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The *PULSE (Prevention Using LifeStyle Education)* trial protocol: a randomised controlled trial of a Type 2 Diabetes Prevention programme for men

Elroy J. Aguiar [a,b,*], Philip J. Morgan [a,c], Clare E. Collins [a,d], Ronald C. Plotnikoff [a,c], Myles D. Young [a,c], Robin Callister [a,b]

[a] *Priority Research Centre for Physical Activity and Nutrition, University of Newcastle, University Drive, Callaghan, NSW 2308, Australia*
[b] *School of Biomedical Sciences and Pharmacy, Faculty of Health and Medicine, University of Newcastle, University Drive, Callaghan, NSW 2308, Australia*
[c] *School of Education, Faculty of Education and Arts, University of Newcastle, University Drive, Callaghan, NSW 2308, Australia*
[d] *School of Health Sciences, Faculty of Health and Medicine, University of Newcastle, University Drive, Callaghan, NSW 2308, Australia*

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ABSTRACT

Background: Intensive lifestyle interventions have been successful in reducing type 2 diabetes incidence. Whether intensive programmes requiring face-to-face contact, trained staff and access to facilities are feasible, on a larger scale, has been debated.
Objectives: The aim of this study 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*) *Programme for Men*' is a 6-month, self-administered, gender-tailored lifestyle intervention, with a multicomponent approach (weight loss, dietary modification, aerobic exercise and resistance training). Eligible men were aged 18–65 years, overweight/obese (BMI 25–40 $kg \cdot m^{-2}$) 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 ($kg \cdot m^{-2}$: 25–29.9; 30–34.9; 35–40) to the intervention or wait-list control group. Data are collected at study entry (baseline), 3 and 6 months. The primary outcome is weight change at 6 months. Secondary outcomes include: fasting plasma glucose, HbA_{1C}, waist circumference, body composition, blood pressure, diet quality, aerobic fitness, muscular fitness and physical activity. Generalised linear mixed models (intention-to-treat) will assess outcomes for treatment (intervention vs. control), time (baseline, 3 and 6-months) and the treatment-by-time interaction.

Abbreviations: AES, Australian Eating Survey; ANZCTR, Australian New Zealand Clinical Trials Registry; AUDIT-C, Alcohol Use Disorders Identification Test; AUSDRISK, Australian diabetes risk tool; BMI, body mass index; BW, body weight; cm, centimetre; CONSORT, Consolidated Standards of Reporting Trials; DPP, diabetes prevention programme; DPS, Diabetes Prevention Study; DQES, Dietary Questionnaire for Epidemiological Studies; DVD, digital video disc; E%, percentage of total energy intake; FFQ, food frequency questionnaire; FPG, fasting plasma glucose; g, gram; GI, glycaemic Index; GS, *Gymstick™*; h, hour; HAPS, Hunter Area Pathology Service; HbA_{1C}, glycosylated haemoglobin; HDL, high density lipoprotein; HOMA-IR, Homeostatic Model Assessment-Insulin Resistance; kg, kilograms; kJ, kilojoule; km, kilometre; L, litre; LDL, low density lipoprotein; m, metre; mg, milligrams; min, minute; mIU, milli-international units; mL, millilitre; mmol, millimoles; n, sample size; PSF, Portion Size Factor; *PULSE*, *Prevention Using LifeStyle Education*; QUICKI, Quantitative Insulin Sensitivity Check Index; RCT, randomised controlled trial; reps, repetitions; RPM, repetitions per minutes; RT, resistance training; s, seconds; SCT, social cognitive theory; SD, standard deviation; SEIFA, Socio-Economic Indexes for Areas; SES, socioeconomic status; SF-12, short form 12; *SHED-IT*, *Self-Help, Exercise and Diet using Internet Technology*; T2D, type 2 diabetes; U, units; US, United States; VO_{2max}, maximal oxygen uptake; μmol, micromoles.

* Corresponding author at: Priority Research Centre for Physical Activity and Nutrition, University of Newcastle, University Drive, Callaghan, NSW 2308, Australia. Tel.: +61 2 4985 4975.
E-mail addresses: Elroy.Aguiar@newcastle.edu.au (E.J. Aguiar), Philip.Morgan@newcastle.edu.au (P.J. Morgan), Clare.Collins@newcastle.edu.au (C.E. Collins), Ron.Plotnikoff@newcastle.edu.au (R.C. Plotnikoff), Myles.Young@newcastle.edu.au (M.D. Young), Robin.Callister@newcastle.edu.au (R. Callister).

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Conclusion: The results will determine the efficacy of a type 2 diabetes prevention programme for men with potential for wide reach and dissemination.
Trial Registration: Australian New Zealand Clinical Trials Registry (ACTRN12612000721808).

1. Introduction

1.1. Background

Diabetes prevalence is rising globally [1]. 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 [1]. Individuals with type 2 diabetes (T2D) have a high risk of cardiovascular disease, retinopathy, nephropathy and neuropathy [2]. It is possible to prevent/delay progression to T2D with lifestyle interventions (e.g., US Diabetes Prevention Program [DPP] [3]; Finnish Diabetes Prevention Study [DPS] [4]), which may increase life expectancy and quality of life, and reduce health care costs [2]. Whether these highly intensive lifestyle programmes requiring face-to-face contact, trained staff and access to facilities are feasible, on a larger scale, has been questioned [5,6]. 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 [7]. The direct cost of the intervention was US$1399 per person over one year, with 54% (US$750) of the cost attributed to staffing [8]. There is a need for effective programmes 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 [9], however there is a paucity of information regarding the feasibility and efficacy of self-administered interventions for T2D 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 [10], however efficacy needs to be established [11,12]. Therefore rigorous trials investigating the feasibility and efficacy of self-administered multicomponent (weight loss, dietary modification, exercise) lifestyle interventions for T2D prevention are needed. Self-administered lifestyle interventions may also be particularly appealing to men who tend to favour programmes that do not require regular face-to-face individual or group sessions [13]. Furthermore, the novel use of a gender-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 programme efficacy.

1.2. Objectives and hypothesis

The aims of this study are to determine the feasibility and efficacy of the "*Type 2 Diabetes PULSE* (*Prevention Using LifeStyle Education*) *Programme for Men*", to improve T2D risk biomarkers in overweight/obese men at risk of T2D (including men already diagnosed with prediabetes). The *PULSE Programme* is a 6-month, self-administered, gender-tailored, multicomponent (weight loss, dietary modification and aerobic exercise + resistance training) lifestyle intervention. We hypothesise that the *PULSE Programme* 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 addresses several evidence gaps in the field of T2D prevention, including the feasibility and efficacy of: i) self-administered lifestyle interventions, ii) multicomponent lifestyle interventions incorporating weight loss strategies, dietary modification, aerobic exercise and resistance training [14], and iii) home-based resistance training [10]. To our knowledge this will also be the first T2D prevention trial gender-tailored for men.

2. Research design and methods

2.1. Study design

This study is an assessor-blinded, parallel-group randomised controlled trial (RCT) for overweight/obese men at high risk of T2D. Eligible participants were stratified (age, BMI) and then randomised to either the 6-month *PULSE Programme* intervention or a wait-list control group. Fig. 1 describes the study flow from recruitment through to baseline and assessments at 3 and 6 months (primary time point). The study is approved by the institution's Human Research Ethics Committee. The study is registered with the Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12612000721808. The design, conduct and reporting of this study will adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [15,16].

2.2. Participants: eligibility, recruitment and screening

The trial recruited overweight/obese men at high risk for T2D, including those already diagnosed with prediabetes. The eligibility and exclusion criteria are described in Table 1. High risk for T2D was based on a score $\geq$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 and has now been completed. 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 1), which included the AUSDRISK tool. Men were also required to pass an adult pre-exercise screening questionnaire [18]. The trial did not exclude men based on their current medication regimen unless a particular medication was