

**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**



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This thesis is submitted in fulfilment of the requirements for the award of the  
degree of:

Doctorate of Philosophy (Human Physiology)

The University of Newcastle, Australia

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### **Statement of originality**

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## **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  
*\* Highly accessed*
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.  
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**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<sub>1c</sub> 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)

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2. Callister, R., Morgan P.J., Collins, C.E., Plotnikoff, R.C., Aguiar, E.J.  
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3. Callister, R., Morgan P.J., Collins, C.E., Plotnikoff, R.C., Aguiar, E.J.  
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Diabetes Foundation), 2013. "Long-term follow up of the PULSE Type 2  
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## **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 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<sub>1c</sub> – 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 combining 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<sup>-1</sup> [-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  $\geq 12$ ) was performed to evaluate the performance of the AUSDRISK tool. In total, 70% of men displayed elevations for FPG or HbA<sub>1c</sub> 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<sub>1c</sub> ( $-0.2\%$  [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.