TO FORGET YOU ARE EVEN WEARING IT!!

NB. If you lose your pedometer or have any problems with the device please email The PULSE Team, PULSE-study@newcastle.edu.au or 4985 4975. **Please understand that these devices are research grade pedometers and are expensive to replace.** We would appreciate it if you look after your pedometer and return it to us promptly at the end of the 7 day period.

Please record the number of steps for each day below. Return this sheet and the pedometer in the enclosed reply paid envelope.

FULL NAME:_____

DAY	NUMBER OF STEPS	ADDITIONAL ACTIVITY* (type and duration)
MONDAY		
TUESDAY		
WEDNESDAY		
THURSDAY		
FRIDAY		
SATURDAY		
SUNDAY		

***If you did an activity like cycling, swimming, contact sports or another activity that does not involve stepping**, please include details (type of activity and duration) in the "Additional Activity" section for that day. **If you forgot to wear your pedometer**, please indicate how long it was removed in the "Additional Activity" section for that day.

Additional Comments :

……

……

……

……

……

Appendix 12 – Process evaluation questionnaire: control group

PULSE - Program Evaluation - Group 2

1. Introduction

Thank you for participating in the PULSE study.

PRIOR to attending your 6-month assessment session we would like you to complete this questionnaire. It will take about 10-15 minutes to complete.

o Please read the instructions for each question carefully.

o Please answer every question as honestly as you can. If you are unsure about how to answer a question, mark the response for the closest answer to how you feel.

o To protect your privacy, your questionnaire data will be de-identified once your participant number has been entered and answers to the questionnaire will be kept confidential.

If you have any concerns regarding this questionnaire, please contact Mr Elroy Aguiar
Ph: (02) 4985 4975 E: PULSE-study@newcastle.edu.au

Thanks again for your participation.

Cheers

The PULSE research team

2. Identification

＊1. What is your first name?

＊2. What is your last name?

3. Participant number (Office Use Only - Please leave this box blank).

3. Recruitment

PULSE - Program Evaluation - Group 2

✱1. Which of the following aspects of the recruitment materials (e.g., posters, radio interview, newspaper article, word of mouth) made the PULSE study appealing for you?

- ☐ Mentioned type 2 diabetes prevention
- ☐ Mentioned weight loss
- ☐ Mentioned getting fit
- ☐ Men only study
- ☐ Tailored for men
- ☐ Picture of an overweight man measuring his waist
- ☐ University based
- ☐ Sounded do-able

Other (please specify)

4. Type 2 Diabetes Risk

✱1. Prior to commencing the PULSE study were you aware that you were at risk for type 2 diabetes?

- ○ Yes
- ○ No

5. Type 2 Diabetes Risk

✱1. How did you know you were at risk for type 2 diabetes?

- ☐ High blood glucose (sugar) value
- ☐ Diagnosed with pre-diabetes
- ☐ Diagnosed with impaired fast glucose (IFG)
- ☐ Diagnosed with impaired glucose tolerance (IGT)
- ☐ My doctor told me I was at risk
- ☐ Family history

Other (please specify)

6. Previous health or weight loss programs

PULSE - Program Evaluation - Group 2

Please answer the following questions regarding previous health improvement or weight loss attempts. Please be honest in your reply.

All responses will be treated in confidence.

*1. Prior to the PULSE study had you made any attempts (e.g., consulted a GP, diabetes specialist, dietitian or other health professional) to reduce your risk for type 2 diabetes?

○ Yes

○ No

If YES please specify

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*2. Prior to the PULSE study had you tried to lose weight?

○ Yes

○ No

7. Previous Weight Loss

*1. Prior to commencing the PULSE study, how many times had you tried to lose weight ?

○ Once or twice

○ 3-5 times

○ More than 5 times

*2. Prior to the PULSE study, HOW had you tried to lose weight? (you can select multiple options)

☐ Attempted weight loss on my own (e.g., did not seek advice or go on a specific program)

☐ Weight Watchers

☐ Jenny Craig

☐ Tony Ferguson

☐ Gut Busters

☐ Fat Blaster

☐ Celebrity Slim

☐ Body Trim

☐ Lemon Detox Diet

☐ Atkins (low carb) Diet

☐ Biggest Loser Club Online

☐ CSIRO Wellbeing Diet

☐ Personal Trainer

☐ Gym Membership

☐ Talked to a doctor

☐ Talked to a dietitian

☐ The SHED-IT Weight Loss Program for Blokes

Other (please specify)

*3. Did you lose any weight using those strategies/programs?

○ Yes

○ No

If YES, how much weight did you lose?

8. The PULSE study

PULSE - Program Evaluation - Group 2

*1. Since you commenced the PULSE study (i.e., in the last 6-months) have you made any OTHER attempts to reduce your risk for type 2 diabetes? (e.g., consulted a GP, diabetes specialist, dietitian or other health professional)

○ Yes

○ No

If YES, please provide some more information

[text box]

*2. Since you commenced the PULSE study (i.e., in the last 6-months), have you used any OTHER strategies to lose weight? (e.g., consulted a GP, diabetes specialist, dietitian or other health professional, other weight loss programs).

○ Yes

○ No

9. The PULSE study

PULSE - Program Evaluation - Group 2

*1. Since you commenced the PULSE study (i.e., in the last 6-months) HOW have you tried to lose weight? (you can select multiple options)

☐ Attempted weight loss on my own (e.g., did not seek advice or go on a specific program)

☐ Weight Watchers

☐ Jenny Craig

☐ Tony Ferguson

☐ Gut Busters

☐ Fat Blaster

☐ Celebrity Slim

☐ Body Trim

☐ Lemon Detox Diet

☐ Atkins (low carb) Diet

☐ Biggest Loser Club Online

☐ CSIRO Wellbeing Diet

☐ Personal Trainer

☐ Gym Membership

☐ Talked to a doctor

☐ Talked to a dietitian

☐ The SHED-IT Weight Loss Program for Blokes

Other (please specify)

10. Group Allocation

PULSE - Program Evaluation - Group 2

*1. At your initial appointment you were allocated to group 2 and told that you would start the PULSE program in 6-months. What was your initial reaction about your group allocation?

☐ I was excited to start the program in 6 months

☐ I did not mind waiting for the program

☐ I did not mind since I wasn't quite ready to start

☐ I was disappointed, but understood the importance of the 2 groups for the purpose of research

☐ I was disappointed, I wanted to start straight away

Other (please specify)

*2. Do you feel that 6-months was a reasonable amount of time to wait before you started the program?

○ Yes

○ No

Additional comments

11. Comments/Feedback

1. Do you have any additional comments or feedback about the PULSE study so far that you think might be useful for researchers?

12. Well done, you're finished!

THANK YOU FOR COMPLETING ALL QUESTIONS. YOUR PARTICIPATION IN THE STUDY IS GREATLY APPRECIATED.

Appendix 13 – Process evaluation questionnaire: intervention group

PULSE - Program Evaluation - Group 1

1. Introduction

Thank you for participating in the PULSE study.

PRIOR to attending your 6-month assessment session we would like you to complete this questionnaire. It will take about 20-25 minutes to complete.

We would like to know what you thought of the PULSE study and would be grateful if you could complete the following questions. Your responses will help us improve the program for the future.

o Please read the instructions above each question carefully.

o Please answer every question as honestly as you can. If you are unsure about how to answer a question, mark the response for the closest answer to how you feel.

o To protect your privacy, your questionnaire data will be de-identified once your participant number has been entered and answers to the questionnaire will be kept confidential.

If you have any concerns regarding this questionnaire, please contact Mr Elroy Aguiar
Ph: (02) 4985 4975 E: PULSE-study@newcastle.edu.au

Thanks again for your participation.

Cheers

The PULSE research team

THE UNIVERSITY OF
NEWCASTLE
AUSTRALIA

2. Identification

*1. What is your first name?

*2. What is your last name?

3. Participant number (Office Use Only - Please leave this box blank).

3. Recruitment

PULSE - Program Evaluation - Group 1

＊1. Which of the following aspects of the recruitment materials (e.g., posters, radio interview, newspaper article, word of mouth) made the PULSE study appealing for you?

☐ Mentioned type 2 diabetes prevention

☐ Mentioned weight loss

☐ Mentioned getting fit

☐ Men only study

☐ Tailored for men

☐ Picture of an overweight man measuring his waist

☐ University based

☐ Sounded do-able

Other (please specify)

4. Type 2 Diabetes Risk

＊1. Prior to commencing the PULSE study were you aware that you were at risk for type 2 diabetes?

○ Yes

○ No

5. Type 2 Diabetes Risk

＊1. How did you know you were at risk for type 2 diabetes?

☐ High blood glucose (sugar) value

☐ Diagnosed with pre-diabetes

☐ Diagnosed with impaired fast glucose (IFG)

☐ Diagnosed with impaired glucose tolerance (IGT)

☐ My doctor told me I was at risk

☐ Family history

Other (please specify)

6. Previous health or weight loss programs

PULSE - Program Evaluation - Group 1

Please answer the following questions regarding previous health improvement or weight loss attempts. Please be honest in your reply.

All responses will be treated in confidence.

*1. Prior to the PULSE study had you made any attempts (e.g., consulted a GP, diabetes specialist, dietitian or other health professional) to reduce your risk for type 2 diabetes?

◯ Yes

◯ No

If YES please specify

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*2. Prior to the PULSE study had you tried to lose weight?

◯ Yes

◯ No

7. Previous Weight Loss

*1. Prior to commencing the PULSE study, how many times had you tried to lose weight ?

◯ Once or twice

◯ 3-5 times

◯ More than 5 times

PULSE - Program Evaluation - Group 1

✱2. Prior to the PULSE study, HOW had you tried to lose weight? (you can select multiple options)

- ☐ Attempted weight loss on my own (e.g., did not seek advice or go on a specific program)
- ☐ Weight Watchers
- ☐ Jenny Craig
- ☐ Tony Ferguson
- ☐ Gut Busters
- ☐ Fat Blaster
- ☐ Celebrity Slim
- ☐ Body Trim
- ☐ Lemon Detox Diet
- ☐ Atkins (low carb) Diet
- ☐ Biggest Loser Club Online
- ☐ CSIRO Wellbeing Diet
- ☐ Personal Trainer
- ☐ Gym Membership
- ☐ Talked to a doctor
- ☐ Talked to a dietitian
- ☐ The SHED-IT Weight Loss Program for Blokes

Other (please specify)

[text box]

✱3. Did you lose any weight using those strategies/programs?

- ○ Yes
- ○ No

If YES, how much weight did you lose?

[text box]

8. The PULSE study

PULSE - Program Evaluation - Group 1

*1. Since you commenced the PULSE study (i.e., in the last 6 months) have you used any OTHER strategies to reduce your risk for type 2 diabetes? (e.g., consulted a GP, diabetes specialist, dietitian or other health professional)

○ Yes

○ No

If YES, please provide some more information

[text box]

*2. Since you commenced the PULSE study (i.e., in the last 6 months), have you used any OTHER strategies to lose weight? (e.g., consulted a GP, diabetes specialist, dietitian or other health professional, other weight loss programs).

○ Yes

○ No

9. The PULSE study

PULSE - Program Evaluation - Group 1

*1. Since you commenced the PULSE study (i.e., in the last 6 months) HOW have you tried to lose weight? (you can select multiple options)

☐ Attempted weight loss on my own (e.g., did not seek advice or go on a specific program)

☐ Weight Watchers

☐ Jenny Craig

☐ Tony Ferguson

☐ Gut Busters

☐ Fat Blaster

☐ Celebrity Slim

☐ Body Trim

☐ Lemon Detox Diet

☐ Atkins (low carb) Diet

☐ Biggest Loser Club Online

☐ CSIRO Wellbeing Diet

☐ Personal Trainer

☐ Gym Membership

☐ Talked to a doctor

☐ Talked to a dietitian

☐ The SHED-IT Weight Loss Program for Blokes

Other (please specify)

10. Group Allocation

*1. At your initial appointment you were allocated to group 1 and told that you would start the program straight away. What was your initial reaction about your group allocation?

☐ Excited - I wanted to start straight away

☐ Neutral - I would not have minded which group I was allocated to

☐ Uncertain - I would have preferred group 2 (starting 6 months later) as I wasn't quite ready to start

☐ Disappointed - I did not want to start straight away

Other (please specify)

11. The PULSE study resources

The following questions relate to the PULSE 'Type 2 Diabetes Prevention for Blokes' handbook (the red A4 book)

PLEASE PROVIDE RESPONSES TO THE FOLLOWING STATEMENTS OR QUESTIONS WITH RESPECT TO THE LAST 6 MONTHS (I.E., SINCE YOU STARTED THE PULSE STUDY). WE WANT TO KNOW WHICH OF THE SUGGESTIONS YOU HAVE USED.

*1. The PULSE 'Type 2 Diabetes Prevention for Blokes' handbook increased my understanding of type 2 diabetes

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*2. The 'Type 2 Diabetes Prevention for Blokes' handbook was enjoyable to read.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*3. How often did you read the 'Type 2 Diabetes Prevention for Blokes' handbook?

○ Never   ○ Once   ○ Twice   ○ Three or more times

*4. The 'Type 2 Diabetes Prevention for Blokes' handbook was:

○ Too Short

○ About right

○ Too Long

*5. I now try to 'create a colourful plate' by including a greater variety of foods (e.g. vegetables and fruit) in a meal.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*6. I now try to eat more low GI (glycaemic index) foods e.g., fruits and vegetables, wholegrain breads and cereals, low fat milk, low fat yoghurt and nuts.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*7. I now try to include more healthy (monounsaturated and polyunsaturated) fats in my diet e.g., nuts, oily fish, healthy oils.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*8. I now try to avoid or limit unhealthy (saturated) fats in my diet, e.g., butter, cream, full cream milk, full fat cheese, fatty cuts of meat.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*9. I now try to include lean cuts of meat and other sources of protein in my diet.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

＊10. I now try to include more fibre in my diet, e.g., wholegrain bread and cereals, lentils, beans, fruits and vegetables.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

＊11. I now eat 5 serves of vegetables

○ 0 days per week   ○ 1-2 day per week   ○ 3-4 days per week   ○ 5-6 days per week   ○ 7 days per week

＊12. I now eat 2 serves of fruit

○ 0 days per week   ○ 1-2 day per week   ○ 3-4 days per week   ○ 5-6 days per week   ○ 7 days per week

＊13. I now skip meals

○ 0 days per week   ○ 1-2 day per week   ○ 3-4 days per week   ○ 5-6 days per week   ○ 7 days per week

＊14. I now eat breakfast

○ 0 days per week   ○ 1-2 day per week   ○ 3-4 days per week   ○ 5-6 days per week   ○ 7 days per week

＊15. I now pack my lunch or choose healthy options if I have to buy lunch

○ 0 days per week   ○ 1-2 day per week   ○ 3-4 days per week   ○ 5-6 days per week   ○ 7 days per week

＊16. I now avoid eating meals or snacking late at night

○ 0 days per week   ○ 1-2 day per week   ○ 3-4 days per week   ○ 5-6 days per week   ○ 7 days per week

＊17. I now try to 'move after meals'

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

12. The PULSE study resources

The following questions relate to the 'PULSE Exercise Support Book for Blokes' (the red A5 book)

PLEASE RESPOND THE FOLLOWING QUESTIONS AND STATEMENTS WITH RESPECT TO THE LAST 6 MONTHS (I.E., SINCE YOU STARTED THE PULSE STUDY)

＊1. The PULSE 'Exercise Support Book for Blokes' was useful.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*2. How did you record your exercise sessions? (you can select more than one option)

☐ Exercise Support Book for Blokes

☐ Calorieking

☐ MyFitnessPal

☐ Other

Please provide details

[text box]

*3. I found the PULSE pedometer useful.

○ Strongly Agree ○ Agree ○ Neutral ○ Disagree ○ Strongly Disagree

*4. I found the body weight exercises useful.

○ Strongly Agree ○ Agree ○ Neutral ○ Disagree ○ Strongly Disagree

*5. I found the gymstick useful.

○ Strongly Agree ○ Agree ○ Neutral ○ Disagree ○ Strongly Disagree

*6. I usually do 30 minutes (or more) of aerobic exercise (walk, jog, swim, cycle).

○ 0 times per week ○ 1-2 times per week ○ 3-4 times per week ○ 5-6 times per week ○ 7 times per week

*7. I usually do 30 minutes (or more) of resistance training (body weight, gymstick, free weights, machine weights)

○ 0 times per week ○ 1-2 times per week ○ 3-4 times per week ○ 5-6 times per week ○ 7 times per week

*8. I feel that my endurance fitness has improved since commencing the PULSE study (i.e., in the last 6 months).

○ Strongly Agree ○ Agree ○ Neutral ○ Disagree ○ Strongly Disagree

*9. I feel that I have gotten stronger since commencing the PULSE study (i.e., in the last 6 months).

○ Strongly Agree ○ Agree ○ Neutral ○ Disagree ○ Strongly Disagree

13. The SHED-IT Weight Loss program

The following questions relate to the
- SHED-IT Weight Loss DVD for Blokes
- SHED-IT Weight Loss Handbook for Blokes (the blue A4 book)
- SHED-IT Weight Loss Log Book for blokes' (the blue A5 book)

PLEASE ANSWER THE FOLLOWING QUESTIONS WITH RESPECT TO THE LAST 6 MONTHS (I.E., SINCE YOU STARTED THE PULSE STUDY)

*1. The SHED-IT weight loss program provided me with the information I needed to help me lose weight.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*2. The SHED-IT weight loss program improved my understanding of physical activity, nutrition and weight loss.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*3. The 'SHED-IT Weight Loss Handbook for Blokes' was enjoyable to read.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*4. How often did you read the 'SHED-IT Weight Loss Handbook for Blokes'?

○ Never   ○ Once   ○ Twice   ○ Three or more times

*5. The 'Mathematics of Weight Loss' (energy balance) was explained in a way that was easy to understand.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*6. Which of 'The 9 Best Weight Loss Tips for Men' did you use? (you can choose more than one)

☐ Read Food Labels

☐ Keep a Healthy Lifestyle Diary

☐ Reduce Kilojoule-dense Snacks

☐ Be Prepared

☐ Every Step Counts

☐ Reduce your Sitting Time

☐ Surf the Urge

☐ Reduce your Portion Sizes

☐ Don't Drink your Kilojoules

*7. The 'SHED-IT Weight Loss DVD for Blokes' was enjoyable to watch.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*8. How often did you watch the 'SHED-IT Weight Loss DVD for Blokes'?

○ Never   ○ Once   ○ Twice   ○ Three or more times

14. Calorieking Website

PULSE - Program Evaluation - Group 1

*1. Have you used the Calorieking website since commencing the PULSE program? (i.e., at some point in the last 6 months)

○ Yes

○ No

15. Calorieking Website

*1. The Calorieking website was easy to use.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*2. Using the Calorieking website to record my food and exercise was time consuming.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*3. The Calorieking website was a valuable tool to help me understand how to lose weight.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*4. The Calorieking user guide was useful.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

16. MyFitnessPal

*1. Have you used the MyfitnessPal app since you commenced the PULSE program? (i.e., at some point in the last 6 months)

○ Yes

○ No

17. MyFitnessPal

*1. The MyFitnessPal App was easy to use.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*2. Using the MyFitnessPal App to record my food and exercise was time consuming.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*3. The MyFitnessPal App was a valuable tool to help me understand how to lose weight.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*4. The MyFitnessPal App user guide was useful.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

18. The PULSE study

*1. I believe that my participation in the PULSE study has decreased my risk of type 2 diabetes.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*2. Being part of a research study has helped me to stick to the program? (i.e., health eating, exercise and weight loss)

○ Strongly Agree

○ Agree

○ Neutral

○ Disagree

○ Strongly Disagree

*3. Knowing that I was accountable (i.e., being followed up by the PULSE team) motivated me to stick to the program (i.e., healthy eating, exercise and weight loss).

○ Strongly agree

○ Agree

○ Neutral

○ Disagree

○ Strongly disagree

*4. There was too much reading to do for the PULSE study.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*5. I would prefer a program that had more regular face-to-face contact than the PULSE study.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*6. As a result of my participation in the PULSE study other members of my family have started to make healthier food choices.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*7. As a result of my participation in the PULSE study other members of my family have become more active.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*8. As a result of my participation in the PULSE study other members of my family have lost weight.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*9. As a result of my participation in the PULSE study one or more of my friends have lost weight.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*10. I have had conversations with friends, co-workers and/or relatives about the PULSE study and the strategies I have learned to reduce my risk for type 2 diabetes.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*11. I would recommend the PULSE study to my friends.

○ Strongly Agree   ○ Agree   ○ Neutral   ○ Disagree   ○ Strongly Disagree

*12. Do you think people you know would be willing to pay for the 6-month PULSE program?

○ Yes

○ No

*13. How much do you think people you know would be willing to pay for the 6-month PULSE program?

[   ]

14. What did you like about the PULSE program?

[   ]

15. Was there anything about the PULSE program that you did not like?

[   ]

16. How can we make the PULSE program better?

17. Do you have any additional comments or feedback about the PULSE study that you think might be useful for researchers?

*18. **Would you be willing to be interviewed about your involvement in the PULSE study?**

○ Yes

○ No

19. Well done, you're finished!

THANK YOU FOR COMPLETING ALL QUESTIONS. YOUR PARTICIPATION IN THE STUDY IS GREATLY APPRECIATED.

Appendix 14 – Statement of contribution: Chapter 2

I attest that Research Higher Degree candidate Elroy Aguiar contributed substantially in terms of study concept and design, data collection, analysis, and preparation of the following manuscript:

Reference:

Aguiar EJ, Morgan PJ, Collins CE, Plotnikoff RC, Callister R. Efficacy of interventions that include diet, aerobic and resistance training components for type 2 diabetes prevention: a systematic review with meta-analysis. Int J Behav Nutr Phys Act. 2014;11. doi:10.1186/1479-5868-11-2

Signature: _____

Professor Robin Callister (Primary Supervisor)

Date: _____

Appendix 15 – Statement of contribution: Chapter 3

I attest that Research Higher Degree candidate Elroy Aguiar contributed substantially in terms of study concept and design, data collection, analysis, and preparation of the following manuscript:

Reference:

Aguiar EJ, Morgan PJ, Collins CE, Plotnikoff RC, Young MD, Callister R. The PULSE (Prevention Using LifeStyle Education) trial protocol: a randomised controlled trial of a Type 2 Diabetes Prevention programme for men. Contemp Clin Trials. 2014;39:132-144. doi:10.1016/j.cct.2014.07.008

Signature: _____

Professor Robin Callister (Primary Supervisor)

Date: _____

Appendix 16 – Statement of contribution: Chapter 4

I attest that Research Higher Degree candidate Elroy Aguiar contributed substantially in terms of study concept and design, data collection, analysis, and preparation of the following manuscript:

Reference:

Aguiar EJ, Morgan PJ, Collins CE, Plotnikoff RC, Callister R. Characteristics of men classified at high-risk for type 2 diabetes mellitus using the AUSDRISK screening tool. Diabetes Res and Clin. 2015;108:45-54.

doi: 10.1016/j.diabres.2015.01.017

Signature: _____

Professor Robin Callister (Primary Supervisor)

Date: _____

Appendix 17 – Statement of contribution: Chapter 5

I attest that Research Higher Degree candidate Elroy Aguiar contributed substantially in terms of study concept and design, data collection, analysis, and preparation of the following manuscript:

Reference:

Aguiar EJ, Morgan PJ, Collins CE, Plotnikoff RC, Young MD, Callister R.

Efficacy of the type 2 diabetes PULSE Program randomised controlled trial. Am

J Prev Med (in press)

Signature: _____

Professor Robin Callister (Primary Supervisor)

Date: _____

Appendix 18 – Acceptance letter: Chapter 5

AJPM Editorial Decision – Inbox

Message

AJPM Editorial Decision

American Journal of Preventive Medicine sent by ees.ajpm.0.321a6c.bf77cf90@eesmail.elsevier.com

Sent: Tuesday, 23 June 2015 4:49 AM
To: Elroy Aguiar

You forwarded this message on 23/06/15 9:24 AM.
Show Forward

Dear Mr. Aguiar:

Thank you for submitting your manuscript (#15-0127-0104R), entitled "Efficacy of the type 2 diabetes PULSE Program randomized controlled trial," to the American Journal of Preventive Medicine.

The editors ask that you revise the manuscript again to address the reviewer concerns listed below.

To revise the manuscript, please resubmit it (with changes noted by highlighting) via ees at http://ees.elsevier.com/ajpm/; go to "Submissions needing revisions" folder. Also, respond to the reviewer and/or editor comments in a cover letter. Please submit your re-revised manuscript by July 13, 2015.

If you have any questions, please contact Angela Beck, Managing Editor, at the Editorial Office: 734-764-8775 or ajpm@umich.edu.

Sincerely,
Matthew L. Boulton, MD, MPH
Editor-in-Chief

William Wadland, MD, MS
Deputy Editor

American Journal of Preventive Medicine
University of Michigan
1415 Washington Heights
Ann Arbor, MI 48109-2029
Tel: 734-936-1590
Fax: 734-936-1615
Email: ajpm@umich.edu

REVIEWERS' COMMENTS (SEE BELOW):

Reviewer #3: Thank you for making revisions to this paper. These have addressed my comments for the most part. Just a couple of outstanding issues ..

1. Cohen's d may be larger than reported here in the abstract and Table 2 (it should be based on the