Development and evaluation of the HEYMAN (Harnessing Ehealth to enhance Young men’s Mental health, Activity and Nutrition) healthy lifestyle program for young adult men aged 18-25 years.

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B.Sc, M.Sc

Thesis submitted in fulfilment of the requirements for the award of the degree of:

Doctor of Philosophy

University of Newcastle

October 2016
Statement of Originality

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to the final version of my thesis being made available worldwide when deposited in the University’s Digital Repository**, subject to the provisions of the Copyright Act 1968.

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Thesis by publication

I hereby certify that this thesis is in the form of a series of published papers of which I am a joint author. I have included as part of the thesis a written statement from each co-author, endorsed by the Faculty Assistant Dean (Research Training), attesting to contribution to the joint publications.

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Finally, I would like to dedicate this thesis to my Mother Angela Ashton, who always supported me and sacrificed a lot in her life to allow me to prosper. I would not be where I am in life without her.
Publications and presentations arising from this thesis

This thesis is presented as a series of six papers. At the time of submission, five of these were published and one presented as a thesis chapter. I am the lead author on all papers.

Manuscripts in peer-reviewed journals: Published


**Conference abstracts: Published in peer-reviewed journals**


**Conference abstracts: Published in peer-reviewed conference proceedings**


Additional publications co-authored during candidature

Prior to commencing my PhD, I worked as a full-time Research Assistant at the Clinical Trials Research Unit (CTRU) at the University of Leeds, United Kingdom. I was involved in developing a systematic review to identify and appraise existing outcome measures for use in the evaluation of childhood obesity treatment interventions. Due to my intellectual and practical contributions, I was invited to contribute as a co-author on a number of publications relating to this research project. Throughout my candidature I worked as a Research Assistant at the University of Newcastle’s Priority Research Centre in Physical Activity and Nutrition and contributed to additional publications. The following publications are consistent with my research focus. However, they sit aside from the research included within this thesis and were therefore not included. Details of the additional publications and conference presentations to which I contributed are listed below.

Additional manuscripts in peer-reviewed journals: published


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## Abbreviations

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<tr>
<td>ABS</td>
<td>Australian Bureau of Statistics</td>
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<tr>
<td>BMI</td>
<td>Body Mass Index</td>
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<tr>
<td>CARDIA</td>
<td>Coronary Artery Risk Development in Young Adults</td>
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<tr>
<td>CONSORT</td>
<td>Consolidated Standards of Reporting Trials</td>
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<tr>
<td>CI</td>
<td>Confidence Intervals</td>
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<tr>
<td>CVD</td>
<td>Cardiovascular Disease</td>
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<td>ED-NP</td>
<td>Energy-Dense, Nutrient Poor</td>
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<td>FPG</td>
<td>Fasting Plasma Glucose</td>
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<td>FFQ</td>
<td>Food Frequency Questionnaire</td>
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<td>HDL</td>
<td>High Density Lipoprotein</td>
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<td>HMRI</td>
<td>Hunter Medical Research Institute</td>
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<td>HEYMAN</td>
<td>Harnessing Ehealth to enhance Young men’s Mental health, Activity and Nutrition</td>
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<td>kJ</td>
<td>Kilojoule</td>
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<td>LDL</td>
<td>Low Density Lipoprotein</td>
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<tr>
<td>MVPA</td>
<td>Moderate to Vigorous Physical Activity</td>
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<tr>
<td>NSW</td>
<td>New South Wales</td>
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<tr>
<td>PA</td>
<td>Physical Activity</td>
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<td>PPM</td>
<td>PRECEDE-PROCEED Model</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<tr>
<td>RCT</td>
<td>Randomized Controlled Trial</td>
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<tr>
<td>SCT</td>
<td>Social Cognitive Theory</td>
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<tr>
<td>SD</td>
<td>Standard Deviation</td>
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<td>SDT</td>
<td>Self Determination Theory</td>
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<tr>
<td>SNAPO</td>
<td>Smoking, Nutrition, Alcohol, Physical activity and/or Obesity</td>
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<td>WHO</td>
<td>World Health Statistics</td>
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*Note.* This list represents the abbreviations used in the main text of the thesis. Additional abbreviations in tables are defined in the bottom row.
Many young adult men (aged 18-25 years) engage in unhealthy lifestyle behaviours such as poor eating habits and physical inactivity. Prolonged undertaking of these behaviours can be detrimental to an individual’s physical and/or mental health and may track into adulthood. Despite this, young men have been seriously under-represented in health behaviour change interventions. This has been attributed in part to programs not appealing to this group and problems in reach, engagement and retention. Participatory based research has potential to overcome previous difficulties as it involves the intended population in every aspect of the research process to ensure the program is matched to their preferences, needs and barriers. However, the effectiveness of this approach has not been explored in young men within a health context.

This thesis presents a series of studies to address this gap in the current evidence base. Overall, these studies relate to the effectiveness of a participatory based research model (PRECEDE-PROCEED) to inform development of the targeted, HEYMAN (Harnessing Ehealth to enhance Young men’s Mental health Activity and Nutrition) healthy lifestyle program for young men. To our knowledge, HEYMAN is the first targeted healthy lifestyle intervention for young adult men that has been informed from a participatory research model. As such the primary aim of this thesis was to evaluate the feasibility of undertaking HEYMAN. The thesis also presents a series of studies investigating six secondary aims, which are briefly described below. As these studies provide important context for the primary aim, the thesis is presented in the following order:

**Secondary aim 1: To examine the extent, range and nature of research focusing on risk behaviours in young males**

To investigate this aim, a comprehensive scoping review was conducted. In total, 100 studies were identified and focussed on: physical inactivity (n=27), alcohol use (n=25), unsafe sexual behaviour (n=21), poor diet (n=5), unsafe vehicle driving (n=5), tobacco
smoking (n=4), recreational drug use (n=2), and tanning/sun exposure (n=1) with no relevant studies targeting violence, gambling or self-harm. Also 10 of the studies targeted multiple risk behaviours. Furthermore, there were 46 studies with exclusively young adult male participants, the remaining studies reported outcomes stratified by age and/or sex. The evidence suggests young men have been targeted to some extent, but this was disproportionate across risk behaviours.

**Secondary aim 2: To investigate the effectiveness of smoking, nutrition, alcohol, physical activity or obesity (SNAPO) interventions in young men and their ability to recruit, retain and engage young men**

Overall, 10 studies were included. Of these, six studies (two nutrition, three alcohol use and one targeting multiple SNAPO risk factors) demonstrated significant positive short-term intervention effects, but the impact was either not assessed beyond the intervention (n=3), had short-term follow-up of 6 months or less (n=2) or not sustained beyond six months (n=1). Furthermore, a high risk of bias was identified across studies, and recruitment and retention was often poor. Effectiveness of engagement strategies was not reported in any studies.

**Secondary aim 3: To identify the motivators and barriers in adopting healthy eating and engaging in physical activity in young adult males, and examine differences by key demographic and behavioural factors**

A mixed-methods approach including qualitative focus groups (n=61) and a cross-sectional online survey (n=282) was implemented. **Healthy eating motivators:** key themes from the focus groups included; improving physical health, complementing sport or performance, improving physical appearance, and social influences (e.g. positive family or peer influence). This was supported in the survey with key motivators identified as ‘to improve overall health’ (64% ranked as key motivator) and ‘body image’ (52%) and ‘to have more energy’ (32%). **PA motivators:** focus group themes included; improving physical appearance, social inclusion, improving physical and mental health, and improving sport related skills or performance. Most common survey responses
were; ‘to improve body image’ (45%), ‘fitness’ (44%) and ‘overall health’ (41%). **Healthy eating barriers:** leading barriers from focus groups included intrinsic (e.g. effort to cook), logistic (e.g. cost, access) and social factors, while most commonly ranked survey responses were: ‘ease of access to unhealthy foods’ (61% ranked as a key barrier), ‘lack of time to cook/prepare healthy foods’ (55%) and ‘lack of motivation to cook healthy foods’ (51%). **PA barriers:** key barriers from focus group were: busy lifestyles, logistic (e.g. cost and access), cognitive-emotional (e.g. intimidation associated with going to the gym) and social factors, while the survey identified ‘lack of motivation’, ‘lack of time to exercise’ and ‘high cost of equipment/facilities’ as key barriers. The survey identified several differences by demographic and/or behaviours factors for motivators and barriers to healthy eating and PA.

**Secondary aim 4:** To explore young males’ preferences for intervention components and delivery medium for a targeted healthy lifestyle program

Key focus group themes included a preference for recruitment via multiple sources, ensuring images and recruiters were relatable; intervention facilitators to be engaging and refrain from discussing negative consequences of being unhealthy. Key program content preferences included skill development and individualised goals and feedback. Overall, focus groups and the survey confirmed a preference for multiple delivery modes, including; face-to-face (group and individual), with support using eHealth technologies. Survey intervention duration preference was three months with four face-to-face sessions per month.

**Secondary aim 5:** To describe the features of a targeted healthy lifestyle program (HEYMAN) for young men that was developed in response to their expressed needs

Key developmental features of the HEYMAN program were: i) formative research with young men (i.e., responses from focus groups and online survey); ii) experience and expertise of the research team; iii) best practice guidelines, iv) health behavioural theory (integrated framework of Social Cognitive Theory and Self Determination Theory) and v) evidence from previous health-related interventions in this population identified
during our systematic review. The 3-month pilot HEYMAN aimed to help participants to improve eating habits, exercise levels and improve overall well-being. Intervention components included eHealth support (website, wearable device, Facebook support group), face-to-face sessions (group and individual), a personalised food and nutrient report, home-based resistance training equipment and a portion control tool.

*Primary aim 1: To evaluate the feasibility of a targeted healthy lifestyle program (HEYMAN) for young adult men aged 18-25 years.*

The feasibility of HEYMAN was evaluated using a pilot RCT in 50 young men aged 18-25 years randomised to intervention (n=26) or waitlist control (n=24). Specifically, this pilot study examined the feasibility of research procedures and intervention components to establish whether the study protocol was adequate to proceed to a fully powered RCT. A 7-week recruitment period was required to enrol the target of 50 young men and a retention rate of 94% was achieved at 3-months post-intervention. Retained intervention participants (n=24) confirmed reasonable levels of program usage for most program components and reasonable levels of program component acceptability for attractiveness, comprehension, usability, support, satisfaction and ability to persuade, with scores ranging from 3.0-4.6 (maximum 5). Overall, results indicated that the research procedures and study protocol were adequate to proceed to a full scale RCT, with some modifications required.

*Secondary aim 6: To estimate the treatment effect of a pilot (HEYMAN) trial on improving objective physical activity levels (steps/day), diet quality and subjective well-being (primary outcomes in subsequent RCT), as well as other lifestyle, psychological, anthropometric and physiological measures (secondary outcomes in the subsequent RCT)*

No significant differences between groups were observed for the selected primary outcomes of steps/day (1012.7, 95%CI= -506.2, 2531.6, p=0.191, Cohen’s d=0.36), diet quality score (3.6, 95%CI= -0.4, 7.6, p=0.081, d=0.48) or total well-being score (0.4, 95%CI= -1.6, 2.5, p=0.683, d=0.11). Significant differences favouring the intervention group over the control group at 3-months were observed for vegetables (1.1 serves/day, 95%CI= 0.1,
2.0, \( p<0.05, d=0.62 \), energy-dense, nutrient-poor foods (-7.2\%, 95\%CI= -12.3, -2.1, \( p<0.01, d=0.73 \)), MVPA (128.0 min/week, 95\%CI= 9.8, 246.2, \( p<0.05, d=0.58 \)), weight (-1.6kg, 95\%CI= -3.0, -0.3, \( p<0.05, d=0.63 \)), BMI (-0.6kg/m\(^2\), 95\%CI= -0.9, -0.2, \( p<0.01, d=0.81 \)), fat mass (-1.4kg, 95\%CI= -2.5, -0.3 \( p<0.05, d=0.67 \)), waist circumference (-3.1cm, 95\%CI= -4.8, -1.4, \( p<0.001, d=0.89 \)), plasma total cholesterol (-0.4mmol/l, 95\%CI= -0.8, -0.1, \( p<0.05, d=0.60 \)), LDL-Cholesterol (-0.5mmol/l, 95\%CI= -0.8, -0.2, \( p<0.01, d=0.83 \)) and ratio of total cholesterol-to-HDL cholesterol (-0.3mmol/l, 95\%CI= -0.6, -0.0, \( p<0.05, d=0.60 \)). Findings demonstrated the potential of HEYMAN to assist young men in making some positive lifestyle changes.

**Discussion**

This thesis determined that the PRECEDE-PROCEED model is a useful guide to inform development of a targeted healthy lifestyle program for young men. This approach demonstrated potential to reach and engage young men into making positive lifestyle changes and provided support for the conduct of a larger, fully-powered RCT with some modifications required. As this is a novel approach, additional high quality RCTs with longer durations and adequate power are required to corroborate or refute findings and further establish the most efficacious and sustainable approaches to improving young men’s health and well-being.
Contribution Statement

As the sole PhD student and project manager of the HEYMAN pilot RCT, I was involved in all aspects of design, implementation and evaluation of the study. A summary of my contribution is provided below.

Acquisition of funding

I was the lead project manager on the two grants that funded this study:


Program development

With support from my supervisors, I led the overall development of the pilot HEYMAN study and the associated formative research (focus groups and online survey) which informed key aspects of the program. Specifically, I was responsible for designing all resources required for HEYMAN including: a responsive website, videos featured on the website and all material for the weekly face-to-face sessions.

Ethics approval and clinical trials registry

I was responsible for drafting, submitting and obtaining ethical approval from the University of Newcastle’s Human Research Ethics Committee for both the formative research (H-2013-0344) and for the HEYMAN pilot trial (H-2015-0445). This involved
developing a study protocol, completing all ethics forms, designing recruitment materials and constructing information statements, consent forms and participant screening procedures. I was also responsible for registering the pilot trial with the *Australian New Zealand Clinical Trials Registry* (ACTRN12616000350426).

**Study measures**

In conferring with my supervisors, I selected all objective and subjective outcome measures used in the HEYMAN study and developed the process evaluation questionnaire which was adapted and informed by previous studies [1, 2]. In addition, I developed the original questions used in the formative research (focus groups and online survey). Specifically, the online survey was pilot tested in an independent sample (n=20 young men) to ensure questions had appropriate test-retest reliability and sufficient clarity, application and overall data quality when used with young Australian men.

**Participant recruitment**

I was responsible for identification and recruitment of young men for three separate studies: focus groups (n=61), online survey (n=282) and HEYMAN pilot study (n=50). I designed and developed all recruitment materials and actively publicised the program by contacting and distributing these materials to the local University, workplaces, technical colleges, businesses and sports clubs. I liaised with the University of Newcastle and HMRI’s media departments to draft a media release for each study. After publication of this release I undertook five local and national radio interviews (e.g., 2NURFM, ABC), one TV news interview (NBN news) and four local newspaper interviews (e.g. Newcastle Herald, Maitland Mercury) to assist in recruitment and overall promotion of the study. I processed all of the eligibility screening data and as project manager fielded enquiries from over 500 young men across the three studies.

**Data collection, entry and management**

I was responsible for co-ordinating the assessment sessions for HEYMAN on two occasions (baseline and follow-up). Prior to the data collection period, I developed an
assessment protocol for completing all measures which was adapted and informed from previous research [1]. Subsequently, I led a comprehensive training session for the research team to ensure they understood the protocol. Although I did not conduct any assessments (for blinding purposes) I attended all sessions to set-up equipment, meet and greet participants, address any concerns the participants had, ensure the randomisation was adhered to and disseminate program resources according to the protocol. Following data collection, I was responsible for entering, cleaning, and de-identifying all data for HEYMAN. In addition, I was accountable for cleaning, and de-identifying data from the formative research (online survey).

Program implementation

With support from a research assistant (Mr Mark Babic) I delivered all weekly group based face-to-face sessions covering topics relating to exercise, healthy eating and stress. In addition, I led all of the one-to-one face-to-face sessions with participants. I controlled all social media posts and monitored the HEYMAN website, continually updating it with new material as the program progressed to help facilitate engagement. I was also the contact person for participants during the study and responsible for managing enquiries.

Data analysis

I completed all quantitative statistical analyses in this thesis. This included: inter-rater reliability analysis, generalised linear mixed model analysis with intention to treat, independent t-tests and chi-squared ($\chi^2$) analysis. The qualitative data analysis in chapter 5 was carried by an independent qualitative researcher.

Presentation of study results

During my candidature, I presented results from my thesis at two International conferences and four National conferences. I was also invited as a guest speaker to present to the Institute of Health and Well-being at the University of Glasgow and Leeds Beckett University (both UK). In 2014, I was awarded first place in the ‘3-minute Thesis’
competition by the Faculty of Health and Medicine and finished overall runner-up in the
grand final of the University wide competition (https://www.youtube.com/watch?v=mO9z8x6mRI).

Awards received during candidature

In 2013, I was awarded the HMRI Felicity Thomson Rainbow Foundation PhD Scholarship, which is a one-year top-up scholarship. In 2014, I was awarded the HMRI Greaves Family Postgraduate Scholarship in Medical Research, which is a two-year top up scholarship awarded to two PhD students from the Hunter Region in a medical related field. I also won a University award for ‘Best PhD confirmation’ from the School of Health Sciences. In 2015, I won an award for ‘best published paper’ in the ‘nutrition and dietetics’ theme from the Priority Research Centre for Physical Activity and Nutrition (University of Newcastle).