



DEFINITIONS



HINTS AND TIPS



FAQs



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Trial Review

Please note that ANZCTR will be unattended from Friday 16th December 2016 until Tuesday 3rd January 2017 due to annual University of Sydney closedown.

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Trial registered on ANZCTR

Trial ID	ACTRN12612000721808
Ethics application status	Approved
Date submitted	4/07/2012
Date registered	5/07/2012
Type of registration	Prospectively registered

Titles & IDs

Public title	The Type 2 Diabetes PULSE study: a research trial to determine the effectiveness of a multi-component prevention program (diet, aerobic exercise, resistance training) for men at high risk of Type 2 Diabetes
Scientific title	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
Secondary ID [1]	Nil
Universal Trial Number (UTN)	U1111-1131-3596
Trial acronym	The Type 2 Diabetes PULSE study - Prevention Using LifeStyle Education
Linked study record	

Health condition

Health condition(s) or problem(s) studied:

Pre-diabetes

Type 2 Diabetes

Obesity

Metabolic syndrome

Condition category

Metabolic and Endocrine

Diet and nutrition

Cardiovascular

Condition code

Diabetes

Obesity

Diseases of the vasculature and circulation including the lymphatic system

Intervention/exposure

Study type	Interventional
Description of intervention(s) / exposure	<p>A 6-month randomised controlled trial of a novel Type 2 Diabetes prevention intervention: The Type 2 Diabetes PULSE study - Prevention Using Lifestyle Education.</p> <p>The Type 2 Diabetes PULSE intervention will consist of a diet and exercise (aerobic and resistance training) program. Men in the intervention group will receive a resource pack with information regarding Type 2 Diabetes prevention.</p>

The dietary intervention will consist of a resource manual with information/tips to improve diet quality and reduce Type 2 Diabetes risk such reducing overall energy intake, reading food labels, reducing portion size, reducing alcohol and sugared beverages, improving quality of diet (low GI carbohydrates, high fibre, low saturated fat), achieving an ideal macronutrient (carbohydrates-fat-protein) profile, reducing salt intake, and increasing fruit and vegetable intake. The participants will be asked to enter their dietary intake into a food and exercise diary (www.calorieking.com.au). The participants will not be prescribed a specific diet or meal plan.

The exercise intervention will consist of both aerobic and resistance training and will be self-administered over the duration of the 6-month intervention. Men will be asked to perform at least 150 mins/wk (5 x 30 min sessions) of moderate intensity aerobic exercise (e.g., walking, jogging, swimming, cycling) and at least 60 mins/wk (2 x 30 min sessions) of resistance training using body weight and Gymstick (an elastic tubing) exercises. The exercise resource manual will provide thorough instruction on how to safely perform the exercise. Participants will also receive an instruction video demonstrating the technique of the prescribed Gymstick and bodyweight exercises. These exercises will be conducted in their homes and will not be supervised. The participants will be also be asked to record the amount of exercise they do in an exercise log book and also into a food and exercise diary (www.calorieking.com.au)

Men will be assessed at baseline, 3- and 6-months on a range of health outcomes. Primary outcomes for the study are weight and fasting plasma glucose. Secondary outcomes will include anthropometric, plasma biomarker, and diet and exercise/fitness measures.

The wait-list control group will receive the intervention after the 6-month time-point and will be followed up for a further 6 months.

Intervention code [1]	Prevention
Intervention code [2]	Lifestyle
Intervention code [3]	Behaviour
Comparator / control treatment	Wait-list control
Control group	Active

Outcomes

Primary outcome [1]	Weight (kg)
<i>Timepoint [1]</i>	Baseline, 3 and 6-months
Secondary outcome [1]	Fasting Plasma Glucose (FPG) (mmol/L)
<i>Timepoint [1]</i>	Baseline, 3 and 6-months
Secondary outcome [2]	Body Mass Index (BMI) - kg/m ²
<i>Timepoint [2]</i>	Baseline, 3 and 6-months
Secondary outcome [3]	Body composition (fat mass % and fat free mass %), using the Inbody 720 bioimpedance analyser.
<i>Timepoint [3]</i>	Baseline, 3 and 6-months
Secondary outcome [4]	Fasting insulin (mmol/L), obtained from a fasting blood sample
<i>Timepoint [4]</i>	Baseline, 3 and 6-months
Secondary outcome [5]	HOMA - Homeostatic Model Assessment for insulin resistance
<i>Timepoint [5]</i>	Baseline, 3 and 6-months
Secondary outcome [6]	QUICKI - Quantitative Insulin Sensitivity Check Index
<i>Timepoint [6]</i>	Baseline, 3 and 6-months
Secondary outcome [7]	Glycosylated haemoglobin (%) - obtained from a fasting blood sample
<i>Timepoint [7]</i>	Baseline, 3 and 6-months
Secondary outcome [8]	Fructosamine (mmol/L) - obtained from a fasting blood sample
<i>Timepoint [8]</i>	Baseline, 3 and 6-months
Secondary outcome [9]	Cholesterols - HDL, LDL and total (mmol/L) - obtained from a fasting blood sample
<i>Timepoint [9]</i>	Baseline, 3 and 6-months
Secondary outcome [10]	Triglycerides (mmol/L) - obtained from a fasting blood sample
<i>Timepoint [10]</i>	Baseline, 3 and 6-months
Secondary outcome [11]	C-reactive protein (nmol/L) - obtained from a fasting blood sample
<i>Timepoint [11]</i>	Baseline, 3 and 6-months
Secondary outcome [12]	Uric acid (mg/dl) - obtained from a fasting blood sample
<i>Timepoint [12]</i>	Baseline, 3 and 6-months
Secondary outcome [13]	Omega-3 index (%) - obtained from a fasting blood sample

Timepoint [13]	Baseline, 3 and 6-months
Secondary outcome [14]	Blood pressure (mmHg) using a standard sphygmomanometer with brachial cuff
	Arterial stiffness markers (central pulse pressure, mmHg, and augmentation index, %) using the Sphygmocor CPV system
Timepoint [14]	Baseline, 3 and 6-months
Secondary outcome [15]	Dietary intake (Australian Eating Survey food frequency questionnaire)
	Daily kJ intake % macro-nutrients
Timepoint [15]	Baseline, 3 and 6-months
Secondary outcome [16]	Portion size questionnaire (DQES Victorian Cancer council)
Timepoint [16]	Baseline, 3 and 6-months
Secondary outcome [17]	Alcohol consumption questionnaire (AUDIT)
Timepoint [17]	Baseline, 3 and 6-months
Secondary outcome [18]	Aerobic fitness - sub-maximal treadmill test for VO ₂ max prediction (mL/kg/min)
Timepoint [18]	Baseline, 3 and 6-months
Secondary outcome [19]	Muscular fitness (using barbell free weights) Upper body strength - 5RM shoulder press (max kg) Upper body endurance - 70% 1RM shoulder press (max repetitions)
	Lower body endurance - body weight squat (max repetitions)
Timepoint [19]	Baseline, 3 and 6-months
Secondary outcome [20]	Physical Activity - pedometers (steps/day)
Timepoint [20]	Baseline, 3 and 6-months
Secondary outcome [21]	Waist circumference at two points using a non-distensible steel measuring tape. 1) Narrowest point between the lower costal border and the top of the iliac crest. 2) Level with the umbilicus
Timepoint [21]	Baseline, 3 and 6-months

Eligibility

Key inclusion criteria	Inclusion criteria - Aged 18-65 years - Overweight or obese men with a body mass index (BMI) between 25 and 40 kg/m ² - An AUSDRISK score of >12 i.e., high risk - Obtained a GP clearance if required confirming they are able to participate in a diet and exercise program - Agree to not participate in other weight loss programs during the study - Pass a health-screening questionnaire - Available for assessment sessions - Have access to a computer with e-mail and Internet facilities
Minimum age	18 Years
Maximum age	65 Years
Gender	Males
Can healthy volunteers participate?	No
Key exclusion criteria	Exclusion criteria - Have T2D or a history of major medical problems such as heart disease - Have orthopaedic or joint problems that would be a barrier to physical activity such as walking, running and resistance training - Recently lost 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

Study design

Purpose of the study	Prevention
Allocation to intervention	Randomised controlled trial
Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)	Participants will be required to pass an eligibility screening and health screening questionnaire. They may be required to obtain a doctors certificate for certain health circumstances. If eligible, they must read the study information statement, and sign and return a consent form indicating they understand the requirement of their participation in the study. Participants will be randomised at an individual level by the trial statistician who will not have any contact

with participants during the trial (see details below). Randomisation codes will be stored in a restricted computer folder, which is not accessible by those assessing participants, those involved in group allocating participants or those participating in data entry for the study.

Methods used to generate the sequence in which subjects will be randomised (sequence generation)

Randomisation into groups will be stratified by BMI category calculated at the baseline assessment (overweight, obese I, obese II) and age categories. The allocation sequence within strata will be generated by a computer-based random number-producing algorithm.

Masking / blinding

Blinded (masking used)

Who is / are masked / blinded?

Intervention assignment

Parallel

Other design features

Wait-list control group will receive the intervention at the 6- months time-point. They will be followed up 6-months later (12 month time-point)

Phase

Not Applicable

Type of endpoint(s)

Efficacy

Recruitment

Recruitment status

Completed

Anticipated date of first participant enrolment

1/08/2012

Actual date of first participant enrolment

24/08/2012

Anticipated date last participant enrolled

Actual date last participant enrolled

7/03/2013

Anticipated date of last data collection

Actual date of last data collection

24/09/2013

Target sample size

150

Actual sample size

101

Recruitment in Australia

Recruitment state(s)

ACT,NSW

Recruitment postcode(s) [1]

2278

Recruitment postcode(s) [2]

2282

Recruitment postcode(s) [3]

2284

Recruitment postcode(s) [4]

2285

Recruitment postcode(s) [5]

2286

Recruitment postcode(s) [6]

2287

Recruitment postcode(s) [7]

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Recruitment postcode(s) [8]

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Recruitment postcode(s) [15]

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Recruitment postcode(s) [16]

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Recruitment postcode(s) [18]

2300

Recruitment postcode(s) [19]

2302

Recruitment postcode(s) [20]

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Recruitment postcode(s) [21]

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Recruitment postcode(s) [22]

2305

Recruitment postcode(s) [23]	2306
Recruitment postcode(s) [24]	2307
Recruitment postcode(s) [25]	2308
Recruitment postcode(s) [26]	2309
Recruitment postcode(s) [27]	2310
Recruitment postcode(s) [28]	2311
Recruitment postcode(s) [29]	2312
Recruitment postcode(s) [30]	2314
Recruitment postcode(s) [31]	2315
Recruitment postcode(s) [32]	2316
Recruitment postcode(s) [33]	2317
Recruitment postcode(s) [34]	2318
Recruitment postcode(s) [35]	2319
Recruitment postcode(s) [36]	2320
Recruitment postcode(s) [37]	2321
Recruitment postcode(s) [38]	2322
Recruitment postcode(s) [39]	2323
Recruitment postcode(s) [40]	2324 - Balickera

Funding & Sponsors

Funding source category [1]	Government body
Name [1]	Hunter Medical Research Institute
Address [1]	Hunter Medical Research Institute HMRI Clinical Research Centre Level 3 John Hunter Hospital Lookout Road New Lambton Heights NSW, 2305
Country [1]	Australia
Funding source category [2]	Other
Name [2]	Queensland Rail (QR) National
Address [2]	QR National GPO Box 456 Brisbane, Qld, 4001
Country [2]	Australia
Primary sponsor type	Individual
Name	Professor Robin Callister
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Secondary sponsor category [1]	Individual
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Other collaborator category [1]	Individual
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Other collaborator category [2]	Individual
Name [2]	Professor Ronald Plotnikoff
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Country [2]	Australia

Ethics approval

Ethics application status	Approved
Ethics committee name [1]	The University of Newcastle Human Research Ethics Committee
Ethics committee address [1]	The University of Newcastle University Drive Callaghan NSW, 2308
Ethics committee country [1]	Australia
Date submitted for ethics approval [1]	26/06/2012
Approval date [1]	09/08/2012
Ethics approval number [1]	H-2012-0232

Summary

Brief summary	<p>The Type 2 Diabetes PULSE (Prevention Using LifeStyle Education) study, is a 6 month research study evaluating the effectiveness of a men only Type 2 Diabetes prevention study that focuses on diet and home-based exercise (aerobic and resistance exercise).</p> <p>Aims: To determine the feasibility and efficacy of a novel multi-component Type 2 Diabetes prevention program (diet + aerobic exercise + resistance exercise)</p> <p>Hypotheses:</p> <p>1. Compared to the wait-list control, the diet + aerobic training + RT intervention will result in a significant and a clinically meaningful reduction in weight as well as improvements in important secondary outcomes such as plasma biomarkers at 3 and 6 months post-baseline.</p> <p>The Type 2 Diabetes PULSE intervention will consist of a diet and exercise (aerobic and resistance training) program. Men in the intervention group will receive a resource pack with information regarding Type 2 Diabetes prevention.</p> <p>The dietary intervention will consist of a resource manual with information/tips to improve diet quality and reduce Type 2 Diabetes risk such reducing overall energy intake, reading food labels, reducing portion size, reducing alcohol and sugared beverages, improving quality of diet (low GI carbohydrates, high fibre, low saturated fat), achieving an ideal macronutrient (carbohydrates-fat-protein) profile, reducing salt intake, and increasing fruit and vegetable intake.</p> <p>The exercise intervention will consist of both aerobic and resistance training and will be self-administered over the duration of the 6-month intervention. Men will be asked to perform at least 150 mins/wk (5 x 30 min sessions) of moderate intensity aerobic exercise (e.g., walking, jogging, swimming, cycling) and at least 60 mins/wk (2 x 30 min sessions) of resistance training using body weight and Gymstick (an elastic tubing) exercises.</p> <p>Men will be assessed at baseline, 3- and 6-months on a range of health outcomes. Primary outcomes for the study are weight and fasting plasma glucose. Secondary outcomes will include anthropometric, plasma biomarker, and diet and exercise/fitness measures.</p> <p>The wait-list control group will receive the intervention after the 6-month time-point and will be followed up for a further 6 months.</p>
Trial website	N/A
Trial related presentations / publications	N/A
Public notes	

Contacts

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Dr Megan Rollo