Mobile Phone Text Message Intervention for People with Hazardous Alcohol Use: Development of Intervention and Evaluation of Effect

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A thesis submitted in fulfilment of the requirements for the degree of

Doctor of Medicine, The University of Auckland, 2019.

Abstract

Background

Alcohol use is a leading risk factor for injuries, diseases, disabilities, and premature death and contributes to large and inequitably-distributed health, social, and economic burdens in societies. Alcohol Screening and Brief Intervention (SBI) is an important evidence-based component of a comprehensive public health strategy to reduce hazardous alcohol use and prevent alcohol-related harm but is often not implemented in the healthcare system due to a range of barriers, including resource constraints. Mobile health (mHealth) approaches show promise as an innovative, low-cost, and scalable way of delivering alcohol SBIs, however the evidence of effectiveness is limited, and more research attention is needed. The aim of this thesis is to develop and evaluate a mobile phone text message intervention for people with hazardous alcohol use.

Methods

This thesis is comprised of four parts: 1) *a systematic literature review* examining the effectiveness of mobile phone text message interventions in reducing hazardous or harmful alcohol use; 2) *the development of a mobile phone text message intervention* for people with hazardous alcohol use, in the inpatient trauma ward setting, involving conceptualisation and creation of content based on Brief Intervention (BI) evidence and behaviour change theory, followed by formative qualitative research with patients and key stakeholders to pre-test and refine the content; 3) *the evaluation of the effect of the mobile phone text message intervention*, compared with usual care, on hazardous alcohol use and alcohol-related harms in a parallel, two-group, single-blind, randomised controlled trial (RCT) in 598 injured patients aged 16-69 years identified as medium-risk drinkers at recruitment, with follow-up at three, six, and 12 months; and 4) *exploration of the participants' perspectives* of the positive and negative aspects of being involved in the study through qualitative analysis of free-text responses to two questions included in the trial's 12-month online survey.

Results

The systematic literature review identified six RCTs, five of which were small feasibility trials with inadequate power to detect statistically significant effects, but which suggested mobile phone text message alcohol interventions may have the potential to reduce alcohol consumption and harms. One large trial in the Emergency Department setting found that an

intervention involving text message assessments and tailored feedback was more effective than no text messages in reducing alcohol consumption and alcohol-related injury at six months follow-up. All trials were conducted in the USA and five of six trials were in young adult participants. The findings of the review suggest that more research in this area is indicated, particularly large studies in different countries and settings, and considering a wider range of ethnicity and age groups.

The mobile phone text message intervention development research identified four key themes that were important to ensuring the intervention text messages were engaging, relevant, and useful for participants: 1) reducing the complexity of message content and structure, 2) increasing the interactive functionality of the text message programme, 3) ensuring an empowering tone to text messages, and 4) optimising the appropriateness and relevance of text messages for Māori and Pacific people. The fourth theme was an important focus of the refinement process and a key strength of this research. The output of this part of the thesis was the content for the 'YourCall' text message intervention, a low intensity, automated, unidirectional intervention designed to reduce alcohol consumption and alcohol-related harms in patients admitted to hospital due to an injury.

The RCT evaluating the effect of the 'YourCall' mobile phone text message intervention revealed that hazardous drinking was significantly lower in the intervention group, compared to controls, at three months and a modest effect was maintained over the 12-month follow-up period (least squares mean difference in Alcohol Use Disorder Identification Test – Consumption [AUDIT-C] scores: -0.322; 95% Confidence Interval: -0.636, -0.008; $p = 0.04$). The intervention effect was similar among Māori and non-Māori, and among younger and older participants. However, the secondary outcomes analysis did not detect any differences between intervention and control groups at 12-months in the measures of alcohol-related harms and troubles, readiness to change drinking patterns, and help-seeking behaviours.

Exploration of participants' perspectives showed mainly positive perceptions of being involved in the study, from both intervention and control group respondents. The most dominant theme that emerged was 'contemplation about alcohol use' suggesting that respondents were prompted to become more aware of, and think about, their alcohol use. The findings suggest there may be research participation effects among participants. It is also possible there has been a treatment effect (i.e. assessment reactivity) for the control group,

which may have decreased the differences in outcome measures between the intervention and control groups and underestimated the effect of the intervention.

Conclusion

This thesis provides evidence of the effectiveness of a mobile phone text message alcohol intervention in reducing hazardous alcohol consumption. MHealth alcohol interventions such as this have potential as an alternative delivery mode for face-to-face BI and could help to address current barriers preventing access to alcohol interventions as part of routine trauma care.

Further research is required into the preventive potential of mHealth alcohol interventions. This thesis suggests that, whilst mHealth alcohol interventions are an important healthcare system response, they are just one component of a multi-pronged strategy for reducing alcohol-related harms and should be considered alongside the 'best-buy' strategies that address alcohol availability, price, and advertising, marketing, and sponsorship.

Acknowledgements

I acknowledge and sincerely thank my supervisors Associate Professor Bridget Kool, Associate Professor Robyn Whittaker, and Professor Shanthi Ameratunga. I am extremely grateful for their guidance, encouragement, time, patience, and dedication. I could not imagine more generous, wise, kind, and inspirational supervisors. I have learned so much from them and will be forever grateful to them for their support and supervision.

I would like to acknowledge and thank my esteemed collaborators and co-authors involved in the development and evaluation of the 'YourCall' intervention. Members of the Intervention Development Team, Professor Papaarangi Reid (the University's Tumuaki and Head of Te Kupenga Hauora Māori), Dr Matt Shepherd, Enid Dorey, Associate Professor Vili Nosa, and Dr Susanna Galea-Singer, provided expert advice during development of the text message intervention. I very much appreciate having had the opportunity to work in collaboration with Dr Matt Shepherd, who led the consultation with Māori groups. The randomised controlled trial would not have been possible without the support from Professor Papaarangi Reid and clinical colleagues Professor Ian Civil (Auckland City Hospital), Mr Matt Walker (North Shore Hospital), and Dr Vanessa Thornton (Middlemore Hospital). Thank you also to Dr Arier Lee who provided excellent biostatistical support and advice.

A number of other people made significant contributions to the 'YourCall' study. I would like to pay a very special tribute to the patients and groups, including the Te Ātea Marino and Tupu Drug and Alcohol Counsellors, who helped to develop the text message content, and to the 598 participants of the trial, whose involvement and feedback was crucial for evaluating the effect of the intervention. I would like to acknowledge and thank the Research Assistants, Trisha Meagher-Lundberg, Tania Milne, Judy Rowden, Juliet Drown, Katherine Moore, Amanda Benson, Christine Holt, and Emma Shields, who worked tirelessly on the trial across the three hospital sites to approach and engage with potential participants and explain the research, to enrol participants and collect baseline data, and to carry out follow-ups. The research team greatly appreciated the help from the hospital ward staff and the hospital trauma co-ordinators; particular thanks to Rhondda Paice and Rangi Dansey and the team at Auckland City Hospital Trauma Service who were very welcoming and supportive. I am also very grateful to the staff at the National Institute for Health Innovation (NIHI), particularly to the trial's Data Managers, Vanessa Singh and John Fa'atui, and the Study Monitor, Karen Carter.

I am grateful for the financial assistance provided by the Health Research Council of New Zealand, who funded this research via a project grant.

There are many other colleagues at the University of Auckland and Counties Manukau District Health Board (CMDHB) who have provided me with advice and encouragement over the years I have been training and working in public health. I am extremely grateful to Dr Doone Winnard, Clinical Director of Population Health, CMDHB, who has been steadfast in her support and has helped me to complete this thesis alongside my work at CMDHB.

Finally, and most of all, I would like to thank my wonderful family who have supported me in so many ways. I thank my husband, John Franich, and our sons Ben and Luke, for their patience and understanding. I thank my parents, Susan and Norman Sharpe, for always being there for me, and my sisters, Cia, Susannah, Amy, and Madeline, for their kindness and caring.

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Abbreviations

ADH	Alcohol Dehydrogenase
ALDH	Aldehyde Dehydrogenase
Amidx	Alcohol Misuse Index
App	A software application designed to run on a mobile device such as a smartphone
AUDIT	Alcohol Use Disorder Identification Test
AUDIT-C	Alcohol Use Disorder Identification Test - Consumption
BAC	Blood Alcohol Concentration
BCT	Behaviour Change Technique
BI	Brief Intervention
CFIR	Consolidated Framework for Implementation Research
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
DALY	Disability Adjusted Life Year
DPDD	Drinks Per Drinking Day
DrInC	Drinker's Inventory of Consequences questionnaire
eBAC	Estimated Blood Alcohol Concentration
ED	Emergency Department
eHealth	Electronic Health (i.e. the use of ICT in support of health)
EMBASE	Excerpta Medica Database
ERIC	The Expert Recommendations for Implementing Change
EPOC	Effective Practice and Organisation of Care
FASD	Foetal Alcohol Spectrum Disorder
FRAMES	Feedback of personal risk or impairment; emphasis on personal Responsibility for change; clear Advice to change; offering a Menu of alternative change options; therapeutic Empathy as a counselling style; and enhancement of patient Self-Efficacy or optimism
GDP	Gross Domestic Product
GENACIS	Gender, Alcohol, and Culture International Study
HDD	Heavy Drinking Day
HDEC	Health and Disability Ethics Committees
HED	Heavy Episodic Drinking
ID	Study Identification number

ICT	Information Communication Technologies
ITT	Intention-To-Treat
MEDLINE	Medical Literature Analysis and Retrieval System Online
mHealth	Mobile Health
MoDeRATE	M-health Delivery for Reducing Alcohol in the Trauma Environment trial
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIHI	National Institute for Health Innovation
NNT	Number Needed to Treat
NZ	New Zealand
OR	Odds Ratio
PDA	Personal Digital Assistant
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PsycINFO	Electronic database of abstracts in the fields of psychological, social, behavioural, and health sciences
RCT	Randomised Controlled Trial
RTC	Readiness To Change
RTD	Ready To Drink
SAFER	Strengthen restrictions on alcohol availability; Advance and enforce drink driving countermeasures; Facilitate access to screening, brief interventions and treatment; Enforce bans or comprehensive restrictions on alcohol advertising, sponsorship, and promotion; Raise prices on alcohol through excise taxes and pricing policies
SBI	Screening and Brief Intervention
SD	Standard Deviation
SIP	Short Inventory of Problems
SMS	Short Message Service
Stats NZ	Statistics New Zealand
TMAP	Text Message Alcohol Program
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

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Please indicate the chapter/section/pages of this thesis that are extracted from a co-authored work and give the title and publication details or details of submission of the co-authored work. Chapter 4. Development of a Mobile Phone Text Message Intervention for People with Hazardous Alcohol Use From: Sharpe S, Shepherd M, Kool B, Whittaker R, Nosa V, Dorey E, Galea S, Reid P, Ameratunga S. Development of a text message intervention aimed at reducing alcohol-related harm in patients admitted to hospital as a result of injury. BMC Public Health 2015;15(815). doi: 10.1186/s12889-015-2130-6

Nature of contribution by PhD candidate	Lead researcher and author, in collaboration with Dr Matthew Shepherd. Literature and evidence review, study design and development, conceptualisation and development of initial text message prototype, conducted pre-testing, qualitative analysis, refinement of content with advice from Intervention Development Team, consulted with Māori and Pacific groups, drafted manuscript, liaised with all co-authors on manuscript review.
Extent of contribution by PhD candidate (%)	75%

CO-AUTHORS

Name	Nature of Contribution
Matthew Shepherd	Conceptualisation and oversight of intervention development process, pretesting of text message content, consultation with Māori groups, review of findings from pretesting, refinement of text message content, reviewed and approved manuscript
Bridget Kool, Robyn Whittaker, Shanthi Ameratunga	Conceptualisation and oversight of intervention development process, review of findings from pretesting, refinement of text message content, reviewed and approved manuscript, supervisors of doctoral candidate
Enid Dorey	Conceptualisation and oversight of intervention development process, provided health psychology input to content development, review of findings from pretesting, refinement of text message content, reviewed and approved manuscript
Vili Nosa	Conceptualisation and oversight of intervention development process, provided Pacific health advice for content development, review of findings from pretesting, refinement of text message content, reviewed and approved manuscript
Susanna Galea-Singer	Conceptualisation and oversight of intervention development process, provided advice on content development from drug and alcohol clinical services perspective, review of findings from pretesting, refinement of text message content, reviewed and approved manuscript
Papaarangi Reid	Conceptualisation and oversight of intervention development process, provided Maori health advice, review of findings from pretesting, refinement of text message content, reviewed and approved manuscript

Certification by Co-Authors

The undersigned hereby certify that:

- the above statement correctly reflects the nature and extent of the PhD candidate's contribution to this work, and the nature of the contribution of each of the co-authors; and

- that the candidate wrote all or the majority of the text.

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Matthew Shepherd		27 May 2019
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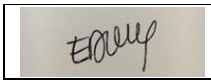
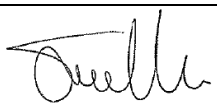
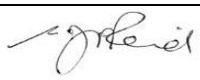
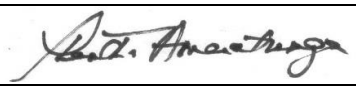
Vili Nosa		28 May 2019
Enid Dorey		27 May 2019
Susanna Galea-Singer		6 June 2019
Papaarangi Reid		28 May 2019
Shanthi Ameratunga		22 May 2019

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Please indicate the chapter/section/pages of this thesis that are extracted from a co-authored work and give the title and publication details or details of submission of the co-authored work. Chapter 5. Randomised Controlled Trial of a Mobile Phone Text Message Intervention for People with Hazardous Alcohol Use: Primary Outcome From: Sharpe S, Kool B, Whittaker R, Lee AC, Reid P, Civil I, Walker M, Thornton V, Ameratunga S. Effect of a text message intervention to reduce hazardous drinking among injured patients discharged from a trauma ward: a randomized controlled trial. npj Digital Medicine 2018;1(1):13. doi: 10.1038/s41746-018-0019-3

Nature of contribution by PhD candidate	Lead researcher and author for the trial, which included: managing funder, ethics, trial registration, and local hospital approvals, processes and reporting; study design and development of data collection questionnaires and study forms/documents/systems; collaboration on the study protocol with HRC grant recipient Professor Shanthi Ameratunga; oversight and day-to-day co-ordination of the trial during recruitment and follow-up phases; data monitoring and quality control; developing the Statistical Analysis Plan, performing descriptive quantitative analyses, and working closely with the study biostatistician on the mixed effects modelling; drafting the manuscript and consulting with co-authors.
Extent of contribution by PhD candidate (%)	80%

CO-AUTHORS

Name	Nature of Contribution
Bridget Kool, Robyn Whittaker, and Shanthi Ameratunga	Study concept, design and protocol development; review of findings of analysis; reviewed and approved the manuscript; provided oversight of trial and supervision of doctoral candidate. SA was the Health Research Council grant principal investigator for this research.
Arier C Lee	Study concept, design and protocol development; statistical analysis; reviewed and approved the manuscript
Papaarangi Reid	Study concept, design and protocol development; research oversight and advice on Māori Health; commented and approved the manuscript
Ian Civil	Study concept, design and protocol development; assisted with locality approval and conduct of study at Auckland City Hospital; reviewed and approved the manuscript
Matthew Walker	Study concept, design and protocol development; assisted with locality approval and conduct of study at North Shore Hospital; reviewed and approved the manuscript
Vanessa Thornton	Study concept, design and protocol development; assisted with locality approval and conduct of study at Middlemore Hospital; reviewed and approved the manuscript

Certification by Co-Authors

The undersigned hereby certify that:

- the above statement correctly reflects the nature and extent of the PhD candidate's contribution to this work, and the nature of the contribution of each of the co-authors; and

- that the candidate wrote all or the majority of the text.

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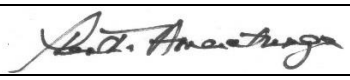
Robyn Whittaker		22 May 2019
Arier C Lee		29 May 2019
Papaarangi Reid		28 May 2019
Ian Civil		30 May 2019
Matthew Walker		29 May 2019
Vanessa Thornton		5 June 2019
Shanthi Ameratunga		22 May 2019

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Nature of contribution by PhD candidate	Lead researcher and author for the trial, which included: managing funder, ethics, trial registration, and local hospital approvals, processes and reporting; study design and development of data collection questionnaires and study forms/documents/systems; collaboration on the study protocol with HRC grant recipient Professor Shanthi Ameratunga; oversight and day-to-day co-ordination of the trial during recruitment and follow-up phases; data monitoring and quality control; developing the Statistical Analysis Plan, performing descriptive quantitative analyses, and working closely with the study biostatistician on the mixed effects modelling; drafting the manuscript and consulting with co-authors.
Extent of contribution by PhD candidate (%)	85%

CO-AUTHORS

Name	Nature of Contribution
Bridget Kool	Study concept, design and protocol development; review of findings of analysis; reviewed and approved the manuscript; provided oversight of trial and supervision of doctoral candidate.
Robyn Whittaker	Study concept, design and protocol development; review of findings of analysis; reviewed and approved the manuscript; provided oversight of trial and supervision of doctoral candidate.
Arier C Lee	Study concept, design and protocol development; statistical analysis; reviewed and approved the manuscript
Papaarangi Reid	Study concept, design and protocol development; research oversight and advice on Māori Health; commented and approved the manuscrip
Ian Civil	Study concept, design and protocol development; assisted with locality approval and conduct of study at Auckland City Hospital; reviewed and approved the manuscript
Shanthi Ameratunga	Study concept, design and protocol development; review of findings of analysis; reviewed and approved the manuscript; provided oversight of trial and supervision of doctoral candidate. SA was the Health Research Council grant principal investigator for this research.

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- that the candidate wrote all or the majority of the text.

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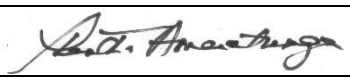
Ian Civil		30 May 2019
Shanthi Ameratunga		22 May 2019

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Please indicate the chapter/section/pages of this thesis that are extracted from a co-authored work and give the title and publication details or details of submission of the co-authored work. Appendix 8. Published Letter to the Editor From: Sharpe S, Kool B, Whittaker R, Ameratunga S. Hawthorne effect in the YourCall trial suggested by participants' qualitative responses. Journal of Clinical Epidemiology 2019; doi: https://doi.org/10.1016/j.jclinepi.2019.05.035

Nature of contribution by PhD candidate	Lead researcher and author for the trial, which included: managing funder, ethics, trial registration, and local hospital approvals, processes and reporting; study design and development of data collection questionnaires and study forms/documents/systems, including those related to the 12-month follow-up survey; collaboration on the study protocol with HRC grant recipient Professor Shanthi Ameratunga; oversight and day-to-day co-ordination of the trial during recruitment and follow-up phases; data monitoring and quality control; performing qualitative analyses; conceived and drafted the manuscript for the Letter and consulted with co-authors.
Extent of contribution by PhD candidate (%)	90%

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Name	Nature of Contribution
Bridget Kool	Study concept, design and protocol development; reviewed and approved the manuscript; provided oversight of trial and supervision of doctoral candidate.
Robyn Whittaker	Study concept, design and protocol development; reviewed and approved the manuscript; provided oversight of trial and supervision of doctoral candidate.
Shanthi Ameratunga	Study concept, design and protocol development; reviewed and approved the manuscript; provided oversight of trial and supervision of doctoral candidate. SA was the principal investigator of the Health Research Council of New Zealand grant funding the YourCall trial

Certification by Co-Authors

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Robyn Whittaker		4 June 2019
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CHAPTER 1: INTRODUCTION

Alcohol use causes large and inequitably-distributed disease, social, and economic burdens in societies.[1-4] Alcohol is an addictive psychotropic drug, a toxin and carcinogen, an intoxicant, and a leading risk factor for intentional and unintentional injuries and a wide range of diseases.[1, 4-6] Within the age group 15 to 49 years, alcohol is the leading risk factor, globally and in New Zealand, for death and disability.[2, 3]

It is well established that alcohol use is a leading risk factor for injury.[2-5] Between 7%-14% of all emergency department (ED) presentations,[7-9] 8%-60% of injury ED presentations,[10] and 23%-50% of trauma centre admissions[11-13] are reported to be alcohol-related. Prevention of alcohol-related trauma requires a multi-pronged public health approach including strategies such as: reducing access to and availability of alcohol, increasing the price of alcohol, controlling sponsorship and advertising, drink-driving countermeasures, and appropriate interventions for hazardous drinkers.[14-16] This thesis is focussed on the latter strategy and specifically explores the delivery of alcohol brief intervention (BI) via a mobile health (mHealth) approach, in the context of trauma care, for people who have presented to hospital following an injury and have been identified through screening to have hazardous alcohol use.

The rationale behind this research is that Screening and Brief Intervention (SBI) is an important evidence-based component of a comprehensive public health strategy to reduce hazardous alcohol use and prevent alcohol-related harm (including injuries) but is often not implemented in the healthcare system due to a range of barriers.[12, 17-22] SBI delivered via an mHealth approach could be a strategy for overcoming such barriers. There are similarities between mHealth and computer/web-based approaches to SBI. There is a substantial literature base on computer/web-based approaches, which overall shows small effects of interventions on alcohol consumption (see Section 2.3). Despite the rapid development and use of mobile phones for medical and public health service delivery and the promise of potential benefits such as mobility, low-cost, high scalability, convenience for users, broad reach, and reducing inequities in access to health information and services,[23-26] the evidence of effectiveness for behaviour change is limited, and more research attention is needed.[24]

1.1 Thesis Aim and Objectives

The aim of this thesis is to develop and evaluate a mobile phone text message intervention[i] for people with hazardous alcohol use.

The specific objectives are:

1. To review the evidence from published studies examining the effectiveness of mobile phone text message interventions in reducing hazardous alcohol use and alcohol-related harms;

2. To develop a mobile phone text message intervention for people with hazardous alcohol use;

3. To assess the effect of the mobile phone text message intervention on hazardous alcohol use and alcohol-related harms;

4. To explore the positive and negative aspects of being involved in the study from the participants' perspectives.

1.2 Role of the Candidate

This thesis arose from my awareness and concern about alcohol-related harm as an important public health issue, a contributor to a wide range of adverse health and social outcomes, and a driver of inequities in health and social outcomes. Through the journey of this thesis, I have come to appreciate, even more so than before, the huge burden of harms from alcohol experienced by individuals, families/whānau, communities, the health system, and society. The vast scale of influence that alcohol and the alcohol industry have within our society is of great concern.

The opportunity to carry out the research described in this thesis came about following my involvement in research investigating risk factors for injuries occurring in the home environment. Further to describing alcohol as a key risk factor for injury, I was interested in contributing to research which was focussed on prevention and early intervention. I was also interested in applying this research to a healthcare setting (i.e. trauma care) which bears a large

[i] In subsequent sections and chapters of this thesis, the terminology 'text message intervention' will be used rather than the more lengthy 'mobile phone text message intervention'. When the terminology 'text message intervention' is used, it refers to text messages sent to mobile phones.

burden from alcohol-related injuries and within which there are a number of barriers to carrying out prevention activities.

In my role as the Research Fellow for the 'YourCall' Intervention Development and Trial (the main focus of this thesis), I led the following aspects:

- Conceptualisation and development (including design and conduct of formative research) of the 'YourCall' text message intervention content, in collaboration with Dr Matthew Shepherd, Māori researcher, and with advice from the Intervention Development Team;
- Obtaining ethics approval from the New Zealand Health and Disability Ethics Committee (HDEC) and 'locality approvals' from the three hospitals and District Health Boards involved in the 'YourCall' Randomised Controlled Trial (RCT);
- Development of study questionnaires, Participant Information Sheets, Consent forms, other study forms and procedure documents;
- Day-to-day co-ordination of the RCT, including hospital site visits, recruitment of participants, and provision of support to Research Assistants during the recruitment and follow-up phases of the trial;
- Development of the Statistical Analysis Plan for the RCT;
- Performing all qualitative analyses and descriptive quantitative analyses;
- Drafting of the four publications referred to in this thesis (i.e. first author of publications related to Chapters Four,[27] Five,[28] Six,[29] and Seven[30]);
- Presentation of research findings at meetings and conferences.

In addition, I worked in close collaboration with other staff involved in the research, as described next.

- I worked closely with the Principal Investigator and Health Research Council grant recipient, Professor Shanthi Ameratunga, and the study Project Manager Associate Professor Bridget Kool, on the study design and protocol (co-author of published study protocol).[31]
- I worked in collaboration with staff at the National Institute for Health Innovation (NIHI), who developed and maintained the study website and online forms (used by study staff for participant registration, baseline data collection, randomisation procedure, and follow-up assessments) and the Information Technology system for

delivery of the text message intervention and follow-up text messages to patients. I provided advice on trial data capture form design and development, support throughout all phases from set-up through to close-out, and support for data management and cleaning.

- I worked in collaboration with the 'YourCall' study biostatisticians on design, planning, and conduct of the analyses. I worked with Dr Arier Lee on the mixed effects modelling, in particular regarding clinical interpretation. Dr Lee ran the models using SAS.
- I assisted the external Study Monitor with planning and conducting Data Monitoring activities and ensuring appropriate documentation was maintained.

I conceived and conducted all aspects of the systematic literature review (Chapter Three) and qualitative exploration (Chapter Seven).

1.3 Structure of the Thesis

This first chapter has briefly introduced the topic, described the aim and objectives of the thesis, and explained the role of the candidate in this research.

Chapter Two provides background information and context for the thesis. It includes an overview of alcohol as an important public health issue and the range of evidence-based strategies currently available to address hazardous alcohol use and alcohol-related harms. The concepts of alcohol SBI and mHealth strategies are defined and explained.

Chapter Three explores text message interventions, a subset of mHealth strategies, in more depth by presenting a systematic literature review of studies examining the effectiveness of mHealth text message interventions in reducing hazardous or harmful alcohol use.

Chapter Four describes the development of content for a text message intervention, based on the established, evidence-based BI model. The intervention is designed in the trauma ward setting and with the aim to reduce hazardous and harmful drinking among patients admitted to hospital following an injury who screen positive for hazardous alcohol use.

Chapter Five presents the methods and results of an RCT evaluating the effect of the text message intervention, compared with 'usual care', on hazardous alcohol use at three, six and 12-months follow-up (primary outcome).

Chapter Six presents the methods and results of the RCT evaluating the effect of the text message intervention on alcohol-related harms at 12-months follow-up (secondary outcomes).

Chapter Seven describes feedback from participants about their experiences of being in the study and, using qualitative methodology, explores the positive and negative aspects of being involved in the study from the participants' perspectives.

Chapter Eight summarises the main findings of the research and provides discussion about how the findings contribute to the published literature relevant to this topic. The strengths and limitations of the research are considered and the implications of the thesis findings for public health practice and future research are discussed.

As Chapters Four, Five, and Six are based on published articles, there may be some repetition of content in the body of the thesis.

CHAPTER 2: BACKGROUND

Alcohol use is an important global public health issue.[1] It is a leading risk factor for death and disability and contributes to large and inequitably-distributed disease, social, and economic burdens in societies.[2-4, 32] This chapter provides a brief overview of the problems and contextual factors associated with alcohol and introduces the range of evidence-based strategies currently available to address hazardous alcohol use and alcohol-related harms. Specific detail is provided on alcohol SBI and mHealth strategies, which are the fields of interest explored in more detail in the body of this thesis (Chapters Three to Seven).

2.1 Alcohol Use and Alcohol-Related Harms

Alcoholic drinks contain ethanol (also known as ethyl alcohol), a chemical compound with the formula C_2H_5OH, produced by fermentation of sugars in fruit (e.g. wine from grapes), grains (e.g. beer from barley), or other plants (e.g. vodka from distillation of ethanol produced by fermentation of potatoes). Alcohol is classed as a psychoactive sedative-hypnotic drug.[33] As described by Babor and co-authors in 'Alcohol: No Ordinary Commodity: Research and Public Policy', alcohol has a "double nature" as both a profitable global commodity and a widely-used drug causing enormous harm and cost to society.[14]

2.1.1 Properties and Metabolism of Alcohol

Alcohol has three important properties through which harm is mediated: it is an intoxicant, a toxic substance, and an addictive drug which can produce dependence.[14] When alcohol is consumed, it is rapidly absorbed from the gastro-intestinal tract into the blood stream and around the body including through the blood-brain barrier.[33] Mild intoxication occurs at blood alcohol levels of 20-100 mg/dL in nontolerant people and includes symptoms such as relaxation, euphoria, mild muscle incoordination, and mild cognitive impairment.[33] At higher blood alcohol levels, symptoms include slurred speech, lack of coordination, ataxia, prolonged reaction time, and severe cognitive impairment.[33] At very high blood alcohol levels, respiratory depression, coma, and even death, can occur.[33]

The metabolism of alcohol causes hypoxia in the liver, the formation of toxins such as acetaldehyde and free radicals, and changes to other molecules involved in the metabolic pathway, all of which contribute to damage to the body's genetic material, cells, and tissues.[34] The main pathway for metabolism of alcohol occurs in the liver through oxidation by the

enzyme alcohol dehydrogenase (ADH) to form acetaldehyde, which is then metabolized by the enzyme aldehyde dehydrogenase (ALDH) to form acetate.[33-35] ADH is also present in the stomach and contributes to metabolism. Females have lower levels of ADH in the stomach, and therefore slower metabolism of alcohol, leading to higher blood alcohol levels than men who consume the same amount of alcohol per kilogram of body weight.[33] There are many genetic variants (isoenzymes) of ADH and ALDH, with different levels of enzyme activity, leading to various physiological responses to alcohol and different influences on tissue damage.[34] For example, approximately half the Taiwanese, Chinese, and Japanese populations have an ALDH isoenzyme with very low activity, resulting in acetaldehyde accumulation after drinking alcohol, which manifests clinically with an alcohol flush reaction, tachycardia, and hypotension.[33, 34]

Another metabolic pathway, the microsomal ethanol oxidising system, is induced by chronic alcohol consumption. An increase in cytochrome P450 isoenzymes in liver cells and other tissues such as the brain, in response to chronic alcohol consumption, contributes to the metabolic tolerance to alcohol seen in people with chronic, high levels of alcohol consumption. Oxidation of alcohol by cytochrome P450 produces acetaldehyde and reactive oxygen species (i.e. free radicals).[34, 35]

Dependence on alcohol is characterised by tolerance to the effects of alcohol, withdrawal symptoms when alcohol use is reduced or stopped, continued use of alcohol despite harmful consequences, preoccupation with alcohol, impaired capacity to control drinking behaviour, and compulsion to use alcohol.[14] Dependence is thought to occur through reinforcing and adaptation effects of alcohol on brain cells, neuroreceptors, and neurotransmitters.[33] Alcohol is reinforcing because consumption triggers the 'reward pathways' of the brain, promoting further consumption. Brain cells adapt to alcohol exposure over time, meaning that increasing amounts of alcohol are needed to achieve desired effects (i.e. tolerance to alcohol occurs).[14, 33]

2.1.2 Terminology Related to Alcohol Use

Consumption of alcohol has two main dimensions by which it is described and measured, i.e. the volume of alcohol consumed and the pattern of drinking.[36] For most harms from alcohol (e.g. diseases and injuries), there is a dose-response relationship, with larger volumes of consumption leading to higher risk of harm. Pattern of drinking over time also affects risk of harm. For example, heavy episodic drinking (HED, defined as consumption of 60 grams or

more of pure alcohol on at least one single occasion at least monthly) is associated with adverse outcomes even if the average volume of alcohol consumption is low.[36]

There are a plethora of inexact terms used to describe patterns of drinking. Some examples include 'heavy drinking' (i.e. a pattern that exceeds a standard or certain daily volume or quantity per occasion), 'moderate drinking' (i.e. a pattern that is contrasted with 'heavy drinking' and denotes drinking that is moderate in amount), and 'binge-drinking' (i.e. a pattern of heavy drinking that occurs in an extended period set aside for the purpose, often with intervening periods of abstinence).[37]

Terms in common use currently include:

- Hazardous alcohol use, i.e. volume and/or pattern of use above recommended guidelines that increases the risk of harmful consequences (e.g. physical, mental, or social) for the user; also known as 'risky drinking'.
- Harmful alcohol use, i.e. volume and/or pattern of use that is already causing damage to health (including physical or mental health) and commonly also has adverse social consequences.
- Dependent drinking (see also Section 2.1.1), i.e. the need for repeated use of alcohol to feel good or to avoid feeling bad, indicating impaired control of alcohol use and use of alcohol despite adverse consequences.[37]

2.1.3 Historical Context of Alcohol Use

It is thought that humans and human ancestral species were exposed, across millions of years of evolution, to low-concentration ethanol in ripe and over-ripe dietary fruits.[38] Alcoholic drinks have been intentionally produced and used in human societies for thousands of years and have served many purposes including: a source of food, an alternative drink to polluted drinking water, medicines, drugs with mood-altering and intoxicant effects, for cultural rituals, for religious rituals and commemorations, socialisation and hospitality, and as a sign of social status.[14, 39] Fermented alcoholic drinks were first produced around the time of crop domestication about eleven thousand years ago.[38] These fermented drinks were of low ethanol concentration and produced occasionally on a small scale in households, tribes, and villages.[36, 38] Development of distillation of alcohol and consequent exposure to higher ethanol concentrations occurred in the Middle East and Asia during the first millennium and spread to Europe during the Middle Ages.[38, 39] During the era of European colonial expansion and

industrialisation, alcoholic beverages were further developed and commercialised and became a widely available commodity.[36, 39] The increased supply and availability of alcohol created much harm during this era (and continues to do so), including in New Zealand.

Alcoholic beverages did not exist in New Zealand prior to colonisation.[40] The history of Māori and alcohol is complex, as outlined by Hutt in the book 'Te Iwi Maori me te Inu Waipiro: He Tuhituhinga Hitori (Māori & Alcohol: A History)': *"Viewed historically, liquor consumption reveals nuances of political, social and cultural resonance by Māori resistant to Pākehā pressures. Alcohol was part of the European onslaught, but its role in the colonisation of New Zealand needs to be understood in its full complexity."*[40] With colonisation, alcohol became widely available in the early 1800s, initially in the Bay of Islands area.[40] Binge-drinking and drunkenness were defining social characteristics of the European (mostly male) colonial population.[41] The temperance movement of the late 1800s and early 1900s grew from concerns about the problem of drunkenness in society.[40, 41]

Māori initially showed a strong dislike for alcohol, naming it *waipiro* (stinking water), but gradually demand for alcohol grew among the Māori population and it began to affect Māori society adversely.[40] Discriminatory laws, introduced from the mid-1800's onwards and not removed until 1948, gave colonisers control over the distribution of alcohol, including the prohibition of consumption of alcohol by Māori in public bars. During this time there were many attempts by iwi to control alcohol use in their communities, including implementing alcohol bans and dry areas.[40, 41] The 1950s-1970s saw an increase in access to, and harm from, alcohol among Māori, contributed to by migration of Māori from rural to urban areas.[40] The Sale of Liquor Act 1989 resulted in liberalisation of the legal framework for control of alcohol sale and supply, and perpetuation of New Zealand's heavy drinking culture.[42] Stark inequities in hazardous alcohol use and alcohol-related harm between Māori and non-Māori are evident to the present day.[43]

2.1.4 New Zealand's 'Alcogenic Environment'

New Zealand's contemporary drinking behaviours and cultures are shaped by a number of complex and interacting factors including historical context, the impacts of colonisation, societal and cultural norms and expectations, ethnicity, gender, age, socio-economic factors, politics and the legal framework for alcohol control, and the influence of the alcohol industry.[41] Through these factors, alcohol use has become embedded in New Zealand society. People live, grow-up, work, play and socialise in social, cultural, and physical environments which

encourage and normalise high alcohol consumption.[42] Two key drivers of the current 'alcogenic environment' are New Zealand's liberal regulatory framework for alcohol control and the unhealthy alcohol commodity industry.

The New Zealand Law Commission's comprehensive review of the regulatory framework for the sale and supply of liquor (2010), led by Sir Geoffrey Palmer, stated that while the liberalisation of New Zealand's liquor laws since 1989 has been associated with some economic benefits for many consumers, the unprecedented availability, affordability and promotion of alcohol is contributing to patterns of high-risk drinking and alcohol-related harm in many communities and population groups. *"The trend towards regarding alcohol as a normal food or beverage product needs to be reversed. In truth, alcohol is no ordinary commodity. Alcohol is a psychoactive drug that easily becomes addictive and that can produce dangerous behaviours in those who drink too much. New Zealanders are reluctant as a nation to face up to the facts. There are many convenient but wrong explanations offered for why the availability of alcohol should not be tightly regulated. But in the end, reality must be faced: it is the product alcohol itself that is the problem."*[42]

The New Zealand Law Commission recommended a package of policy reforms be implemented, however the new Sale and Supply of Alcohol Act 2012 included only some of the recommendations and did not include key policies which would improve the alcohol environment, such as increasing the price of alcohol through excise tax increases, increasing the purchase age for alcohol to 20 years of age, regulating promotions, advertising and sponsorship of alcohol, and more controls on licensed premises (such as a reduction in opening hours).[42, 44]

Although "the product alcohol is the problem", it is also an important commodity which generates huge profits for a range of people and companies involved in a range of economic activities including growing, manufacturing, distributing, advertising, marketing, and selling alcohol products.[14, 42] In a manner similar to other unhealthy commodity industries (such as tobacco and unhealthy foods), alcohol industry players use sophisticated strategies and approaches, the 'commercial determinants of health', to promote their products and shape the alcohol environment and consumer choices.[45] Within an environment of rising consumer demand, increased size and global reach of transnational companies, and international trade agreements, the alcohol industry exerts its influence through aggressive marketing (including via digital and social media), lobbying against effective policies (and for soft policies and

voluntary and self-regulation), corporate social responsibility strategies, and extensive supply chains.[45-51]

2.1.5 Alcohol Consumption

The World Health Organization (WHO) has estimated worldwide alcohol consumption in 2016 was 6.4 litres of pure alcohol per capita (aged ≥15 years), with a quarter of this comprising unrecorded alcohol consumption (i.e. home-made or informally produced or sold outside normal government controls).[1] Of total recorded alcohol consumed, 45% was spirits, 34% was beer, 12% was wine, and nine percent was other alcoholic beverages.[1] Levels and patterns of alcohol consumption vary between regions and countries of the world due to differences in a range of factors such as level of economic development, culture and religion, sociodemographic factors, abstention rates, preferred alcoholic beverages, and the way in which alcohol is consumed (with frequency of drinking and quantity of alcohol consumed when drinking being two important dimensions of consumption).[1, 14, 36]

Recorded alcohol consumption is highest in economically developed countries, lower in parts of Africa and Asia, and particularly low in Muslim countries.[1, 36] The WHO has estimated worldwide abstention in 2016 was 57% of the population aged ≥15 years, but with wide variation ranging from high abstention in countries with low alcohol per capita consumption (e.g. Eastern Mediterranean countries) and low abstention in countries with high alcohol per capita consumption (e.g. European countries).[1] In all regions in 2016, compared with men, a lower proportion of women were current drinkers (females 32%, males 54%), total alcohol consumption per capita per year among drinkers aged ≥15 years was lower in women (females seven litres of pure alcohol, males 19 litres), and prevalence of heavy episodic drinking among those aged ≥15 years who drink was lower in women (females 20%, males 50%).[1]

New Zealand's estimated alcohol consumption in 2016 was 10.7 litres of pure alcohol per capita (aged ≥15 years), higher than the worldwide value of 6.4 litres per capita per year, and similar to values for other high income countries (e.g. Australia 10.6 litres, Canada 8.9 litres, France 12.6 litres, Germany 13.4 litres, Ireland 13.0 litres, Netherlands 8.7 litres, Norway 7.5 litres, Sweden 9.2 litres, Switzerland 11.5 litres, United Kingdom (UK) 11.4 litres, United States of America (USA) 9.8 litres).[36] Of total recorded alcohol consumed in New Zealand in 2016, 38% was beer, 33% was wine, 29% was spirits, and <1% was other alcoholic beverages. Alcohol consumption per capita per year among drinkers aged ≥15 years was lower in women (females seven litres of pure alcohol, males 20 litres, total 14 litres), and prevalence of heavy

episodic drinking among those aged ≥15 years who drink was lower in women (females 24%, males 58%, total 43%).[1]

In New Zealand, the most accurate regularly-reported indicator of total alcohol consumption is from Statistics New Zealand (Stats NZ) data on alcohol available for consumption each year.[52] This does not include unrecorded sources of alcohol available for consumption (which the WHO estimates above include). In 2018, 8.8 litres of pure alcohol per person aged ≥15 years were available for consumption. Expressed in terms of standard drinks (where one standard drink contains 10 grams of alcohol), this equates to 1.9 standard drinks per person aged ≥15 years per day, or 2 standard drinks per person aged ≥18 years per day. Although over the last 15 years, the total volume of pure alcohol available per year is trending upwards (30.0 million litres in 2003, 32.0 million litres in 2008, 32.9 million litres in 2013, and 34.8 million litres in 2018), the volume of pure alcohol available per year per person aged ≥15 years has fluctuated (8.9 in 2003 and 8.8 litres in 2018, with peak volume 9.6 litres in 2010 and lowest volume 8.7 litres in 2015).[52]

The most recent information from the New Zealand Health Survey (2017/18 data) indicates that 79% of New Zealanders aged ≥15 years reported drinking alcohol in the past 12 months.[53] Drinking alcohol was more likely in men (83%) than women (75%). Fifty-seven percent of 15-17-year olds reported consuming alcohol in the past 12 months. Drinking alcohol was less likely in Asian (55%) and Pacific (54%) adults than non-Asian and non-Pacific adults respectively, and in adults living in the most socioeconomically-deprived areas (67%) than those living in the least socioeconomically-deprived areas (86%).[53]

In 2017/18, 20% of all adults aged ≥15 years and 25% of past-year drinkers (estimated to be approximately 775,000 people) reported drinking alcohol in a manner considered hazardous to their health (defined as an AUDIT[ii] questionnaire score of eight or more[54, 55]). Hazardous drinking rates were higher in men (27% of all adult men, 33% of male past-year drinkers) than women (13% of all adult women, 17% of female past-year drinkers). By age-group, hazardous drinking was highest in young people aged 18–24 years (32% of all adults this age, 38% of past-year drinkers this age). By ethnicity, hazardous drinking was highest in Māori adults (32%

[ii] Alcohol Use Disorder Identification Test (AUDIT) is a 10-item questionnaire, developed by the WHO as a simple method for screening for hazardous, harmful, and dependent alcohol use. Responses to each question are scored from 0 to 4, and then added to a total score between 0 and 40. A total score of 8-15 indicates hazardous alcohol use, 16-19 indicated harmful use, and 20 or more indicates possible dependence. See Appendix 1 for further detail about the AUDIT.

of all Māori adults, 40% of past-year drinkers who are Māori), followed by Pacific (19% of all Pacific adults, 36% of Pacific past-year drinkers) and European/Other (21% of all European/Other adults, 25% of European/Other past-year drinkers), and lowest in Asian adults (7% of all Asian adults, 12% of Asian past-year drinkers). For adults living in the most socioeconomically deprived areas, hazardous drinking rates were higher (22% of all adults living in these areas and 32% of past-year drinkers living in these areas) than those living in the least socioeconomically deprived areas (16% of all adults living in these areas and 19% of past-year drinkers living in these areas).[53]

2.1.6 Alcohol-Related Harms

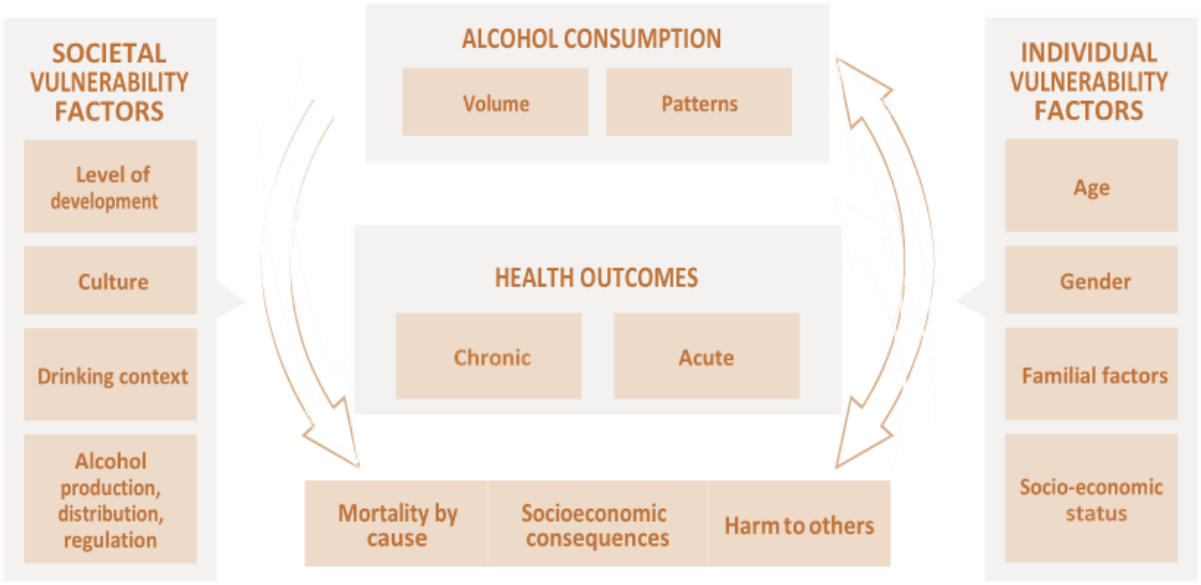
Alcohol is an addictive, psychotropic drug, a toxin and carcinogen, an intoxicant, a leading cause of intentional and unintentional injury, and a component cause of more than 200 disease conditions, including alcohol dependence, liver cirrhosis, cardiovascular disease, and cancers.[1, 4-6, 36, 56-58] In New Zealand, one in three people who consume alcohol have reported being harmed by their own drinking in the past year.[59] Factors associated with a higher risk of alcohol-related harm include being male, younger age, Māori ethnicity, or living in a very deprived area of New Zealand.[59]

The use of alcohol can also result in harm to other individuals, such as family members, friends, co-workers, and strangers (for example due to injury, violence, mental health issues, time off work, and economic harms).[1, 36] Of great concern are the substantial harms to unborn babies from maternal alcohol use.[60] Foetal Alcohol Spectrum Disorder (FASD) is recognised as a leading preventable cause of intellectual and developmental disabilities.[1] There is a lack of information in New Zealand on the incidence and prevalence of FASD.[61] However, it is known that a high percentage of women drink alcohol during pregnancy.[61] Rossen et al. recently reported that in a large representative New Zealand study of pregnant women, 71% drank alcohol before becoming pregnant, 23% drank alcohol during the first trimester, and 13% drank alcohol after the first trimester.[62] Conservative estimates have been made that 600 to 3,000 babies are born with FASD each year in New Zealand.[63, 64]

Pathways of alcohol-related harm (Figure 1) are determined by a range of factors, including alcohol consumption volumes and patterns, individual factors (such as age, gender, ethnicity, socio-economic status), and societal factors (such as drinking cultures and context, and alcohol controls and regulations).[36] Adverse health outcomes can be acute or chronic in nature, and

include injury and disease, morbidity and mortality, and are often accompanied by social consequences.[36]

Figure 1. Conceptual Causal Model of Alcohol Consumption and Harms



Source: World Health Organization. Global Status Report on Alcohol and Health. Geneva: WHO, 2014.

Globally, harmful use of alcohol causes a large disease, social, and economic burden in societies.[1-4, 36] In 2016, alcohol was the seventh leading risk factor globally for both deaths (accounting for 5.2% of deaths or 2.8 million deaths) and Disability Adjusted Life Years (DALYs), accounting for 4.2% of DALYs or 99.2 million DALYs.[2] Within the age group 15 to 49 years, alcohol was the leading risk factor globally for death and disability.[2, 3] Alcohol causes a larger share of the total disease burden than previously reported and the risk of all-cause mortality, and of cancers specifically, rises with increasing levels of consumption. The level of consumption that minimises health loss due to alcohol use is zero.[3]

In New Zealand, it is estimated that 5.4% of all deaths under 80 years of age in 2007 (802 deaths) and 6.5% of all healthy life lost among 0-79 year olds in 2004 (28,403 DALYs) were attributable to alcohol consumption.[43, 65] Overall, 43% of deaths were due to injuries, 30% due to cancers, and 27% due to other diseases. There were marked differences in mortality by sex and ethnicity. Twice as many deaths occurred in men compared with women, and the age-standardised death rate for Māori was 2.4 times the rate for non-Māori. Cause of death varied by age with predominantly more injury deaths in younger people and predominantly more chronic disease deaths in older people.[43]

The top five causes of death were:

- Māori males: road traffic injuries, other unintentional injuries, self-inflicted injuries, alcoholic liver cirrhosis, and drownings.
- Non-Māori males: road traffic injuries, alcoholic liver cirrhosis, self-inflicted injuries, other unintentional injuries, and oesophageal cancer.
- Māori females: breast cancer, road traffic injuries, ischaemic heart disease, alcoholic liver cirrhosis, and haemorrhagic stroke.
- Non-Māori females: breast cancer, haemorrhagic stroke, alcoholic liver cirrhosis, colon cancer, and road traffic injuries.[43]

The top five causes of DALYs were:

- Males: alcohol use disorders, road traffic injuries, self-inflicted injuries, other unintentional injuries, and cirrhosis of the liver.
- Females: alcohol use disorders, breast cancer, road traffic injuries, cirrhosis of the liver, and other unintentional injuries.[43]

The alcohol-related cancer deaths accounted for 4.2% of all cancer deaths under 80 years of age in 2007.[66] Cancers attributable to alcohol included in this analysis were cancers of the mouth and oropharynx, larynx, oesophagus, liver, colon, rectum, and female breast. Although risk of cancer increased with higher levels of alcohol consumption, half the cancer deaths were due to lower levels of consumption, i.e. less than four standards drinks per day. In women, breast cancer accounted for 61% of alcohol-attributable cancer deaths, and 36% of these deaths were attributed to relatively low consumption of less than two standard drinks of alcohol per day.[66]

More recently, the 2016 Global Burden of Disease Study has shown that alcohol was ranked the eighth leading risk factor for deaths among people of all ages in New Zealand accounting for 3.9% of total deaths.[67] Among people aged 15-49 years, alcohol was ranked the leading risk factor, accounting for 16.8% of total deaths in this age group. For disability, alcohol was ranked the fourth leading risk factor for DALYs among people of all ages, accounting for five percent of total DALYs in New Zealand. Among people aged 15-49 years, alcohol ranked as the leading risk factor for DALYs, accounting for 7.3% of total DALYs in this age group.[67]

The total social costs of harmful alcohol use are significant. Analysis for the year 2005/6 estimated that the harmful use of alcohol cost New Zealand just under $5 billion.[68] Approximately two thirds of this was made up of tangible costs (lost output/labour costs, justice

sectors costs, and health costs) and one third intangible costs. Tangible costs due to alcohol and other drug use were equivalent to 2.9% of Gross Domestic Profit (GDP) in 2005/6. (This was not separated out for alcohol and other drugs, but alcohol comprised 74% of the total tangible costs.) The authors estimated, based on international studies, that 50% of social costs could be avoided.[68]

2.2 Strategies to Reduce the Harms of Alcohol

There is clear evidence about the strategies that effectively prevent and reduce the harmful use of alcohol.[14-16] The strongest, most cost-effective strategies include taxation that increases prices, restrictions on the physical availability of alcohol, drink-driving countermeasures, brief interventions with at risk drinkers, and treatment of drinkers with alcohol dependence.[69] In New Zealand, a detailed set of recommendations based on international evidence and localised to the New Zealand setting was put forward by the New Zealand Law Commission in 2010, prior to the review of the Sale of Liquor Act 1989 (now replaced with the Sale and Supply of Alcohol Act 2012).[42] Despite being evidence-based, public health strategies to reduce alcohol-related harm often meet with resistance from policy-makers. As discussed in Section 2.1.4, an important reason for this includes the enormous power of alcohol corporations which exert influence through 'commercial determinants of health' and reduce the capacity and willingness of governments to implement effective alcohol policies.[16, 46, 70, 71]

In summary, the strategies recommended to reduce the harms of alcohol, based on international and local evidence,[14-16, 42] include:

- increasing the price of alcohol (e.g. through taxation and minimum-unit pricing),
- increasing the minimum legal purchase age,
- reducing access to and availability of alcohol,
- controlling advertising, promotion, and sponsorship of alcohol,
- drink-driving countermeasures,
- SBIs with at-risk drinkers, and
- treatment for people with alcohol dependence.

The high impact strategies have recently been summarised by the WHO using the acronym 'SAFER', i.e.: Strengthen restrictions on alcohol availability; Advance and enforce drink driving countermeasures; Facilitate access to screening, brief interventions and treatment; Enforce bans or comprehensive restrictions on alcohol advertising, sponsorship, and

promotion; Raise prices on alcohol through excise taxes and pricing policies.[72] Each of these will now be discussed in more detail.

2.2.1 Strengthen Restrictions on Alcohol Availability

Reducing the availability of alcohol is a cost-effective and pro-equity measure for preventing and reducing alcohol harm.[16, 73] Increased alcohol outlet density is associated with hazardous consumption[74, 75] and increased alcohol-related harm.[75, 76] Alcohol outlets are more likely to be situated in socioeconomically deprived areas,[77, 78] further contributing to unequal distribution of alcohol-related harms. Strong evidence supports reduced trading hours as a strategy for reducing alcohol-related harms.[79]

Young people are more vulnerable to alcohol-related harm than other age groups.[36] Alcohol can adversely affect brain development.[80] Raising the purchase age reduces access to alcohol among young people, reduces harmful youth drinking, and raises the age at which young people start drinking.[14, 81]

2.2.2 Advance and Enforce Drink Driving Countermeasures

The risk of motor vehicle related injury increases exponentially with increasing alcohol consumption.[5] In New Zealand, it is estimated that over one quarter of road traffic injuries involve alcohol.[60] Laws setting a zero or low level of blood alcohol concentration at which people may drive legally and enforcement of laws significantly reduce drink-driving and alcohol-related driving fatalities.[14]

2.2.3 Facilitate Access to Screening, Brief Interventions, and Treatment

In healthcare settings, screening, BI/advice with at-risk drinkers, and referral to specialist services when indicated reduce hazardous drinking and alcohol-related harms.[14] Detoxification is an effective treatment for alcohol dependence and addiction.[14, 57] Health professionals have an important role to play in helping people to reduce or stop their drinking and to access the help they need.[57, 72]

2.2.4 Enforce Bans or Comprehensive Restrictions on Alcohol Advertising, Sponsorship, and Promotion

Restrictions on alcohol advertising, sponsorship, and promotion are high impact and cost-effective measures to prevent and reduce alcohol harm.[16, 73] Alcohol advertising and promotion

increase the likelihood that people, particularly young people, will start to use alcohol, drink more if they are already drinking, and makes it more difficult for hazardous users to abstain.[14,16]

2.2.5 Raise Prices on Alcohol Through Excise Taxes and Pricing Policies

Increasing the price of alcohol is the most cost-effective and pro-equity strategy to reduce alcohol-related harm.[32] It delays the start of drinking, reduces the volume consumed per occasion by young people, and has a greater effect on heavy drinkers.[16, 73, 82]

2.3 Screening and Brief Intervention

The concept and ideas of Screening and Brief Intervention (SBI) have existed and evolved over many decades.[83, 84] SBI is a secondary prevention strategy, i.e. prevention of alcohol problems through systematic screening to identify risk or harm at an early stage followed by BI to help reduce alcohol-related risk or harm.[85] The concept involves 1) identifying people, through use of a screening tool such as the 10-question AUDIT,[iii] who are drinking in a way that is hazardous to their health or who are already experiencing alcohol-related problems, and 2) providing BI, which has three key steps: a) giving feedback and information about the person's alcohol use, b) listening and discussing the issue, and c) giving advice, discussing options, and helping with goal-setting.[86-88] If indicated, people are referred for specialist help. SBI and referral for further treatment when indicated are important components of a comprehensive public health strategy to reduce hazardous alcohol use and prevent alcohol-related harm.[14,15,72]

BI is a patient-centred approach, grounded in social-cognitive theory, and designed to motivate patients to change their behaviour.[85, 87] BI is typically delivered by generalist healthcare workers (rather than addiction specialists) and is provided to patients with hazardous and harmful drinking patterns (i.e. those considered at 'medium risk', rather than those with alcohol-use disorders, alcohol dependence, or addiction). BIs are usually short time-limited 'simple advice' conversations but may also include longer 'brief counselling' sessions involving an expanded assessment, help with goal setting, and provision of specific tools and strategies for behaviour change.[87] Important elements often included in BI have been summarised by the acronym FRAMES, i.e.: Feedback of personal risk or impairment, emphasis on personal Responsibility for change, clear Advice to change, offering a Menu of alternative

[iii] See Appendix 1 for detail about the AUDIT.

change options, therapeutic Empathy as a counselling style, and enhancement of patient Self-Efficacy or optimism.[89]

There is a large body of literature investigating the effectiveness of SBI in a wide range of healthcare settings, including general practice and emergency/trauma care settings.[14, 84, 85, 89-91] For the general practice setting, there is robust evidence that brief alcohol interventions are effective at reducing hazardous and harmful drinking.[92] A meta-analysis of one-year follow-up data from 22 RCTs assessing 5856 patients found BI reduced the quantity of alcohol consumed in those receiving BI, compared with a control group, by 38g per week (about four standard drinks) on average.[85] Further evidence has shown that screening followed by very brief advice involving simple feedback and information is just as effective as more intensive BI strategies.[93]

For the ED setting, the evidence for the effectiveness of SBI has been ambiguous. However, a recent large meta-analysis of 28 RCTs including 14,456 patients found evidence for small effects of BIs.[94] Small but significant reductions were found in the quantity of alcohol consumed per week, the intensity of alcohol consumed (e.g. amount of alcohol consumed per occasion), and the number of binge-drinking occasions.[94] Further evidence has shown that more intensive interventions do not show benefit over shorter approaches (i.e. screening with very brief advice/feedback).[95]

For injured patients attended to in trauma care settings, SBI has been reported to reduce alcohol intake, injury recidivism and other alcohol-related harms.[11, 91, 94] In a systematic review of BI studies for injury patients, Nilsen and colleagues concluded that, although it was difficult to provide evidence on the results of BI due to heterogeneity of studies, 11 of the 12 studies that compared pre- and post-BI results observed a significant effect of BI on at least some of the outcomes of interest (alcohol intake, risky drinking practices, alcohol-related negative consequences, and injury frequency).[91]

In addition to the extensive body of literature related to face-to-face SBI, the last two decades have seen the emergence of literature focussed on the use of computers and the Internet to deliver SBI. Two recent systematic reviews and meta-analyses found evidence that, in people with hazardous or harmful drinking patterns who were not seeking treatment, electronic SBI may have a modest effect in lowering alcohol consumption.[96, 97] In their meta-analysis of 17 studies, Donoghue and colleagues (2014) reported there was a significant reduction in weekly alcohol consumption between intervention and control conditions between three months and less than 12 months follow-up, but not for 12 months follow-up or greater.[96] The overall mean

difference in alcohol consumed per week between those in the intervention and control groups was 17 grams (i.e. nearly two standard drinks). Kaner and colleagues (2017), in a meta-analysis of 41 studies ranging in follow-up from one to 12 months, reported that people using a digital intervention consumed approximately 23 grams of alcohol per week (i.e. nearly two and a half standard drinks) less than control group participants who received no or minimal interventions.[97]

The SBI approach has been criticised for having only modest efficacy for reducing alcohol consumption and for there being gaps in evidence about implementation in the real world (i.e. translation of research into practice).[98] However, the principles of Geoffrey Rose's 'Mass Strategy'[99] would indicate that, if many people who drink alcohol in a hazardous way could make modest reductions in consumption, this would make a significant impact on hazardous alcohol use and alcohol-related harm at a population level.[84, 100] Also, this approach would be most effective as part of a comprehensive public health strategy involving legislative public health measures and changes to the alcohol environment.[14, 15, 72]

2.3.1 Barriers to Implementation of Screening and Brief Intervention

Internationally and in New Zealand, SBI has been infrequently implemented in healthcare settings, including primary care and trauma care.[12, 17, 18, 86, 101, 102] Research has indicated a range of barriers to implementation, including: attitudes towards alcohol; fears about damaging professional/patient relationships; a lack of knowledge, confidence, and skills among health professionals about SBI; a lack of organisational support and resource; and other competing healthcare priorities.[17-22, 101, 103] Facilitating factors include: training for health professionals with follow-up support; availability of simple screening tools; clarity about the intervention and professional role definition as to who is responsible for the intervention; having adequate time; and ensuring acceptability for patients.[21, 22]

Although, in general, health professionals recognise the importance of asking about and addressing patients' alcohol use, attitudes towards alcohol create barriers in carrying this out. Many health professionals are unaware or not up to date on the effects of alcohol, the recommended 'lower risk' alcohol consumption guidelines, and recommended approaches and interventions to address alcohol problems. Alcohol is viewed as a 'taboo' subject, difficult to bring up in a consultation, and potentially stigmatising of patients and damaging to the professional/patient relationship. Some professionals report feeling hypocritical in carrying out SBI, due to their own alcohol use. However, research suggests that patients do not mind being

asked about alcohol, suggesting a discrepancy between what health professionals think patients want and what patients expect of health professionals.[18, 21, 22]

Organisational/institutional barriers are key factors in preventing the uptake of SBI. Barriers reported include: a lack of leadership in organisations with regard to recognising alcohol as a public health problem and supporting actions to reduce alcohol harms; a lack of resources for training and ongoing support for health professionals, for managing workloads and for providing adequate time for alcohol consultations; and a lack of referral options and clear referral mechanisms. These factors lead, understandably, to reluctance by staff to address alcohol with patients and prevent the uptake of SBI.[18, 21, 22]

2.3.2 Implementation Strategies for Screening and Brief Intervention

Implementation strategies are "methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice."[104] They are very important in implementation science as they describe *how* to change healthcare practice and are necessary for translation of research evidence into practice.[104, 105] Implementation strategies vary widely and can comprise a single component strategy or a number of strategies combined into a multifaceted implementation strategy.[104] The Expert Recommendations for Implementing Change (ERIC) study provided a published taxonomy, developed through a consensus development process, of 73 implementation strategies with terms and definitions.[106] Another shorter taxonomy has been provided by the Effective Practice and Organisation of Care (EPOC) Cochrane Review Group.[105]

There is an emerging literature on implementation strategies to address barriers to implementation of alcohol SBI,[107-112] including a systematic review and meta-analysis by Keurhorst and colleagues (2015).[107] The review included 29 studies, which varied in implementation strategies with 11 studies utilising professional-orientated strategies (e.g. educational meetings, educational outreach visits, audit and feedback), three studies utilising organisational-orientated strategies (e.g. change in scope and nature of services or service delivery), one study utilising a patient-orientated strategy (i.e. printed educational materials), six studies utilising a combination of professional- and organisational-orientated strategies (e.g. educational meetings plus changes in services or systems), and eight studies utilised various combinations of professional, organisational, patient, and financial strategies. The study found increased SBI activity resulted from multi-component strategies compared with single-

component strategies, e.g. combining education (professional-orientated) with patient self-management materials (patient-orientated) was more effective than just one element.[107]

As part of implementation of SBI and alongside selection of appropriate implementation strategies, it is also critically important to consider context and setting.[109, 113, 114] Context includes geographical, epidemiological, socio-cultural, socio-economic, ethical, legal, and political factors. Setting is the specific physical location, in which an intervention is implemented.[113] In order for SBI to be implemented in an effective and sustainable manner, it needs to be adapted for local context and setting factors, whilst retaining the core 'active ingredients' of SBI.[109, 114]

2.4 Mobile Health Strategies

Mobile Health (mHealth) approaches to intervention/programme delivery show potential as a strategy for overcoming barriers to implementation and for increasing uptake of, and reducing inequities in access to, healthcare information and services. The WHO has defined mHealth as "the use of mobile devices – such as mobile phones, patient monitoring devices, personal digital assistants (PDAs) and wireless devices – for medical and public health practice."[23] It is a 'subset' which sits under the broader domain of Electronic Health (eHealth), which is defined as "the cost-effective and secure use of information communication technologies (ICT) in support of health and health related fields"[23]

WHO's most recent global survey of eHealth (2016) reports rapid uptake of mHealth in both developed and developing countries and describes the field as "burgeoning".[23] Common types of mHealth programmes seen globally include toll-free emergency helplines, health call centres, appointment reminders, community mobilisation/health promotion campaigns, access to health information and databases, mobile telehealth consultations, emergency and disaster response and management, access to patient records, education resources, data capture and transmission for patient monitoring, and data collection for health surveys. Many of these programmes involve adding another channel (i.e. mobile) to extend current service delivery, which can be transformative due to the enormous reach and ubiquitous nature of mobile phones.[23]

Mobile phones have been referred to as "the most accessible form of mediated communication in world history" and text messaging has become "one of the most frequently used forms of mobile communication".[115] Global uptake of mobile phones is high and has increased from 2.2

billion global mobile phone subscriptions (82 per 100 inhabitants) in 2005 to more than 7 billion (>120 per 100 inhabitants) in 2015, with mobile broadband subscriptions also increasing rapidly to cover 86% of people in developed countries and 39% in developing countries.[23] In developing countries, mobile communication technologies are reaching remote areas which have never had fixed telephone lines and computer infrastructures.[23]

In the New Zealand 2013 Census, access to mobile phones within households was 86% for Māori, 85% for Pacific Peoples, and 87% for the total population, up from 78%, 73%, and 79%, respectively, in 2006.[116] Information from the most recent Internet Service Provider Survey shows that 3,847,000 mobile phones were connected to the internet over the cellular network in New Zealand, at 30 June 2017, up 11% from June 2016.[117]

The potential benefits of mHealth strategies include: mobility, low-cost and cost-effectiveness, high scalability, convenience for users, broad reach to people of different ethnic, age and socio-economic groups, and reduction in inequities in access to health information and participation in healthcare services.[23-26, 118] An emerging body of literature indicates mHealth interventions have the potential to efficiently deliver high quality healthcare services and promote behaviour change,[115, 119-121] however a recent systematic review of reviews concludes that the evidence for efficacy is still limited.[24] This review of 12 systematic reviews, including 371 studies, found that the most common type of mHealth interventions studied were text messaging interventions, for a range of different purposes including reminder, alert, education, motivation, and prevention. Positive impacts of mHealth interventions were seen in the areas of chronic disease management, lifestyle factors (e.g. reducing weight in overweight patients, smoking cessation), attendance rates (due to appointment reminders), and adherence to medications.[24]

An mHealth approach utilising text messages could be an appropriate and effective way to deliver alcohol SBI. Mobile phones are integrated into people's every-day lives and text messaging via mobile phones is a common, convenient, and accepted way of communicating. People can choose if and when they read or respond to a text message. Some people may prefer the anonymous nature of text messages related to alcohol. As BI is by definition 'brief', it may be appropriate to utilise text messaging to send short, succinct messages providing advice, information, and motivation for change. In addition, the fact that text messages can continue to be sent over a period of time (e.g. weeks or months) could offer an opportunity to provide ongoing BI support to people.

2.5 Summary

This chapter has presented background information and context for the thesis. It has provided an overview of alcohol as an important public health issue and introduced the concepts of alcohol SBI and mHealth, which the body of the thesis explores in more detail. The following chapter explores text message interventions, a subset of mHealth strategies, in more depth by presenting a systematic targeted review of text message intervention studies for hazardous alcohol use and alcohol-related harm.

CHAPTER 3: SYSTEMATIC REVIEW OF THE EFFECTIVENESS OF MOBILE PHONE TEXT MESSAGE INTERVENTIONS IN REDUCING HAZARDOUS OR HARMFUL ALCOHOL USE

Text message interventions, a subgroup of mHealth interventions, are reported to show great promise as a way of increasing access to healthcare information and programmes, supporting behaviour change, and reaching a broad range of people in an acceptable and convenient manner.[24, 115, 118-121] This chapter systematically reviews the evidence from published studies examining the effectiveness of mobile phone text message interventions in reducing hazardous alcohol use and alcohol-related harms (Thesis Objective One). This chapter reports the objectives, methods, results, and conclusions of the systematic literature review.

3.1 Introduction

Alcohol-related digital interventions have been the subject of recently published systematic literature reviews, including Kaner and colleagues' Cochrane review 'Personalised digital interventions for reducing hazardous and harmful alcohol consumption in community-dwelling populations' (2017)[97] and Donoghue and colleagues' systematic review and meta-analysis of 'the effectiveness of electronic SBI for reducing levels of alcohol consumption' (2014).[96] However, no published systematic reviews were located which focus specifically on RCTs which evaluate the effectiveness of alcohol text message interventions in people whose alcohol consumption has been identified/screened as being hazardous or harmful.

The objective of this systematic literature review is to assess the effectiveness of text message interventions in reducing hazardous alcohol use and alcohol-related harms. The questions being addressed in this review are: In adults with hazardous or harmful alcohol use, are text message interventions a) more effective compared with no intervention, and b) just as effective compared with usual care interventions (e.g. face-to-face interventions), in reducing alcohol consumption and/or reducing alcohol-related harms?

3.2 Methods

Methods and reporting of this systematic review were guided by the 'General methods for Cochrane reviews' section of the Cochrane Handbook for Systematic Reviews of Interventions[122] and the Preferred Reporting Items for Systemic Reviews and Meta-Analyses (PRISMA) statement and checklist.[123]

3.2.1 Criteria for Considering Studies for this Review

The inclusion criteria for this review were as follows.

- *Types of studies:* RCTs published in English language. Very small trials (less than 10 participants in each trial arm) were excluded.
- *Types of participants:* People of any age whose alcohol consumption has been identified/screened as being hazardous or harmful.
- *Types of interventions:* Mobile phone text message interventions aimed at reducing alcohol consumption and/or alcohol-related harms. Trials were excluded if text messaging was an adjunct to face-to-face, computer or web-based alcohol interventions.
- *Types of outcome measures:* Any measures of alcohol consumption (such as quantity, frequency of consumption, frequency of heavy drinking or binge-drinking, drinking above or within recommended guidelines) and/or alcohol-related harm (such as health or social problems). Trials reporting outcomes at any length of follow-up were considered.

3.2.2 Search Methods for Identification of Studies

A systematic search of the published literature was undertaken to identify RCTs which met the inclusion criteria listed above. Potentially eligible trials were identified in September 2018 by searching the electronic databases MEDLINE, EMBASE, and PsycINFO using search terms for alcohol use, combined with search terms for text messaging and RCTs (see Appendix 2 for complete search strategies). Search terms were informed by those used in recent systematic reviews by Donoghue and colleagues,[96] and Kaner and colleagues (2017[97] and 2018[124]). In addition, the Cochrane Library (www.cochranelibrary.com) and Google Scholar were searched

using key search terms, and relevant review articles and papers meeting the inclusion criteria were hand searched. No date restrictions were applied.

3.2.3 Data Collection and Analysis

Selection of Studies

Systematic searches using the strategies described above were conducted. Citations were downloaded to Microsoft Excel. Titles and abstracts were screened against the inclusion criteria. Potentially eligible trials were identified, and full text papers were retrieved. Reasons for exclusion of studies were recorded.

Data Extraction and Management

Data were extracted from the included studies into a table of characteristics of included studies (see Table 1). The data domains included in the tables were informed by the Cochrane Handbook.[122] They included: methods, participants and setting, interventions, outcomes, results, notes (including funding source and declarations of interest). Details extracted on participants and setting included: country of trial, number of participants, age and other characteristics of participants, and eligibility criteria.

Assessment of Risk of Bias in Included Studies

Risk of bias was assessed using the criteria and approach outlined in the Cochrane 'Risk of bias tool'.[122] Information on the following items was extracted from the included studies: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias. A judgement was made for each item regarding whether the 'Risk of bias' was low, high, or unclear. The criteria used for assigning judgements of low, high, or unclear risk were those provided in the Cochrane Handbook.[122]

Data Analysis

Study characteristics, 'Risk of bias' of the included studies, and an overview of treatment effects of text message interventions for reducing alcohol consumption and alcohol-related harm were described in a narrative synthesis. Meta-analysis was not undertaken as the included studies were not sufficiently homogeneous, in terms of participants, interventions, outcome measures, and follow-up time points, to provide a meaningful summary. Participants in

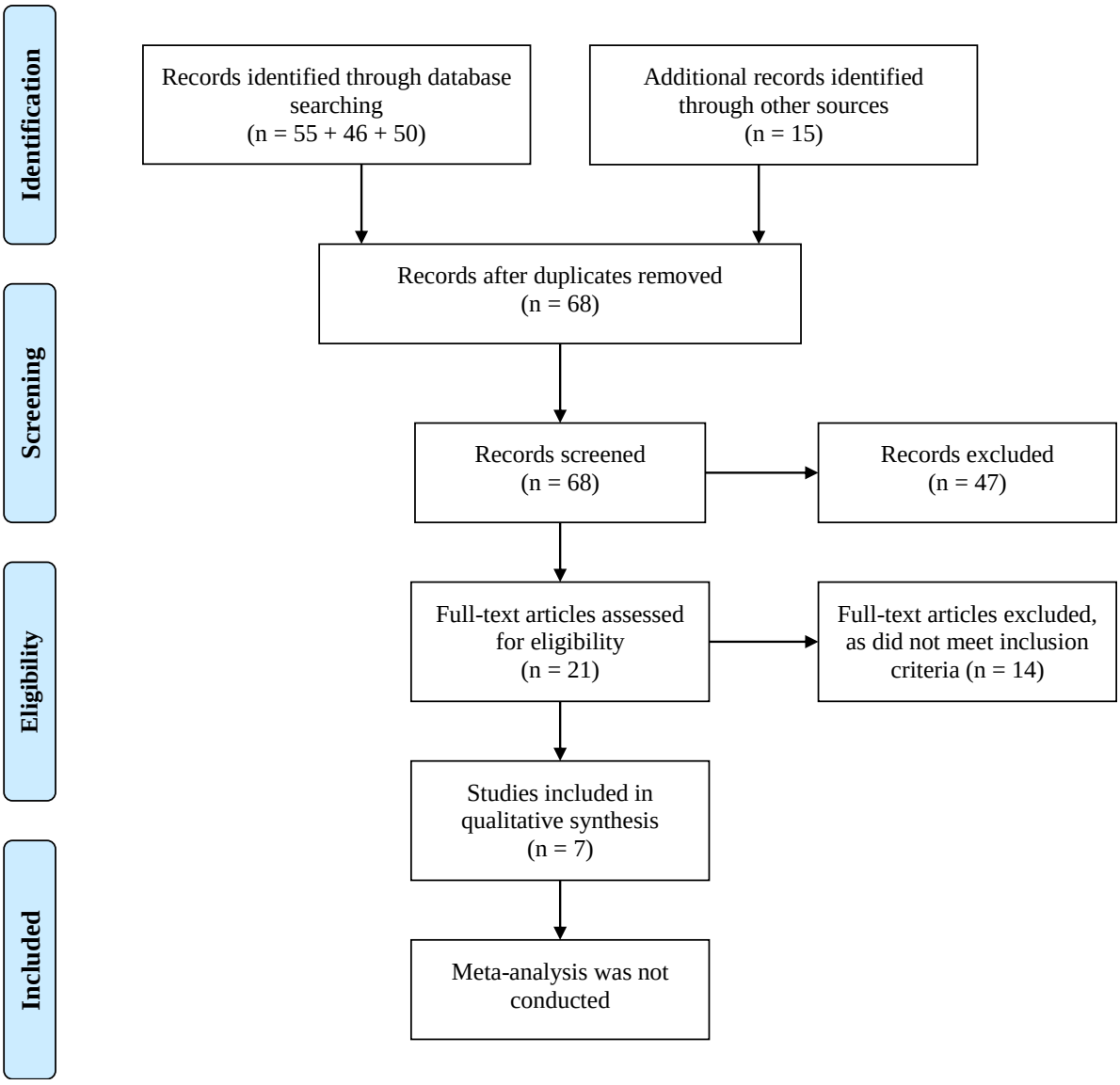
included studies were college students, or community-dwelling adults, or ED young adult patients. Participants were included in studies based on different definitions of hazardous drinking. Interventions were all text message-based but were very variable in terms of frequency of messaging, length of intervention and content of messages. Studies differed in the measures of alcohol consumption and harm outcomes used and the time points for follow-up.

3.3 Results

The literature search strategy identified 68 records which were screened against the inclusion criteria (Figure 2). Forty-seven records were excluded at this stage. Twenty-one full text papers were retrieved and examined in more detail for eligibility. From these, seven papers met the eligibility criteria and were included in the review. Fourteen papers were excluded due to:

- the text message intervention being an adjunct to a web-based intervention, a telephone counselling intervention, or face-to-face therapy/treatment (n=6)[125-130];
- participants not identified/screened as having hazardous or harmful alcohol consumption (n=4)[131-134];
- comparison of alcohol consumption or harm outcome measures between intervention and control groups was not made (n=2)[135, 136];
- intervention was an mHealth application (app) and did not involve text messaging (n=1)[137];
- RCT was very small with <10 participants in each arm (n=1).[138]

Figure 2. PRISMA Flow Diagram



3.3.1 Description of Included Studies

A description of each study is provided in Table 1 'Characteristics of included studies.' Seven papers describing six trials are described (one trial being reported in two published papers).

Setting and Participants

All six trials were conducted in the USA, three among college/university students,[139-141] one in adults aged 21 to 65 years who were seeking help to reduce their alcohol use and were recruited via online alcohol-help websites,[142] and two in young adults aged 18 to 25 years who presented to the ED.[143-145] Funding of all trials was through research grants (mainly from the National Institute on Alcohol Abuse and Alcoholism [NIAAA]).

The mean age of participants in the five trials among young adults ranged from 18 to 22 years and the participants in the remaining trial (Muench[142]) had a mean age of 43.2 years. High percentages of participants in all trials were females (64-77%) and of White/Caucasian race (48-94%).

Trials differed in their definitions of hazardous drinking for trial eligibility. Bock et al.[139] and Cadigan et al.[140] included college students who reported at least one heavy drinking episode in the past two weeks, and one heavy drinking episode when tailgating (i.e. partying before a sporting event) in the past year, respectively. Merrill et al. included participants based on the NIAAA criteria for risky drinking (men five or more drinks/day or 15 or more drinks/week, for women four or more drinks/day or eight or more drinks/week)[141] and Muench et al. included participants if they consumed at least 13 (for women) and 15 (for men) standard drinks per week.[142] In the Suffoletto et al. trials, participants were included if they had AUDIT-C[iv] scores indicating hazardous drinking (score of ≥three for women and ≥four for men).[143-145]

Study Design

Five trials were relatively small pilot or feasibility RCTs, with participant numbers ranging from 45 to 157 (Bock et al. n=60 across two trial arms,[139] Cadigan et al. n=133 across two arms,[140] Merrill et al. n=68 across two arms,[141] Muench et al. n=157 across five arms,[142] and Suffoletto et al. 2012 n=45 across three arms[143]). One large trial by Suffoletto and colleagues (2014[144] and 2015[145]) included 765 participants across the three trial arms (i.e. Intervention, Assessment, and Control groups).

Control Conditions

There was a range of control conditions against which the alcohol text message interventions were compared. In two trials, the control groups received text messages that were not alcohol related (Bock, general motivational texts[139]; Merrill, fun facts[141]). In four trials, the control groups received text messages that were alcohol related, either educational information texts (Cadigan[140]) or alcohol assessment texts (Muench,[142] Suffoletto 2012[143] and 2014/2015[144, 145]). The third group in the two Suffoletto et al. trials did not receive text messages. No trials examined the effectiveness of a text message intervention compared with usual care, such as face-to face BI/feedback for hazardous alcohol use.

[iv] AUDIT-C is a short form version of the full 10-item AUDIT. It consists of the first three 'consumption' questions of the full AUDIT.

Interventions

The text message interventions tested in these trials differed from one another in their frequency of messages, length of intervention, and content of the text messages. Apart from the trial by Cadigan and colleagues,[140] which was event based (i.e. drinking prior to a football game) and involved just one personalised text message per participant being sent on the morning of a football game, interventions involved multiple text messages over many weeks. For example: Merrill, one text/day for 28 days[141]; Muench, one text/day for 12 weeks[142]; Bock, six messages/week on Thursdays, Fridays, Saturdays, and Sundays for six weeks[139]; Suffoletto, weekly for 12 weeks[143]; Suffoletto, twice/week on Thursdays and Sundays for 12 weeks.[144, 145]

Interventions in the included studies can be divided into two categories based on whether the text message content was personalised or tailored to the individual participants, or not. Interventions tested by Bock et al.,[139] Merrill et al.,[141] and two arms (i.e. 'Loss-Framed' and 'Gain-Framed' messaging groups) of the trial by Muench et al.[142] were not personalised. The intervention tested by Bock et al. contained text messages with facts about alcohol, strategies to limit use and risks, and motivational content.[139] The intervention tested by Merrill et al. contained normative feedback about alcohol use and consequences and information on protective behavioural strategies.[141] The 'Loss-Framed' messaging arm of Muench and colleagues' trial contained information on the consequences of drinking, while the 'Gain-Framed' arm contained information about the benefits of reducing alcohol consumption.[142] In contrast, the trials by Cadigan et al.,[140] Suffoletto et al.,[143-145] and two arms (i.e. 'Statically Tailored' and 'Tailored Adaptive' groups) of the trial by Muench et al.,[142] contained personalised feedback about alcohol use and risks. The 'Tailored Adaptive' group (Muench[142]) and the intervention groups in the Suffoletto et al. trials[143-145] received the most tailored and proactive text message content, including content related to goal setting, motivation to reduce alcohol use, and strategies for cutting down.

Outcomes

Trials measured alcohol consumption and harm outcomes. All trials measured heavy or 'binge' drinking self-reported by participants. Cadigan et al. looked at heaving drinking in relation to an event (i.e. a football game),[140] whereas the other trials examined the number of heavy drinking days reported over the past two weeks (Bock[139]) or four weeks (Merrill[141]) or 30 days (Muench,[142] Suffoletto 2012,[143] Suffoletto 2014,[144] and Suffoletto 2015[145]). All trials, except for Suffoletto et al., 2012,[143] explored a measure of alcohol-related harms. Three trials

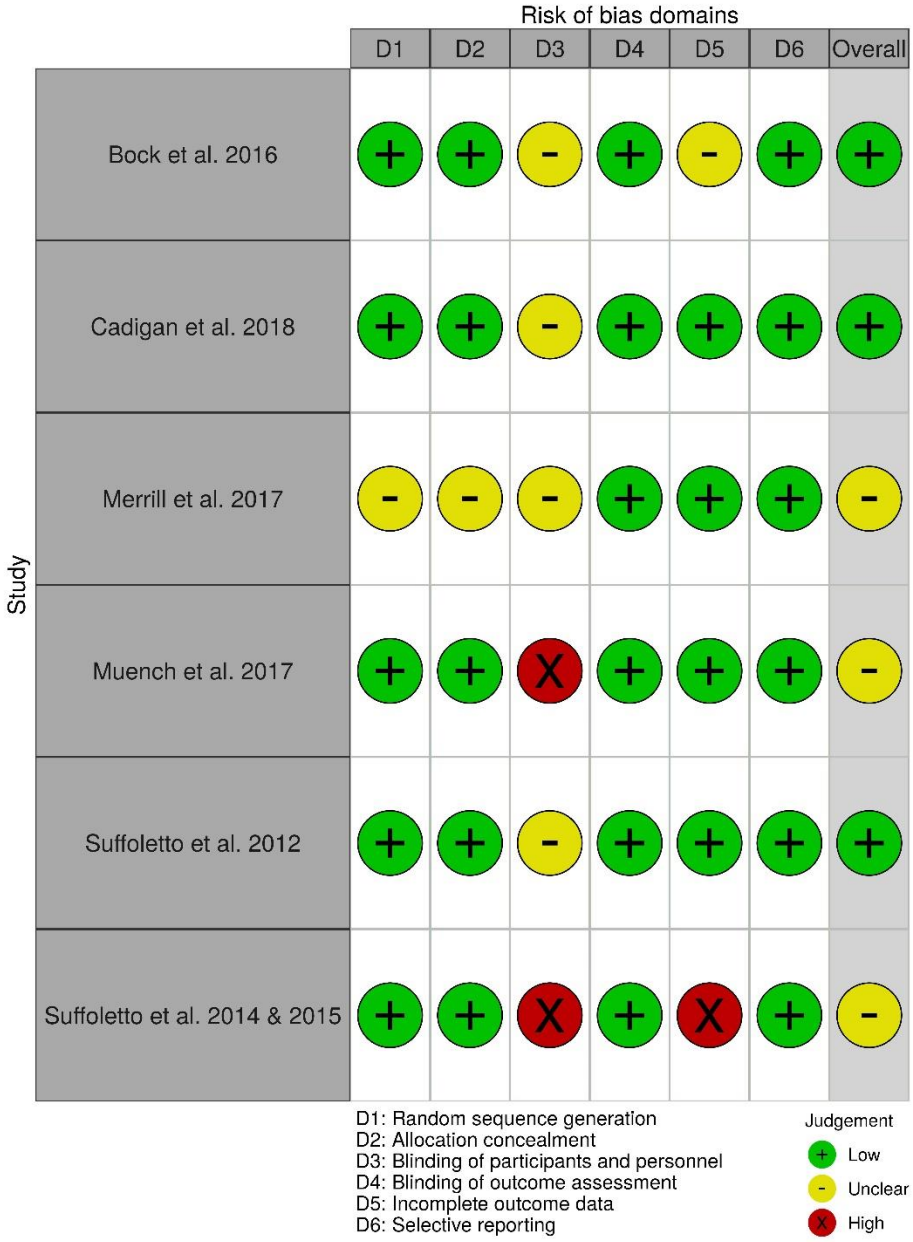
(Bock,[139] Cadigan,[140] and Merrill[141]) measured negative alcohol consequences using the Brief Young Adult Alcohol Consequences Questionnaire and one trial (Muench[142]) used the Short Inventory of Problems (SIP). Suffoletto et al. (2014[144] and 2015[145]) measured prevalence of alcohol-related injury in the past three months (yes/no) as a secondary outcome. All trials measured outcomes at the time point of completion of the text message intervention delivery. Just three trials continued follow-up past this time point: Bock et al., for a further six weeks, i.e. to 12 weeks from baseline[139]; Cadigan et al., for a further month, i.e. one month from baseline[140]; and Suffoletto et al. (2014 and 2015) for a further six months, i.e. to nine months from baseline.[144, 145]

3.3.2 Risk of Bias in Included Studies

Randomisation and allocation concealment were considered adequate in all trials, except for one trial (Merrill[141]) for which an assessment was not able to be made due to insufficient information. Although all trials were assessed as having adequate blinding of outcomes assessments (because outcomes were assessed by automated online surveys), blinding of providers and/or participants is likely to have been an issue. Four trials did not provide adequate information on blinding. Muench et al. reported their trial as a "single-bind" trial in which personnel were not blind.[142] In the trial by Suffoletto et al. (2014 and 2015) it is likely participants were not blind to treatment allocation because they were told they could receive no texts, Sunday texts for 12 weeks, or both Thursday and Sunday texts for 12 weeks.[144, 145]

Attrition bias is not likely to be an issue for the five small pilot studies as these studies contained small numbers of participants and had very high retention rates. However, the large RCT by Suffoletto et al. (2014, 2015) was assessed as having high risk of attrition bias due to loss-to-follow-up.[144, 145] Follow-up rates were 78% at three months, 63% at six months, and 55% at nine months.[144, 145] All trials were assessed as having low risk for selective reporting. Measures were reported as specified in the methods sections of the published papers. Three trials (Muench, Suffoletto 2012, and Suffoletto 2014 and 2015) were documented as having been registered with ClinicalTrials.gov and reporting was consistent with information available on the register. An overall summary of risk of bias for all included studies is shown in Figure 3.

Figure 3. Summary Assessment of Risk of Bias



This Risk of Bias figure was created using the *robvis* tool: *Luke A McGuinness (2019). robvis: An R package and web application for visualising risk-of-bias assessments.* https://github.com/mcguinlu/robvis

3.3.3 Summary of Results of Text Message Intervention Trials

The results of the five small pilot or feasibility trials included in this review should be viewed with caution due to their small sizes and inadequate power to detect statistically significant effects of interventions on alcohol consumption and harms. However, overall the results are encouraging and suggest alcohol text message interventions may have the potential to reduce alcohol consumption and harms.

Regarding heavy drinking outcomes, two of the small trials (Merrill[141] and Bock[139]) showed no statistically significant difference between intervention and control conditions, although both showed promising reductions in alcohol consumption in the intervention groups. The other three small trials (Cadigan,[140] Muench,[142] and Suffoletto[143]) showed statistically significant reductions in heavy drinking in the intervention groups compared with control conditions at the time point of completion of the text message intervention. Cadigan et al. also tested effectiveness at one-month follow-up and found no difference.[140]

Regarding alcohol-related harms, four of the five small trials measured alcohol negative consequences. Bock et al.[139] and Cadigan et al.[140] reported statistically significant differences between intervention and control conditions in alcohol negative consequences at the time point of completion of the intervention, however this difference was not sustained at subsequent follow-up points (Bock, six weeks[139]; Cadigan, one month[140]). Merrill et al.[141] and Muench et al.[142] reported no differences between intervention and control conditions for alcohol negative consequences.

The largest trial included in this review is that by Suffoletto and colleagues (2014 and 2015).[144, 145] This trial was a three-arm RCT in 765 18 to 25-year olds presenting to the ED setting. The study compared the effectiveness of an intervention involving text message assessments and tailored feedback (SA+F) with text message assessments alone (SA) and no text messages (control group) in reducing alcohol consumption and alcohol-related injury at six months follow-up (i.e. six months after completion of the 12-week text message intervention, or nine months from baseline). At nine months from baseline, compared with controls, participants in the SA group showed no differences in outcomes, and the SA+F group had:

- greater reductions in the number of heavy drinking days (Incident Rate Ratio 0.69, 95% Confidence Interval (CI) 0.59-0.79);
- lower binge-drinking prevalence (Odds Ratio (OR) 0.52, 95% CI 0.26-0.98);
- fewer drinks per drinking day (beta -0.62, 95% CI -1.10 to -0.15); and
- lower alcohol-related injury prevalence (OR 0.42, 95% CI 0.21-0.88).[145]

Table 1. Characteristics of Included Studies

Bock et al., 2016[139]	
Methods	Two-arm parallel RCT comparing a 'Text Message Alcohol Program' (TMAP) for alcohol-related harm reduction with a text message general motivational control condition. Intention-to-treat (ITT) analysis performed: not stated.
Participants	Community college students in the USA; eligible if aged 18-28 years, reported at least one day in the past two weeks of drinking at least four drinks, and used text messaging; recruited through flyers at community colleges and then research staff sent interested students a link to a screening survey. Number randomised = 60 (stratified by gender and frequent heavy drinking status); mean age 21.8, female 61.7%, White/Caucasian 81.7%, Hispanic 10.0%, frequent heavy drinkers (defined as three or more heavy drinking episodes in the previous two weeks) 36.7%, mean number of drinking days/month 19.8, mean number of heavy drinking days/month 7.1.
Interventions	**Intervention group** (n=31) received TMAP, six messages per week for six weeks delivered on a set schedule: Thursday evening (n=1), Friday and Saturday evenings (n=2 each), and Sunday evening (n=1). Text message content covered three domains: facts about alcohol, strategies to limit alcohol use and alcohol-related risks, and motivational messages. Within each of these domains, messages represented content topics, i.e.: pregaming, safety, caring, driving/social responsibility, consequences, limits/strategies, awareness of physical sensations related to alcohol use/over-use, planning, and fun/emotion/social. TMAP participants could also test any of five keywords which would generate a reply providing a particular service or link. **Control group** (n=29) received general motivational text messages (not focussed on alcohol or harm reduction) on the same schedule as the Intervention group. In both groups, each text was followed by a brief message requesting the participant to rate the text from 1 to 10, where 10 was "liked it a lot".
Outcomes	Number of heavy drinking episodes in the last two weeks; peak estimate blood alcohol concentration (eBAC, calculated using highest number of drinks and time spent consuming them); number of negative alcohol-related consequences experienced during the past six weeks assessed using the Brief Young Adult Alcohol Consequences Questionnaire. Assessed at six and 12 weeks.
Results	One or less heavy drinking episode in the past two weeks: at six weeks TMAP participants 51.6%, controls 27.6%, OR=2.80 (95% CI 0.95, 8.22), p=0.06; at 12 weeks TMAP participants 48.4%, controls 34.5%, OR=1.78 (95% CI 0.63, 5.04), p=0.28. Peak eBAC: at six weeks, TMAP participants mean=0.11, controls mean=0.14, p=0.10; at 12 weeks TMAP participants mean=0.10, controls mean=0.11, p=0.18. Reported zero negative alcohol consequences: at six weeks TMAP participants 35.5%, controls 10.3%, OR=4.77 (95% CI 1.17, 19.40), p=0.03; at 12 weeks TMAP participants 38.7%, controls 17.2%, OR=3.03 (95% CI 0.91, 10.11), p=0.07.
Notes	Study explored feasibility, acceptability, and preliminary efficacy of TMAP program. Authors stated that although the study was not statistically powered to achieve significance, positive changes were observed in drinking behaviours favouring the active intervention. They

	concluded that overall TMAP provides encouraging results and the need for a larger efficacy trial is justified. Loss to follow-up: 56 (93.3%) and 53 (88.3%) participants completed six- and 12-week assessments respectively. Funding: a grant from the NIAAA. Stated that none of the authors have any conflicts of interest.

Risk of bias

Item	Judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation took place upon completion of an online survey.
Allocation concealment (selection bias)	Low risk	Allocation is assumed to have taken place digitally, i.e. on completion of online survey.
Blinding of participants and personnel (performance bias)	Unclear risk	Insufficient information.
Blinding of outcome assessment (detection bias)	Low risk	Outcome data collection was automated (i.e. participants were emailed a link to online follow-up assessments).
Incomplete outcome data addressed (attrition bias)	Unclear risk	Insufficient information. Loss to follow-up is stated, but no information on loss to follow-up numbers for each group, or reasons for dropout.
Selective reporting (reporting bias)	Low risk	Measures specified in methods are reported. No information indicating trial was registered.

Cadigan et al, 2018[140]

Methods	Two-arm parallel RCT comparing a text message event-specific personalised feedback intervention for alcohol use and harm reduction (TXT PFI) with a text message alcohol educational information control condition (TXT ED). ITT analysis performed: not stated.
Participants	University students at a large university in the Midwest of the USA; eligible if aged at least 18 years, had tailgated (i.e. partied before a sporting event) at a university home football game within the past 30 days, had a binge drinking episode (4+ drinks for women, 5+ drinks for men) when tailgating in the past year, were planning on tailgating during the current university football season, and had a cell phone with text message capabilities; recruited through a pre-screener survey administered from a University-wide email system and sent to all students. Number randomised = 133 (stratified by gender); mean age 21.01 years, female 71%, White/Caucasian 71%, mean number of drinks/week 15.36 (intervention group) 17.16 (control group), mean number of drinks when tailgating 6.14 (intervention group) 6.33 (control group).
Interventions	**The TXT PFI group** (n=72) received one text message on the morning of a football game with content tailored to the participant's tailgating alcohol use, alcohol-related problems, and drinking norms. **The TXT ED control group** (n=61) received one text message on the morning of a football game with content that provided general information about the effects of alcohol on the body. Length of text messages were approximately 125 words in both groups.
Outcomes	Number of drinks; peak estimated blood alcohol concentration (eBAC, calculated using the number of drinks and number of hours of drinking reported by participants); alcohol-related problems assessed using the Brief Young Adult Alcohol Consequences Questionnaire. Assessed the morning after the tailgating/football game event (tailgating alcohol outcomes) and at one-month follow-up (past 30 days typical alcohol use outcomes).
Results	Number of drinks while tailgating: significantly fewer drinks reported in TXT PFI group than TXT ED group (mean drinks 5.67 vs 7.08,

	p<0.01). Number of drinks per week, reported at one-month follow-up: no significant difference between groups, p=0.20. Peak eBAC: at tailgating follow-up TXT PFI group had a significantly lower peak eBAC than TXT ED group (mean eBAC 0.092 vs 0.126, p<0.001); at one-month follow-up TXT PFI group had a significantly lower peak eBAC than TXT ED group (mean eBAC 0.123 vs 0.159, p<0.001). Alcohol-related problems: no significant effect (p>0.05) at tailgating follow-up; at one-month follow-up TXT PFI group reported significantly fewer alcohol-related problems than TXT ED group (mean problem score 4.91 vs 6.63, p<0.01).
Notes	Authors concluded that the findings offer preliminary support for the efficacy of an event-specific text message intervention in reducing alcohol use for heaving drinking college students when tailgating. Results generalized at the one-month follow-up suggested event-specific interventions can impact typical drinking outcomes. Providing normative feedback on peer alcohol use was a mechanism of behaviour change. Loss to follow-up: Of 72 TXT PFI participants, 70 completed tailgating follow-up and 69 completed one-month follow-up. Of 61 TXT ED participants, 60 completed tailgating follow-up and 60 completed one-month follow-up. Funding: grants from the NIAAA. Stated that none of the authors have any conflicts of interest.

Risk of bias

Item	Judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised "via a random number table".
Allocation concealment (selection bias)	Low risk	Participants "were scheduled to come to the laboratory for an enrolment meeting where they provided informed consent, were randomized into one of two conditions….via a random number table stratified by gender and completed baseline measures on a laboratory computer".
Blinding of participants and personnel (performance bias)	Unclear risk	Insufficient information. Unclear whether delivery of interventions was automated or not.
Blinding of outcome assessment (detection bias)	Low risk	Outcome data collection was automated (i.e. participants were emailed a link to online follow-up assessments).
Incomplete outcome data addressed (attrition bias)	Low risk	Very low loss-to-follow-up.
Selective reporting (reporting bias)	Low risk	Measures specified in methods are reported. No information indicating trial was registered.

Merrill et al, 2017[141]

Methods	A pilot two-arm parallel RCT comparing a text message intervention that delivered normative feedback to heavy drinking college students with a text message control condition that delivered fun facts. ITT analysis performed: not stated.
Participants	Residential four-year university students in the USA; eligible if second-year students, aged 18-20 years, met the NIAAA criteria for risky drinking (for men ≥ 5 drinks/day or >14 drinks/week, for women ≥ 4 drinks/day or >7 drinks/week), and used text messaging at least weekly; excluded if reported being in treatment for alcohol use disorder, had an AUDIT score of 20 or higher, or inability to receive text messages; recruited via email from the university. Number randomised = 68; mean age 18 years, female 77% (intervention) 65% (control), White/Caucasian 58% (intervention) 65%

	(control), Hispanic 6% (intervention) 24% (control), mean number of drinks/drinking day 4.46 (intervention group) 5.16 (control group), mean number of heavy drinking episodes in past four weeks 3.88 (intervention group) 3.65 (control group).
Interventions	**Intervention group** (n=34) received one text message per day at 7pm for 28 days with content containing normative feedback about alcohol use, alcohol consequences, and protective behavioural strategies. **Control group** (n=34) received one text message per day at 7pm for 28 days with fun fact content (not alcohol related).
Outcomes	Average number of standard drinks consumed in a single drinking occasion in the past four weeks; frequency of heavy episodic drinking (4+ drinks for females, 5+ drinks for males) in the past four weeks, peak estimated blood alcohol concentration (eBAC, calculated using the number of drinks consumed on their heaviest drinking day in the last four weeks and the hours over which those drinks were consumed); number of alcohol-related consequences in the past four weeks assessed using the 24-item Brief Young Adult Alcohol Consequences Questionnaire. Assessed at 28 days (i.e. immediately at completion of text message intervention and control delivery).
Results	No significant between-group differences at follow-up. Intervention group showed significant reductions between baseline and follow-up on peak eBAC, frequency of heavy episodic drinking, and negative consequences.
Notes	Authors concluded that the pilot RCT provided strong support for the feasibility and acceptability of the intervention. It was not powered to detect significant effects and did not observe differences in drinking behaviour or norms as a function of the intervention condition. However, they did observe significant reductions across most outcomes in the intervention group. No loss to follow-up. Funding: support from the NIAAA. Stated that none of the authors have any conflicts of interest.

Risk of bias

Item	Judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information.
Allocation concealment (selection bias)	Unclear risk	Insufficient information.
Blinding of participants and personnel (performance bias)	Unclear risk	Insufficient information. Likely that participants were not blind. It is stated that 26 participants reported sharing text messages with a friend in the opposite condition.
Blinding of outcome assessment (detection bias)	Low risk	Outcome data collection was automated (i.e. participants completed an online survey at follow-up).
Incomplete outcome data addressed (attrition bias)	Low risk	No loss-to-follow-up.
Selective reporting (reporting bias)	Low risk	Measures specified in methods are reported. No information indicating trial was registered.

Muench et al, 2017[142]

Methods	A pilot single-blind parallel RCT comparing four different types of alcohol reduction-themed text messages, i.e. Loss-Framed messaging (LF), Gain-Framed messaging (GF), Statically Tailored content (ST), Tailored Adaptive content (TA), with a self-monitoring mobile assessment (MA) control condition. ITT analysis performed: Yes.

Participants	Setting: USA; participants recruited through online alcohol screening and help-seeking sources, such as AlcoholScreening.org and Moderation.org. Advertisements offered individuals worried about their drinking the opportunity to screen for a research study to find out if texts could help them manage their alcohol consumption. Eligible if consumed at least 13 and 15 standard drinks per week for women and men respectively (reduced halfway through the trial from 21 and 24 standard drinks per week), were willing to reduce their drinking to non-hazardous levels by study completion, were between the ages of 21-65, owned a mobile phone and were willing to receive and respond to text messages, were fluent in English, could read at the eighth grade level. Excluded if drank more than 45 standard drinks per week, demonstrated clinically severe alcoholism, scored above 12 on the Short Alcohol Withdrawal Scale, presented with a current substance use disorder, used marijuana more than twice weekly in the past month, reported a serious psychiatric illness, were already in alcohol treatment, reported a medical condition that precluded drinking alcohol, pregnancy or desire to become pregnant while in the study, reported a desire to pursue long-term abstinence, demonstrated a lack of understanding of the study protocol or ready difficulty. Number randomised = 157, five withdrawn within first week; an additional 19 force-randomised to a 'no-alcohol language group'; mean age 43.2 years, female 74.9%, White/Caucasian 93.5%, Hispanic 2.4%, mean number of drinks/week 24.9, mean number of heavy drinking days/week 3.4.
Interventions	**LF group** (n=31) received text messages daily at 6pm for 12 weeks with content about the consequences of problem drinking. **GF group** (n=31) received text messages daily at 6pm for 12 weeks with content about the benefits of reducing drinking to safe guidelines. **ST group** (n=32) received text messages daily at 6 pm for 12 weeks with tailored content based on individual responses to the baseline assessment. **TA group** (n=33) received text messages daily at 6pm with tailored content similar to the ST group plus three additional components: messages varied based on goal achievement in prior week, two additional messages were sent that included the participant's name, and participants were able to proactively text automated keywords in order to receive support. **MA control group** (n=30) received, once weekly, four questions about the past week's drinking. Participants in all conditions received the MA as their base programme.
Outcomes	Primary outcomes were weekly sum of standard drinks; weekly sum of heavy drinking days. Secondary outcomes were number of days without drinking per week; consequences of heavy drinking (as measured by the Short Inventory of Problems). Assessed at 12 weeks.
Results	Weekly sum of standard drinks in the 30 days prior to the week 12 assessment showed that participants in all treatment groups reduced their weekly alcohol consumption more than the control group except for the GF group ($p<0.09$) with the TA group yielding the largest effects ($p<0.001$). Weekly sum of heavy drinking days was similar – i.e. participants in all treatment groups reduced the weekly heavy drinking days more than the control group except for the GF group ($p=0.15$) with TA group yielding the largest effects ($p<0.001$). All treatment groups increased the number of days without drinking, except the LF group ($p=0.08$), when compared with control group, with largest effect in TA group ($p=0.02$).

	There were no significant reductions in consequences in treatment groups compared with control group.
Notes	The authors concluded that the results of this pilot indicate that remote automated text messages delivered daily can help adult problem drinkers reduce drinking frequency and quantity significantly more than once-a-week self-tracking messages, and that tailored adaptive texts yield the largest effect sizes compared to the self-tracking control. There were no significant differences between active messaging groups, but the study was not powered to detect differences between active groups and larger samples are needed. Loss to follow-up: Of 157 randomized, five were withdrawn in the first week, five were lost to follow-up, and one discontinued the intervention. Funding: grant from the NIAAA. Stated that the lead author has equity in a mobile health company for health behaviour change and consults with mobile technology companies.

Risk of bias

Item	Judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants "were randomized to one of the five study conditions by the project research assistant, stratified by gender and alcohol consumption. Envelopes were created based on gender and high and low drinking, with equal chances of being selected into groups".
Allocation concealment (selection bias)	Low risk	As above.
Blinding of participants and personnel (performance bias)	High risk	Single blind: personnel not blind.
Blinding of outcome assessment (detection bias)	Low risk	Outcome data collection was automated (i.e. participants completed an online survey at follow-up).
Incomplete outcome data addressed (attrition bias)	Low risk	Small loss-to-follow-up; ITT analysis.
Selective reporting (reporting bias)	Low risk	Measures specified in methods are reported. Reporting is consistent with trial registration information.

Suffoletto et al, 2012[143]

Methods	Pilot feasibility RCT comparing a text message feedback with goal setting intervention (Intervention), a text message drinking assessment (Assessment), and a control group. ITT analysis performed: not stated.
Participants	Setting: three Emergency Departments in Western Pennsylvania USA; Eligible if aged 18-24 years, spoke English, were identified as hazardous drinkers (AUDIT-C score 4+ for men and 3+ for women), owned a personal cellular phone with text message features. Excluded if too ill to participate, were seeking treatment for alcohol use, reported previous treatment for alcohol dependence, reported current treatment for any psychiatric condition. Number randomised = 45; mean age 21 years, female 64%, Black race 24%, enrolled in college 82%, median AUDIT-C score 5 (interquartile range 4-6), mean number of drinks/drinking day in prior month 4.6, mean number of heavy drinking days in prior month 5.2.
Interventions	**Assessment group** (n=15) received, once a week for 12 weeks, a series of standard automated text messages asking about frequency of drinking in the last week and maximum quantity of drinks over a 24-hr period in

	the last week (based on the NIAAA recommendations for the "Ask" component of alcohol brief interventions). **Intervention group** (n=15) received, once a week for 12 weeks, the same assessment text messages as the Assessment group above. In addition, they received further text messages covering content describing safe-drinking guidelines, assessing their willingness to set a goal to reduce drinking, and providing strategies for cutting down or exercises to assess decisional balance (based on the NIAAA recommendations for the "Advise/Assist" component of alcohol brief interventions). **Control group** (n=15) received one text each week for 12 weeks stating: "Pittsburgh Alcohol Research: Look for our email in x weeks to complete your final survey".
Outcomes	Outcomes were exploratory. Text message-based drinking outcomes: days drinking per week, maximum drinks per drinking day (DPDD), number of weeks with a heavy drinking day (HDD). Timeline Follow Back-based drinking outcomes: number of HDDs, DPDD, percentage of subjects with no HDDs. Agreement between Text message and Timeline Follow Back reports. Assessed at 3 months follow-up.
Results	Exploratory analysis of treatment effect at three months showed significant differences between groups in the change in number of HDDs and number of DPDD in the last month. Post hoc testing showed the differences existed between the Intervention and Assessment groups only. Across the last four weeks, there was good correlation between Text message and Timeline Follow Back reports, suggesting that text message may provide a valid method of assessing drinking behaviour.
Notes	The authors concluded that "text messages can be used to assess drinking in young adults and can deliver brief interventions to young adults discharged from the ED. Text message-based interventions have the potential to reduce heavy drinking, but larger studies are needed to establish efficacy". Loss to follow-up: 13%. Of 45 participants, 39 (87%) completed three-month follow-up, 12 of 15 (80%) Assessment group, 14 of 15 (93%) Intervention group, 13 of 15 (87%) Control group. Funding: three grants acknowledged. Conflicts of interest: not stated.

Risk of bias

Item	Judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Research Associates used consecutively numbered, sealed opaque envelopes containing assignment information prepared using a computer-generated set of random numbers in blocks of 15".
Allocation concealment (selection bias)	Low risk	As above.
Blinding of participants and personnel (performance bias)	Unclear risk	Insufficient information.
Blinding of outcome assessment (detection bias)	Low risk	Outcome data collection was automated (i.e. participants completed an online survey at follow-up).
Incomplete outcome data addressed (attrition bias)	Low risk	Loss to follow-up 13%.
Selective reporting (reporting bias)	Low risk	Measures specified in methods are reported. Reporting is consistent with trial registration information.

Suffoletto et al, 2014[144]; Suffoletto et al, 2015[145]	
Methods	A 3-arm RCT comparing text message (SMS) assessments and feedback (SA + F), text message assessments (SA), and a control condition with no text messages. ITT analysis performed: Yes.
Participants	Setting: EDs of four urban teaching hospitals in Pittsburgh, Pennsylvania USA; potentially eligible participants were identified from the electronic triage log. Eligible if aged 18-25 years, were medically stable, not seeking treatment for drugs or alcohol, spoke English, had not been enrolled in any alcohol-related study in the previous year, were identified as hazardous drinkers (AUDIT-C score 4+ for men and 3+ for women). Excluded if had past treatment for drug use or psychiatric disorders, no cell phone ownership with text messaging, current enrolment in high school. Number randomised = 765; mean age 22.0 years (SA+F) 22.0 (SA) 21.8 (Control), female 65.4% (SA+F) 63.8% (SA) 67.0% (Control), Black race 41.2% (SA+F) 44.9% (SA) 44.9% (Control), Hispanic 5.7% (SA+F) 5.1% (SA) 8.1% (Control), White/Caucasian race 49.5% (SA+F) 50.0% (SA) 47.6% (Control), median AUDIT-C score 6.3 (SA+F) 6.3 (SA) 6.2 (Control).
Interventions	**SA group** (n=196) received, on Sundays for 12 weeks, automated text messages assessing the largest number of drinks that the individual had consumed on any occasion that weekend. **SA+F group** (n=384) received, on Thursdays for 12 weeks, text messages assessing whether the individual had a weekend drinking plan. If a plan to drink was reported, they were asked whether they were willing to set a goal to limit drinking. Based on participant's response, they received tailored feedback messages aimed at increasing motivation toward reduced alcohol consumption. Each Sunday they received the same assessment text messages as the SA group. They also received further tailored feedback that supported low weekend alcohol consumption or aimed to encourage reflection on their alcohol consumption. **Control group** (n=185) did not participate in any text messaged related to alcohol use.
Outcomes	Primary outcomes: number of binge drinking days (4+ drinks for females, 5+ drinks for males) over the past 30 days, binge drinking prevalence (yes/no) over the past 30 days. Secondary outcomes: drinks per drinking day over the past 30 days, alcohol-related injury prevalence (yes/no) over past 3 months. Assessments at three, six, and nine months. Assessed at three-months follow-up.
Results	At nine months, participants in the SA+F group reported greater reductions in number of binge drinking days than participants in the control group (Incident rate ratio 0.69, 95% CI 0.59-0.79), lower binge drinking prevalence (OR 0.52, 95% CI 0.26-0.98), less drinks per drinking day (beta -0.62, 95% CI -1.10 to -0.15) and lower alcohol-related injury prevalence (OR 0.42, 95% CI 0.21-0.88). Participants in the SA group did not reduce drinking or alcohol-related injury relative to controls.
Notes	The authors concluded that an interactive text message intervention was more effective than self-monitoring or control in reducing alcohol consumption and alcohol-related injury prevalence up to six months after intervention completion. Follow-up: 78% of participants at three-months, 63% at six-months, 55% at nine-months. Funding: grants acknowledged.

	Conflicts of interest: lead author has a copyright for a 'text message system to longitudinally assess alcohol consumption and provide psycho-educational feedback' which was licensed to HealthStratica LLC and is a consultant for HealthStratica.

Risk of bias

Item	Judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was generated in blocks of eight for each recruitment site by a computer-generated algorithm and allocated electronically".
Allocation concealment (selection bias)	Low risk	As above.
Blinding of participants and personnel (performance bias)	Low risk (personnel) High risk (participants)	"Participants were not told to which group they were randomized to minimize expectation bias. Research associates were blind to treatment allocation." "Participants were told that they could receive no texts, Sunday texts for 12 weeks, or both Thursday and Sunday texts for 12 weeks."
Blinding of outcome assessment (detection bias)	Low risk	Outcome data collection was automated (i.e. participants completed follow-up surveys by logging into a password-protected website).
Incomplete outcome data addressed (attrition bias)	High risk	High attrition.
Selective reporting (reporting bias)	Low risk	Measures specified in methods are reported. Reporting is consistent with trial registration information.

3.4 Discussion

This systematic review of the published literature included six RCTs (resulting in seven publications) which have assessed the effectiveness of mobile phone text message interventions in reducing hazardous alcohol use and alcohol-related harms. Five trials were relatively small heterogeneous pilot or feasibility RCTs.[139-143] Although the results of these trials should be viewed with caution due to their small sizes and inadequate power to detect statistically significant effects, their findings suggest alcohol mobile phone text message interventions may have the potential to reduce alcohol consumption and harms.

One of the six trials included in this review is a large (n= 765) three-arm trial by Suffoletto and colleagues (2014 and 2015) of 18 to 25-year olds in an ED setting.[144, 145] The study found that the intervention involving text message assessments and tailored feedback (SA+F) was more effective than no text messages (control group) in reducing alcohol consumption and alcohol-related injury at six months follow-up (i.e. six months after completion of the 12-week text message intervention, or nine months from baseline).

This trial meets the criteria for 'low risk of bias' across all but two items assessed. There are likely to be quality issues related to inadequate blinding of participants (potentially difficult or

impossible to achieve in such intervention trials where one group receives text messages and a control group does not) and the high rate of attrition over the follow-up period. In addition, all trials in this review include outcomes measures which are based on self-reported information. This could lead to measurement bias.

The findings of this review suggest that alcohol text message interventions are more effective compared with no intervention in reducing alcohol consumption and harms (e.g. alcohol-related injuries), however there are very few trials, and only one large adequately powered trial. There were no trials comparing text message alcohol interventions with usual care interventions (e.g. face-to-face alcohol BI). All trials included in this review were conducted in the USA and five of six trials were in young adult participants (three being in college/university students). The two Suffoletto et al. trials were conducted with participants presenting to the ED, whereas the other four trials were in college or community-dwelling adults. Therefore, the findings may not be applicable to other countries or ethnicity groups, age groups, and settings.

The strengths of this review include the use of a comprehensive search strategy and methodology consistent with recommended guidelines for systematic reviews. However, it is possible that trials have been missed. This review includes published articles only and does not include unpublished or 'grey' literature. This review does not include articles published in languages other than English. The inclusion criteria for this review ensured that this review was focussed on RCTs of text message interventions which included participants with hazardous or harmful alcohol consumption and measured outcomes related to alcohol consumption and/or alcohol-related harms. This meant that trials were excluded if they involved mobile phone apps or interventions in which text messaging was an adjunct, participants with low risk alcohol consumption, or measures not related to alcohol.

The findings of this review imply that more studies of the effects of alcohol text message interventions are needed. Although alcohol text message interventions have great potential for reducing alcohol consumption and harms, only one large RCT was located demonstrating effectiveness of a 12-week text message intervention compared with no intervention. More large scale, robust studies are required, in different countries and settings, and considering a wider range of ethnicity and age groups.

3.5 Summary

This chapter reports the methods and results of a systematic literature review of the effectiveness of mobile phone text message interventions in reducing hazardous or harmful alcohol use. Five small pilot or feasibility RCTs and one large RCT in 18 to 25-year olds presenting in the ED setting suggest that alcohol text message interventions are more effective compared with no intervention in reducing alcohol consumption and harms. However, more evidence is needed, particularly trials examining the effectiveness of alcohol text message interventions in different countries, settings, and groups of people.

CHAPTER 4: DEVELOPMENT OF A MOBILE PHONE TEXT MESSAGE INTERVENTION FOR PEOPLE WITH HAZARDOUS ALCOHOL USE

This chapter addresses Thesis Objective Two: To develop a mobile phone text message intervention for people with hazardous alcohol use. The content presented in this chapter is from the published paper *'Sharpe S, Shepherd M, Kool B, Whittaker R, Nosa V, Dorey E, Galea S, Reid P, Ameratunga S. Development of a text message intervention aimed at reducing alcohol-related harm in patients admitted to hospital as a result of injury. BMC Public Health 2015;15(815). doi: 10.1186/s12889-015-2130-6'.* Copyright for this article is covered under the Creative Commons Attribution License 4.0.[v]

4.1 Introduction

Injury is the largest contributor to New Zealand's alcohol-related burden of disease,[60, 65, 146] and alcohol is considered the leading risk factor for injury.[4, 5, 147, 148] One in three New Zealanders who consume alcohol have reported being harmed by their own drinking in the past year.[59] Factors associated with a higher risk of alcohol-related harm were being male, younger age, Māori ethnicity, or living in a very deprived area of New Zealand.[59]

SBI is an important component of a comprehensive public health strategy to reduce hazardous alcohol use and prevent alcohol-related harm. A large body of evidence has established the effectiveness of SBI in a wide range of health-care settings.[14, 84, 85, 89, 90] For injured patients attended to in trauma care settings, BI can reduce subsequent alcohol intake and alcohol-related harms.[91] In a systematic review of BI studies for injury patients, Nilsen and colleagues concluded that, although it was difficult to provide evidence on the results of BI due to heterogeneity of studies, 11 of the 12 studies that compared pre- and post-BI results observed a significant effect of BI on at least some of the outcomes of interest (alcohol intake, risky drinking practices, alcohol-related negative consequences, and injury frequency).[91]

In New Zealand, however, SBI is infrequently implemented in trauma care settings. A retrospective analysis of trauma registry data (n=1970) and hospital records (n=120) of adults aged ≥18 years with unintentional injury admitted to Auckland City Hospital, a tertiary-level

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metropolitan trauma centre, reported that none of the 120 records reviewed had documentation indicating a structured questionnaire-based alcohol screening had been conducted and just one patient was recorded as having received a brief alcohol intervention. This was despite 23% of patient records containing documentation indicating problem drinking and/or evidence of alcohol consumption prior to injury.[12] Similar findings of low uptake are also reported in the USA despite the recommendation that SBI is incorporated as a routine component of trauma care.[17, 86] A USA national survey of ED directors at Level I and Level II trauma centres found that, of the 46% who responded to the survey, only 15% reported having formal screening and intervention policies in their ED.[17] Previous research has indicated a range of barriers to implementation, including lack of resources and training of health professionals.[12, 17, 19, 20]

The use of mobile phones as the mode of BI delivery could address some of these barriers. Communicating via text message is cost-effective, highly scalable, and has the potential to reduce inequities in access to health promotion messages and services.[25, 118] Because of the high uptake of mobile phones globally, the reach of mHealth interventions could be extensive. Mobile phone uptake is high among Māori and Pacific peoples in New Zealand. As described in Chapter Two, in the New Zealand 2013 Census, access to mobile phones within households was 86% for Māori, 85% for Pacific Peoples, and 87% for the total population. In contrast access to telephone and the Internet were lower for Māori (72% and 67%) and Pacific Peoples (77% and 65%) than the total population (87% and 82%).[116]

Text messages, which are by definition short in length, could be a particularly appropriate mechanism for delivering BI for hazardous drinking, as suggested by three small feasibility studies.[143, 149, 150] Suffoletto & colleagues (2012) demonstrated the potential of a BI via text message to reduce harmful drinking in a RCT among 45 hazardous drinkers aged 18 to 24 years seen in three urban EDs in Western Pennsylvania, USA.[143] In a randomised controlled feasibility study in Dundee, UK, Crombie & colleagues found that a text message BI could engage participants, disadvantaged men aged 25 to 44 years who were recruited through primary care and community outreach, and had the potential to modify their binge-drinking behaviour.[149] In a qualitative study of 30 trauma inpatients aged ≥16 years in Auckland, New Zealand, Kool et al. found that the majority of participants supported the idea of a text message intervention for hazardous drinking.[150] This study found that receptiveness to messages would be increased if messages were non-judgemental and supportive, evidence-based, informative (e.g. information on the consequences of drinking and providing practical advice), and

culturally relevant for Māori. Participants in this feasibility study noted the importance of ensuring the messages were not delivered too frequently and the need to be mindful of avoiding a sense of invasion of privacy and confidentiality.

Suffoletto & colleagues (2014) have reported the findings of a large three-arm RCT of a 12-week text message alcohol intervention for ED patients aged 18 to 25 years, carried out at four urban hospitals in Pittsburgh, Pennsylvania.[144] Patients reporting hazardous alcohol consumption on screening were eligible to participate and were randomised to one of three groups: text message intervention involving assessments and feedback (n=384), text message assessments only (n=196), no text messages (control, n=185). At three-months follow-up, the intervention group showed small reductions from baseline in self-reported binge-drinking days (intervention group: -0.51; 95% CI -0.10, -0.95, cf. assessment group: 0.90; 95% CI 0.23, 1.6, and control group: 0.41; 95% CI -0.20, 1.0) and the number of drinks consumed per drinking day (intervention group: -0.31; 95% CI -0.07, -0.55, cf. assessment group: 0.10; 95% CI -0.27, 0.47 and control group: 0.39; 95% CI 0.06, 0.72).

Whilst there is a large body of literature pertaining to alcohol BIs in trauma care settings, there are just the four studies outlined above which explore mHealth alcohol BIs, with just Kool et al. being specifically focussed on the trauma inpatient setting, and none which focus on developing and testing content which is culturally appropriate for an indigenous population. Building on the information noted by Kool et al. as the foundation, our research group formulated the concept of a proactive, automated text message BI service aimed at reducing hazardous drinking and alcohol-related harm among adults admitted to hospital following an injury and who screen positive for alcohol misuse. The plan for this study was to tailor the text message content to suit different demographic groups (e.g. age, gender, and Māori and Pacific ethnic groups), and design the delivery of the BI to be resource-efficient, accessible to youth and socio-economically disadvantaged groups, and scalable nationwide.

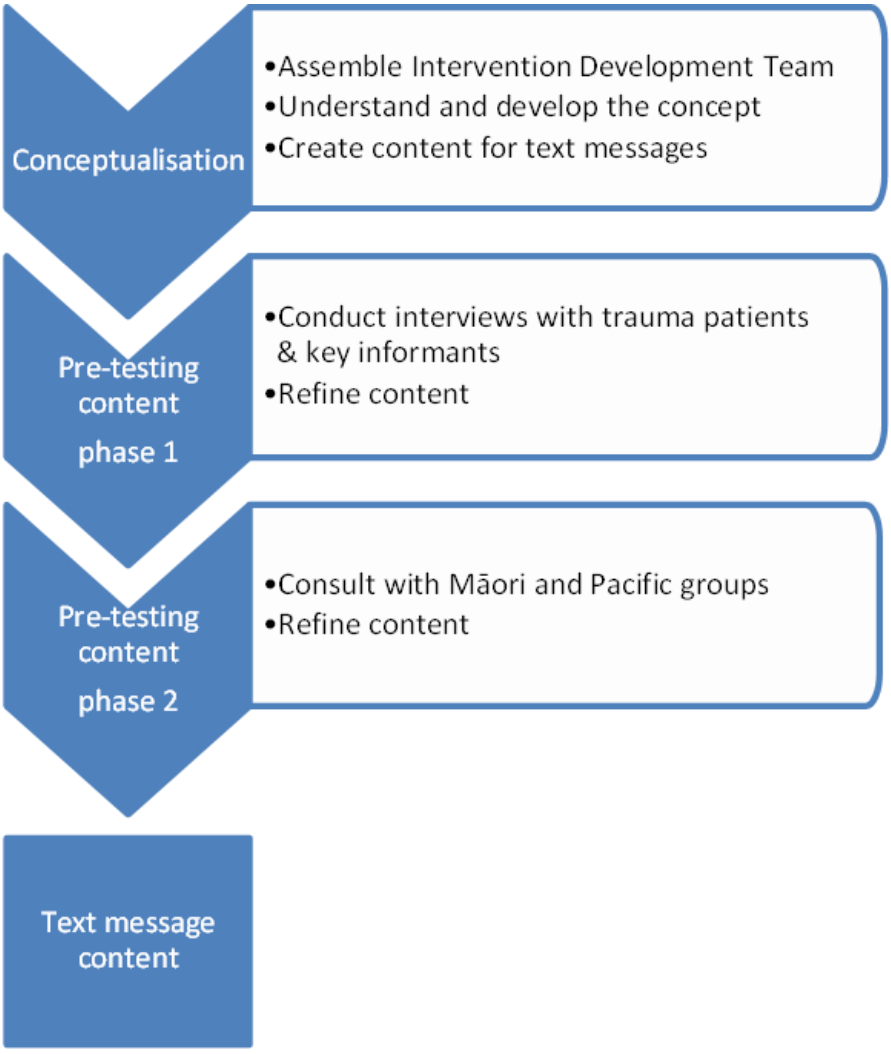
An Intervention Development Team (the authors of the published paper) was assembled to oversee and guide the development of the text message intervention. The team was comprised of experts in mobile phone health technology, drug and alcohol clinical services, clinical and health psychology, public health, youth health, and Māori, Pacific, and Asian health. The group discussed and developed the intervention concept, created the initial text message content, reviewed findings from pre-testing, and made decisions about refinements of text message content and structure.

This aim of this study was to pre-test the text message BI content so that the content could be improved and refined to enhance its acceptability and potential effectiveness in the local context. It was intended that the effectiveness of the refined intervention in reducing harmful drinking would subsequently be evaluated in an RCT.

4.2 Methods

The methodologic approach is described in Figure 4 and was informed by Whittaker and colleagues' model for developing and evaluating mHealth interventions.[151] This model describes a process in which the intervention created is based on theory and evidence, the target audience is involved to ensure the intervention is engaging and useful, and there is a focus on implementation from the outset.

Figure 4. Process for Text Message Intervention Content Development



The initial text message content was created based on the BI model[87] and the Stages of Change behaviour change theory[152] which underpins the model. BI has three key steps: 1) giving feedback and information about a person's current behaviour (in this case, hazardous alcohol use), 2) listening and discussing the issue, and 3) giving advice, discussing options, and helping with goal-setting.[86-88] The Development Team wanted to mimic the underlying key BI elements as far as possible, whilst being mindful of the limitation that text messaging lacks the face-to-face interpersonal component of conventional BI. Using Microsoft Excel, we mapped the key elements of BI (as described by Babor & Higgins-Biddle[87]) and recommendations for its use in a trauma setting (the American College of Surgeons Committee on Trauma[86]) against a variety of behaviour change techniques (BCTs)[vi] and crafted short messages for each of the key elements (Table 2).[vii] Readability testing showed the content of these messages had a Flesch-Reading Ease score of 66.6 and Flesch-Kincaid Grade Level score of 6.6.

We carried out a small qualitative research study to pre-test the text message content. The pre-testing was conducted in two phases: 1) interviews with trauma inpatients and key informants and 2) consultation with Māori and Pacific groups.

A purposive sampling approach was taken to ensure a mix of ethnicity groups, age groups and gender among the trauma inpatients interviewed and to ensure the views of key stakeholders were heard. The aim of the sampling strategy was to select a range of patients and key informants in order to gain insights and understanding about their perceptions regarding the content, accessibility of the messages and structure of the intervention. This study was not designed to select a statistically representative sample in order to make empirical generalisations representative of all trauma inpatients.

In the first phase of pre-testing we aimed to recruit 15 adult trauma inpatients (five Māori patients, five Pacific patients, and five patients of other ethnicities) and five key informants from the following organisations: Auckland City Trauma Service (clinical service; clinical nurse co-ordinator), Alcohol HealthWatch (non-governmental agency; director), Accident

[vi] BCTs are defined as observable and replicable components designed to change behaviour. Within an intervention, they are the smallest components compatible with retaining the postulated active ingredients and can be used alone or in combination with other BCTs. *(From: Michie S, Wood C, Johnston M, Abraham C, Francis J, Hardeman W. Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions. Health Technology Assessment 2015;19(99):1–188*)

[vii] See Appendix 3 for a table (updated after this paper was published and as part of the research described in Chapter Seven) showing the text messages mapped against BI elements and BCTs, using an updated taxonomy of BCTs.

Compensation Corporation (injury-related social insurance agency; injury prevention consultant), Auckland Council (regional authority; community action facilitator), and National Hauora Coalition (primary health organisation; medical practitioner).

Trauma inpatient participant selection and in-depth individual interviews were carried out over a four-week period during May 2012 at Auckland City Hospital. Patients could be included if they were aged 16 to 60 years, had been admitted to hospital with an injury and were under the care of the Trauma Service, used a mobile phone, were alcohol users, and could complete an interview in English. Patients were excluded if they had a cognitive deficit, a serious psychiatric disorder, or were pregnant. Potential participants were identified prospectively by daily review of the Trauma Service admission register followed by discussion with the trauma co-ordinator and/or ward staff, and then were approached in person by an interviewer and invited to take part. Three interviewers in total conducted individual face-to-face interviews, which ranged from 30 to 60 minutes in length. Interviews with Māori participants were conducted by a Māori researcher, and interviews with Pacific participants were conducted by a researcher who identified with Cook Island and European ethnicities. The third interviewer was New Zealand European.

All potential participants (inpatients and key informants) were provided a Participant Information Sheet and those taking part in the study gave their written informed consent. Interviews were semi-structured, with an interview guide used as an outline and prompt (Appendix 4). The questions and guide were developed by the first and second authors of the published paper, in consultation with the Development Team. Topics explored during the interviews included: opinions on text message ideas and wording (a paper-based text message prototype was provided), which messages worked well and why, which messages didn't work well and why, interactivity of intervention, cultural relevance of messages, and tone of messages. Interviews were audio-recorded and transcribed by a commercial transcription service.

In addition to the interview, a short survey to capture basic demographic details and the participant's AUDIT-C score[153] was administered.[viii] Ethnicity data was collected by using the standard ethnicity question from the New Zealand Census, as recommended by the New

[viii] AUDIT-C is a short form version of the full 10-item AUDIT. It consists of the first three 'consumption' questions of the full AUDIT.

Zealand Ministry of Health.[154] Trauma inpatient participants received a $20 shopping voucher as a token of appreciation for taking part in the study.

The interview transcriptions were analysed at two levels: 1) by each text message, to analyse feedback and suggestions related to the content of each message, and 2) for cross-cutting themes that emerged related to content and structure of the text message intervention. A General Inductive approach was used for the second level data analysis.[155] Analyses were conducted using NVivo 9 qualitative analysis software. Interview transcripts were entered into NVivo and the raw text was examined in detail. Coding was applied to the text to indicate feedback on specific messages (level one analysis) and to indicate categories or themes (level two analysis). Within each category, the text was searched for a range of viewpoints and quotations were selected to show this range, as well as the core meaning of a theme.

Based on the findings from this small qualitative research study, the Intervention Development Team refined the content and structure of the intervention. Subsequently, a second phase of consultation was undertaken with Māori drug and alcohol counsellors (Te Ātea Marino), Pacific drug and alcohol counsellors (Tupu), Pacific staff at the University of Auckland, and Māori researchers, to enhance the relevance, appropriateness and acceptability of the text message intervention content to Māori and Pacific communities.

Ethical approval for the qualitative research component was obtained from the Northern X Regional Ethics Committee (NTX/11/EXP/307), the Auckland District Health Board, and the Waitemata District Health Board.

Table 2. Original Text Message Content

Message number	Week of programme	Day of programme	Text message	Brief Intervention element	Behaviour change techniques
1	1	1	Thanks 4 joining the study. Txt messages will be coming 2 your mobile over the next 4 weeks. Call xxx free if you have any study-related problems		
2	1	2	The survey showed your alcohol drinking is hazardous compared with other people. We recommend you think about cutting down	Feedback about screening results; recommendation	Feedback; comparison/discrepancy
3	1	4	***For females:*** Recommended drinking limit for females=max 2 drinks/day and max 10 drinks/week. 1 drink=100mls wine or 330mls beer or 30mls spirits or half a premix (RTD) ***For males:*** Recommended drinking limit for males=max 3 drinks/day and max 15 drinks/week. 1 drink=100mls wine or 330mls beer or 30mls spirits or half a premix (RTD)	Information on drinking limits	Information
4	1	6	Alcohol can cause injuries, diseases like cancer, depression, weight gain…plus hangovers are awful! Make a list of the pros and cons of drinking too much alcohol	Information on hazards of drinking; encourage/motivate RTC	Information on consequences; Persuasive communication; motivators for change; pros and cons
5	2	8	Would you be willing to make changes to reduce your drinking? If your answer is 'Yes', txt 1 to yyy. If your answer is 'No', txt 2 to zzz	Assess RTC	Assessment; Support/encourage change; Prompt intention formation
If answer ‘Yes’ to Message ID 5:					
6	2	10	Great news that you are willing to reduce your alcohol use! Keep your reasons in mind. We would like to help and will txt you tips and advice	Encourage/motivate RTC	Support/encouragement
7	2	11	***For females:*** Consider setting a goal to reduce drinking to within safe limits: max 2 drinks/day, max 10 drinks/week. (1 drink=100ml wine or 330ml beer or 30ml spirits)	Advice based on RTC 'Yes': Goal	Goal setting

			For males: Consider setting a goal to reduce drinking to within safe limits: max 3 drinks/day, max 15 drinks/week. (1 drink=100ml wine or 330ml beer or 30ml spirits)		
8	3	15	Plan ahead 4 cutting down your alcohol use. Consider setting some drinking rules for yourself. See easeuponthedrink.org.nz for more info	Advice based on RTC 'Yes': Plan	Planning; Coping strategies; prompt self-monitoring
9	3	17	Consider sharing your goal and plan with friends and family. They can provide support and might want to join in and reduce their alcohol drinking too	Advice based on RTC 'Yes': Strategies/tips	Coping strategies; Support/encouragement
10	3	19	Ideas for helping you cut down: consider planning alc-free days, measure and track drinks, alternate alc and non-alc drinks, avoid risky circumstances	Advice based on RTC 'Yes': Strategies/tips	Coping strategies; Support/encouragement
11	4	22	Reward yourself 4 your successes. Learn from slip-ups but don't dwell on them. Don't give up on your goal to reduce drinking!	Advice based on RTC 'Yes': further support	Support/encouragement; review of goal; self-reward; relapse prevention
12	4	24	You can get more free and confidential support from Alcohol Helpline 0800 787 797, or by contacting your family doctor	Follow-up	Information; Support/encouragement
13	4	27	Thanks for taking part in the study. We will txt u in 2 months to see how u r going.		
If answer 'No' to Message ID 5:					
14	2	10	Thanks 4 your reply. Drinking alcohol is your choice. Txts to follow about ways to minimise harm from alcohol	Advice based on RTC 'No'	Support; Coping strategies
15	2	11	Reduce your risk of injury on a single occasion of drinking by setting a limit of no more than 4 standard drinks. (1 drink=100ml wine or 330ml beer or 30ml spirits)	Advice based on RTC 'No'	Information; Coping strategies
16	3	15	Consider planning alc-free days, pacing yourself when drinking, alternating alc and non-alc drinks, taking smaller sips, eating before or while u r drinking	Advice based on RTC 'No'	Coping Strategies, Planning

17	3	17	Drinking too much alcohol can cause problems for you, your family, your friends. See easeuponthedrink.org.nz for easing up tips	Advice based on RTC 'No'	Information; Support/encouragement
18	3	19	Plan ahead so you get home safely. Arrange a designated driver. Put some cash aside and share a taxi. If you have to walk home, go with a friend	Advice based on RTC 'No'	Coping Strategies, Planning
19	4	22	We encourage you to think about your drinking. You may have bad experiences, regrets, worries. One day you may decide u want to make a change	Advice based on RTC 'No'	Support/encouragement; Prompt intention formation
12	4	24	You can get more free and confidential support from Alcohol Helpline 0800 787 797, or by contacting your family doctor	Follow-up	Information; Support/encouragement
13	4	27	Thanks for taking part in the study. We will txt u in 2 months to see how u r going.		

RTC= Readiness to Change

4.3 Results

Nineteen trauma inpatients were approached, 14 were interviewed, and five declined or were not eligible due to not being drinkers. Participants ranged in age from 17 to 50 years and the majority were male (Table 3). Four participants identified as New Zealand Māori. One of these participants also identified as Cook Island Māori and another as Niuean. Three participants identified as Samoan, five were European, and two were Asian (Chinese and Filipino). AUDIT-C scores ranged from zero to nine with a median of five. Nine participants were categorised as having a pattern of drinking considered hazardous (AUDIT-C score ≥3 for women and ≥4 for men). Injuries sustained by participants included limb fractures or lacerations (n=6), head injuries (n=4), chest injuries (n=2), fractured pelvis (n=1), fractured lumbar vertebra (n=1). Alcohol was a contributing factor in four cases.

Table 3. Characteristics of Trauma Inpatients

Characteristic	Number of participants
Gender	
Male	11
Female	3
Age group	
16 – 34 years	9
35 – 54 years	5
Ethnic group	
Māori	4[a]
Pacific Peoples	5[a]
European	5
Asian	2
Employment status	
Employed	7
Student	5
Unemployed or Other	2
AUDIT-C score indicating hazardous drinking[b]	
Non-hazardous drinking	5
Hazardous drinking	9

[a] The ethnicity data in this table is reported using the total response (overlapping) method. Where a person reported more than one ethnic group, that individual has been counted in each applicable group. Totals therefore do not add up to 100 percent. One participant identified as New Zealand Māori and Cook Island Māori. Another participant identified as New Zealand Māori and Niuean.

[b]AUDIT-C is scored on a scale of 0-12; in men a score of 4 or more, and in women a score of 3 or more, is considered positive for identifying hazardous drinking or active alcohol use disorders.

4.3.1 Phase One: Feedback on Specific Text Messages

Participants provided many suggestions for improvements to the content of each text message. A commonly expressed issue was specific words not being easily understood or relevant to people. For example, the use of the word 'hazardous' in message two (*'The survey showed your alcohol drinking is hazardous compared with other people. We recommend you think about cutting down'*) was not felt to be appropriate by the majority of participants:

> *"Hazardous is a bit of a big word for some folks isn't it. Usually hazardous you think of bombs and explosions." (Male, New Zealand European inpatient, non-hazardous drinker.)*

However, one participant liked the direct nature of this message:

> *"I think that's really good because then it kind of makes people think maybe I'm hurting other people or hurting myself." (Female, Filipino inpatient, hazardous drinker.)*

The information-laden content (summarising low risk drinking guidelines and the definition of a 'standard' drink) of text message three positioned at this early stage of the intervention was generally perceived to be negative and off-putting:

> *"Well there's quite a bit of information there, most people probably turn it off at that point. Well the problem with text messages you know, texts are usually some social thing,…." (Male, New Zealand European inpatient, non-hazardous drinker.)*

One respondent aged in his early 20s indicated that this kind of message would be meaningless for him and his friends: *"I think people our age would laugh. I don't think they'd take any notice of it to be honest, … So you don't drink just to drink, you drink to get drunk, that sounds really bad but that's how it is." (Male, Samoan inpatient, hazardous drinker.)*

In addition, we were advised by a key informant that the use of the words 'recommended drinking limits' was not a helpful approach.

> *"So a limit's actually meaningless. What language …we're trying to find ways of sharing I suppose, is the risk, levels of risk and low risk, you know beyond two standard drinks you are at higher risk. So it's not about trying to set a limit …you know it's like a speed limit, people treat it as a target, they think I can drive 100… in actual fact they should be thinking about the conditions and is it wet and perhaps I should be driving you know 80 today on this road…So we're trying to get people away from the idea of limits." (Key informant.)*

Many participants noted that instead of receiving this information message during the first week of the text message intervention, they would rather receive a message that was linking them into existing services and advice. In the prototype, such a message (number 12) was planned for the fourth week. This was perceived to be too late in the intervention, particularly for people who might feel anxious after receiving the message or who might want to take prompt action and seek help based on information provided early in the intervention process. Many participants liked the idea of having a website link in addition to a free-call number for the Alcohol Helpline.

A key element of BI is motivating and encouraging people to change their behaviour. Behaviour change techniques include providing information on consequences, using persuasive communication, discussing motivators for change, and thinking about the pros and cons of drinking alcohol. Some of these ideas were incorporated in text message number four, with the aim of encouraging people to contemplate their drinking, the effects of drinking, and stimulate readiness to change. In general, participants liked this text message. They were interested in thinking about pros and cons and the effects of alcohol, and in many cases displayed a lack of knowledge about alcohol and its effects on the body.

> *"… I like that it actually gives you something you can do on your own, how it's like suggest that you make a list of pros and cons. It's kind of like a tool you can use so that's quite helpful." (Female, Samoan inpatient, hazardous drinker.)*

> *"It's got a little bit of information in it and it also makes you think. If you did a list yourself for or against, you know, pros and cons, …you know there's more negative stuff to it than there is positive." (Male, New Zealand European inpatient, hazardous drinker.)*

It was clear that there were a wide range of motivators and it would be very difficult to create one message that would appeal to people of different age, gender, and ethnicity groups. However, many participants talked about the effect of alcohol consumption not just on themselves, but on their family/whānau and friends, suggesting an important motivator in communities.

> *"…You have got to find what's going to motivate each individual person in a way, and it's going to vary, person to person…so that's the tricky part isn't it and I can imagine some people at this point will just turn off, you know the negative sort of message about*

the cancer, weight gain, that sounds bad and better go and have a drink." (Male, New Zealand European inpatient, non-hazardous drinker.)

"… is it something more about …, the effect of too much drinking on your friends and family or something." (Male, New Zealand European inpatient, non-hazardous drinker.)

"Family, there's always a family issue, it's stressing when someone ends up here [i.e. in hospital]." (Male, Māori/Niuean inpatient, hazardous drinker.)

Following on from the 'motivator' text message, text message number five (at the beginning of week two of the text message intervention) was proposed to be a question evaluating a person's readiness to change.[88, 156] The intervention would branch at this point, with those responding 'Yes' receiving text message relevant to making changes, and with those responding 'No' receiving supporting messages providing information and encouraging contemplation about drinking alcohol. Many participants didn't like this message, as highlighted in these next quotes. These feelings may be due to participants not being comfortable committing to a goal which has been assigned by others, is framed in a way that is not desirable to the participant, and is not linked with any specific contexts or strategies (i.e. implementation intentions) that might help with goal striving.[157, 158]

"Me personally I wouldn't like that one because I've only just started on this, haven't really had much time to think about things. It might be a bit too soon." (Male, New Zealand European inpatient, hazardous drinker.)

"I'm debating about, because you've got if you're willing to make changes, yes or no. If you've answered 'no' and you are still getting texts coming through…Yeah, might make them annoyed." (Key informant.)

"I was just thinking you're asking questions and then they're asked to provide a response but they're not told why? So I would think well what's the point of replying…it's not giving me any reason to do that. What may happen if I do that?" (Female, New Zealand European inpatient, non-hazardous drinker.)

4.3.2 Phase One: Cross-Cutting Themes

Responses from participants were also explored for themes that cut across all text messages. There were four main themes related to reducing the complexity of message content and

intervention structure, increasing the interactivity of the intervention, ensuring an empowering tone to text messages, and optimising cultural appropriateness and relevance.

4.3.2.1 Theme One: Complexity of Message Content and Structure

It was clear that the message content, as originally designed, was too complex, contained too much health/technical jargon and was not focussed adequately on reducing health literacy demands on people.

> *"One thing that I learnt about text messaging stuff, people switch off after too many words." (Key informant.)*

> *"Yeah, you don't really want to read too much." (Female, Filipino inpatient, hazardous drinker.)*

> *"Because I mean the health language doesn't, you know, it's not, it just doesn't gel…Is it a bit medical, is it a bit sort of medicalised?" (Key informant.)*

> *"I think you have got to road test the language…the language is pretty complex for most people." (Male, New Zealand European inpatient, non-hazardous drinker.)*

In relation to the use of text language and abbreviations, most participants like to have words spelt in full, but were happy with short abbreviations such as 'you' abbreviated to 'u' and 'for' abbreviated to '4'.

> *"Actually like English is my second language so I just like text fully, full English." (Male, Chinese inpatient, non-hazardous drinker.)*

> *"I prefer it when people don't use text language because it is too hard to read sometimes." (Female, Filipino inpatient, hazardous drinker.)*

There was positive feedback about the proposed length of the intervention and the frequency of receiving text messages. Most respondents thought the prototype's four-week length and frequency of one text message every two days were reasonable and appropriate.

> *".. that's reasonable…definitely long enough." (Male, New Zealand European inpatient, hazardous drinker.)*

> *"I think that's good yes, because people's interest loses after sort of six weeks or so, so probably four weeks is a good timeframe." (Key informant.)*

"If you are getting a text every day then you might start to ignore it, but if you get one every couple of days it might get through actually..." (Male, New Zealand European inpatient, hazardous drinker.)

4.3.2.2 Theme Two: Interactive Functionality of the Text Message Programme

The prototype was designed as an automated and unidirectional text message intervention, although attempts were made to personalise content to some extent. This was well received although some participants voiced a desire for the intervention to have more interactive functions, so that they could text back and forth with someone.

"You have definitely got some good ideas here. I think maybe some of them text back so you know that they are getting through? Maybe a text back to every one of these... so you know they are getting through." (Male, New Zealand European inpatient, hazardous drinker.)

"You're more likely to be honest or take more notice if you think there is somebody at the other end that sent me this text, not a machine that sent me that text. I think you would get a better response because people then feel, oh someone is making all this effort I should make an effort as well, rather than, like you get texts from x [a mobile phone provider] or y [a mobile phone provider] and it's automated, and you go oh yeah, whatever." (Key informant.)

A small number of participants said automation wasn't a negative aspect for them and that they appreciated the anonymous nature of the text message intervention.

"... Pacific Island culture in general it's like there are a lot of things that you don't talk about... so I think people would sign up for this because it seems like something you can do personally that you don't have to tell people about. So you don't have to talk about it...I think getting the texts would be helpful cause then it would be like a way for you to kind of like reflect and then like cut down." (Female, Samoan inpatient, hazardous drinker.)

4.3.2.3 Theme Three: Tone of Messages

The importance of the tone of the messages to be empowering and encouraging, and not in any way condescending or laying blame, was a common feature in the feedback received.

"People could take it one or two ways. They could agree with it or they could feel as though they could be being judged in some way and they don't even know the people

who are really judging them, saying that. Some people could get offended and some people might not." (Male, New Zealand European inpatient, hazardous drinker.)

"It just seems more approachable if you're saying that like you recommend it instead of you should cut down bla bla bla…I quite like the tone of it…Cause it kind of makes you like reflect. And it doesn't seem too direct, you have to think about your drinking, it's just real like it would be a good idea, it seems more helpful. As opposed to, like, confrontation." (Female, Samoan inpatient, hazardous drinker.)

4.3.2.4 Theme Four: Language Alignment

Māori, Pacific, and Asian participants were specifically asked what they thought about having greetings in their own language in the content of text messages. The majority responded that they thought this would be a good idea to help make the intervention more personalised and engaging.

"Different greetings…. Because it's just the sense of them knowing who you are and where you're from. They've done the research in terms of understanding what ethnic background you are." (Male, Samoan inpatient, hazardous drinker.)

"It should be just Kia ora because not all Māori can speak Te Reo." (Male, Māori/Niuean inpatient, hazardous drinker.)

For many participants, acknowledging the important role of family/whānau in their lives was central to the intervention content, particularly the 'motivator' text message to be delivered during week one of the intervention. For Māori participants, not only was the concept of whānau important, but also utilisation of the word 'whānau'.

"I think a lot of things when they are done in a family sort of setting, you know, maybe work better." (Male, Māori inpatient, hazardous drinker.)

".. whānau is real, everybody know that word…it could personalise it a bit…appeal to them more." (Male Māori/Niuean inpatient, hazardous drinker.)

There was support from participants for a Te Reo Māori translation of the text messages. But it was also seen to be important to have the choice of an English version with some relevant Te Reo Māori words incorporated, as participants said there were many Māori who were not fluent in Te Reo Māori.

"It might have more meaning for some people if it is in Te Reo, they might feel more responsible I guess." (Key informant.)

"... what we have to keep in mind in the population is that while there are fluent speakers of Te Reo, there are also many Māori that aren't so there are key words like greetings, whānau is definitely a word that is used by non-Māori as well but I think it is keeping that in mind or having the option for a translated version as well but they choose that option." (Key informant.)

4.3.3 Phase Two: Consultation with Māori and Pacific Groups

Following revision and refinement of the text message intervention prototype based on findings from the first phase of pre-testing described above, consultation with Māori and Pacific groups was undertaken. Further refinements included reducing the number and length of text messages, changing content to be more relevant for Māori and Pacific audiences (e.g. inserting Te Reo Māori words of encouragement in appropriate places, changing specific words if the meaning was not clear), and translating the text messages to Te Reo Māori.

During this phase, the name of the text message intervention was considered. Substantial feedback was received during the pre-testing phase and consultation with Māori and Pacific groups that indicated the initial name 'MoDeRATE' (M-health Delivery for Reducing Alcohol in the Trauma Environment trial) was unappealing, not engaging nor empowering, and lacked meaning. For many people, 'moderation' in relation to drinking was not a familiar concept. An advertising agency was engaged to help come up with a new name. Three options were trialled and from these the name 'YourCall' was chosen. This name was seen to be positive, inspiring, and represented a challenge or 'call to action'.

4.3.4 Final Version of Text Message Intervention

The final version of the text message intervention had three main language-based text message pathways for people to choose between: 1) text messages in English with Te Reo Māori words of welcome and encouragement, 2) text messages in Te Reo Māori, and 3) text messages in English (with an option to receive a greeting in Samoan, Tongan, Cook Island Māori, Niuean, Tokelauan, Tuvaluan, or Fijian).

The finalised structure of the text message intervention was less complex compared with the original prototype. It consisted of 16 text messages in total spread over a one-month period

(Table 4).[ix] Single messages were to be sent at two-day intervals, with two exceptions, when two related messages were to be sent in tandem, half an hour apart. Messaging was designed to commence on a Monday and finish on a Saturday. Text messages falling on a weekday were to be sent at 7pm and those falling on a weekend-day were to be sent at 3pm.

The four text messages in 'Week One' contained content that welcomes the text message recipient, gives them feedback about their drinking, links them to existing services (e.g. free-phone alcohol helpline), and encourages contemplation about their drinking. The first text message in 'Week Two' contained an empathetic, yet clear recommendation to cut down on drinking. This was followed during the rest of 'Week Two and Three' by six messages focussed on providing information and tips/strategies about reducing alcohol consumption. The final three text messages in 'Week Four' contained supportive and encouraging content with the key messages re-iterated. Overall, the readability of the revised content was improved (Flesch-Reading Ease score 76.4 and Flesch-Kincaid Grade Level score 5.2).

[ix] See Appendix 3 for a table (updated after this paper was published and as part of the research described in Chapter Seven) showing the text messages mapped against BI elements and BCTs, using an updated taxonomy of BCTs.

Table 4. YourCall Text Message Intervention Content

Week of programme	Day of programme	English*	English with some Te Reo Māori words	Te Reo Māori
1	1 (Mon)	From YourCall: Hi, thanks 4 taking part in the study. Over the next 4 weeks we will be sending u txts with info & ideas	From YourCall: Tena koe. Thanks 4 taking part in the study. Over the next 4 weeks we will be sending u txts with info & ideas	Mai i TōWaea: Tēnā koe. Ngā mihi ki a koe i whai wāhi mai ki te rangahautanga. Mō te 4 wiki e tū mai nei ka tuku kupu kawe pārongo, kawe whakaaro ki a koe
1	3 (Wed)	YourCall: Your survey responses show your drinking is harmful 2 your health. Make a positive change in your life – cut down or quit	YourCall: Kia ora. Your survey responses show your drinking is not good 4 your health and wairua. Make a positive change in your life – cut down or quit	TōWaea: Kia ora. Nā ō whakautu rangahau kua kitea kāore e pai te waipiro ki tō hauora, wairua hoki. Tahuri ki te pai hei oranga mōu–whakaitia, whakamutua rānei
1	3 (Wed)	YourCall: U can get confidential support from Alcohol Helpline ph 0800 787 797 web alcoholdrughelp.org.nz or your doctor	YourCall: Kia ora. U can get confidential support from Alcohol Helpline ph 0800 787 798 web alcoholdrughelp.org.nz or your doctor	TōWaea: Kia ora. Ka taea te tautoko matatapu mai i te Alcohol Helpline waea 0800 787 798, ipurangi alcoholdrughelp.org.nz, mai i tō tākuta rānei
1	5 (Fri)	YourCall: Alcohol may be causing problems for u, your family & friends. We encourage u 2 think about your drinking and its impact on your life	YourCall: Kia ora. Alcohol may be causing problems for u, your whānau & friends. We encourage u 2 think about your drinking and its impact on your life & whānau	TōWaea: Kia ora. Kei te whakararu pea te waipiro i a koe, i tō whānau, i ō hoa hoki. Tēnā, āta whakaarohia tō inuinu me ana pānga ki a koe, oti rā ki te whānau
1	7 (Sun)	YourCall: U might find it helpful 2 think about the good things & the not so good things about your drinking. Making a list can help	YourCall: U might find it helpful 2 think about the good things & the not so good things about your drinking. Making a list can help	TōWaea: He āwhina pea ina whakaaro koe mō ngā mea pai me ngā mea kāore i te tino pai e pā ana ki tō inuinu. He āwhina anō pea tētahi rārangi
2	9 (Tues)	YourCall: We recommend u cut down or quit alcohol. Making a positive change can be hard, try small steps	YourCall: Kia ora. We recommend u cut down or quit alcohol. Making a positive change can be hard, try small steps. Kia kaha!	TōWaea: Kia ora. Ko tā mātou tūtohu me whakaiti, me mutu rānei te inu waipiro. He uaua pea te tahuringa ki te pai, iti nei, iti nei ka taea. Kia kaha!
2	11 (Thurs)	YourCall: Ideas 4 cutting down: plan no-alcohol days, have water between drinks, try low alcohol drinks like light beer. Check out easeuponthedrink.org.nz	YourCall: Kia ora. Ideas 4 cutting down: plan alcohol-free days, have water between drinks. Check out easeuponthedrink.org.nz	TōWaea: Kia ora. He whakaaro mō te whakaiti: whakaritea he rā kore inu, me inu wai i waenga i ngā inu. Tirohia easeuponthedrink.org.nz
2	13 (Sat)	YourCall: Keep track of your drinks. U could use a diary. 1 drink = 1 small bottle beer, half an RTD, half a glass wine or 1 shot spirits	YourCall: Kia ora. Keep track of your drinks. U could use a diary. 1 drink= 1 small bottle beer, half an RTD, half a glass wine or 1 shot spirits. Mauri ora	TōWaea: Kia ora. Kautehia ō inu. Whakamahia he rātaka ina hiahia. 1 te inu = 1 te pātara pia iti, he haurua RTD, he haurua wāina, 1 te inu waipiro. Mauri ora
3	15 (Mon)	YourCall: Reduce your chance of injuries & health problems by having no more than 2	YourCall: Kia ora. Reduce your chance of injuries & health problems by having no	TōWaea: Kia ora. Whakaitihia te tūpono wharanga, rarunga hauora hoki mā te inuinu

		drinks per day and at least 2 no-alcohol days per week	more than 2 drinks per day and at least 2 alcohol-free days per week. Mauri ora	iti iho i ngā inu e 2 ia rā, me ngā rā kore-waipiro e 2 rā ia wiki. Mauri ora
3	17 (Wed)	YourCall: Think of 1 thing u can do 2 cut down your drinking. Plan ahead & take action!	YourCall: Kia ora. Think of 1 thing u can do 2 cut down your drinking. Plan ahead & take action! Kia kaha	TōWaea: Kia ora. Whakaarohia ake kotahi mahi e taea ai e koe te whakaiti tō inuinu. Whakaritea he mahere, whāia! Kia kaha
3	19 (Fri)	YourCall: Don't drive if u have had alcohol. Arrange a sober driver, share a taxi, take a bus, walk with a friend	YourCall: Kia ora. Don't drive if u have had alcohol. Arrange a sober driver, share a taxi, take a bus, walk with a mate	TōWaea: Kia ora. Mena kua inu koe, kaua e taraiwa waka. Whakaritea he taraiwa kore inu, hopu tekehī, hopu pahi, hīkoi tahi me tētahi hoa rānei
3	21 (Sun)	YourCall: Think about sharing your goal with friends or family. They can give u support and may also want 2 cut down	YourCall: Kia ora. Think about sharing your goal with friends or whānau. They can give u support and may also want 2 cut down. Tu meke	TōWaea: Kia ora. Whakaarotia te tiri i tō whāinga ki ō hoa, ki tō whānau rānei. Mā rātou koe e tautoko, ka hiahia whakaiti te inuinu hoki pea rātou. Tumeke
4	23 (Tues)	***For males:*** YourCall: Its best not to drink alcohol at all if your health is not so good or u are on medication ***For females:*** YourCall: Its best not to drink alcohol at all if u are pregnant or might get pregnant, your health is not so good or u are on medication	***For males:*** YourCall: Its best not to drink alcohol at all if your health is not so good or u are on medication ***For females:*** YourCall: Its best not to drink alcohol at all if u are pregnant or might get pregnant, your health is not so good or u are on medication	***For males:*** TōWaea: He pai ake te kore inu mena kāore tō hauora i te pai, e kai pire ana rānei koe ***For females:*** TōWaea: He pai ake te kore inu waipiro mena kei te hapū, ka hapū pea rānei koe, kāore i te pai tō hauora, e kai pire ana rānei koe
4	25 (Thurs)	YourCall: Reward yourself 4 making progress with your goal - but not with alcohol! Don't give up on your goal, try small steps	YourCall: Kia ora. Reward yourself 4 making progress with your goal - but not with alcohol! Don't give up on your goal, try small steps. Kia kaha	TōWaea: Kia ora. Me whakanui koe i a koe anō mō te whakatata atu ki tō whāinga–engari kaua mā te waipiro! Kaua e whakarērea tō whāinga, kia āta haere. Kia kaha
4	27 (Sat)	YourCall: Remember that u can get confidential help from Alcohol Helpline 0800 787 797 or your doctor	YourCall: Kia ora. Remember that u can get confidential help from Alcohol Helpline 0800 787 798 or your doctor	TōWaea: Kia ora. Kaua e wareware ka taea te āwhina matatapu mai i Alcohol Helpline 0800 787 798, mai i tō tākuta rānei
4	28 (Sun)	YourCall: Make a positive change in your life - cut down or quit drinking alcohol. Thanks 4 taking part in the study – great effort! We'll be in touch in 2 months	YourCall: Kia ora. Make a positive change - cut down or quit drinking alcohol. Thanks 4 taking part in the study. We'll be in touch in 2 months. Kia kaha	TōWaea: Kia ora. Tahuri ki te pai – whakaitia, whakamutua rānei te inu waipiro. Ngā mihi mōu i whai wāhi mai. Hei te 2 marama ka whakapā atu anō mātou. Kia kaha

*The Day 1 text message has an option to receive a greeting in the following Pacific languages: Samoan, Tongan, Cook Islands, Niuean, Tokelauan, Tuvaluan, or Fijian.

4.4 Discussion

This chapter describes the development of appropriate (or therapeutic) content for a text message intervention aimed at reducing hazardous drinking and alcohol-related harm among trauma inpatients. Following conceptualisation and creation of initial text message content based on the BI model and behaviour change theory, the text message content was pre-tested with trauma inpatients, key informants, and Māori and Pacific groups, familiar with the setting and context for the proposed intervention. Four key themes were identified that were important to ensuring the text messages were engaging, relevant, and useful for potential recipients: 1) reducing the complexity of message content and structure; 2) increasing the interactive functionality of the text message programme; 3) ensuring an empowering tone to text messages; and 4) optimising the appropriateness and relevance of text messages for Māori and Pacific people. Consultation on the latter theme with Māori and Pacific groups helped us to further improve the text messages. The final version of the 'YourCall' intervention had three pathways for people to choose between: 1) text messages in English with Te Reo Māori words of welcome and encouragement, 2) text messages in Te Reo Māori, and 3) text messages in English (with an option to receive a greeting in Samoan, Tongan, Cook Island Māori, Niuean, Tokelauan, Tuvaluan, or Fijian).

The development approach and refinement of the resulting text message intervention have a number of strengths. The intervention is underpinned by established BI theory and evidence and the content development process was guided by a group of people purposively selected for their expertise in topic areas relevant to this intervention (i.e. drug and alcohol clinical services, mobile phone health technology, clinical and health psychology, youth health, and Māori, Pacific and Asian health). The pre-testing conducted with the target audience, key informants, and Māori and Pacific groups provides confidence that the text message content is engaging, relevant, and culturally appropriate. The involvement of Māori and Pacific researchers was critical for being able to carry out the pre-testing in an effective and appropriate way. The resulting intervention is a proactive programme of 16 brief text messages delivered over a four-week period, utilising an 'every-day' technology that is already integrated into people's lives.

There are also some limitations with this research. Pre-testing the text message prototype with trauma inpatients involved a small number of participants (n=14). Seven Māori and Pacific patients were interviewed, rather than the intended number of ten, as fewer than expected Māori and Pacific patients presented during the recruitment period. Although participants were

selected purposively, more males (n=11) than females (n=3) were interviewed. This may reflect the fact that more injury inpatients are male.[12] In addition, although all participants drank alcohol (one of the inclusion criteria), five of 14 participants had AUDIT-C scores indicating non-hazardous drinking. Inclusion of these participants enabled the viewpoints of a wide range of alcohol users to be explored. Furthermore, individuals with non-hazardous usual drinking patterns could also incur injuries in the context of a drinking episode. The purposive participant selection process could have been improved by allowing a longer recruitment period or extending recruitment to another hospital in Auckland. This would have enabled recruitment of the intended number of Māori and Pacific participants and a larger number of female participants.

Although a small number of inpatients were interviewed, this was supplemented by interviews with key informants and consultation with Māori and Pacific groups, including drug and alcohol counsellors. By the end of this process, a wide range of issues had been explored and addressed. More particularly, a point had been reached where the researchers were not gaining any new or different opinions or gleaning any significant new pieces of information, consistent with data saturation, a key attribute of rigour in a qualitative research study. While the study was not designed to yield empiric findings that are generalizable to all trauma patients, it provided rich insights regarding diverse perspectives relevant to our research objectives.

The initial feedback on the text messages from the target audience involved showing them proposed messages on paper. This is likely to be quite a different experience from receiving the messages at random times within the context of their busy and complex daily lives. However, the study group found this to be an important first step in the development process with members of the target audience. The development process used in this study continues to be built upon and refined by others.[118, 159, 160] The full participant experience of the programme (and the individual messages) within the 'free living' context can only be tested in a formal evaluation.

An important challenge, when determining the extent to which the development of an intervention should be guided by user preferences, is the possibility that content that is more consistent with preferences of users may not necessarily equate to more effective interventions. Indeed, a degree of challenge to what participants consider appealing may be necessary to prompt a realistic appraisal of the risks and harms associated with their drinking. Consequently, while the findings of this study have been used to ensure that the content of the messages are

clear, unambiguous and accessible, the overarching principles of BIs in this field are relied on to define the specific content. The result is a low intensity 'brief' mHealth intervention consistent with the concept of BI.

The text message intervention is designed to be automated and unidirectional, which aids the ability to provide a cost-effective and scalable service. A limitation of this is the relative lack of personalisation and interactive functionality. This was reflected in feedback from respondents who expressed the positive attributes of being able to interact with the service provider, e.g. texting back and forth with someone, although others indicated some value in a less personalised approach which provided a greater level of assurance regarding privacy. A recent mHealth qualitative study by Ranney et al. (n=20) found that adolescent females (presenting in ED and at high-risk for violence and depressive symptoms) understood that text messages might be automated, but that they should be individually tailored with some two-way communication. Participants said that both automated and as-needed messages (i.e. messages that could be requested) would be useful.[161] Another approach is that of Renner and colleagues' who have explored the idea of people creating their own text messages, which are then delivered at times stipulated by the recipient based on their own drinking habits.[162] While the YourCall text-message intervention did not have formal interactive features due to resource constraints, we included text messages which provide respondents with the free-phone number for the New Zealand Alcohol & Drug Helpline.

This research demonstrates a robust methodology for developing a text message intervention, based on components of Whittaker and colleagues' model.[151] The research has built on previous feasibility work[150] to progress the concept of a brief text message intervention for hazardous alcohol use from a hypothetical idea to a fully-developed intervention. A key component of this process is the involvement of the target audience and other stakeholders to provide feedback on the prototype.

An important focus of this research was the creation of culturally appropriate text messages, to assist with engagement. In New Zealand, where Māori and Pacific peoples experience inequities in the burden of alcohol-related injury outcomes and other alcohol-related harms, it is critical that interventions are developed which are relevant for the diverse realities of Māori and Pacific peoples and are implemented via channels (such as mobile phone) which have the potential to reduce inequalities in access to healthcare services.[25, 118]

4.5 Summary

This chapter has described the development of a text message intervention (called 'YourCall'), underpinned by established BI evidence and behaviour change theory, and designed with the aim to reduce hazardous and harmful drinking among patients admitted following an injury who screen positive for hazardous alcohol use. While text messages remove the interpersonal component of BI, they can be viewed as an approach that distils BI to its core information elements. A formative research process involving feedback from the target audience, service providers, and other key stakeholders was used to contextualise the content of the intervention and enhance its acceptability and appropriateness for the intervention setting. The next important step, i.e. evaluating the effectiveness of the intervention, is the topic of Chapters Five and Six.

CHAPTER 5: RANDOMISED CONTROLLED TRIAL OF A MOBILE PHONE TEXT MESSAGE INTERVENTION FOR PEOPLE WITH HAZARDOUS ALCOHOL USE: PRIMARY OUTCOME

This chapter addresses Thesis Objective Three: To assess the effect of the text message intervention on hazardous alcohol use. The content presented in this chapter is adapted from the published paper *'Sharpe S, Kool B, Whittaker R, Lee AC, Reid P, Civil I, Walker M, Thornton V, Ameratunga S. Effect of a text message intervention to reduce hazardous drinking among injured patients discharged from a trauma ward: a randomized controlled trial. npj Digital Medicine 2018;1(1):13. doi: 10.1038/s41746-018-0019-3'.* Copyright for this article is covered under the Creative Commons Attribution License 4.0.[x]

5.1 Introduction

Hazardous alcohol use is a leading risk factor for injury.[4, 5, 148] Between 7%-14% of all ED presentations,[7-9] 8%-60% of injury ED presentations,[10] and 23%-50% of trauma centre admissions[11-13] are reported to be alcohol-related. Prevention of alcohol-related trauma requires a multi-pronged public health approach including strategies that reduce access to and availability of alcohol, control sponsorship and advertising, drink-driving countermeasures, and appropriate interventions for hazardous drinkers.[14-16]

Screening for hazardous alcohol use and BI in trauma care settings has been reported to reduce alcohol intake, injury recidivism and other alcohol-related harms.[11, 91, 94] Despite inclusion in several guidelines,[86, 88, 163] the implementation of BIs in busy clinical settings is challenged by time and resource constraints.[12, 17, 19, 20] MHealth text message approaches could contribute to reducing these barriers. Communicating via text messages is cost-effective, highly scalable, and has the potential to transform access to health promotion information and services due to the high uptake of mobile phones globally and the ubiquity of text messaging. Mobile phones have been referred to as "the most accessible form of mediated communication in world history" and text messaging has become "one of the most frequently used forms of mobile communication".[115]

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MHealth text message approaches show promise as an alternative delivery mode for alcohol BI.[143, 144, 149, 150] An RCT of a 12-week text message alcohol intervention in 765 young-adult ED patients found small but significant decreases in binge-drinking days and the number of drinks consumed per drinking day in the intervention group compared with assessment and control groups at three months follow-up.[144] A recently published Cochrane Collaboration systematic review of personalised digital interventions for reducing hazardous and harmful alcohol consumption in community-dwelling populations found moderate quality evidence that digital interventions lower alcohol consumption.[97] The reviewers determined that there was insufficient information available to assess the impact of this mode of delivery on outcomes. Given the potential scalability and access to more disadvantaged communities, the scant evidence relating to the impact of mHealth text message approaches (only one study[144] in this review employed this mode of delivery) is a particularly important research gap.

The study group developed a proactive, low intensity, automated mobile phone text message intervention drawing on BI principles ('YourCall') designed to reduce hazardous drinking and alcohol-related harm among adults admitted to hospital following an injury. Following a feasibility study,[150] the programme content was created, pre-tested, and refined. As described in Chapter Four and a published article,[27] the programme was designed to be culturally relevant, appropriate, accessible, and engaging for Māori and Pacific audiences. The intervention consisted of a total of 16 text messages spread over a four-week period and provided people the choice of three main language-pathways: 1) text messages in English with Te Reo Māori words of welcome and encouragement, 2) text messages in Te Reo Māori, and 3) text message in English with an option to receive a greeting in Samoan, Tongan, Cook Island Māori, Niuean, Tokelauan, Tuvaluan or Fijian. The intervention length and frequency of text messages balanced the need to provide the core information elements of BI with a focus on keeping the frequency of messages to a minimum. This approach was informed by the feedback from participants during our feasibility study. Four text messages in the first week contained content that welcomed the recipient, gave feedback about their drinking, linked them to existing services (e.g. free-phone alcohol helpline), and encouraged contemplation about their drinking. The first text message in the second week contained an empathetic yet clear recommendation to cut down on drinking. This was followed during the second and third weeks by six messages focussed on providing information and tips or strategies about reducing alcohol consumption. The final three text message in the fourth week contained supportive and encouraging content with the key messages re-iterated.[27]

This trial aimed to evaluate the effect of the 'YourCall' text message BI (compared with usual care) in reducing hazardous drinking among adults admitted to hospital following an injury.

5.2 Methods

5.2.1 Study Design

A simple, two-group, parallel, RCT was conducted to evaluate the 'YourCall' intervention, the protocol for which has been published.[31] The methods were performed in accordance with relevant regulations and guidelines. The trial was funded by the Health Research Council of New Zealand, approved by the New Zealand Health and Disability Ethics Committee (12/NTB/28), and was registered with the Australian New Zealand Clinical Trials Registry (anzctr.org.au; Identifier: ACTRN12612001220853).

5.2.2 Participants

Participants were inpatients aged 16 to 69 years admitted for an injury-related cause to one of the three trauma-admitting hospitals (North Shore, Auckland City, and Middlemore) in Auckland, New Zealand's largest city (population 1.4 million). In order to be eligible, they had to be current drinkers, use a mobile phone which was not shared with someone else, be able to read and send text messages, be able to complete surveys in English, be expected to be discharged home, and be competent to provide informed consent. During recruitment (March 2013), two eligibility criteria were broadened to increase the number of potentially eligible participants. The upper age limit was increased from 60 to 69 years and the initial restriction of only including people admitted for 24 hours or more was replaced with including all hospital admissions regardless of length of stay. Pregnant women, tourists, and patients with self-harm injuries were excluded.

Using procedures described in the published protocol,[31] eligible patients were identified, information about the study was provided,[xi] and written informed consent was obtained from those interested in participating in the trial. Study participants were then screened for hazardous drinking using the AUDIT.[55]

Patients were included in the trial if they were considered to be at medium risk of alcohol problems (AUDIT scores: 7-15 for females; 8-15 for males). Patients with higher scores were

[xi] Participant Information Sheet is provided in Appendix 5.

excluded as the appropriate management involves counselling, specialist evaluation and treatment.[87]

5.2.3 Randomisation and Masking

Trial participants were randomly assigned by computer to receive the 'YourCall' intervention or a control program (usual care). Computer-based randomisation ensured balance in treatment assignment for randomisation factors including age (16-29 years, 30-69 years), sex, ethnicity (Māori, non-Māori) and recruitment hospital. Due to the nature of the intervention only single blinding was possible (i.e. researchers only). Research assistants (blind to treatment allocation) enrolled participants, undertook all baseline data collection, and initiated the computer-based randomisation procedure for each participant at the time of their discharge from hospital.

5.2.4 Procedures

All participants received an information brochure (*The straight up guide to standard drinks*[164]) at the time of enrolment. Those allocated to the intervention group received the 'YourCall' programme's 16 text messages sent over four weeks, starting seven to 10 days after discharge from hospital.[27, 31] Control group participants received one text message following discharge from hospital. This message acknowledged their participation in the trial and indicated they would be contacted in three months' time.

Baseline assessments included collection of demographic data and screening for hazardous alcohol use using the AUDIT.[xii] Follow-up self-reported assessments were conducted at three, six, and 12 months. At three and six months, questions were delivered via text message with participants responding via text. Responses were recorded automatically in the data management system. Participants were invited to complete an online survey at the 12-month time point.[xiii] Those not responding at the follow-up points were contacted by phone by research assistants and assessments were conducted via telephone.

5.2.5 Outcomes

The primary trial outcome was the difference in hazardous alcohol use between the intervention and control groups at three months. Maintenance of effect was examined at six and 12 months. Hazardous alcohol use at follow-up was assessed using the AUDIT-C tool.[165] This comprises

[xii] The Baseline Questionnaire is provided in Appendix 6.
[xiii] The 12-month survey form is provided in Appendix 7.

the first three questions of the 10-item AUDIT, scored on a scale of 0-12. This tool was chosen for use in this trial as a short set of questions was necessary in order to reduce the burden on trial participants (particularly given the questions were delivered and answered via text message) and to minimise assessment reactivity. The AUDIT-C tool is known to have sound psychometric properties[165, 166] and has been validated for identification of hazardous alcohol use in a range of settings including with admitted trauma patients[167] and online with adults seeking help for their drinking.[168] The tool has favourable test-retest reliability, including over one and three month intervals,[166] and allows the accurate monitoring of patients' risk over time.[165] This gives confidence that the tool is likely to be sufficiently responsive to change at the follow-up time-points of this trial. Despite the common use of AUDIT-C in research studies including in online formats,[143, 169] the instrument has not, to the research team's knowledge, been formally validated for use via text message nor been delivered via text message in other published studies for follow-up purposes. In addition, it is commonly used as a screening tool, rather than an outcome measurement tool.

Serious adverse events reported by participants or next-of-kin were recorded. At enrolment, participants were given information on texting-back 'stop' at any time if they did not wish to receive further 'YourCall' text messages. A register of unsolicited text-backs from participants was reviewed daily with responses guided by the study protocol.

5.2.6 Statistical Analysis

A sample size of at least 570 was expected to provide 80% power, at the 0.05 level of significance and with 70% follow up, to detect a true difference of 0.5 (7.5%) between the intervention and control groups in their mean three-month AUDIT-C scores. Sample size calculation was informed by estimates of injury discharges from the study hospitals and the published literature on distribution in AUDIT-C scores in previous trials. The sample size of 570 was based on a conservative estimate that 25% of patients screened would have AUDIT scores in the eligibility range for medium risk of alcohol problems and that 75% would choose to participate. The sample size was large relative to most alcohol intervention studies conducted previously. By recruiting patients from all major trauma-admitting hospitals in the Auckland region, it was anticipated that sufficient participants would be recruited to determine effects on alcohol consumption and related harms with adequate statistical power in a resource efficient manner.

The study also aimed to recruit as many Māori participants as possible with a minimum of 20% of the total sample, a situation deemed feasible given the ethnic distribution in the Auckland region. This sample size was expected to provide good power to test consistency in effect for Māori compared with non-Māori.

Baseline demographic variables (age, sex, ethnic group), employment and education, mobile phone usage, cigarette smoking and recreational drug usage, self-reported role of alcohol in the injury, nature of injury, and AUDIT-C mean scores were summarised. [31]

AUDIT-C scores at three, six and 12 months were analysed using the mixed-effects model for repeated measures. Treatment group, visit, group and visit interaction, the randomisation variables of age, gender, ethnicity and hospital were assessed as fixed effects, baseline AUDIT-C measure as a covariate, and participant as a random effect in the mixed-effect model. [31] The primary outcome was determined by the treatment effect at three months. An unstructured variance (co)variance structure was used to model the within-subject error. The Kenward-Roger method was used to estimate the denominator degrees of freedom for fixed effects.

To assess the effectiveness of the intervention for Māori and non-Māori, a pre-planned secondary analysis of the primary outcome was repeated with treatment and ethnicity (Māori vs non-Māori) interaction added to the model.[31] A post hoc interaction analysis also examined if the treatment effect varied by age group, given the suggestion that some brief interventions for alcohol use are less effective among youth. As the study was not powered to test for these interactions, the results need to be interpreted with caution.

All analyses were performed using SAS version 9.4 (SAS Institute Inc. Cary NC). All statistical tests were two-tailed, and a five percent significance level was maintained throughout. All evaluations were performed on the ITT principle, i.e. participants were analysed in the group they were randomised regardless of whether they were withdrawn or there was a protocol deviation. No adjustments for multiplicity were made for any of the outcomes. No imputations were made for missing data.

Two per protocol analyses[xiv] were also performed on the primary outcome as sensitivity analyses. In the first, the per protocol population consisted of all randomised participants

[xiv] Whereas Intention-to-treat (ITT) analysis compares treatment groups with all participants included in the groups to which they were randomised regardless of whether they completed their allocated 'treatment' or not, per protocol analysis compares treatment groups with only participants included who completed the 'treatment' as originally allocated and described in the study protocol.

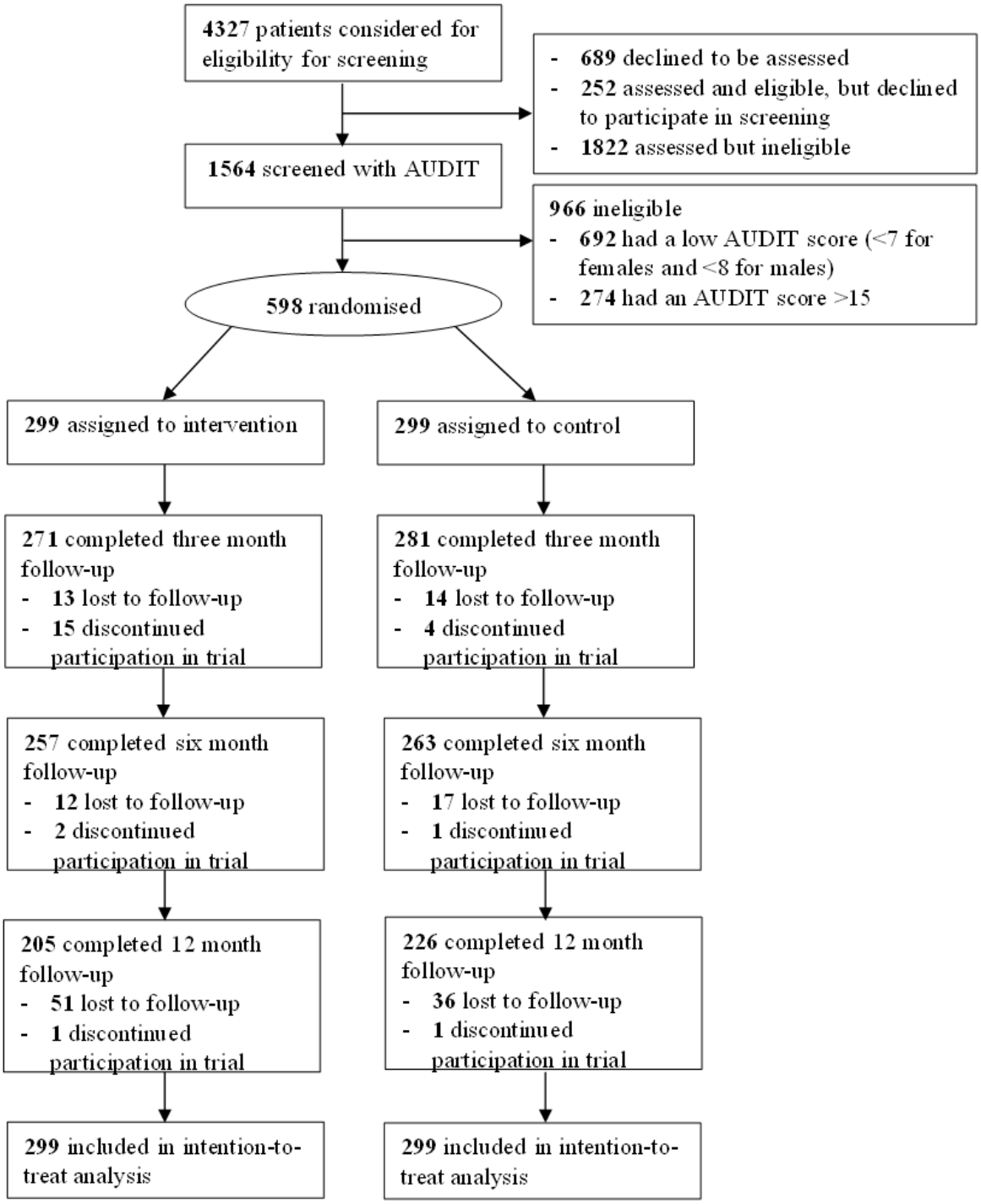
excluding eight participants who had a protocol violation due to an intervention commencement delay of more than two weeks. The per protocol population in the second sensitivity analysis comprised all randomised participants excluding the 167 participants who were lost-to-follow-up or discontinued their participation during the trial.

5.3 Results

Participants were recruited from November 9, 2012, to December 19, 2013. Follow-up was completed by February 2, 2015. As outlined in the participant flow diagram (Figure 5), 598 of the 1,564 potentially eligible participants who were screened met the trial inclusion criteria. Of the 299 participants randomly allocated to the intervention group, 271 (91%), 257 (88%) and 205 (69%) provided data at three-, six- and 12-months follow-up, respectively. Among the 299 participants in the control group, follow-up data at three, six and 12 months were available for 281 (94%), 263 (88%), and 226 (76%), respectively.

Of 22 intervention group participants who texted back ‘stop’ during the intervention delivery period, five discontinued participation in the trial and one was lost to follow-up. Of these 22 participants, 16 were males and 11 were aged 16-29 years. By ethnicity, two were Māori, four were Pacific People, 12 were New Zealand European, and four had other ethnicities. All participants were included in ITT analyses.

Figure 5. CONSORT Flow Diagram for YourCall Trial



5.3.1 Baseline and Drinking Characteristics

Baseline characteristics of the two groups were similar with participants aged 16-29 years accounting for approximately half the trial participants and males accounting for almost 70% (Table 5). Twenty-one percent of participants were Māori. Nearly 60% of participants drank alcohol ≥2 times per week, one third drank >6 drinks per typical drinking occasion, and 37% drank ≥6 drinks per occasion weekly or more often.

The percentage of participants with a non-hazardous drinking status measured using the short form of the AUDIT (AUDIT-C score of <3 for females and <4 for males) increased from 0% at baseline to 9.9% in the control group and 13.4% in the intervention group at three months; 13.6% in the control group and 15.1% in the intervention group at six months, and 11.9% in the control group and 13.7% in the intervention group at 12 months (Table 6).

Differences in non-hazardous drinking status between intervention and control groups at the three follow-up time points (i.e. 3.5%, 1.5% and 1.8% at three, six, and 12 months respectively) equate to Numbers Needed to Treat (NNTs) of 29, 67, and 56 respectively. (This is the number of hazardous drinkers who would need to be delivered this intervention in order to result in one drinker moving from hazardous to non-hazardous status).

At baseline, observed mean AUDIT-C scores were 6.82 (95% CI 6.62-7.03) in the control group and 6.87 (95% CI 6.68-7.06) in the intervention group. During follow-up, reductions in hazardous alcohol use occurred in both groups (Figure 6). Based on the mixed-effects models, the estimated mean AUDIT-C scores in the control group decreased to 5.92 (95% CI 5.63-6.22) at three months, 5.67 (95% CI 5.36-5.98) at six months, and 5.64 (95% CI 5.33-5.94) at 12 months. In the intervention group, the equivalent scores were 5.61 (95% CI 5.31-5.91) at three months, 5.27 (95% CI 4.96-5.49) at six months, and 5.38 (95% CI 5.06-5.70) at 12 months.

Table 5. Baseline Characteristics

Characteristics	Control group n=299 n (%)*	Intervention group n=299 n (%)*
Female	86 (28.8)	85 (28.4)
Age (mean, SD)	34 (13)	34 (13)
Age groups		
16-29 years	144 (48.2)	145 (48.5)
30-69 years	155 (51.8)	154 (51.5)
Ethnic groups		
Māori	64 (21.4)	62 (20.7)
Pacific Peoples	34 (11.4)	42 (14.1)
Asian	15 (5.0)	12 (4.0)
NZ European & Other	186 (62.2)	183 (61.2)
Hospital to which participant admitted		
Middlemore Hospital	123 (41.1)	123 (41.1)
North Shore Hospital	87 (29.1)	87 (29.1)
Auckland City Hospital	89 (29.8)	89 (29.8)
Employment		
Employed	236 (78.9)	219 (73.2)
Student	31 (10.4)	40 (13.4)
Unemployed	13 (4.3)	18 (6.0)
Other	19 (6.4)	22 (7.4)
AUDIT-C score (mean, 95% CI)	6.82 (6.62-7.03)	6.87 (6.68-7.06)
Drinking characteristics from AUDIT-C items		
Drinks alcohol two or more times per week	178 (59.5)	174 (58.2)
Drinks more than six drinks per typical drinking occasion	100 (33.4)	101 (33.8)
Drinks six or more drinks per occasion weekly or more often	110 (36.8)	110 (36.8)
High volume of alcohol consumed per week typically[a]	102 (34.1)	104 (34.8)
Current cigarette smoker		
Yes	102 (34.1)	97 (32.4)
No	197 (65.9)	201 (67.2)
Unknown/Refused to answer	0 (0)	1 (0.3)
Current use of recreational drugs		
Yes	59 (19.7)	64 (21.4)
No	239 (79.9)	233 (77.9)
Unknown/Refused to answer	1 (0.3)	2 (0.7)
Participant thinks their drinking played a role in the injury		
Yes	41 (13.7)	42 (14.1)
No	258 (86.3)	257 (86.0)
Participant thinks someone else's drinking played a role in the injury		
Yes	27 (9.0)	22 (7.4)
No	272 (91.0)	277 (92.6)
Mechanism of injury		
Fall	103 (34.5)	118 (39.5)
Struck by or against something	62 (20.7)	51 (17.1)

Cutting or piercing	57 (19.1)	45 (15.1)
Motor vehicle crash	36 (12.0)	39 (13.0)
Assault	9 (3.0)	10 (3.3)
Other	32 (10.7)	36 (12.0)
Nature of injury[b]		
Lower limb (fractures, wounds, sprains)	132 (38.8)	131 (36.9)
Upper limb (fractures, wounds, sprains)	106 (31.2)	117 (33.0)
Other musculoskeletal	53 (15.6)	59 (16.6)
Head injuries	28 (8.2)	22 (6.2)
Internal (thoracic, abdominal, pelvic)	11 (3.2)	12 (3.4)
Other	10 (2.9)	14 (3.9)
Intent of injury		
Non-intentional	288 (96.3)	293 (98.0)
Intentional	9 (3.0)	5 (1.7)
Undetermined	2 (0.7)	1 (0.3)

AUDIT-C is Alcohol Use Disorders Identification Test-Consumption. [a] Derived from combining AUDIT-C items 1 (i.e. frequency of drinking) and 2 (i.e. number of drinks consumed on a typical drinking occasion) to determine the number of drinks consumed per week typically, represented by 21 different categories or code pairs. In this analysis, high volume was defined as categories '5-6 drinks 2-3 times/week', '7-9 drinks 2-3 times/week', '10 or more drinks 2-3 times/week', '3-4 drinks 4 or more times/week', '5-6 drinks 4 or more times/week', '7-9 drinks 4 or more times/week', and '10 or more drinks 4 or more times/week'. [b] Participants could indicate one or more responses for these questions, therefore values in each column do not add up to 100%. ***** Number and % are provided, unless otherwise indicated.

Table 6. Drinking Characteristics of Participants at Baseline and Follow-up Time Points

Drinking characteristics	Control group n (%)	Intervention group n (%)
Baseline	*n=299*	*n=299*
Drinks alcohol two or more times per week[a]	178 (59.5)	174 (58.2)
Drinks more than six drinks per typical drinking occasion[b]	100 (33.4)	101 (33.8)
Drinks six or more drinks per occasion weekly or more often[c]	110 (36.8)	110 (36.8)
High volume of alcohol consumed per week typically[d]	102 (34.1)	104 (34.8)
Non-hazardous drinking status[e]	0 (0.0)	0 (0.0)
Three-month follow-up point	*n=272*	*n=262*
Drinks alcohol two or more times per week	146 (53.7)	110 (42.0)
Drinks more than six drinks per typical drinking occasion	76 (27.9)	80 (30.5)
Drinks six or more drinks per occasion weekly or more often	79 (29.0)	66 (25.2)
High volume of alcohol consumed per week typically	81 (29.8)	60 (22.9)
Non-hazardous drinking status	27 (9.9)	35 (13.4)
Six-month follow-up point	*n=250*	*n=245*
Drinks alcohol two or more times per week	124 (49.6)	120 (49.0)
Drinks more than six drinks per typical drinking occasion	59 (23.6)	43 (17.6)
Drinks six or more drinks per occasion weekly or more often	58 (23.2)	52 (21.2)
High volume of alcohol consumed per week typically	70 (28.0)	56 (22.9)
Non-hazardous drinking status	34 (13.6)	37 (15.1)
12-month follow-up point	*n=226*	*n=205*
Drinks alcohol two or more times per week	126 (55.8)	102 (49.8)
Drinks more than six drinks per typical drinking occasion	40 (17.7)	42 (20.5)
Drinks six or more drinks per occasion weekly or more often	66 (29.2)	54 (26.3)
High volume of alcohol consumed per week typically	55 (24.3)	44 (21.5)
Non-hazardous drinking status	27 (11.9)	28 (13.7)

[a] Derived from AUDIT-C item 1 "How often do you have a drink containing alcohol?"

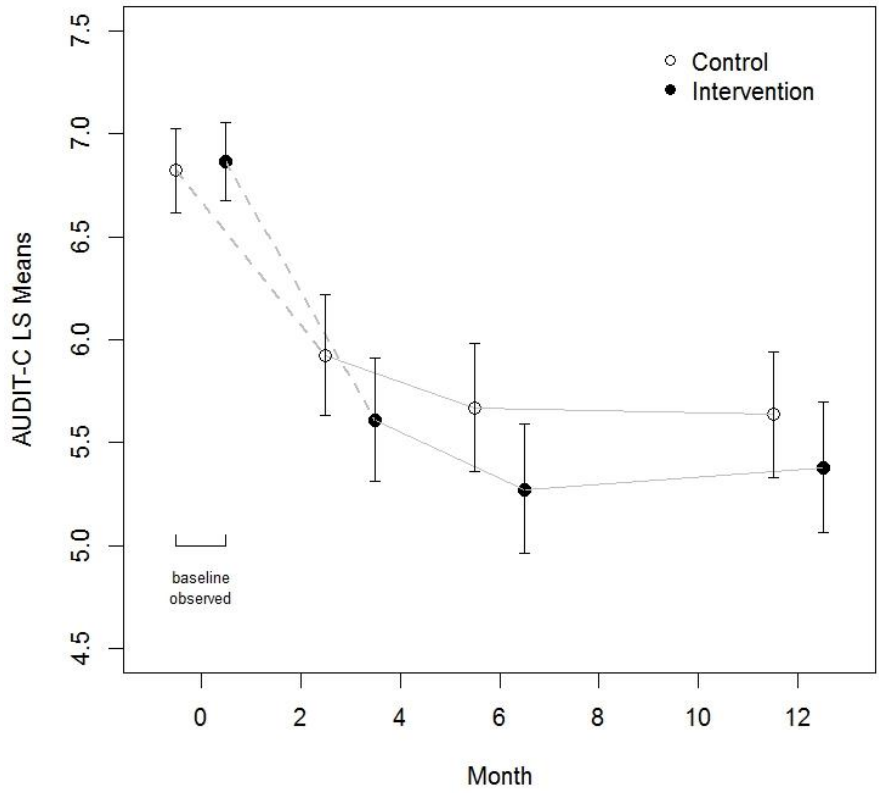
[b] Derived from AUDIT-C item 2 "How many drinks containing alcohol do you have on a typical day when you are drinking?"

[c] Derived from AUDIT-C item 3 "How often do you have six or more drinks on one occasion?"

[d] Derived from combining AUDIT-C items 1 (i.e. frequency of drinking) and 2 (i.e. number of drinks consumed on a typical drinking occasion) to determine the number of drinks consumed per week typically, represented by 21 different categories or code pairs. In this analysis, high volume was defined as categories '5-6 drinks 2-3 times/week', '7-9 drinks 2-3 times/week', '10 or more drinks 2-3 times/week', '3-4 drinks 4 or more times/week', '5-6 drinks 4 or more times/week', '7-9 drinks 4 or more times/week', and '10 or more drinks 4 or more times/week'.

[e] Non-hazardous drinking status is defined at the 3, 6, and 12-month follow-up points as an AUDIT-C score of <3 for females and <4 for males. At baseline, all participants were assessed as hazardous drinkers, and this was an eligibility criterion for participation in the trial.

Figure 6. Least Squares Mean AUDIT-C Scores at Baseline and Three, Six, and Twelve-Month Follow-up Points from a Mixed Model for Repeated Measures Analysis



Treatment group	Mean AUDIT-C score (95% Confidence Interval)			
	Baseline	Three-month follow-up	Six-month follow-up	Twelve-month follow-up
Control	6.82 (6.62-7.03)	5.92 (5.63-6.22)	5.67 (5.35-5.98)	5.64 (5.33-5.94)
Intervention	6.87 (6.68-7.06)	5.61 (5.31-5.91)	5.27 (4.96-5.49)	5.38 (5.06-5.70)

5.3.2 Primary Outcome

The mixed-effects model, which included the fixed effects of age, sex, hospital, and ethnicity, and co-variate baseline AUDIT-C, found the mean AUDIT-C score in the intervention group was on average 0.322 lower (95% CI -0.636, -0.008; p=0.04) than the control group (Table 7). This modest but significant effect was maintained across the 12-month follow-up period. Pre-planned secondary analysis revealed a non-significant interaction of treatment and ethnicity. The least squares mean difference in AUDIT-C scores among the Māori subgroup was -0.50 (95% CI -1.21-0.21) and among the non-Māori subgroup was -0.28 (95% CI -0.63-0.07). Similarly, a post hoc analysis revealed there was no evidence of a statistically significant difference in treatment effect between younger (16-29 years) and older (30-69 years) patients.

The least squares mean difference in AUDIT-C scores among the younger patients was 0.27 (95% CI -0.19-0.73) and among the older patients was 0.37 (95% CI -0.07-0.80).

In the first per protocol sensitivity analysis, which excluded eight participants with a protocol violation (i.e. delay in commencing the text message intervention), the treatment effect was relatively unchanged. The estimated AUDIT-C score in the intervention group was on average 0.313 lower (95% CI -0.630, 0.005; p=0.05) than the control group.

In the second per protocol sensitivity analysis which excluded 167 participants who were lost-to-follow-up or discontinued participation during the trial period, there was minimal difference in the treatment effect. The estimated AUDIT-C score in the intervention group was on average -0.335 lower (95% CI -0.673 to 0.004; p=0.05) than the control group.

One serious adverse event was recorded during the study. This was the death of a participant, the cause of which (myocardial infarction) was unrelated to the trial. No adverse events were detected through daily reviews of the register of text-backs from participants. 'Stop' messages were sent by 22 participants (7% of intervention group).

Table 7. Results of Mixed Modelling for the Primary Outcome

Fixed effect	**Difference of Least Squares Means**			**Type 3 tests**	
	Estimate	**95% CI**		**F Value**	**Pr > F**
AUDIT-C at baseline				113.17	<.001
Treatment (Ref=Control)				4.05	0.04
Intervention	-0.322	-0.636	-0.008		
Time (Ref=3 month)				6.19	0.002
6 months	-0.296	-0.474	-0.118		
12 months	-0.260	-0.463	-0.057		
Treatment*Time (Ref=Control, 3 month)				0.23	0.79
Age Group (Ref 16 - 29)				5.02	0.03
30 - 69	-0.360	-0.676	-0.044		
Sex (Ref=male)				1.41	0.24
Female	-0.218	-0.580	0.143		
Hospital (Ref=Hospital 3)				1.12	0.33
Hospital 1	-0.282	-0.662	0.098		
Hospital 2	-0.219	-0.626	0.188		
Ethnic group (Ref=Non-Māori)				2.44	0.12
Māori	-0.318	-0.719	0.081		

5.4 Discussion

This trial found that a low intensity, automated, culturally appropriate, brief text message intervention, delivered to adults aged 16 to 69 years who had been admitted to hospital due to injury and screened positive for hazardous drinking of medium risk, led to a modest but significant reduction in hazardous drinking in the intervention compared with control (usual care) group. This effect was maintained across the follow-up time points (three, six and 12 months) and was similar among Māori and non-Māori, and among younger (16-29 years) and older (30-69 years) participants.

In this trial, hazardous drinking was measured using the AUDIT-C score (range 0-12; score of ≥3 for females and ≥4 for males indicates hazardous drinking). The 0.3 lower AUDIT-C score on average in the intervention group compared with control group equates to a five percent average reduction in score for the intervention group compared with controls, based on the mean AUDIT-C score in the control group at three months of 5.92. To contribute to understanding the clinical significance of the intervention effect, it is also useful to consider the descriptive findings related to absolute risk reductions in hazardous drinking status. The NNTs of 29, 67, and 56 at the three, six, and 12-month follow-up points respectively, are higher than those reported for face-to-face alcohol BIs[170] and are similar to NNTs reported for brief advice to support smoking cessation.[171]

The effect size found in this trial is comparable to the findings of previously published trials of face-to-face alcohol BIs[85, 94, 172] and a text message alcohol intervention.[144] Importantly, the 'YourCall' intervention effect was sustained throughout the 12 month follow-up period, a finding that differs from other studies which generally show a waning of effect over a year.[172] This may reflect the fact that this mHealth intervention was delivered over a four-week period with tailoring of messages to take account of days of the week when recreational drinking is likely to be more common.

While this trial was not designed to explain why the intervention was effective, there are several features that we consider may have contributed to this finding. Text messaging as a modality for BI may have advantages over traditional face-to-face BI as it is easily integrated into people's lives using a familiar 'every-day' technology and in a way that is convenient and non-intrusive. For some people who are reluctant to access support through formal services, the anonymity provided by the automated service may have served as a positive characteristic. Providing a sequence of text messages over time may have resulted in a "booster" effect. While

the study did not investigate different frequencies of text message delivery to assess dose effects, the approach with 16 text messages over four weeks appears to have delivered the necessary BI information components. In addition, the linkage of this intervention to a significant event (i.e. a hospitalisation due to an injury) was designed to use a 'teachable moment' when participants are more likely to consider this type of intervention helpful and timely.[173] There are also important characteristics related to the carefully crafted content of the text messages, which were pre-tested with the target audience and key stakeholders and refined during the development stage. The messages were intentionally simple and easy-to-understand, empathetic and non-judgemental in tone, and underwent cultural and language tailoring.

The participants in the trial were hazardous drinkers at medium risk of harm (AUDIT score 7-15 for women and 8-15 for men), they were not seeking help for alcohol issues, and the intervention was of very low intensity. While these characteristics may result in an underestimation of the potential effect of mobile health interventions on all problem drinkers, BIs are treatments designed specifically for medium-risk drinkers rather than drinkers at higher risk of harm and dependent on alcohol.[87] In medium risk groups, low intensity or 'very brief' interventions are reported to be just as effective as more intensive interventions.[85, 94, 172]

The similar treatment effect among Māori and non-Māori is of particular importance in the New Zealand context. Māori people experience disproportionate harm from alcohol compared with other ethnic groups.[59] Given the burden of comprehensive health inequities borne by Māori, interventions must be shown to be equally effective for Māori in order to ensure that these efforts do not unwittingly increase inequity. The study focus on developing culturally appropriate content that would engage Māori people and be relevant to Māori lived realities may have contributed to the equivalence of treatment effects. A previous trial evaluating an mHealth smoking cessation intervention which incorporated Māori-specific test messages found the intervention was as effective for Māori as non-Māori at increasing quit rates.[174]

The effect of alcohol screening on study groups, as seen in the reduction in mean AUDIT-C in the control group in this study, has been noted in other studies.[175] Reasons for this observation could include an effect from the screening/assessment process on hazardous drinking,[175-178] regression to the mean[179]; the effect of being unwell with an injury and/or recovering from surgery, therefore not taking part in usual activities; and the influence of participating in a research study.[180] The trial design, however, gauged the impact of the intervention, over and above these potential phenomena.

The strengths of this RCT include its large size, good follow-up rates at three months, broad age range, generalisability to adult inpatient trauma care patients (regardless of whether alcohol played a role in the injury), focus on medium-risk drinkers (a previously neglected group), and recruitment practices that ensured participation of Māori patients (21% of study participants; nine percent of the Auckland Region population aged 15-69 years[181]).

The study findings, however, must also be interpreted in light of limitations, particularly the differential loss to follow-up (31% and 24% in the intervention and control groups at 12 months). The sensitivity analysis excluding participants who were lost-to-follow-up or discontinued their participation was reassuring in that the treatment effect was relatively unchanged. The larger proportion of participants lost from the intervention group may be partly explained by the more frequent texts, and therefore prompts, that this group had to text back 'stop'. This was activated by 22 participants although only six discontinued participation or were lost to follow-up.

Self-reported drinking measures are known to be susceptible to measurement bias[182] as people tend to under-report the frequency and quantity of drinking (for example, due to not being able to accurately recall their drinking[183, 184] or due to social desirability bias[182, 185]). Also, given the lack of sufficient power to undertake more detailed sub-group analyses, masking of different effects in subgroups cannot be ruled out. Aspects not explored in this study but worthy of future research include the specific intervention elements that account for its effectiveness, levels of interactivity or booster doses that could enhance benefits, and reasons why some participants elected to 'stop' the messages.

The findings of this trial provide further evidence to support the emerging literature about the effectiveness of text message interventions designed to reduce hazardous drinking. While the absolute effects are likely to be modest, these could have important effects at the population level. As a delivery mode, mHealth strategies expand the options available to healthcare services to provide low cost, highly scalable, time-saving interventions. These may particularly appeal to patients given the convenience of access, integration into daily life, cultural appropriateness, and technological engagement. With high and expanding mobile phone coverage world-wide, these aspects make mHealth interventions for hazardous alcohol use particularly salient in economically disadvantaged groups and low- and middle-income countries.

Further research should address the barriers that can impede the implementation of screening and BI, including mHealth options, into every-day practice in healthcare settings, including trauma care. This is critical to translating research evidence to best practice in 'real world' settings.

5.5 Summary

Compared with usual care, the 'YourCall' intervention (a low intensity mobile phone text message intervention based on BI principles) resulted in a modest but significant reduction in hazardous drinking among patients admitted following an injury. The intervention effect (in terms of mean group differences) was sustained over the 12-month follow-up period and similar in Māori and non-Māori participants. MHealth interventions are scalable, low cost approaches that could overcome barriers to implementing BIs in clinical settings. The next chapter evaluates the effect of the 'YourCall' intervention on the secondary outcomes: alcohol-related harms, participants' readiness to change (RTC) hazardous drinking patterns, and participants' help-seeking behaviours.

CHAPTER 6: TWELVE-MONTH FOLLOW-UP SURVEY: SECONDARY OUTCOMES

The effect of the 'YourCall' intervention on hazardous alcohol use, i.e. the primary outcome of the RCT, has been described in Chapter Five. Chapter Six builds on these findings and addresses the effect of the text message intervention on alcohol-related harms, i.e. secondary outcomes of the RCT (Thesis Objective Three). A paper based on the content of Chapter Six has been published: *'Sharpe S, Kool B, Whittaker R, Lee AC, Reid P, Civil I, Ameratunga S. Effect of a text message intervention on alcohol-related harms and behaviours: secondary outcomes of a randomised controlled trial. BMC Research Notes 2019;12:267. doi: 10.1186/s13104-019-4308-y.'* Copyright for this article is covered under the Creative Commons Attribution License 4.0.[xv]

6.1 Introduction

The harms associated with alcohol are a significant national and global issue. As described in Chapter Two, harms from alcohol cause large health, social, and economic burdens to people, communities, and society.[1, 3, 4] Harms are wide-ranging (e.g. physical, mental, and behavioural health issues; friendship and relationship problems; work and employment problems; financial and legal problems) and include harms to people from their own drinking as well as harms to people because of another person's drinking.[59, 60]

As already outlined in this thesis, face-to-face alcohol SBIs have been shown to reduce alcohol consumption and alcohol-related harms,[91, 92, 94] and digital (including mHealth) approaches to alcohol SBI show promise.[97] The 'YourCall' trial primary outcome finding (Chapter Five) has provided evidence that a low intensity, automated, culturally appropriate, text message intervention led to a significant reduction in hazardous drinking in the intervention group compared with control (usual care) group. In addition, this effect was maintained across the follow-up time points (three, six and 12 months) and was similar among Māori and non-Māori, and among younger (16-29 years) and older (30-69 years) participants.

This chapter describes the methods and reports the findings of a 12-month follow-up survey, which aimed to evaluate the effect of the 'YourCall' text message intervention (compared with usual care) on a range of alcohol-related harms, as well as participants' levels of RTC

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hazardous drinking patterns and participants' help-seeking behaviours. The hypothesis was that in comparison to hazardous drinkers discharged from hospital following an injury admission who received usual care, those who received the text message intervention incorporating brief intervention from harm principles would have experienced less alcohol-related adverse health and social consequences at the 12-month follow-up point.

6.2 Methods

6.2.1 Study Design and Participants

The study design, patient population and eligibility criteria for the RCT have been previously described (Chapter Five, Section 5.2), and reported in published papers.[28, 31] To recap, a simple, two-group, parallel, RCT was conducted in 598 trauma inpatients with medium-risk hazardous drinking patterns, comparing the effects of the 'YourCall' text message intervention with 'usual care' on hazardous drinking and alcohol-related harms. The trial was approved by the New Zealand Health and Disability Ethics Committee (12/NTB/28), was registered with the Australian New Zealand Clinical Trials Registry (anzctr.org.au; Identifier: ACTRN12612001220853), and followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[186] Written informed consent was obtained from all participants.

6.2.2 Procedures

As described previously (Chapter Five, Section 5.2.4), intervention group participants received the 'YourCall' programme's 16 text messages sent over four weeks, commencing 7-10 days after discharge from hospital. Following discharge from hospital, control group participants received one text message which acknowledged their participation in the trial and indicated they would be contacted in three months' time. The 'YourCall' intervention is a low intensity, automated mobile phone text message programme, drawing on BI principles[87] and Stages of Change behaviour change theory,[152] designed to reduce hazardous drinking and alcohol-related harm among adults admitted to hospital following an injury. The intervention development process and text message content have been previously described (Chapter Four).

Participants completed baseline assessments which included collection of demographic data and screening for hazardous alcohol use using the AUDIT and were invited to complete follow-up at three and six months (AUDIT-C assessments via text message), and 12 months (AUDIT

and other alcohol-related questions via a web-based survey). Those who did not respond were contacted by phone by research assistants and assessments were conducted via telephone.

The 12-month web-based survey[xvi] was developed in LimeSurvey (open source software). Participants were asked two sets of 'drinking consequences' questions drawn from the Gender, Alcohol, and Culture International Study (GENACIS) (http://www.genacis.org./11).[187] These comprised seven questions relating to possible alcohol-related 'harms' in the previous 12 months and seven questions relating to possible alcohol-related 'troubles'. Respondents were also asked questions about their current feelings towards their RTC in relation to their drinking behaviour using a visual analogue scale[188] and alcohol-related help-seeking behaviours.

6.2.3 Secondary Outcomes

The secondary outcomes presented in this chapter are the differences between the intervention and control groups, at the 12-month follow-up point, in self-reported alcohol-related harms, alcohol-related troubles, RTC, and help-seeking behaviours.

Alcohol-related harms and troubles were assessed using the 'Alcohol Harms' seven-item checklist[76, 189] and 'Alcohol Troubles' seven-item checklist,[76, 189] containing questions related to possible alcohol-related 'harms' or 'troubles' that the respondent may attribute to their drinking in the preceding 12-month period (Table 8). Alcohol Harms and Alcohol Troubles scores were calculated as the sum of the seven harm or trouble questions, each with a possible value 0-2, and total score between 0-14.

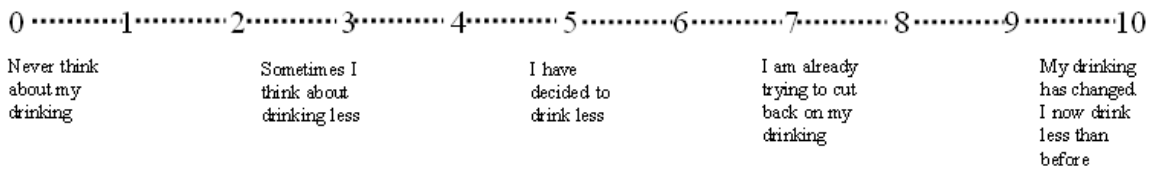
RTC was assessed using the Readiness to Change ruler, a Visual Analogue Scale from 0 to 10.[190] Respondents are asked to select the number that best described how they feel about changing their drinking behaviour (Table 8).

To assess help-seeking behaviour, participants were asked whether they did any of the following: a) rang the Alcohol Drug Helpline (offers free confidential professional help and advice); b) visited the Alcohol Drug Helpline website; c) visited any other websites for information or help relating to alcohol use; d) talked with a doctor or other health professional about their drinking; e) talked with anyone else, such as friends or family, about their or others' drinking (Table 8). 'Behaviours a – d' (reflecting professional sources of help) were assessed as a composite outcome called 'Help-seeking behaviours 1', i.e. whether participants reported

[xvi] See Appendix 7 for the 12-month survey (paper form version).

any of ‘a – d behaviours’ involving help-seeking from recommended alcohol help sources or online sources. ‘Behaviour e’ was assessed separately (called ‘Help-seeking behaviours 2’) as it involved talking with friends or family as distinct from ‘professional’ sources and also involved discussion about the respondent or other people’s alcohol use.

Table 8. Survey Questions Drawn on to Assess Secondary Outcomes

Questions asked in online survey at 12-month follow-up point
Alcohol harms During the 12 months since you joined the study, has your drinking had a harmful effect: 1) On your work, studies or employment opportunities? *No/Yes, once or twice/Yes, more than twice* 2) On your housework or chores around the house? *No/Yes, once or twice/Yes, more than twice* 3) On your marriage/intimate relationships? *No/Yes, once or twice/Yes, more than twice* 4) On your relationships with other family members, including your children? *No/Yes, once or twice/Yes, more than twice* 5) On your friendships or social life? *No/Yes, once or twice/Yes, more than twice* 6) On your finances? *No/Yes, once or twice/Yes, more than twice* 7) On your physical health? *No/Yes, once or twice/Yes, more than twice*
Alcohol troubles In the 12 months since you joined the study, have you had any of the following experiences? 1) Have you had trouble with the law about your drinking and driving? *No/Yes, once or twice/Yes, more than twice* 2) Have you had an illness connected with your drinking that kept you from working on your regular activities for a week or more? *No/Yes, once or twice/Yes, more than twice* 3) Have you lost a job, or nearly lost one, because of your drinking? *No/Yes, once or twice/Yes, more than twice* 4) Have people annoyed you by criticising your drinking? *No/Yes, once or twice/Yes, more than twice* 5) Has your spouse or someone you lived with threatened to leave or actually left because of your drinking? *No/Yes, once or twice/Yes, more than twice* 6) Have you lost a friendship because of your drinking? *No/Yes, once or twice/Yes, more than twice* 7) Have you got into a fight while drinking? *No/Yes, once or twice/Yes, more than twice*
Readiness to change Using the ruler below, please select the number that best describes how you feel right now and enter this into the box below: 
Help-seeking behaviours In the 12 months since you joined the study did you do any of the following? a) Ring the Alcohol Helpline? *Yes / No* b) Look at the Alcohol Helpline website? *Yes / No* c) Look at any other websites for information or help about alcohol? *Yes / No* d) Talk with a doctor or other health professional about your drinking? *Yes / No* e) Talk with anyone else, such as friends or family, about your or their drinking? *Yes / No*

These questions were asked at the 12-month follow-up point, but not at baseline, due to concerns about the length of the baseline assessment and the need to minimise potential treatment effects for the control group.[175, 177]

6.2.4 Statistical Analysis

The sample size for this study was calculated to detect a significant difference in the primary outcome at three months. As previously described (Chapter Five, Section 5.2.6), a sample size of at least 570 was expected to provide 80% power, at the 0.05 level of significance and with 70% follow up, to detect a true difference of 0.5 (7.5%) between the intervention and control groups in their mean 3-month AUDIT-C scores.

Data were analysed following a pre-specified analysis plan. Baseline demographic variables (age, sex, and ethnic group), employment, AUDIT-C mean scores, and 12-month survey question responses were summarised for the intervention and control groups.

The differences between the intervention and control groups in secondary outcome measures were analysed using logistic regression models adjusted for the randomisation variables of age, sex, hospital centre, ethnicity, and baseline AUDIT-C score.

Data analyses were performed using SAS version 9.4 (SAS Institute Inc. Cary NC). All statistical tests were two-tailed and at five percent significance level. All evaluations were performed on the ITT principle, i.e. participants were analysed in the group in which they were randomly assigned regardless of whether they were withdrawn or there was a protocol deviation. No adjustments for multiplicity were made for any of the outcomes. No imputations were made for missing data.

6.3 Results

As previously described in Chapter Five, Section 5.3, and shown in Figure 5, 598 of the 1,564 potentially eligible participants who were screened met the trial inclusion criteria. The characteristics of the two groups were similar at baseline (Chapter Five, Table 5). The mean age of participants was 34 years (SD=13), with just under half aged 16-29 years. Just under 30% of participants were female. Twenty-one percent of participants were Māori. Observed mean AUDIT-C scores were similar between the two study arms (control group: 6.82 [95% CI 6.62-7.03]; intervention group: 6.87 [95% CI 6.68-7.06]).

Twelve-month follow-up data was provided by 226 (76%) of the 299 control group participants and 205 (69%) of the 299 intervention group participants. The percentages of females and Māori respondents at 12 months were similar to those at baseline, however there were fewer participants in the 16-29-year-old group at 12 months compared to baseline (Table 9). The mean age of respondents at 12-months was 35.6 (SD=13).

Table 9. Characteristics of Participants at Baseline and Twelve-Months

Characteristics	Baseline		12-month follow-up point	
	Control group n=299 n (%)	Intervention group n=299 n (%)	Control group n=226 n (%)	Intervention group n=205 n (%)
Female	86 (28.8)	85 (28.4)	67 (29.6)	63 (30.7)
Age (mean, SD)	34 (13)	34 (13)	36 (13)	35 (13)
Age group 16-29 yrs	144 (48.2)	145 (48.5)	90 (39.8)	94 (45.9)
Māori ethnicity	64 (21.4)	62 (20.7)	43 (19.0)	36 (17.6)

6.3.1 Description of Participants' Responses

Participants' responses to the 12-month survey (Table 10) showed that alcohol-related harms and troubles in the past year were experienced by a large percentage of both the control and intervention groups. Of those who responded to the 'alcohol harms' questions (225 [75%] of control group and 199 [67%] of intervention group), over half (124 [55%] of control group and 106 [53%] of intervention group) reported alcohol-related harmful effects in one or more of the following domains: work, studies, or employment; housework or chores around the house; marriage/intimate relationships; relationships with other family members including children; friendships or social life; finances; physical health. Of those who responded to the 'alcohol troubles' questions (223 [75%] of control group and 200 [67%] of intervention group), one third of both control and intervention groups (76 [34%] and 65 [33%], respectively) reported alcohol-related troubles in one or more of the following domains: the law; illness connected with drinking; losing or nearly losing a job; feeling annoyed by other people's criticisms of their drinking; having a spouse or someone close leave or threaten to leave; loss of a friendship; getting into a fight.

More than half the respondents (116 [53%] of control group and 105 [53%] of intervention group) reported having decided to reduce their drinking, be trying to do this, or to have made a change and reduced their drinking. A small number of respondents (24 [11%] of the control group and 31 [16%]) of intervention group) had sought help with their drinking through contacting a health professional, via the free and confidential Alcohol Drug Helpline, or

through seeking information or help from online sources ('help-seeking behaviours 1' in Table 10). In contrast, 90 (41%) control group respondents and 85 (43%) intervention group respondents reported talking with others, such as friends or family, about their drinking or that of the friend/family ('help-seeking behaviours 2' in Table 10).

Table 10. Summary of Responses to Twelve-Month Survey

12-month survey domains and questions	**Control group n=226**	**Intervention group n=205**
	n (%)	**n (%)**
Alcohol harms	*n=225*	*n=199*
Reports a harmful effect during the past 12 months from drinking alcohol[a]	124 (55.1)	106 (53.3)
Alcohol troubles	*n=223*	*n=200*
Reports experiencing trouble during the past 12 months from drinking alcohol[b]	76 (34.1)	65 (32.5)
Readiness-to-change	*n=220*	*n=198*
Has decided to, is trying to, or is currently drinking less alcohol[c]	116 (52.7)	105 (53.0)
Help-seeking behaviours 1	*n=219*	*n=194*
Reports any of the following behaviours in the last 12 months: a) ringing Alcohol Helpline, b) looking at Alcohol Helpline website, c) looking at other website for information or help about alcohol, d) talking with a doctor or other health professional about respondent's drinking	24 (11.0)	31 (16.0)
Help-seeking behaviours 2	*n=222*	*n=197*
Reports having talked in the last 12 months with someone else, such as friends or family about the respondent or someone else's drinking	90 (40.5)	85 (43.2)

[a]Alcohol Harms score of 1 or more (i.e. score of 0 indicates no harm, and a score of 1 or more indicates one or more harms)
[b]Alcohol Troubles score of 1 or more (i.e. score of 0 indicates no troubles, and a score of 1 or more indicates one or more troubles)
[c]Score of 5 or more on 'Readiness-to-change ruler'

6.3.2 Secondary Outcomes

The logistic regression models adjusted for age, sex, hospital, ethnicity and baseline AUDIT-C score (Table 11) found that there were only small and non-significant differences between intervention and control groups in relation to self-reported alcohol-related harms (OR 0.88; 95% CI 0.60-1.30, p=0.53) and alcohol-related troubles (OR 0.89; 95% CI 0.59-1.35, p=0.58). The evidence of an intervention effect on increased help seeking in relation to alcohol use from professional and informal sources was also weak ('help-seeking behaviours 1': OR 1.67; 95% CI 0.93-3.01, p=0.09; and 'help-seeking behaviours 2': OR 1.16; 95% CI 0.7-1.72, p=0.48). RTC responses were similar in the two groups (OR 1.06, 95% CI 0.72-1.58, p=0.77).

Table 11. Results of Logistic Regression Models for the Secondary Outcomes

Secondary outcome variable	Odds Ratio	95% Confidence Interval	p value
Alcohol Harms			
Intervention vs Control	0.88	0.60-1.30	0.53
Alcohol Troubles			
Intervention vs Control	0.89	0.59-1.35	0.58
Readiness-to-change			
Intervention vs Control	1.06	0.72-1.58	0.77
Help-seeking behaviours 1			
Intervention vs Control	1.67	0.93-3.01	0.09
Help-seeking behaviours 2			
Intervention vs Control	1.16	0.78-1.72	0.48

6.4 Discussion

This chapter reports the effect at 12-months follow-up of the 'YourCall' intervention, a low intensity, automated, culturally appropriate text message intervention, on the secondary outcomes of alcohol-related harms, RTC, and help-seeking behaviours. The primary outcome finding of the RCT (described in Chapter Five) was that the intervention led to a significant reduction in hazardous drinking in the intervention group compared with control (usual care) group. This RCT did not, however, detect any important differences between the intervention and control groups in the self-reported secondary outcome measures. In other words, the intervention did not lead to a reduction in alcohol-related harms, an increase in RTC, nor an increase in help-seeking behaviours.

These findings are similar to those of an RCT by D'Onofrio and colleagues examining the efficacy of face-to-face BI compared with scripted discharge instructions in patients aged 18 years or older who presented to an urban ED in Connecticut, USA, and who screened above guidelines for 'low risk' drinking or presented with an alcohol-related injury.[191] In addition to primary outcome measures related to alcohol consumption, this trial also evaluated negative consequences related to drinking, patterns of primary medical care and alcohol-related treatment services utilization, and RTC drinking patterns as secondary outcomes. At 12 months follow-up no changes were detected between treatment groups for six negative consequences (three consequences related to alcohol use and driving, injuries while drinking, legal problems, and days of missed work), health service utilization, nor RTC scores. Unlike the 'YourCall' trial, the D'Onofrio study did not find any treatment effect for alcohol consumption measures.

There are also some similarities to the findings of an RCT which evaluated BI delivered by telephone call, compared with standard care, to injured adults aged 18 years or older who

presented at an urban trauma centre or two community hospital EDs in Rhode Island, USA, and who were assessed as having high-risk alcohol use (Mello and colleagues, 2013).[192] This study found that the BI group had a significantly greater decrease compared with the control group in the mean number of alcohol-related injuries between baseline and 12-month follow-up. However, there were no differences detected between treatment groups for alcohol consumption nor alcohol-related negative consequences measured using the Drinker's Inventory of Consequences questionnaire (DrInC, a 45-items covering a broad range of alcohol-related events).[193]

Previously published trials of face-to-face alcohol BIs more often report the effects of BI on alcohol consumption, with fewer trials reporting the effect of BI on alcohol-related harms. Schmidt and colleagues' 2015 'meta-analysis of the effectiveness of alcohol screening with brief interventions for patients in emergency care settings' investigated the effects of BI on alcohol consumption but did not consider other alcohol-related outcomes.[94] In their discussion the authors acknowledge this is a limitation of the study and comment that "a meta-analysis of other broader outcomes (such as injuries, alcohol-related problems, readiness to change, driving behaviour, etc.) remains challenging due to the heterogeneous and limited reporting of such outcomes in the existing literature".

Nilsen and colleagues' systematic review of emergency care alcohol BIs for injury patients (2008),[91] which examined 14 intervention studies, reported that four studies explored 'alcohol-related negative consequences', four studies explored injury frequency, and one study reported use of alcohol treatment services, as outcome measures of interest at follow-up points. Studies were heterogeneous involving a range of different interventions, length or intensity of interventions, and methodologies. Reductions in alcohol-related negative consequences in intervention groups as compared with comparison groups were reported in three of four studies which explored this outcome. Two of these studies used the DrInC questionnaire to measure self-reported negative consequences experienced from drinking,[194, 195] one study used the SIP (a 15-item version of DrInC),[196] and one study used the Alcohol Misuse Index (Amidx; a 10-item measure).[197] Reductions in injury frequency were reported in two of four studies which explored this outcome. One study reported that a higher percentage of patients in the BI group used alcohol treatment services compared with the control group.

The Cochrane Collaboration systematic review by Kaner and colleagues (2017)[97] aimed to assess the effectiveness of digital interventions for reducing hazardous and harmful alcohol

consumption and alcohol-related problems. Whilst they found moderate-quality evidence, from the review of 57 studies involving a total of 34,390 participants, that digital interventions may lower alcohol consumption, they were not able to reach conclusions about alcohol-related problems. The authors state that "thirteen studies reported some measure of alcohol problems or consequences, but on many different scales, so it was difficult to compare across studies. Some studies in students reported a trend toward reduction in alcohol-related problems."

While the 'YourCall' trial was not designed to describe the population distribution of alcohol-related harms, it is concerning to note that among the respondents (both intervention and control groups), over half reported experiencing one or more alcohol-related 'harms', and one third reported experiencing alcohol-related 'troubles', in the year since their hospital admission. These proportions are higher than those found in a cross-sectional postal survey of a nationally representative sample of 1924 New Zealand residents aged 18-70 years: among respondents who were current drinkers, 34% reported having experienced alcohol-related harm in the past 12 months and 13% reported having experienced alcohol-related trouble (measured using the 'Alcohol Harms' and 'Alcohol Troubles' checklists).[59] The findings of the 'YourCall' study are particularly notable given the participants were hazardous drinkers at only *medium* risk of harm (AUDIT score 7-15 for women and 8-15 for men) and that, for most participants, their injury-related hospital admission was not alcohol-related (from baseline characteristics: participant thought their drinking played a role in the injury – 14% of control group, 14% of intervention group; participant thought someone else's drinking played a role in the injury – 9% of control group, 7% of intervention group).

Furthermore, given the relatively high prevalence of harms/troubles in the study population and the finding that over half the respondents reported a favourable RTC score (i.e. had decided to reduce their drinking, were trying to do this, or to had actually made a change and reduced their drinking), it is interesting to note that a relatively small percentage of respondents (11% of control group and 16% of intervention group) had sought help with their drinking from a professional source. Of the 16 text messages comprising the text message intervention (received by the intervention group only), one message sent twice (once during the first week and once during the fourth/last week of the intervention) related specifically to advice on where to access "confidential support" and specified the Alcohol Helpline free phone number and website address and "your doctor". In contrast, a higher percentage (41% of control group and 43% of intervention group) reported having talked with friends or family. One text message sent on Sunday of the third week of the intervention encouraged participants to share their goal

(related to cutting down on alcohol) with friends or family and suggested that family can give support and may also want to consider cutting down.

The primary outcome finding of this trial was that the 'YourCall' text message intervention led to a significant reduction in hazardous drinking in the intervention group compared with control (usual care) group. However, at 12 months follow-up there were no differences between intervention and control groups in alcohol-related harms and troubles. There are several possible explanations for this. The content of the text message intervention focussed mainly on aspects related to reducing alcohol consumption rather than alcohol harms. For example, there were messages providing feedback about the participant's drinking, linking them to existing services if they wanted help, encouraging contemplation about their drinking, recommending they cut down on drinking, and providing information and tips/strategies about reducing alcohol consumption. Just two messages contained specific content related to alcohol harms: one message advised participants not to drive if they had been drinking, and for women, another message advised not to drink if pregnant. Perhaps if the intervention had contained enhanced messaging regarding harm reduction, in addition to the consumption reduction content, it may have had a stronger effect on alcohol-related harm.

Another explanation is that pathways of alcohol-related harm are complex and alcohol-related harms are determined by a broad range of factors. Although alcohol consumption volumes and patterns of individuals are important, there are many other factors (e.g. individual and behavioural factors, effects of other people's drinking, societal and alcohol policy factors, and commercial determinants of health) that contribute to causing harms,[1, 16, 45] hence the reasoning that a multi-pronged public health approach is required to reduce harm caused by alcohol.[14, 15, 72] As well as an effective health sector response (including SBI), effective harm reduction strategies are needed that address the price, availability, and advertising and marketing of alcohol.[16] BI cannot be expected, whether delivered face-to-face or via mHealth or eHealth modalities, to alone lead to reductions in alcohol-related harms.

It is also possible that there is a treatment effect that this study was not able to detect. As the study was powered for the primary outcome and not the secondary outcomes examined in this chapter, Type II error could account for the weak treatment effects observed. Another issue to note is that the baseline assessment, screening, and repeated administration of the AUDIT-C at follow-up could have acted as a form of treatment for the control group, possibly creating a beneficial effect and decreasing differences in secondary outcome measures between the

intervention and control groups. This has been discussed in the previous chapter and in other studies.[175-178, 191]

The strengths of this trial have been discussed in the previous chapter and include the trial's RCT design, large size, broad age range, generalisability to adult inpatient trauma care patients, focus on medium-risk drinkers, and recruitment practices that ensured a high participation of Māori patients. The study was not limited to patients wanting to change their drinking or wanting help, therefore also included participants who may have been pre-contemplative. As mentioned above, many BI trials only measure alcohol consumption outcomes. This trial has included alcohol-related harms and troubles, RTC, and help-seeking behaviours as secondary outcomes. Alcohol-related harms and troubles were measured using the 7-item 'Alcohol Harms' and 7-item 'Alcohol Troubles' questionnaires, which measured a broad range of harms and troubles, whilst not being as long and time-consuming for participants as some other tools.

However, there are several limitations to acknowledge. Firstly, as mentioned in the previous chapter, follow-up rates at 12 months were lower than those at three and six months and differed between the two treatment groups (69% in the intervention group and 76% in the control group). Intervention group participants were able to text back 'stop' if they didn't want to continue to receive text messages. Six of 22 participants who texted 'stop' discontinued their participation or were lost to follow-up. Secondly, all measures in this trial are self-reported by participants and are known to be susceptible to measurement bias.[182] Self-reporting may lead to inaccuracies such as under-reporting (for example, from problems with recall about drinking[183, 184] or due to social desirability bias[182, 185]). Thirdly, the sample size calculation for this RCT was determined for the primary outcome and not the secondary outcome analyses, and subgroup analyses for secondary outcomes were not planned or undertaken.

In conclusion, although mHealth BIs are promising strategies for helping people to reduce their alcohol consumption and change their drinking patterns, the findings outlined in this chapter raise questions about the role of mHealth BI in reducing alcohol-related harms. Further research is required to investigate if enhanced programme content on harms, sources of support for self-management, and motivation to change could strengthen the effectiveness of mHealth text message interventions. More research is also required that explores, improves, and standardises measures and tools for measuring alcohol-related harms. Future trials should include outcomes that address alcohol-related harms in addition to alcohol consumption.

6.5 Summary

The 'YourCall' trial primary outcome finding was that the text message intervention led to a significant reduction in hazardous drinking in the intervention group compared with control (usual care) group. However, as described in this chapter, at 12-months follow-up there were no important differences between intervention and control groups in the secondary outcomes of alcohol-related harms and troubles, RTC drinking patterns, nor participants' help-seeking behaviours. This may be because the intervention messages were mostly focussed on alcohol consumption reduction. Regardless of the potential benefits that could accrue, BIs should be viewed as a health sector strategy that is one component of a multi-pronged public health approach. Alcohol-related harms are inequitably-distributed at a societal level and mediated by complex and multi-factorial pathways including pervasive commercial determinants of health.[1, 16, 45] Consequently, addressing the price, availability, advertising and marketing of alcohol should remain cornerstones of equity-focused harm reduction strategies.[16, 198]

CHAPTER 7: TWELVE-MONTH FOLLOW-UP SURVEY: PERCEPTIONS OF PARTICIPANTS

In the previous two chapters, study findings related to the effect of the intervention on hazardous alcohol use (i.e. a significant reduction in hazardous drinking in the intervention group compared with the control group) and alcohol-related harms (i.e. no differences between the groups) have been outlined and discussed. Chapter Seven describes feedback from participants about their experiences of being in the study and explores the positive and negative aspects of being involved in the study from the participants' perspectives (Thesis Objective Four). A Letter to the Editor based on findings described in Chapter Seven has been published in the Journal of Clinical Epidemiology and is provided in Appendix 8.

7.1 Introduction

The 'YourCall' RCT was designed to evaluate quantitative outcomes, i.e. the effect of the intervention in reducing hazardous alcohol use (primary outcome) and alcohol-related harms (secondary outcome). This chapter aims to broaden the insights from this research by incorporating qualitative methodology in order to explore the perceptions of respondents and their experiences of being in the study. Such exploration could lead to an increased understanding about the primary and secondary outcome findings, insights about why the intervention may or may not have been effective for people, and the generation of questions for future research.

Understanding participants' experiences in this research study is particularly relevant for exploring the potential influence of Hawthorne effects (i.e. biases in research findings due to that fact that simply participating in a study can modify behaviour[199]) on the primary and secondary outcome findings described in Chapters Five and Six. Hawthorne effects (also known as research participation effects[180]) are frequently referred to by researchers and there is evidence that such effects exist, however there is much that is not known about the mechanisms and size of the effects and the conditions under which they operate.[200] Within the alcohol SBI field of study there is a body of published literature which explores and demonstrates the presence of assessment reactivity (i.e. the effect of participants completing alcohol use assessments which may create a bias through exerting a 'treatment effect' on control group participants).[175, 176, 201] However, a recently published RCT among New Zealand university students found no evidence to support the existence of Hawthorne effects in relation

to alcohol consumption self-reported through surveys administered online.[199] In this trial, the authors 'dismantled' the Hawthorne effect into two components (the effect of participants' awareness that the behaviour is being monitored and the effect of assessment reactivity). While concluding that Hawthorne effects are unlikely to be important in studies involving online data collection, the authors suggested that more research is needed in other research contexts.[199]

This chapter describes the methods and reports the findings of a 12-month follow-up survey, which, in addition to evaluating the effect of the 'YourCall' text message intervention (compared with usual care) on secondary outcomes (covered in the previous chapter), also explores the perceptions of participants. The aim of this chapter is to describe the positive and negative aspects of being involved with the study, from the respondents' perspectives. Written comments from respondents on specific questions have been analysed using a qualitative approach.

7.2 Methods

The study design, patient population and eligibility criteria, ethics approval, trial registration, study procedures and intervention details for the RCT have been previously described in Chapter Five (Section 5.2), Chapter Six (Section 6.2), and reported in published papers.[28, 31]

The text message intervention content, as described in Chapter Four, was developed based on the BI model and Stages of Change behaviour change theory. The key elements of BI and a variety of behaviour change techniques (BCTs)[xvii] were used to guide the crafting of the text messages, which were then pre-tested with the target audience and service providers, consulted on with key stakeholders, and reviewed and refined.

Table 17 in Appendix 3 summarises the text messages, and the BI elements and BCTs that apply to each message. BCTs are described as recommended by Michie and colleagues' in their recently published consensus document outlining a taxonomy of 93 distinct, non-overlapping BCTs with clear labels and definitions.[202]

The 12-month web-based survey[xviii] contained questions related to the trial primary and secondary outcomes (i.e. questions on alcohol use, possible alcohol-related 'harms' and

[xvii] BCTs are defined as observable and replicable components designed to change behaviour. Within an intervention, they are the smallest components compatible with retaining the postulated active ingredients and can be used alone or in combination with other BCTs.
[xviii] See Appendix 7 for the 12-month survey (paper form version).

'troubles', RTC, alcohol-related help-seeking behaviours), and also contained questions about participants' experiences of being in the study. Participants were asked: "What were some of the good things about being in this study?" and "What did you like the least about being in this study?". Analysis of responses to the latter two questions are presented in this chapter. Participants who did not respond to the web survey were contacted by research assistants to complete assessments via telephone.

Free text responses to these questions were analysed using a General Inductive approach.[155] The purpose of this approach is "to allow research findings to emerge from the frequent, dominant, or significant themes inherent in raw data."[155] The process involves in-depth reading of the text and consideration of meaning of the text and the creation of categories or themes comprising 'upper level' categories (which are likely to be derived from the research aims) and 'lower level' categories (derived from multiple readings of the raw data). The category system is revised, and refined, and appropriate quotations are selected that convey the themes.

It is important to acknowledge the role of the researcher in an inductive approach to analysing qualitative data, as interpretations of the raw data are shaped by the assumptions and experiences of the researcher(s) conducting the analyses.[155] Researcher(s) make decisions about what is more and less important and findings can be expected to differ between researchers.

Analyses were conducted using Microsoft Office Excel 2016. Participants' responses were entered into Excel and examined in detail. Coding was applied to indicate ideas or meanings ('lower level' analysis). Ideas or meanings were grouped into theme categories ('upper level' analysis). Analyses were conducted separately for intervention and control groups and themes that emerged were compared in a descriptive manner. Relevant quotations were selected to describe the lower level categories. The originator of quotes is indicated by the following information contained in brackets following the quote: control/intervention group, unique study ID, gender, age group, and ethnicity.

7.3 Results

As previously described in Chapter Five, Section 5.3, and shown in Figure 5, 598 of the 1,564 potentially eligible participants who were screened met the trial inclusion criteria. Twelve-month follow-up data was provided by 205 (69%) of the 299 intervention group participants

and 226 (76%) of the 299 control group participants. The characteristics of the two groups were similar at baseline (see Chapter Five, Table 5).

7.3.1 Response Rates for Free-Text Survey Questions

Free-text responses to the two questions, which are the subject of this chapter, were provided by more than half the study group (Table 12). For the question "What were some of the good things about being in this study?", comments were provided by 330 participants (77% of those who completed the 12-month follow-up; 55% of the total study group), with respondent numbers similar for both groups (163 intervention group, 167 control group).

For the question "What did you like the least about being in this study?", comments were provided by 296 participants (69% of those who completed the 12-month follow-up; 49% of the total study group), with respondent numbers similar for both groups (147 intervention group, 149 control group).

Response rates by sex, ethnicity (Māori and non-Māori), and age-groups, for both questions, are provided in Table 12. Compared with the study baseline characteristics, the percentages of females and Māori providing feedback at 12 months were similar to baseline, however there were relatively fewer participants in the 16-29-year age group providing feedback at 12 months compared to participation at baseline.

Table 12. Participants' Responses to Free-Text Questions in Twelve-Month Survey

	Control group	**Intervention group**	**Total**
	n (%)	**n (%)**	**n (%)**
What were some of the good things about being in this study?	167 (55.8)	163 (54.5)	330 (55.2)
Female	45 (26.9)	44 (27.3)	89 (27.0)
Māori ethnicity	37 (22.2)	30 (18.4)	67 (20.3)
Age group 16-29 years	62 (37.1)	72 (44.2)	134 (40.6)
What did you like the least about being in this study?	149 (49.8)	147 (49.2)	296 (49.5)
Female	42 (28.2)	39 (26.5)	81 (27.4)
Māori ethnicity	33 (22.1)	28 19.0)	61 (20.6)
Age group 16-29 years	56 (37.6)	66 (44.9)	122 (41.2)

7.3.2 Positive and Negative Perceptions

Overall, the majority of responses portrayed positive perceptions of being in the study. This was found for both questions and for both intervention and control groups. In response to being asked "What were some of the good things about being in this study?", 90% (n=147) of comments from intervention group respondents were positive, eight percent (n=13) were negative, and two percent (n=3) were neutral, and similar in the control group, (positive 89%, n=149; negative 7%, n=12; neutral 4%, n=6). Responses were similar for males and females, and by age group (16-29 years, ≥30 years) and ethnicity (Māori, non-Māori).

For the question "What did you like the least about being in this study?", 62% (n=91) of comments from intervention group respondents indicated that there was nothing they didn't like or indicated something positive, 37% (n=54) of comments were negative, and one percent (n=2) were neutral. Responses from the control group were more positive overall, with 74% (n=111) indicating there was nothing they didn't like or indicating something positive, 24% (n=35) stating something negative, and two percent (n=3) indicating a neutral perception. There were higher proportions of positive responses from males, older respondents (age group ≥30 years), and Māori respondents.

7.3.3 Thematic Analysis

The general inductive analysis of free-text responses to both questions revealed five 'upper level' categories or themes: contemplation about alcohol use; decision made or action taken to change behaviour; characteristics of text messages; involvement in a research study; and "not for me". The 'upper level' themes and their associated 'lower level' themes are summarised in Table 13 and discussed in more detail in the following sections.

Table 13. Overview of Upper and Lower Level Themes

Upper level themes	Lower level themes	Dominance of theme
Contemplation about alcohol use	Learning & awareness "It made me think" Alcohol drinking habits - frequency and quantity Reminder function	The most dominant theme emerging from the free-text responses Lower level category themes appear in both treatment groups; "it made me think" was the strongest sub-theme
Examples of quotations from respondents:	*"It made me realize how much I was actually drinking, learnt what a standard drink is"* (Control, ID 10792, male, 16-19 years, Māori) *"It was a good way to make me think about drinking and its impact on both myself and those around me."* (Control, ID 11855, female, 30-34 years, NZ European.) *"Thinking about maybe I am drinking too often and sometimes too much."* (Control, ID 14133, female, 50-54 years, NZ European.) *"It's a great reminder about how to control my alcohol."* (Intervention, ID 11950, male, 30-34 years, Pacific.)	
Decision made or action taken to change behaviour	Decision to make a change A change has been made	Less dominant theme Lower level category themes appear in both treatment groups
Examples of quotations from respondents:	*"A reminder that alcohol is actually an issue, my decision to refrain from drinking was much easier having texts coming through to support me."* (Intervention, ID 11057, female, 20-24 years, Māori.) *"More self-awareness. Helped me in making a conscious decision to reduce my intake."* (Control, ID 10538, male, 35-39 years, NZ European.)	
Characteristics of text messages	Timing & frequency Relevance of content Phone credit	Dominant theme Differences between treatment groups Positive and negative perspectives related to the first two lower level themes
Examples of quotations from respondents:	*"The texts came regularly and were a gentle reminder to me."* (Intervention, ID 10239, female, 45-49 years, NZ European.) *"I started to find the regular texts quite intrusive... it just went on for so long."* (Intervention, ID 14212, male, 40-44 years, NZ European.) *"The concern and advice was timely and helpful. Kept me focused on cutting down alcohol."* (Intervention, ID 10678, female, 60-64 years, NZ European.) *"I never had credit to reply back to text messages"* (Intervention, ID 11057, female, 20-24 years, Māori.)	
Involvement in a research study	Helping others Appreciation of study attributes	Dominant theme Theme and sub-themes emerged more strongly in the control group
Examples of quotations from respondents:	*"I like to help progress knowledge and so am happy to help research."* (Control, ID 10165, male, 50-54 years, NZ European.) *"I like the idea of a research project to do with alcohol."* (Intervention, ID 11009, male, 40-44 years, NZ European.) *"It was simple and easy to take part in. Also liked the initial company in the hospital."* (Control, ID 10348, female, 20-24 years, NZ European.)	
"Not for me"	Not relevant "I am not a heavy drinker"	Less dominant theme Evident in intervention group only
Examples of quotations from respondents:	*"Didn't really relate to my situation."* (Intervention, ID 10249, female, 30-34 years, NZ European.) *"This study was just not for me as I'm not a heavy drinker."* (Intervention, ID 11203, female, 20-24 years, Māori.)	

7.3.3.1 Theme One: Contemplation About Alcohol Use

Contemplation about alcohol use was the most dominant theme to emerge from the free-text responses, from both the intervention and control groups. This theme is comprised of four lower level categories: learning and awareness; "it made me think" (the most dominant lower level category); alcohol drinking habits – frequency and quantity; and reminder function. These themes were demonstrated in both groups and suggest that many respondents were pre-contemplative regarding their hazardous alcohol use prior to being involved in this study.

Learning and Awareness

Respondents commented that they learned something about alcohol and/or became more aware about the effects of alcohol. For example, one intervention group respondent valued *"learning about alcohol and what it can do to people"* (ID 11238, female, 25-29 years, NZ European). A control group respondent wrote that being in the study *"made me realise how much I was actually drinking, learnt what a standard drink is"* (ID 10792, male, 16-19 years, Māori).

"It Made me Think"

Many respondents used the words *"made me think"*, indicating that they were prompted to think about their alcohol use and think about making a change.

> *"I often got a txt while I was drinking and it made me think."* (Intervention, ID 11085, male, 40-44 years, NZ European.)
>
> *"Made me think about drinking habits and the effects and consequences it may have."* (Intervention, ID 14312, male, 30-34 years, Māori.)
>
> *"It made me think about how much I drink which made me realise it needed to reduce, which it has."* (Control, ID 14455, female, 35-39 years, Māori.)
>
> *"Just made me think twice about my drinking and kind of helped me to be a better person."* (Control, ID 11688, male, 25-29 years, Pacific.)
>
> *"It was a good way to make me think about drinking and its impact on both myself and those around me."* (Control, ID 11855, female, 30-34 years, NZ European.)

In addition to the word 'think', respondents used a variety of other words to indicate 'contemplation' of their alcohol use, such as: consider, look objectively at, being conscious of, reflect, realise, check, evaluate, focus, and assess. For example: *"Gave you an opportunity to*

consider your drinking habits and how they influence your everyday life" (control, ID 14594, female, 20-24 years, Māori). Contemplation about alcohol also occurred in relation to other people and family, as demonstrated in the following comments:

> *"I looked at how we as a family treat alcohol."* (Intervention, ID 14098, male, 30-34 years, NZ European.)

> *"Helped me think about my drinking as well as some of the people around me's drinking."* (Intervention, ID 10667, female, 25-29 years, Māori.)

> *"I was motivated to talk to my children and grandchildren about drinking and social drinking. The effects and damage, foetal alcohol syndrome."* (Control, ID 11171, female, 60-64 years, Māori.)

Alcohol Drinking Habits – Frequency and Quantity

Drinking habits/patterns emerged as an important concern for respondents. Two key content sub-categories emerged; these were a) the frequency of their drinking and b) the quantity of alcohol that they were drinking. It is possible that the predominance of these aspects has arisen due to the use of AUDIT-C questions during follow-up (at three, six and 12 months), with question one focussed on drinking frequency, and questions two and three focussed on quantity of alcohol consumed.

> *"Increased my awareness of how often I was drinking."* (Intervention, ID 11379, male, 30-34 years, NZ European.)

> *"Made me more conscious of my drinking habits by putting a quantifiable amount on how much I drink monthly."* (Intervention, ID 14319, female, 20-24 years, NZ European.)

> *"Thinking about maybe I am drinking too often and sometimes too much."* (Control, ID 14133, female, 50-54 years, NZ European.)

Reminder Function

As part of contemplation about alcohol use, some participants indicated that 'being reminded' was important for them. It is not clear from the feedback what specifically provided them with the reminder function, e.g. whether it was text messages or being involved in the study in general. However, this sub-theme was more prominent among intervention group participants, suggesting that the text message intervention may have contributed to the reminder function.

Participants commented on being reminded about a range of aspects, including their drinking patterns, the effects of alcohol, that they should reduce their consumption, and how to do this.

> *"It's a great reminder about how to control my alcohol."* (Intervention, ID 11950, male, 30-34 years, Pacific.)

> *"It is full of positive points that others can take away – helpful reminder in terms of being responsible around drinking. I have stopped because of my health and I don't like the taste."* (Intervention, ID 11690, male, 25-29 years, Māori.)

> *"It just changed me – kind of reminded me about what I should be doing*." (Intervention, ID 12110, female, 20-24 years, Pacific.)

> *"I was reminded that I was feeling uncomfortable with my drinking habits and that they had become habitual."* (Control, ID 10912, female, 35-39 years, NZ European.)

7.3.3.2 Theme Two: Decision Made, or Action Taken to Change Behaviour

A less prominent, yet important, theme to emerge in both groups was respondents deciding to change their drinking behaviour (i.e. lower level category: planning to make a change) or having acted to change their drinking behaviour (i.e. lower level category: a change has been made). Respondents' comments differed from those described in Theme One as they displayed the concepts of 'preparation' or 'action', rather than 'contemplation'. With reference to the Stages of Change behaviour change theory, Theme Two comments suggest these respondents reached a more advanced stage of alcohol-related behaviour change than most other respondents.

One respondent mentioned being 'ready' to make a change:

> *"It changed my life – I needed to stop drinking to do my assignments. I am ready to stop drinking."* (Intervention, ID 11196, male, 30-34 years, Pacific.)

Some respondents wrote about the changes they had made to their drinking behaviour.

> *"I cut down 100% on my drinking, for my own wellbeing."* (Intervention, ID 11277, male, 16-19 years, Latin American.)

> *"A reminder that alcohol is actually an issue, my decision to refrain from drinking was much easier having texts coming through to support me."* (Intervention, ID 11057, female, 20-24 years, Māori.)

> *"To be honest it has made me think about my drinking through personal participation. My level of drinking has decreased and my general well-being has improved this year. I do enjoy drinking mostly beer and a little wine. But I have tried to keep it to a modest limit most of the time. And I'm pleased with that."* (Intervention, ID 10905, male, 45-49 years, NZ European.)

And this from a control group respondent:

> *"Made me more accountable for my drinking. Have changed from drinking every night to once or twice and can say NO to drinking."* (Control, ID 11776, female, 45-49 years, NZ European.)

Reflection about 'making a conscious decision' were common among both groups, for example:

> *"More self-awareness. Helped me in making a conscious decision to reduce my intake."* (Control, ID 10538, male, 35-39 years, NZ European.)

7.3.3.3 Theme Three: Characteristics of Text Messages

A strong theme to emerge from the analysis of comments from respondents related to the characteristics of the text messages. Perceptions were both positive and negative. The main lower level categories that emerged from the comments were: timing and frequency of text messages; relevance of the content of text messages; and the need for phone credit. Although the comments of both study groups were similar regarding concern about phone credit, they were otherwise very different, as described in more detail in the following sections.

Timing and Frequency

There were two equally prominent perspectives from intervention group participants. The first perspective was that the text messages were timely and had appropriate frequency. The regularity and reminder function of texts were noted.

> *"I always seemed to get texts while drinking….good timing."* (Intervention, ID 10401, male, 16-19 years, NZ European.)

> *"The texts came regularly and were a gentle reminder to me."* (Intervention, ID 10239, female, 45-49 years, NZ European.)

The second perspective was that the text messages were too frequent and became annoying and intrusive. Such responses may indicate that some participants were not ready to address their drinking and would be expected given that eligibility for the study was based on a person's AUDIT score indicating medium risk of harm and did not include the requirement to be help-seeking or ready to make a change to drinking behaviour.

> *"I felt like I was constantly being texted."* (Intervention, ID 14702, female, 50-54 years, NZ European.)

> *"I started to find the regular texts quite intrusive... it just went on for so long."* (Intervention, ID 14212, male, 40-44 years, NZ European.)

> *"Sometimes the texts started at a time when I was busy with other stuff."* (Intervention, ID 11113, male, 35-39 years, NZ European.)

Comments from control group participants, who only received AUDIT-C text messages at the follow-up points, suggested that text messages were too infrequent and that more text messages were wanted. For example, in answering what they like the least about the study, one control group participant wrote: *"Maybe the distance between texts -the 3 and 6 months. I'd like them more often so feels like they are doing something."* (Control, ID 11027, female, 16-19 years, Māori.) Some responses suggest that some participants may have been unaware they were in the control group yet found the messages (i.e. the AUDIT C assessment questions at follow-up) somewhat useful.

Relevance of Content

There were both positive and negative perspectives from intervention group participants regarding the nature of the content. Many respondents thought the content was helpful, clear, and concise, and provided useful reminders.

> *"The concern and advice was timely and helpful. Kept me focused on cutting down alcohol every day."* (Intervention, ID 10678, female, 60-64 years, NZ European.)

> *"Clear and concise messages that were easily understood."* (Intervention, ID 10026, male, 40-44 years, Māori.)

> *"As I continued to get the messages it reminded me in my mind, made me think about what I was doing. The messages were quite in your face."* (Intervention, ID 14250, male, 40-45 years, NZ European.)

> *"The texts were my guideline when they came up. The day before I got the last text we were due to have a big party and it just reminded me about not drinking too much."* (Intervention, ID 11591, male, 35-39 years, Māori.)

However, others had contrasting views.

> *"I didn't really find the text messages thought-provoking."* (Intervention, ID 10677, female, 35-39 years, Māori.)

> *"A lot of the texts or questions didn't really relate to me."* (Intervention, ID 14292, male, 16-19 years, NZ European.)

One respondent provided thoughtful feedback about the framing of the content:

> *"The text messages generally expressed the negative side of drinking. I think for people to be more likely to accept the messages they should express the positives associated with NOT drinking or alternative benefits of not drinking rather than always focusing on negative aspects. For example reminders that productivity is improved the following day if you don't drink the night before….."* (Intervention, ID 11289, male, 20-24 years, NZ European.)

From the control group respondents' perspectives, similar to the previous category above, feedback not surprisingly suggested that not enough information was provided regarding advice on low risk drinking guidelines and that more help and support was wanted. One respondent stated: *"Didn't really make me aware of how much I was drinking or if I should cut down*" (Control, ID 14518, male, 30-34 years, NZ European). Others mentioned the lack of feedback, acknowledgement, and regular contact.

It is interesting to note that there were no comments in the feedback from respondents about cultural or language aspects of the text message content. Creation of culturally appropriate text messages and language alignment were important components of the development of the text message intervention (see Chapter Four) and there were three pathways that participants could choose between: text messages in English with Te Reo Māori words of welcome and encouragement, text messages in Te Reo Māori, and text messages in English (with an option

to receive a Pacific language greeting). Ten participants received the intervention in English with some Te Reo Māori words, three received the intervention in Te Reo Māori, fourteen received the intervention with a Pacific language greeting (three chose Samoan, two chose Cook Island Maori, five chose Tongan, and four chose Fijian), and 272 received the intervention in English.

Phone Credit

Feedback was provided from a small number of respondents that they often did not have enough phone credit to reply to text messages, for example: *"I never had credit to reply back to text messages"* (Intervention, ID 11057, female, 20-24 years, Māori), suggesting cost may be a barrier to interventions of this nature.

7.3.3.4 Theme Four: Involvement in a Research Study

In response to being asked about the good things about being in this study, many respondents wrote about how they felt about contributing to research or about positive attributes of the study. Although comments on this theme came from both treatment groups, interestingly this theme emerged more strongly in the control group than in the intervention group.

Helping Others

Many respondents provided feedback that suggested they felt happy about helping others, about contributing to a research study, and to progressing knowledge about alcohol-related behaviours.

> *"I like the idea of a research project to do with alcohol."* (Intervention, ID 11009, male, 40-44 years, NZ European.)

> *"Just happy to help and be a part of the study."* (Control, ID 12090, male, 40-44 years, NZ European.)

> *"I like to help progress knowledge and so am happy to help research."* (Control, ID 10165, male, 50-54 years, NZ European.)

Appreciation of Study Attributes

Respondents appreciated many aspects of the study, including ease of participation, the $20 voucher provided in recognition of their involvement, and communication and help from study personnel.

"Reminding me there are people out there willing to help." (Intervention, ID 12096, male, 16-19 years, NZ European.)

"It was simple and easy to take part in. Also liked the initial company in the hospital." (Control, ID 10348, female, 20-24 years, NZ European.)

7.3.3.5 Theme Five: "Not for me"

Some intervention group participants provided responses indicating that they didn't like being involved in the study because the concept or content was not relevant to them.

"Didn't really relate to my situation." (Intervention, ID 10249, female, 30-34 years, NZ European.)

"I am not a heavy drinker"

A distinct perspective was expressed by some respondents, who did not believe their drinking patterns were hazardous and therefore the study and intervention did not apply to them. This was despite having been involved in an informed consent process at recruitment and AUDIT screening at baseline which indicated medium risk of alcohol problems (i.e. AUDIT score 7-15 for women and 8-15 for men). As mentioned above, eligibility for the study did not include being help-seeking or ready to change hazardous drinking behaviour.

This perspective is shown in the following quotes:

"This study was just not for me as I'm not a heavy drinker." (Intervention, ID 11203, female, 20-24 years, Māori.)

"Makes you aware of the problems and I am glad I am not like that. Feel sorry for those who are. I found the questions were aimed at someone with drinking problems." (Intervention, ID 10013, male, 30-34 years, NZ European.)

"As I don't drink too much I don't think I was the right fit for the study." (Intervention, ID 10278, male, 25-29 years, Indian.)

"Well first of all I'm not an alcoholic, secondly I found that this was a waste of my time and thirdly I don't think I want to take part in any more surveys because it is just wasting my time. I don't drink heavily at all. Maybe once a blue moon…" (Intervention, ID 14424, female, 25-29 years, Pacific.)

7.4 Discussion

This chapter reports qualitative findings from two questions of the online 12-month follow-up survey of the 'YourCall' trial which related to respondents' experiences of participating in the trial.

7.4.1 Summary of Findings

Overall, the majority of responses indicated positive experiences of being in the study, for both intervention and control groups. General inductive analysis revealed five main themes: 1) contemplation about alcohol use; 2) decision made or action taken to change behaviour; 3) characteristics of text messages; 4) involvement in a research study; and 5) "not for me".

The most dominant theme was 'contemplation about alcohol use' and included sub-themes related to: learning and awareness about alcohol and alcohol problems; people responding that being in the study "made them think" about their and others' alcohol consumption; contemplation specifically about frequency and quantity of alcohol consumed; and being 'reminded' about alcohol, it's effects, that they should cut down and how to do this. This theme was dominant in both the intervention and control groups.

Theme Two (decision made/action taken) was a less dominant theme, yet important, because it indicates some participants (in both intervention and control groups) were motivated to decide that they intended to change their drinking behaviours or to actually make a change, e.g. reduce their alcohol consumption or stop drinking alcohol completely.

Theme Three emerged from responses that specifically referred to characteristics of the text messages and included sub-themes about the timing and frequency of messages, the relevance of the content, and the importance of having mobile phone credit in order to participate. Positive and negative perspectives were evident for the first two sub-themes. Some intervention group participants liked the timing, frequency and found the content helpful, whereas other intervention group participants found the text messages annoying, intrusive, and not helpful. In general, control group participants wanted more text messages and more content.

Theme Four (involvement in the study) was a dominant theme, with many respondents, particularly those in the control group, indicating their appreciation of the study and that helping others by being involved in a research study was an important aspect for them.

Theme Five (“not for me”) was a less dominant theme, yet important, because it shows that some respondents thought that the study wasn’t relevant to them or they weren’t the right fit for the study (i.e. it’s “not for me”) because they weren’t heavy drinkers.

7.4.2 Strengths and Limitations of this Research

The strengths of this research include the use of a robust qualitative research methodology to draw on rich data from respondents and develop themes describing respondents’ thoughts, feelings, and perceptions. The qualitative approach has allowed detailed descriptive insights about respondents’ experiences to be gained, which supplement the quantitative primary and secondary outcome findings.

However, there are several limitations with this research. Firstly, the response rate to the two questions drawn on for this analysis was relatively low; 55% of the total study group responded to the question “what were some of the good things about being in the study?” and 49% of the total study group responded to the question “what did you like the least about being in this study?”. Secondly, the questions were very general and referred to ‘the study’ rather than specifically to the ‘intervention’. This was necessary as the questions needed to be relevant to both the intervention and control groups, however it makes it difficult to draw conclusions regarding the intervention itself. Also, the general and open-ended nature of the questions means that respondents note the thing(s) that come to mind but does not necessarily mean that other components or aspects are not liked (or liked). Thirdly, the analysis and interpretation were conducted by the thesis author and it is expected that a different researcher may make different interpretations and report different findings. The risk of incorrect interpretation could have been mitigated by a team approach to analysis and interpretation, for example detailed readings being undertaken, and meanings shared, by at least two people.

7.4.3 Meaning and Implications of the Findings

The positive perceptions and experiences expressed by participants, and the themes that emerged from their feedback, suggest that research participation effects may be present in this study, among both the intervention and control groups. The finding that the ‘involvement in a research study’ theme appeared to emerge more strongly in feedback from control group respondents than from intervention group respondents raises the possibility that research participation effects may have been stronger in the control group. Also, given the dominance of the ‘contemplation about alcohol use’ theme, and presence of the ‘decision made or action

taken to change behaviour' theme, among control group respondents, it is possible that the baseline screening/assessment process and AUDIT-C follow-up assessments (as well as being involved in a research study about alcohol) stimulated participants to contemplate and change their alcohol-related behaviours. This phenomenon (known as the Hawthorne effect), which has been mentioned in previous chapters and is the subject of a substantial body of published literature,[175-177, 191, 199-201, 203] may have created a beneficial effect and decreased differences in outcome measures between the intervention and control groups. In other words, the intervention may be more effective than reported in this thesis. If the phenomenon were experienced equally in both the intervention and control groups, an impact on the effect of the intervention would not be expected. If, however, the control group were differentially influenced (i.e. experienced additional therapeutic effect over and above the research participation effects experienced by both groups), this could potentially lead to bias in the trial and an underestimation of the effect of the text message intervention.

Although the survey questions explored in this chapter were general questions asking about experiences of being in the study, and not specifically about perceptions of the text message intervention itself (which would only apply to the intervention group), the findings provide clues about possible hypotheses or theories about why the intervention may have been helpful (or not) to people. Findings suggest that the structure (e.g. timing and frequency) and content of the text messages provided support that people needed to think about and make a change in behaviour. On the other hand, negative aspects suggest that some people found the text messages too frequent, annoying, or not meaningful. For some people, a mHealth approach might not be the most appropriate modality for delivering BI.

Three of the five themes, 'contemplation about alcohol use', 'decision made or action taken to change behaviour' and 'not for me', reflect the underpinning theoretical basis of BI, i.e. the Stages of Change theory.[152] Feedback from respondents suggests that, through receiving text messages and/or being involved in the study, many people were motivated to *contemplate* their alcohol use, *prepare* themselves for making a change in alcohol-related behaviours, or *act* to reduce or stop their drinking. Others remained *pre-contemplative* (i.e. theme "not for me"). The primary outcome finding of a significant reduction in hazardous alcohol use in the intervention group compared with control group (Chapter Five) reflects the *action* Stage of Change. Secondary outcome analysis found no difference between treatment groups in RTC drinking behaviours (Chapter Six). However, this qualitative analysis suggests an influence on people who may have been pre-contemplative and have been stimulated to think about their drinking.

Participants were not asked specifically about their perceptions of individual text messages and BCTs, therefore it is not possible to draw conclusions about which messages or BCTs were helpful or not, or which were more effective as an 'active ingredient' than others. However, the dominance of the 'contemplation about alcohol use' theme and "it made me think" sub-theme suggests that messages crafted based on BI elements and BCTs related to stimulating contemplation may have resonated well with participants. For example, the fourth message in the first week of the intervention, *"Alcohol may be causing problems for u, your family & friends. We encourage u 2 think about your drinking and its impact on your life,"* was designed to provide feedback and to encourage contemplation and motivation to change. This was followed up with a message two days later, *"U might find it helpful 2 think about the good things & the not so good things about your drinking. Making a list can help,"* which utilised a 'pros and cons' BCT to encourage contemplation. Messages designed to stimulate contemplation may be particularly important for a pre-contemplative audience. In this study, participants were not 'help-seeking' and did not need to be 'ready to change' or wanting to reduce their alcohol intake in order to be eligible. Perhaps if this audience had been offered a follow-up or 'booster' intervention, they may have progressed further in their behaviour change journey from contemplation to determination and action. Other researchers have previously noted that interventions may need to incorporate a broader range of BCTs, greater intensity, and longer intervention periods to maximise patient engagement.[139, 144]

Other BCTs used in the intervention to help people think about their alcohol use were feedback on behaviour and outcomes of behaviour, providing support, instructions on low-risk drinking, information about health consequences, and credible source. BCTs used to encourage preparation and action included goal setting, action planning, encouraging commitment to a goal, support, instructions/ideas on how to cut down on alcohol, self-monitoring, behaviour substitution, and verbal persuasion about capability (Table 17).

Associations between BCTs and digital alcohol interventions and effectiveness have been reported by Kaner and colleagues (2017) and Garnett and colleagues (2018), as part of a Cochrane Collaboration systematic review which assessed the effectiveness of digital interventions for reducing hazardous and harmful alcohol consumption and alcohol-related problems.[97, 204] They reported that the BCTs of behaviour substitution, problem solving, and credible source were significantly associated with greater alcohol reduction than interventions without these BCTs. Other BCTs, such as self-monitoring, goal setting and review of behavioural/outcome goals, may be effective. Kaner and colleagues note that the reporting of

the underpinning theory of, and BCTs used in, digital alcohol interventions is poor. Such information is important for informing the development of future interventions and ensuring they include effective components.[97]

7.4.4 Implications for Future Research

As discussed in the published literature, future BI trials should pay careful attention to assessment of control participants and utilise study designs and methodology which minimise the potential for bias.[175, 201] Examples of strategies proposed in the literature include: reducing the burden of assessment on the control participants (i.e. consideration of the number, length, frequency, and content of assessments);[175, 201] ensuring blinding of participants to the purpose of the study in order to limit social desirability bias;[175, 201] ensuring adequate sample size, mix, and randomisation;[201] using study designs and analyses that limit the impact of regression to the mean;[175, 201] and using study designs which enable the potential effect of assessment reactivity to be evaluated (such as Solomon 4-group study design).[177] In addition, more high-quality methodological trials and qualitative studies exploring the influence of the Hawthorne effect would be helpful, particularly to understand how the effects occur, how large they are, and in which research contexts they are likely to occur.[199, 203]

Future research should focus on further refining the design and content of the text message intervention as well as the approach for its use. For example, content could be improved to be more strengths-based and focus on the benefits of reducing alcohol consumption. An approach where an mHealth text message intervention is offered as one option on a 'menu' of BI delivery modalities may help to target the intervention to those most likely to engage and reduce the number of dissatisfied people (i.e. the "it's not for me" group).

Future research should also focus on exploring specific questions with intervention groups, using qualitative methodologies, to understand in more detail why and how messages help participants (or not), which specific BCT components of the intervention are the most effective, and whether there are any intervention messages or components that participants think are missing and would be helpful to include. The 'YourCall' study was not designed to explain the reasons why the intervention may or may not be effective, nor to determine the components, features, or 'active ingredients' that may have contributed to effectiveness. However, these aspects are critical for further developments and improvements in mHealth interventions and have been identified as a current research gap and important area of focus for future research work.[97]

7.5 Summary

This chapter reports qualitative findings about participant's perceptions about being involved in the study. Overall, the majority of responses indicated positive experiences for both intervention and control groups. General inductive analysis of respondents' feedback revealed five main themes: 1) contemplation about alcohol use; 2) decision made or action taken to change behaviour; 3) characteristics of text messages; 4) involvement in a research study; and 5) "not for me". Three of the five themes (i.e. numbers one, two, and five) reflect the Stages of Change theory, which underpins BI. The perceptions and experiences expressed by participants, and the themes that emerged from their feedback, suggest a positive effect from being involved in the study, for both intervention and control group participants. Findings also suggest there may have been a differential positive effect on control group participants, in which case it is possible there may have been a treatment effect for the control group and the intervention effects in the RCT may have been underestimated.

CHAPTER 8: DISCUSSION

The aim of this thesis was to develop and evaluate a mobile phone text message intervention for people with hazardous alcohol use. This was achieved through four specific objectives:

1. To review the evidence from published studies examining the effectiveness of mobile phone text message interventions for reducing hazardous alcohol use and alcohol-related harms (Chapter Three);

2. To develop a mobile phone text message intervention for people with hazardous alcohol use (Chapter Four);

3. To assess the effect of the mobile phone text message intervention on hazardous alcohol use and alcohol-related harms (Chapters Five and Six);

4. To explore the positive and negative aspects of being involved in the study from the participants' perspectives (Chapter Seven).

This final chapter begins with a brief overview of the thesis and a summary of the findings of the research. This is followed by a discussion about how the findings contribute to the existing literature in the field of mHealth interventions for people with hazardous alcohol use. Next, the strengths and limitations of the thesis research are considered. The final sections provide discussion about implications of the thesis findings for public health practice and future research.

8.1 Overview of Thesis

As described in Chapter Two, alcohol is an addictive psychotropic drug, a toxin and carcinogen, and an intoxicant.[14] Alcohol use is a leading risk factor for injuries, diseases, disabilities, and premature death in New Zealand and globally.[1, 3] It contributes to large and inequitably-distributed burdens in societies yet is normalised and deeply embedded in many societies, including New Zealand. Harms from alcohol affect not only the individual alcohol user, but can also cause great harm to other people, including unborn babies (from FASD). While they are complex and multi-factorial, alcohol-related harms are preventable. A substantial evidence-base provides clear direction about the strategies that effectively prevent and reduce the harmful use of alcohol.[14-16, 32] The high impact strategies have been summarised by WHO using the acronym 'SAFER', i.e.: Strengthen restrictions on alcohol availability; Advance and enforce drink driving countermeasures; Facilitate access to SBIs and treatment;

Enforce bans or comprehensive restrictions on alcohol advertising, sponsorship, and promotion; Raise prices on alcohol through excise taxes and pricing policies.[72]

This thesis has focussed in depth on the third high impact strategy 'Facilitate access to SBIs and treatment', and specifically on mHealth interventions as a strategy for overcoming barriers to implementation of alcohol SBI and for increasing access (and reducing inequities in access) to health promotion services. The use of mobile phones for medical and public health service delivery is developing rapidly and has many potential benefits such as mobility, low-cost, high scalability, convenience for users, broad reach, and reducing inequities in access to health information and services.[23-26] However, although the emerging research evidence indicates mHealth interventions have potential for supporting behaviour change and impacting health outcomes, the evidence for efficacy is limited and more research attention is required.[24]

8.1.1 Thesis Objective One: To Review the Evidence from Published Studies Examining the Effectiveness of Mobile Phone Text Message Interventions in Reducing Hazardous Alcohol Use and Alcohol-Related Harms

As no published systematic reviews relating to Objective One could be identified, a systematic review of the effectiveness of mobile phone text message interventions in reducing hazardous or harmful alcohol use was undertaken (Chapter Three). This systematic review was required in order to understand the evidence-base for text message alcohol interventions, describe the needs for research in this area, and provide context for the proposed development of a text message intervention (Objective Two).

The systematic review identified six RCTs,[139-143, 145] five of which were small pilot or feasibility trials with inadequate power to detect statistically significant effects. Their findings suggested alcohol text message interventions *may* have the potential to reduce alcohol consumption and harms. One large trial in 18-25-year olds presenting to the ED setting found that an intervention involving text message assessments and tailored feedback was more effective than no text messages in reducing alcohol consumption and alcohol-related injury at six months follow-up.[145] All trials were conducted in the USA and five of six trials were in young adult participants. The findings of the review suggest that more research in this area is indicated, particularly large studies in different countries and settings, and considering a wider range of ethnicity and age groups.

8.1.2 Thesis Objective Two: To Develop a Mobile Phone Text Message Intervention for People with Hazardous Alcohol Use

Chapter Four described the methods and results of the development of a text message intervention for people with hazardous alcohol use to be evaluated in a subsequent RCT (the 'YourCall' trial). Development involved conceptualisation and creation of the intervention content based on the BI model[87] and Stages of Change behaviour change theory,[152] pre-testing with trauma inpatients, key informants, and Māori and Pacific groups, and refinement of the text message content. This research identified four key themes that were important to ensuring the text messages were engaging, relevant, and useful for participants: 1) reducing the complexity of message content and structure, 2) increasing the interactive functionality of the text message programme, 3) ensuring an empowering tone to text messages, and 4) optimising the appropriateness and relevance of text messages for Māori and Pacific people. The fourth theme was an important focus of the refinement process and a key finding of this research. As Māori and Pacific people experience inequities in the burden of alcohol-related harms, it is critical that interventions developed are culturally appropriate, relevant for the diverse realities of people's lives, and delivered via channels (such as mobile phone) which ensure equitable access to health promotion information and services.

The output of this aspect of the thesis was the content for the 'YourCall' text message intervention, a low intensity, automated, unidirectional intervention designed to reduce alcohol consumption and alcohol-related harms in patients admitted to hospital due to an injury. The intervention had three pathways for people to choose between: 1) text messages in English with Te Reo Māori words of welcome and encouragement, 2) text messages in Te Reo Māori, and 3) text messages in English (with an option to receive a greeting in Samoan, Tongan, Cook Island Māori, Niuean, Tokelauan, Tuvaluan, or Fijian). The final intervention consisted of 16 text messages over four weeks.

8.1.3 Thesis Objective Three: To Assess the Effect of the Mobile Phone Text Message Intervention on Hazardous Alcohol Use and Alcohol-Related Harms

Chapters Five and Six described the methods and results of a two-group, single-blind, RCT in 598 injured admitted patients aged 16-69 years identified as medium-risk drinkers at recruitment. The trial evaluated the effectiveness of the 'YourCall' text message intervention, compared with 'usual care' in reducing hazardous alcohol use (primary outcome, Chapter Five) and alcohol-related harms (secondary outcome, Chapter Six). The findings revealed that,

compared to controls, hazardous drinking was significantly lower in the intervention group at three months and a modest effect was maintained over the 12-month follow-up period. The intervention effect was similar among Māori and non-Māori, and among younger and older participants. However, the secondary outcomes analysis described in Chapter Six did not detect any differences between treatment groups in the measures of alcohol-related harms and troubles, RTC drinking patterns, and help-seeking behaviours.

8.1.4 Thesis Objective Four: To Explore the Positive and Negative Aspects of Being Involved in the Study from the Participants' Perspectives

The quantitative findings of Chapters Five and Six were supplemented with qualitative insights describing the perceptions of participants involved in the study, based on feedback from questions asked as part of a survey conducted at the 12-month follow-up point. Overall, the majority of responses indicated positive perceptions of being involved in the study, from both intervention and control group respondents. Qualitative analysis of respondents' feedback revealed five main themes: 1) contemplation about alcohol use (positive aspects); 2) decision made or action taken to change behaviour (positive aspects); 3) characteristics of text messages (positive and negative aspects); 4) involvement in a research study (positive aspects); and 5) "not for me" (negative aspects). Three of the five themes (i.e. numbers one, two, and five) reflect the Stages of Change theory,[152] which underpins BI.

Key insights from this qualitative research were the suggestion of research participation effects among participants (both intervention and control groups) and the suggestion that the positive perceptions and aspects expressed by control group participants (including dominance of the 'contemplation about alcohol use' theme and the 'involvement in a research study' theme) indicate there may have been a treatment effect for the control group. It is possible that the baseline assessment process, AUDIT-C follow-up assessments, and being involved in a research study about alcohol may have stimulated control group participants to contemplate and change their alcohol-related behaviours (in a differential manner to that of the intervention group), creating a beneficial effect in the control group and decreasing the differences in outcome measures between the intervention and control groups.

8.2 Contribution of the Thesis Findings to the Literature

The findings of this thesis contribute to the research literature in the field of mHealth alcohol interventions. The findings add to both the substantial existing literature on alcohol SBI and

the early emerging literature on digital alcohol interventions. In particular, this thesis contributes to knowledge regarding the development process of mHealth alcohol interventions, the effectiveness of mHealth interventions in reducing alcohol consumption and alcohol-related harms, and the methodological issues related to treatment effect on control groups, and provides discussion about the role of mHealth alcohol interventions as part of a broad public health approach to alcohol problems.

8.2.1 MHealth Alcohol Intervention Development Process

With the rapid uptake of mobile phones globally, many text message programmes and mobile 'apps' have been developed, however there are concerns about the lack of consideration of evidence, theory, and behaviour change techniques when designing and developing mHealth programmes or interventions[97, 151, 205] and the low quality of many programmes/interventions.[206] There is a need for studies which describe the processes and outcomes of mHealth development in a transparent and open way and contribute to advancing knowledge and practice in this field.[97, 207, 208]

The development process of the 'YourCall' text message intervention, as described in Chapter Four and shown in Figure 4, followed the steps in Whittaker and colleagues' model for developing and evaluating mHealth interventions[151] and included a series of iterations to ensure the text message content was engaging, useful, and culturally appropriate. At the time this work was conducted, there were a small number of published feasibility studies of alcohol text message interventions,[143, 149, 150] but none that followed a transparent model with defined steps.

Recently, two interesting studies in the alcohol mHealth field have been published which followed a systematic and transparent development process. Thomas et al. (2016) followed a model by Obroms and colleagues[207] (a further iteration of the Whittaker model[151] used for the YourCall trial) to develop a text message intervention targeting alcohol consumption among university students.[209] The model was found to be valuable with the development process resulting in significant changes being made to the original text messages. Another study by Garnett et al. (2018) outlined the development process for an alcohol reduction smartphone app ('Drink Less') for people with excessive alcohol consumption, which involved two main phases: selection of intervention components based on empirical evidence and a theoretical framework; and design and translation of the components into app modules incorporating multiple iterations of user testing and design modification.[208] The effect of the intervention components on reducing alcohol consumption were then evaluated in a controlled trial,[210] an

important step in determining which components should be included in order to optimise the intervention.[211, 212]

8.2.2 Effectiveness of Intervention

This thesis has expanded the evidence base for mHealth alcohol interventions and shown that the 'YourCall' text message intervention was effective in reducing alcohol consumption in people with medium-risk hazardous drinking levels, compared with a control (usual care) group. This is just the second published large RCT evaluating the effect of an alcohol text message intervention. The other trial, by Suffoletto et al.[144, 145] (described in detail in Chapter Three), also found significant reductions in hazardous alcohol consumption measures in the treatment group who received a 12-week-long intervention involving text message assessments and tailored feedback, compared with an assessment-only group and a control group who did not receive any text messages.

The 'YourCall' and Suffoletto trials are similar in that they both utilised text messaging to promote behaviour change related to alcohol use in patients who were not seeking help for their alcohol use. However, the two trials differ in many ways. The Suffoletto trial was conducted in the USA in 18-25-year olds presenting to the ED, whereas the 'YourCall' trial was conducted in New Zealand in a wide age group (16-69-year olds) of adults admitted to hospital due to injury. Patients were eligible for the Suffoletto trial if they were hazardous drinkers (AUDIT-C score ≥4 for men and ≥3 for women), whereas the 'YourCall' trial only included people with medium-risk hazardous drinking levels on screening (AUDIT scores 8-15 for men and 7-15 for women). The Suffoletto trial intervention was 12-weeks duration and relatively intensive, involving assessments and feedback tailored to increase participants' motivation to reduce alcohol consumption. In comparison, the 'YourCall' intervention was low intensity (16 text messages over 4 weeks), automated, had content that was tailored to ensure engagement and resonance with Māori and Pacific audiences, and was delivered to participants irrespective of their level of motivation to reduce their alcohol consumption.

This thesis has also addressed the importance of measuring both alcohol consumption and alcohol-related harm outcomes. While the 'YourCall' trial primary outcome analysis revealed a significant reduction in hazardous alcohol consumption associated with the intervention at three months and maintained across 12 months follow-up, no significant differences were identified between the treatment and control groups in measures of alcohol-related harms at 12 months follow-up. Possible explanations have been discussed (Chapter Six) and include the

focus of the text message content (i.e. being mainly on reducing alcohol consumption), methodological reasons (such as treatment effect of controls), and the complexity of alcohol-related harm pathways.

This thesis has highlighted the gap and inconsistencies in the SBI literature related to measuring alcohol-related harm outcomes. Many face-to-face SBI trials only consider alcohol consumption measures, and in those that do consider alcohol-related harms, measures and outcomes are varied and difficult to compare across trials. With regard to the alcohol text message intervention literature (summarised in Chapter Three), the large trial by Suffoletto et al. reported a lower prevalence in the treatment group of alcohol-related injury over the past three months but did not explore any other measures of alcohol-related harms. Four of the five small alcohol text message trials considered in Chapter Three measured alcohol negative consequences, using either the Brief Young Adult Alcohol Consequences Questionnaire or the SIP.[139-142] Two trials reported differences in alcohol negative consequences at the time of completing the intervention, however these were not sustained at subsequent follow-ups.[139, 140]

8.2.3 Treatment Effect for Controls

This thesis has incorporated qualitative methods to gain insights into the perceptions of study participants. As mentioned earlier in this chapter, one such insight is the possibility that there was a treatment effect for the control group in the 'YourCall' trial, suggesting that the intervention may be more effective than reported. This thesis adds to the body of literature describing this issue in alcohol SBI trials[175, 176, 191, 199, 201] and highlights the need to utilise study designs which minimise the potential for bias (such as reducing the burden of assessment on control participants and ensuring adequate blinding and randomisation of participants)[175, 182, 201] and which enable the potential effect of assessment reactivity to be evaluated (such as Solomon 4-group study design).[177]

8.2.4 Role of mHealth Alcohol Interventions

This thesis has provided evidence for the role alcohol text message interventions can play in helping people to reduce hazardous alcohol consumption. It has also provided discussion about the contribution such mHealth interventions could play as part of a broad public health approach to reducing hazardous alcohol use and alcohol-related harm. While the effect of the 'YourCall' intervention in reducing hazardous alcohol consumption was modest, it is never-the-less indicative of the potential of an alternative delivery mode for BI which is low-cost,

scalable, and could address barriers associated with face-to-face BI. However, SBI is just one component of a multi-pronged strategy for reducing hazardous alcohol use and alcohol-related harms and should be considered alongside strategies that address alcohol availability, price, and advertising, marketing, and sponsorship.[14, 15, 72]

There is a substantial evidence-base about the effectiveness and cost-effectiveness of alcohol harm reduction strategies[15, 16, 69] and clear recommendations about the 'best buys' for alcohol harm reduction.[73, 213] However, there are very few published studies which examine alcohol-related reduction strategies from an equity and social determinants perspective.[198] This gap is described in a literature review by Roche et al. (2015).[198] The authors' assessment of alcohol harm reduction strategies found that town planning, zoning and licensing of alcohol outlets, interventions targeting licensed venues, and interventions targeting the social determinants of vulnerable populations had the greatest potential to decrease inequities in alcohol consumption and harms. They assessed SBI as having weak-moderate potential to decrease inequities and noted that: "These interventions rely on at-risk groups having equal access to the intervention sites and related support mechanisms (e.g. attending healthcare services, sports clubs and workplaces). They also assume that all members of a particular group will react to the intervention in a similar way." Roche and colleagues suggested that tailoring of interventions for subgroups may be required. They also reported that interventions that rely on the use of technology may increase inequities due to disadvantaged groups lacking access to technology (such as computers) and having limited technological literacy.[198]

Whilst the above recommendations and commentary by Roche et al. are acknowledged, the findings of this thesis point to the potential for mobile-phone text message alcohol interventions to increase access to health promotion services for a broad range of people, and reduce inequities in access for vulnerable groups, using technology which is convenient for people and integrated into their daily lives. As discussed in this thesis, uptake of mobile phones in New Zealand is very high, with access to mobile phones within households being equitable for Māori and Pacific Peoples.[116] Text-messaging has become one of the most frequently used forms of mobile communication, is low-cost, and can be used via basic, less expensive mobile phones.

The findings of this thesis also indicate the potential for interventions to be effective for different population subgroups, if this is a focus from the outset. In New Zealand, Māori people experience disproportionate harm from alcohol compared with other ethnic groups.[59] An

important focus of the 'YourCall' intervention development was to incorporate processes to ensure the content was culturally appropriate, relevant, and engaging. This may have contributed to the trial finding of a similar treatment effect among Māori and non-Māori participants.

8.3 Strengths of this Research

This research has addressed the important local, national, and global issue of hazardous and harmful alcohol use. More specifically, the research has focussed on the emerging topic area of mHealth alcohol interventions, for which there is currently little published literature. This research has been undertaken with several important considerations in mind, which are underpinning strengths of this work:

- The New Zealand context, where alcohol use contributes to substantial and inequitably-distributed harms, particularly for Māori people;
- The potential for technologies like mobile phone interventions to reduce barriers to health information and services, and to reduce inequities in access and health outcomes (or at least not make inequities worse), if developed, tested, and implemented appropriately;
- An understanding of the broad public health approach to reducing alcohol-related harm, which includes SBI alongside the 'best buy' strategies of reducing alcohol availability, increasing the price of alcohol, and regulating the advertising, marketing, and sponsorship of alcohol.

This research utilised a robust, rigorous, and systematic mixed methods research approach to develop and evaluate a mobile phone text message intervention for people with hazardous alcohol use. The systematic review of effectiveness of mHealth text message interventions in reducing hazardous or harmful alcohol use (Chapter Three) involved a comprehensive search strategy and methodology consistent with the Cochrane Collaboration guidelines for systematic reviews.[122] The development and evaluation of the 'YourCall' text message intervention was guided by Whittaker and colleagues' model[151] and involved a series of steps with qualitative and quantitative components. The research process included conceptualisation of the text message intervention and formative research to pre-test the intervention content (Chapter Four), a large RCT to test effectiveness (Chapters Five and Six), and further qualitative investigation of participants' perceptions regarding being involved in the study. Strengths of

this model include a focus on the intervention being created based on theory and evidence, involvement of the target audience in intervention development to ensure the intervention is engaging and useful, taking an iterative approach so that improvements can be made based on target audience and key stakeholder feedback, and the use of the RCT research design (considered the 'gold standard' for a clinical trial) to test effectiveness.[151]

A further strength of this research is the participation of Māori in the intervention design, development, and evaluation. It is critically important from indigenous rights and equity perspectives that research in New Zealand is conducted in a way that is consistent with the principles of Te Tiriti o Waitangi and that respects and responds to the rights and needs of Māori people.[214, 215] As outlined in Chapter Two and throughout this thesis, Māori people experience unfair and unacceptable inequities in hazardous alcohol use and alcohol-related harms.[43, 53, 59] When new interventions are developed they should be relevant, engaging, and appropriate for Māori and should be evaluated for effectiveness for Māori people.

This research had a key focus on developing text message content that was relevant for the diverse realities of Māori people's lives. This was achieved through working in partnership with Māori researchers in the Intervention Development Team, ensuring Māori people had the opportunity to participate in the target audience formative research, and consulting with Māori groups to further refine the text message content, including translation of the text messages to Te Reo Māori.

The RCT had a key focus on using culturally appropriate recruitment practices and set a goal of ensuring that at least 20% of trial participants were Māori people. This was achieved, with 21% of study participants identifying as being of Māori ethnicity. (Nine percent of the Auckland region population aged 15 to 69 years of age have Māori ethnicity.[181]) The primary outcome of the RCT (i.e. the difference in hazardous alcohol use between treatment and control groups at three months, with maintenance of effect examined at six and 12-months follow-up) included examining the intervention effect among Māori and non-Māori participants and was found to be similar in both groups.

8.4 Limitations of this Research

This research has a number of limitations related to the overall approach taken and within each research step of the development and evaluation process. Whilst the model[151] underpinning this research is robust, it does require a long period of time to conduct the research. This may be a

particular issue when new or emerging technologies are involved as the technologies and/or their use may change very quickly, so that by the time the research findings are available, the technology and/or its use has moved on and the research findings are redundant.[207, 216] With the increasing use of smartphones, alcohol reduction apps are becoming available.[205, 208] This may mean that text message interventions become less relevant. However, text messaging still remains a common and popular channel of communication[115] and text messaging interventions may be more likely to have an impact on inequities in alcohol use and harms compared with delivery of messaging via apps, as the latter rely on access to smartphones.

As mentioned in earlier chapters of the thesis, each step in the research process had some limitations. In the literature review (Chapter Three), some trials did not meet the inclusion criteria and therefore have not been considered. For example, unpublished/grey literature, non-English language articles, and trials that were not RCTs were not included. Only trials of alcohol text message interventions were included, i.e. trials of mobile phone apps and trials in which hazardous or harmful alcohol consumption were not measured as outcomes were excluded.

In the intervention development step (Chapter Four), the main limitation was issues with recruitment of participants, resulting in a small number of trauma inpatient participants being involved in phase one of the pre-testing study. However, this was followed by a second phase involving consultation with Māori and Pacific groups, which supplemented the phase one findings and allowed further refinement and improvement.

In the conduct of the RCT (Chapters Five and Six), there were three main limitations. Firstly, there were issues with retention of participants at 12 months and the differential loss to follow-up between the intervention (31%) and control group (24%) at 12 months. The larger proportion of participants lost from the intervention group may be partly explained by the more frequent texts received by this group. Secondly, the trial utilised self-reported outcome measures which are known to be susceptible to measurement bias as people tend to under-report the frequency and quantity of drinking (for example, due to issues with recall or social desirability biases).[182-185] Thirdly, is the suggestion of a possible treatment effect for the control group. This is evidenced by the reduction in mean AUDIT-C seen in the control group and the findings from the 12-month survey questions explored in Chapter Seven.

In the qualitative research related to questions from the 12-month follow-up survey (Chapter Seven), there were three main limitations. Firstly, the response rate was relatively low for the

two questions examined. Secondly, the questions posed to participants were very general and referred to 'the study' rather than to 'the intervention'. As previously explained, this was necessary as the survey questions needed to be relevant to both the intervention and control group participants. Thirdly, although this step in the research was useful in gaining insights about participants' perceptions about the positive and negative aspects of being involved in the study, it may have been more helpful to focus on making further improvements to the text message intervention by undertaking qualitative research focussed specifically on people who had received the text message intervention, e.g. focus groups with intervention recipients soon after they received the intervention text messages. Such research was not conducted as part of this research as it would have influenced the evaluation of the intervention effect, which was measured at the three, six, and 12-month follow-up points.

This thesis acknowledges the personal lens and experiences that the researcher/candidate brings to all aspects of this research. This is particularly salient when considering the potential for bias due to framing, analyses, and interpretations that are shaped by the researcher's assumptions, experiences, and personal beliefs.[155] Rigour of qualitative research can be enhanced by reflexivity, whereby the researcher is thoughtfully aware of being part of the research process and reflects on the degree of influence they exert on the findings.[217, 218] For the qualitative components of the research described in Chapter Four, risk of bias was reduced by involving a team of researchers, including Māori and Pacific researchers, and consulting with Māori and Pacific groups in an iterative process to develop and refine the text message intervention. For the qualitative analysis described in Chapter Seven, findings may have differed if analysed and interpreted by another researcher, and the analysis process would have been strengthened by involving a team of researchers with diverse backgrounds and perspectives.

Similarly, in relation to the quantitative components of the research described in Chapters Five and Six, it is important to consider the concept of personal equipoise, which exists when the researcher is uncertain about whether one arm of the trial offers greater harm or benefit than the other arm.[219] When there is personal equipoise, the researcher has no personal preconceived preferences about the ability of the intervention to have a better outcome than the control.[220] In this research, it is conceivable that bias may have been introduced due to lack of objectivity on the part of the researcher, given the involvement in both developing and evaluating the intervention. However, the RCT study design (including the computer randomisation

procedure and blinding of researchers to participant allocation) provides confidence that bias has been minimised.

8.5 Implications for Public Health Practice

This research provides evidence of the effectiveness of a mobile phone text message intervention in reducing alcohol consumption in the trauma care setting. It is the second large RCT in this setting to show this, the first being the Suffoletto trial (ED setting).[145] There is substantial evidence that face-to-face alcohol BI is effective, and now emerging evidence that text message BI is effective also. The findings of this thesis suggest that mHealth interventions such as the 'YourCall' intervention should be considered as an option for patients as part of routine trauma care.

It must be acknowledged that the 'YourCall' intervention is not likely to be appropriate for everyone. While an mHealth text message approach is engaging and preferable for some people, it may not be appropriate for others. For some people, aspects of text messaging such as convenience, content and reminders, and anonymity, may be helpful. Other people may find text messaging annoying and intrusive or prefer a face-to-face interpersonal approach for BI. To accommodate patient preferences and provide choice, the 'YourCall' intervention could be offered a part of a 'menu of options' for BI, alongside face-to-face counselling, telephone counselling, and other resources such as web-based and paper-based information and tools.

The 'YourCall' text message intervention was developed in response to the opportunity presented by mHealth technologies to play a role in reducing barriers to the implementation of SBI. The 'YourCall' intervention is a low-cost, scalable way of delivering BI which does not rely on health professional capability and capacity to deliver BI. Despite this, barriers to implementation remain. These include delays in translation of research into practice, a lack of organisational support and funding, and other competing healthcare priorities in times of resource constraint.[19-22, 114] However, a critical barrier is attitudes towards alcohol of health professional and health system staff.[21, 22] As outlined in Chapter Two, many staff in the health system are not up-to-date on the effects of alcohol and the evidence-based strategies to address alcohol-related harms. Staff lack knowledge, confidence, and skills to have conversations with patients about alcohol. They may feel hypocritical asking about alcohol or providing screening due to their own alcohol use, may perceive alcohol to be a 'taboo' subject, or may not even think to ask about alcohol because alcohol use is normalised within society. Work needs to be undertaken in the health system to change the existing 'alcohol culture' so that asking about

alcohol and providing access to BI (including interventions such as 'YourCall') are a normal part of routine care.

Implementing the 'YourCall' intervention into existing trauma care services in hospitals and embedding it as part of usual practice would require an approach that addressed the wide range of barriers outlined above as well as identifying enablers such as referral pathways for patients to access the intervention and information technology systems for intervention delivery. There are a number of theories, models, and frameworks that could be used to facilitate implementation.[221] The Consolidated Framework for Implementation Research (CFIR) would be a particularly appropriate framework due to its comprehensive yet pragmatic approach.[222] CFIR consists of five domains (i.e. the intervention, outer setting, inner setting, the individuals involved, and the process by which implementation is accomplished) each containing a number of factors that must be considered in order for implementation to be successful. The first domain is related to characteristics of the intervention, for example, adaptation of the intervention into a particular organisation. The second and third domains are overlapping and dynamic, but generally the outer setting describes the economic, political, and social contexts within which the organisation exists, and the inner setting covers factors such as organisational structure, culture and readiness for implementation. The fourth domain includes the characteristics of the individuals involved in implementing and delivering the intervention, such as knowledge, self-efficacy, and roles in the organisation. The final domain is the active change process of implementation and involves functions such as planning, engaging, executing, reflecting, and evaluating.[222]

Implementation of interventions such as the 'YourCall' intervention, and SBI more broadly, should be implemented in a way that contributes to reducing inequities in hazardous alcohol use and alcohol-related harms. Given that Māori people experience a disproportionate burden of harm from alcohol, it is critical that they receive equitable access to evidence-based, effective interventions. The current 'status quo' situation, with lack of access to culturally appropriate alcohol SBI and barriers created by the health system, is contributing to inequities for Māori and is a breach of Te Tiriti o Waitangi. Alongside, or instead of, the CFIR model described above, an indigenous framework such as He Pikinga Waiora Implementation Framework[223] should be used to guide implementation of interventions such as 'YourCall'. This framework includes four key elements: cultural centeredness; community engagement; systems thinking; and integrated knowledge translation. Because the framework is centred on

indigenous knowledge and self-determination, it provides a strong foundation for enhancing the implementation of health interventions for Māori.[223]

This thesis provides evidence of the effectiveness of 'YourCall', a mobile phone text message intervention, and support for its implementation as part of usual practice. However, a key message of this thesis is that SBI strategies (including mHealth strategies for BI) need to be implemented as part of a comprehensive multi-pronged public health approach. Using the Ottawa Charter[224] as a framework for health promotion, the 'YourCall' intervention and other SBI strategies can be viewed as part of *'Reorienting the healthcare system toward prevention of illness and promotion of health'* as well as *'Developing personal skills related to reducing alcohol use'*. MHealth and other SBI interventions are unlikely to be able to reduce alcohol use alone, and this thesis raises questions about the role of mHealth BI in alcohol harm reduction. The most cost-effective, 'best-buy', pro-equity strategies for alcohol-harm reduction lie within the Ottawa Charter domains of *'Build healthy public policy'* and *'Create supportive environments',* i.e. addressing alcohol availability, price, and alcohol marketing, sponsorship and promotion through policy, culture, and physical and social environmental changes. Strategies within the Ottawa Charter domain *'Strengthening community action'* are also important for empowering communities and fostering local advocacy, initiatives, and solutions,[15, 42] but are currently hindered in New Zealand by the current alcohol regulatory system which does not enable community voices to be heard (for example in decision-making related to local policies).[225-227]

8.6 Implications for Future Research

This research has provided evidence of the effectiveness of the 'YourCall' text message intervention in reducing hazardous alcohol consumption. However, there are still a number of unanswered questions and areas for further research in relation to this particular intervention, including those outlined next.

- Could the intervention be improved? For example, if the content were to focus on alcohol harm reduction and how to access help (as distinct from alcohol consumption reduction alone) the intervention may have a stronger effect on harm reduction and help-seeking measures. In addition, there are a range of findings from the qualitative analysis of 12-month survey questions (Chapter Seven) that could be considered, such as making the content more strengths-based and focused more on the benefits of reducing alcohol consumption.

- Why did the intervention work and which behaviour change components were most effective? The 'YourCall' study was not designed to explain the reasons why the intervention was effective, or why it may have worked for some people but not for others. Any future trials of 'YourCall' and other mHealth interventions should consider incorporating qualitative methodology that can explore these questions.
- Could the intervention have an effect on injury outcomes? As alcohol use is a key risk factor for injury and this intervention was designed and tested in the trauma care setting, it would be interesting to explore whether the intervention may have reduced injury presentations and admissions in the treatment group compared with control group.
- Might the 'YourCall' intervention be as or more effective in different settings? Future trials could consider testing the effectiveness of the text message intervention in settings such as ED, General Practice, medical inpatient wards, and beyond healthcare settings (for example, in social sector settings).
- What is the cost-effectiveness of the 'YourCall' intervention? Economic evaluation research could be conducted.
- Might there be potential for a different delivery model? For example, incorporating 'YourCall' as part of a 'menu of options' for BI to allow people to select the modality of BI that they prefer (e.g. face-to-face individual counselling, support group, telephone call, 'YourCall' text message intervention) or utilising an online self-administered screening tool (such as AUDIT) which then links to BI options.
- Another consideration in relation to exploring different delivery models is whether the 'YourCall' intervention concept and content could be translated, adapted or expanded into a mobile phone app. Further research would be required to develop an app and evaluate its effect in reducing hazardous alcohol use. There is an emerging literature on apps for hazardous and harmful alcohol use, including research on app development,[208, 210] engagement,[228] feasibility,[229] acceptability,[230] usability factors and user typologies,[231, 232] however there is limited evidence to date of the efficacy of apps for reducing hazardous alcohol use. Two recently published RCTs of mobile alcohol apps showed no changes in alcohol consumption outcomes.[233, 234] It is important not to assume that mobile apps would be more effective than mobile text message interventions. Buller et al. conducted a trial comparing a mobile app with text messaging to support smoking cessation. They found that the mobile app was feasible for delivering cessation support but did not move people to quit smoking as quickly as

text messaging. They postulated that "text messaging may work better because it is simple, well known, and delivered to a primary inbox."[235] It would be interesting to carry out a similar study comparing the 'YourCall' text message intervention with a 'YourCall' app intervention.

Future research is needed regarding appropriate methods for conducting alcohol BI trials. The issue of a possible treatment effect for the control group implies that BI trials should pay more attention to how control participants are assessed, utilise study designs and methodology which minimise bias, and incorporate qualitive research components to further explore participants' experiences.[175, 201, 203] In addition, there is a need to improve and standardise tools used to measure alcohol-related harms. This should include both harms to the individual from their own drinking as well as harms to the individual for another person's drinking.

Future research should also investigate and evaluate implementation strategies that address the wide range of barriers that currently exist in providing equitable and sustainable access to alcohol SBI. Although the 'YourCall' trial has shown the effectiveness of a mHealth strategy for alcohol BI, it remains to be seen whether this can be translated into 'real-world' healthcare settings. As outlined in Chapter Two, increased SBI activity has been found to occur as the result of multi-component implementation strategies rather than single-component strategies.[107] It is more likely that a mHealth strategy such as the 'YourCall' intervention will be more successfully translated into practice, if it is accompanied by other strategies, thereby comprehensively addressing a range of barriers to SBI.

As discussed by Roche and colleagues in their review of the evidence about which alcohol interventions and policies have the greatest potential to decrease inequities in alcohol consumption and alcohol-related harms, there are very few published studies that apply an equity lens to alcohol interventions and policies.[198] They highlight the need for increased knowledge about how best to reduce inequities in alcohol consumption and alcohol-related harms and state that a "greater emphasis on equity in research and policy remains an imperative."[198]

8.7 Conclusion

This thesis provides evidence of the effectiveness of a mobile phone text message intervention in reducing alcohol consumption in people with medium-risk hazardous drinking patterns who were screened in the trauma care inpatient setting. MHealth interventions such as this have potential as an alternative delivery mode for BI and could help to address current barriers preventing access to alcohol interventions for patients as part of routine trauma care.

A focus of the intervention development was to incorporate processes to ensure the content was culturally appropriate, relevant, and engaging. This may have contributed to the trial finding of a similar treatment effect among Māori and non-Māori participants. This is very important in the New Zealand context, where Māori people experience disproportionate harms from alcohol compared with other ethnic groups. Interventions must be shown to be equally effective (at the very least) for Māori in order to ensure interventions do not contribute to increasing inequities.

While the trial revealed a significant reduction in hazardous alcohol consumption associated with the intervention, no significant differences were identified between the treatment and control groups in measures of alcohol-related harms at 12-months follow-up. Alcohol-related harms are mediated by complex and multi-factorial pathways including pervasive commercial determinants of health. This thesis suggests that, whilst mHealth alcohol interventions (alongside face-to-face and other digital options) are an important healthcare system response, SBI is just one component of a multi-pronged strategy for reducing hazardous alcohol use and alcohol-related harms and should be considered alongside strategies that address alcohol availability, price, and advertising, marketing, and sponsorship.

Appendix 1: The Alcohol Use Disorders Identification Test

The Alcohol Use Disorder Identification Test (AUDIT) is a 10-item questionnaire, developed by the WHO as a simple method for screening for hazardous, harmful, and dependent alcohol use. Responses to each question are scored from zero to four, and then added to a total score between zero and 40. A total score of eight to 15 indicates hazardous alcohol use, 16-19 indicated harmful use, and 20 or more indicates possible dependence.

The first three questions of the AUDIT are concerned with alcohol consumption and ask about frequency of drinking, typical quantity, and frequency of heavy drinking. The second three questions assess alcohol dependence symptoms and ask about impaired control over drinking, failure to do what was normally expected, and morning drinking. The last four questions are related to harmful alcohol use and enquire into feelings of guilt after drinking, blackouts, alcohol-related injuries, and concern from others.

The AUDIT was developed and evaluated over several decades and has a number of advantages:

- Cross-national standardisation and validation, designed for international use;
- Provides accurate measures of risk across groups including age, gender, and culture;
- Designed for primary healthcare use, also tested in a variety of subpopulations and settings including ED cases, university students, elderly hospital patients, and drug users;
- High reliability;
- Short and easy to use.

Various cut-points in total scores have been considered and studied to identify optimal sensitivity and specificity to distinguish hazardous and harmful alcohol use. At a cut-point of eight, most studies have found favourable sensitivity and acceptable specificity. A cut-point of 10 will provide greater specificity, but lower sensitivity. Reducing the cut-point to seven for women and men over age 65 years increases sensitivity for these groups.[55]

Appendix 2: Search Strategies for Literature Review

Table 14. MEDLINE Search Strategy

Ovid MEDLINE(R) Epub Ahead of Print, In Process & Other Non-Indexed Citations, Ovid MEDLINE (R) Daily, and Ovid MEDLINE (R) 1946-Present; Searched 13th September 2018		
#	**Search Statement**	**Results**
1	exp Alcohol-Related Disorders/	107937
2	exp Alcohol Drinking/	63453
3	("alcohol use" or alcoholic$).tw.	85818
4	(alcohol adj3 (drink$ or intoxicat$ or use$ or abus$ or misus$ or risk$ or consum$ or withdraw$ or detox$ or treat$ or therap$ or excess$ or reduc$ or cessation or intervention$ or harm$)).tw.	114759
5	(drink$ adj3 (excess or heavy or heavily or harm or harmful or hazard$ or binge or problem$)).tw.	17953
6	1 or 2 or 3 or 4 or 5	232597
7	exp Text Messaging/	2011
8	text messag$.ti,ab.	2963
9	SMS.ti,ab.	4856
10	short message service.ti,ab.	750
11	7 or 8 or 9 or 10	7906
12	randomized controlled trial.pt.	468418
13	controlled clinical trial.pt.	92635
14	randomi$.ab.	517270
15	randomly.ab.	297191
16	trial.ab.	439299
17	12 or 13 or 14 or 15 or 16	1173783
18	6 and 11 and 17	88
19	limit 18 to humans	56
20	limit 19 to english language	55

Table 15. EMBASE Search Strategy

Embase 1980 to 2018 Week 37; Searched 13th September 2018		
#	**Search Statement**	**Results**
1	exp alcoholism/	99547
2	exp alcohol intoxication/	10651
3	exp alcohol abuse/	33644
4	exp drinking behavior/	43259
5	("alcohol use" or alcoholic$).tw.	114635
6	(alcohol adj3 (drink$ or intoxicat$ or use$ or abus$ or misus$ or risk$ or consum$ or withdraw$ or detox$ or treat$ or therap$ or excess$ or reduc$ or cessation or intervention$ or harm$)).tw.	154548

7	(drink$ adj3 (excess or heavy or heavily or harm or harmful or hazard$ or binge or problem$)).tw.	23492
8	1 or 2 or 3 or 4 or 5 or 6 or 7	285343
9	exp text messaging/	3524
10	text message$.ti,ab.	2739
11	short message service.ti,ab.	808
12	SMS.ti,ab.	6400
13	9 or 10 or 11 or 12	10571
14	8 and 13	261
15	limit 14 to (randomized controlled trial or controlled clinical trial)	64
16	limit 15 to human	64
17	limit 16 to english language	64
18	limit 17 to article	46

Table 16. PsycINFO Search Strategy

PsycINFO 1806 to September Week 2 2018; Searched 13th September 2018		
#	**Search Statement**	**Results**
1	exp Alcoholism/	29637
2	exp Alcohol Intoxication/	3018
3	exp Alcohol Abuse/	46465
4	exp Drinking Behavior/	69296
5	("alcohol use" or alcoholic$).tw.	48012
6	(alcohol adj3 (drink$ or intoxicat$ or use$ or abus$ or misus$ or risk$ or consum$ or withdraw$ or detox$ or treat$ or therap$ or excess$ or reduc$ or cessation or intervention$ or harm$)).tw.	73925
7	(drink$ adj3 (excess or heavy or heavily or harm or harmful or hazard$ or binge or problem$)).tw.	15473
8	1 or 2 or 3 or 4 or 5 or 6 or 7	107311
9	exp Text Messaging/	673
10	text message$.ti,ab.	1185
11	short message service.ti,ab.	300
12	SMS.ti,ab.	1296
13	9 or 10 or 11 or 12	2627
14	control$.ti,ab.	632637
15	random$.ti,ab.	180675
16	14 or 15	732173
17	8 and 13 and 16	50

Appendix 3: Text Messages Mapped Against Brief Intervention Elements and Behaviour Change Techniques

Table 17. YourCall Text Message Intervention Content, Brief Intervention Elements, and Behaviour Change Techniques

Week of programme	Day of programme	English language version of text messages*	BI elements	BCTs**
1	1 (Mon)	From YourCall: Hi, thanks 4 taking part in the study. Over the next 4 weeks we will be sending u txts with info & ideas		
1	3 (Wed)	YourCall: Your survey responses show your drinking is harmful 2 your health. Make a positive change in your life – cut down or quit	Feedback on alcohol screening Recommendation to cut down	2.2 feedback on behaviour 3.1 social support 9.1 credible source
1	3 (Wed)	YourCall: U can get confidential support from Alcohol Helpline ph 0800 787 797 web alcoholdrughelp.org.nz or your doctor	Information (about support & service options)	3.1 social support
1	5 (Fri)	YourCall: Alcohol may be causing problems for u, your family & friends. We encourage u 2 think about your drinking and its impact on your life	Feedback Encourage contemplation & motivation to change	2.7 feedback on outcome(s) of behaviour
1	7 (Sun)	YourCall: U might find it helpful 2 think about the good things & the not so good things about your drinking. Making a list can help	Encourage contemplation and motivation to change	9.2 pros and cons
2	9 (Tues)	YourCall: We recommend u cut down or quit alcohol. Making a positive change can be hard, try small steps	Advice Goal setting Empathy	9.1 credible source 1.1 goal setting
2	11 (Thurs)	YourCall: Ideas 4 cutting down: plan no-alcohol days, have water between drinks, try low alcohol drinks like light beer. Check out easeuponthedrink.org.nz	Advice Help with goal – tips & strategies	4.1 instruction on how to perform behaviour 8.2 behaviour substitution
2	13 (Sat)	YourCall: Keep track of your drinks. U could use a diary. 1 drink = 1 small bottle beer, half an RTD, half a glass wine or 1 shot spirits	Help with goal – tips & strategies Information	2.3 self-monitoring of behaviour
3	15 (Mon)	YourCall: Reduce your chance of injuries & health problems by having no more than 2 drinks per day and at least 2 no-alcohol days per week	Information Help with goal – tips & strategies	4.1 instruction on how to perform behaviour

				5.1 information about health consequences
3	17 (Wed)	YourCall: Think of 1 thing u can do 2 cut down your drinking. Plan ahead & take action!	Help with goal	1.4 action planning
3	19 (Fri)	YourCall: Don't drive if u have had alcohol. Arrange a sober driver, share a taxi, take a bus, walk with a friend	Advice	4.1 instruction on how to perform the behaviour
3	21 (Sun)	YourCall: Think about sharing your goal with friends or family. They can give u support and may also want 2 cut down	Support Encourage sharing & discussion	3.3 social support
4	23 (Tues)	For males: YourCall: Its best not to drink alcohol at all if your health is not so good or u are on medication For females: YourCall: Its best not to drink alcohol at all if u are pregnant or might get pregnant, your health is not so good or u are on medication	Information	5.1 information about health consequences
4	25 (Thurs)	YourCall: Reward yourself 4 making progress with your goal - but not with alcohol! Don't give up on your goal, try small steps	Encouragement Build self-efficacy	10.3 nonspecific reward 1.9 commitment 15.1 verbal persuasion about capability
4	27 (Sat)	YourCall: Remember that u can get confidential help from Alcohol Helpline 0800 787 797 or your doctor	Information (about support and service options)	3.1 social support
4	28 (Sun)	YourCall: Make a positive change in your life - cut down or quit drinking alcohol. Thanks 4 taking part in the study – great effort! We'll be in touch in 2 months	Advice & encouragement	9.1 credible source 3.1 social support 15.1 verbal persuasion about capability

*The Day 1 text message has an option to receive a greeting in the following Pacific languages: Samoan, Tongan, Cook Islands, Niuean, Tokelauan, Tuvaluan, or Fijian. There were also options to have a version of the text messages in English with some Te Reo Māori words or a version of the text messages translated to Te Reo Māori.

** Behaviour change techniques from Michie S, Wood C, Johnston M, Abraham C, Francis J, Hardeman W. Behaviour change techniques: the development and evaluation of a taxonomic method for reporting and describing behaviour change interventions. Health Technology Assessment 2015;19(99):1–188.

Appendix 4: Summary of Interviewer Guide

The content of this document was developed by the research team as a guide for the interviewers. It was designed to act as a prompt for the interviewers during face-to-face semi-structured interviews with participants, rather than a rigid set of questions. The interviewers were able to be flexible, adapting the questions and asking other questions as needed, depending on the participant and the ideas that emerged during the interview.

Part One: Exploring views on content of text messages

The following prompts were adapted and asked in relation to each text message:

1. What do you think about this message? (E.g. language and tone.)
2. Does the message make sense to you? Why/why not?
3. Purpose:
    a. What do you think the message is trying to tell you?
    b. Our idea with this message is to [*add specific purpose of message*]. What are your thoughts about this? Do you think the message achieves the purpose intended?
4. The above were complemented with more general content questions such as:
    - What particular types of information might motivate you to want to make a change?
    - What sorts of messages would work for you?
    - Do you think messages should be different for different groups of people?
    - What groups should we think about having different messages for? (E.g. gender, age, ethnic groups.)

Part Two: Perceptions about length of intervention and frequency of messages

1. What do you think about the length of this intervention, i.e. 4 weeks?
2. How do you feel about getting text messages frequently?
3. What frequency of text messages would work for you?
4. Consider the first week of messages. How do these messages make you feel? Are they too far apart? What do you think about the level of support provided during the first week?

Part Three: Perceptions about interactivity

1. How could we improve this programme?
2. What other functions would you like to be offered?
3. Do you think the programme should be more interactive? (E.g. should you be able to text for more information or motivational tips? How soon would you want a reply?)

Part Four: Cultural aspects

[*These questions were adapted depending on the ethnicity of the participant.*]

1. We want to ensure the messages are relevant for Māori participants. How can we do this?
2. What things do you think are important to consider for text messages for Māori people?
3. Do you think it would be useful to have text messages or words in Te Reo Māori?

Appendix 5: Participant Information Sheet and Consent Form

Participant Information Sheet

The YourCall Study: the effectiveness of text messaging to address hazardous drinking behaviours among admitted trauma patients

Kia ora, Kia orana, Talofa, Malo e lelei, Fakaalofa atu, Talofa ni, Fakatalofa atu, Bula vinaka, Hello.

We invite you to take part in a study of mobile phone text messages and alcohol use. The study is called 'YourCall' and is run by staff at The University of Auckland.

Alcohol problems are common among New Zealanders. This study aims to find out if a text message service can help to reduce alcohol use and alcohol harms like injuries. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't change the care you get. If you do want to take part in the study, but change your mind later, you can pull out of the study at any time. You don't have to give a reason.

To help you make your mind up about taking part, we ask that you please read this Information Sheet. It sets out why we are doing the study and what it would involve if you took part. The Research Assistant will go through this information with you and answer any questions you may have. You may also want to talk about the study with other people, such as family, whānau, friends, or healthcare staff. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page. You will be given a copy of the Information Sheet to keep.

<u>Why a text message study?</u>

Many New Zealanders have mobile phones and use text messaging. Text messages have been shown to be a good way to help people make changes (e.g. quit smoking) to improve their health and wellbeing. Getting text messages is easy for people. Text

messaging can help to make health advice more available to people. Many studies have shown that helping people to cut down on alcohol helps to prevent injuries. The next step is to see if sending people text messages also helps to reduce alcohol use and prevent injuries.

How many people can be in the study?

We would like there to be at least 570 people to be in the study.

Who can be in the study?

To take part in the study you must:

- Be between 16 years and 69 years of age.
- Have had an injury and been admitted to hospital.
- Have had an injury that was either an accident or was caused by some-one else.
- Be going home when you leave hospital (i.e. not going to another hospital).
- Be able to give written permission to take part in the study.
- Drink alcohol (even if just a small amount).
- Own or use a mobile phone, which is for your own use (i.e. not shared with some-one else).
- Be willing and able to read and send text messages.
- Be able to read English.
- Not be pregnant.
- Not be a visitor to New Zealand.

Where will the study take place?

The study is taking place at Middlemore Hospital, Auckland City Hospital, and North Shore Hospital. A Research Assistant will meet with you once or twice while you are hospital. After that you will not need to meet with us again. The text messages will be sent to you after you leave hospital.

What is involved in taking part in the study?

If you decide that you would like to take part in the study, we will ask you to give us your permission in writing. To do this we ask that you read and sign the Consent Form. You can discuss this with anyone you choose and can take as much a time as you need.

A Research Assistant will then fill out a survey with you on an iPad computer. The first part of the survey asks questions about your alcohol drinking. The computer will add up your answers and work out a score. If your score is in the middle range, you will continue with the study. If your score is low or high, you will not be able to be in the study and your meeting with the Research Assistant will finish.

If your score is in the middle range, the Research Assistant will ask you some more questions about yourself, such as your mobile phone number and details, smoking and drug use, and your job and education. The Research Assistant will also get information from your hospital notes about your injury.

On the first or second Monday after you leave hospital, you will get a text message on your mobile phone. The message will tell you when we will be sending you more text messages. There are two options that may happen. Either:

1) We will send you text messages over the next year (up to 5 text messages at 3 and 6 months), or

2) We will send you text messages every few days over the first month. Then we will send you text messages over the next year (up to 5 text messages at 3 and 6 months).

Whether you are put in Group 1 or Group 2 is decided by a process called randomisation. This is done by a computer. It is a bit like tossing a coin and means the decision is made by chance.

One year after starting the study you will be asked to fill in a short survey either online or by phone. We will send a text message to your mobile phone to let you know when it is time to do this survey.

Also, at the end of the study we will be looking to see how many people in the study have had an injury during the year. To do this we will be use your National Health Index (NHI) number to link to ACC and Ministry of Health information. We will not need to contact you at this time, but it is important that you know we will be collecting your injury health information and that you agree that we can do this.

What happens if you want to stop getting the text messages, once they have started?

You can ask for the text messages to be stopped and you don't have to give a reason. You can text back STOP if you want messages to stop coming to your phone. Our computer system will stop any more text messages coming from us. One of our study staff will contact you by phone to check whether you also want to pull out of the study completely.

What is the time span of the study?

Each person will be in the study for one year. The study will run for a total of two years as it will take us about one year to enrol everyone and another year to follow-up everyone.

What are the risks and benefits to you of taking part in the study?

We do not think there will be any risks with this study. However, taking part in this study will take a small amount of your time. You will need to fill in the first form with the Research Assistant. You will need to text back to the text messages sent to you and fill in a final survey at the end of the year. The total time will be about 30-40 minutes over one year.

We will give you a small koha to cover the cost of the text messages you send to us. It will not cost you anything to get the text messages from us.

By taking part in the study you will help us to find out if a mobile phone text message service can help people to cut down on alcohol and prevent injuries. If it works, the text message service could be offered to other people.

What would happen if you were injured in the study?

If you were injured due to taking part in this study, which is unlikely, you would be eligible for compensation from ACC. Your case would be assessed by ACC according to the 2001 Injury Prevention Rehabilitation and Compensation Act.

How confidential will the information you collect on me be?

We need to collect personal details such as your name, home and email addresses, phone numbers, and details of a contact person. This is so we can contact you if needed during the study. These details will be stored separately from any other personal study information such as the surveys. They will only be linked to the study information by a confidential registration number.

The study files and all other information provided will be confidential. Nothing that could identify you will be used in any reports on this study. All computer records will be password protected and stored on a secure server.

What will happen after the study ends?

The information we get from you will be securely stored at The University of Auckland for 10 years. It will then be destroyed. This information cannot be used in the future for other studies.

After the study ends in 2014, we will analyse the information and write reports. The study findings may be published in medical journals, but this can take several years.

After the study ends, the text message service will not be available from the people organising the YourCall Study. If the text message service is found to be helpful, it is likely the service would be made generally available to people, for example through the Alcohol and Drug Helpline.

Ethical Approval

This study has been approved by the Northern B Health and Disability Ethics Committee. Reference number: 12/NTB/28

Your Rights

Taking part is your choice. You do not have to take part in this study. If you agree to take part, you can pull out at any time and this won't change the care you get.
You have the right to access information about you that we collect as part of the study. It is your right to ask questions at any time during the study.

Where can you go for more information about the study, or to raise concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact the researchers.

Principal Investigator: Professor Shanthi Ameratunga
Telephone: [redacted]
Email: [redacted]

Project Manager: Dr Bridget Kool
Telephone: [redacted]
Email: [redacted]

Research Fellow: Dr Sarah Sharpe
Telephone [redacted]
Email: [redacted]

If you want to talk to someone who isn't involved with the study, you can contact an independent Health and Disability Advocate.

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the Northern B Health and Disability Ethics Committee (HDEC) that approved this study:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Māori Cultural Support

For Māori cultural support please contact:
(Insert specific contact details for each locality)

Consent Form

REQUEST FOR INTERPRETER

English	I wish to have an interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero	Ae	Kao
Samoan	Oute mana ‘o ia iai se fa ‘amatala upu	Ioe	Leai
Tongan	‘Oku ou fiema ‘u ha fakatonulea	‘Io	‘Ikai
Cook Island	Ka inangaro au I tetai tangata uri reo	Ae	Kare
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai

1. I have read and I understand the Information Sheet about taking part in a mobile phone text message research study.

2. I have had the opportunity to ask questions. I am satisfied with the answers I have been given.

3. I understand that taking part in this study is voluntary (my choice) and that I may pull out of the study at any time and this will in no way affect my care**.**

4. I understand that my participation in this study is confidential and that nothing which could identify me will be used in any reports on this study.

5. I have had time to consider whether I should take part.

6. I know who to contact if I have any questions about the study.

7. I am prepared to take part in the study.

8. I give the researchers permission to send text messages to my mobile phone number.

Declaration by participant:

I have read or have had read to me in my first language, and I understand, the Information Sheet. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this study.

I have been given a copy of the Participant Information Sheet and Consent Form to keep.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____

Appendix 6: Baseline Questionnaire

Participant DOB	Participant initials	Registration Number
|_|_|_|_|_1|9_|_|	|_|_|_|_|	|_|_|_|_|

Note to Research Assistant: Please make sure the participant has provided written informed consent before proceeding with Form B.

PART 1

1. Assessment Details

Q Number	Label	Field format
1.01	Date of assessment	Date DD/MM/20YY

2. Questions about alcohol

Q Number	Label	Field format
2.01	How often do you have a drink containing alcohol	(0) Never (Skip to 2.09) (1) Monthly or less (2) 2 to 4 times a month (3) 2 to 3 times a week (4) 4 or more times a week
2.02	How many drinks containing alcohol do you have on a typical day when you are drinking? *(Use picture card to show examples of drink quantities. 1 drink= 10 gm alcohol, ie 100mls wine, 330ml beer, 30 mls spirits.)*	(0) 1 or 2 (1) 3 or 4 (2) 5 or 6 (3) 7,8 or 9 (4) 10 or more
2.03	How often do you have six or more drinks on one occasion? *(Use picture card to show examples of drink quantities. 1 drink= 10 gm alcohol, ie 100mls wine, 330ml beer, 30 mls spirits.)*	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily (Skip to 2.09 if total score for 2.02 and 2.03=0)
2.04	How often during the last year have you found that you were not able to stop drinking once you had started?	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily
2.05	How often during the last year have you failed to do what was normally expected from you because of drinking?	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily
2.06	How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily

2.07	How often during the last year have you had a feeling of guilt or remorse after drinking?	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily
2.08	How often during the last year have you been unable to remember what happened the night before because you had been drinking?	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily
2.09	Have you or someone else been injured as a result of your drinking?	(0) No (2) Yes, but not in the last year (4) Yes, during the last year
2.10	Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down?	(0) No (2) Yes, but not in the last year (4) Yes, during the last year
	Do not continue to PART 2 if: ○ *Females: AUDIT score is <7 or >15* ○ *Males: AUDIT score is <8 or >15* *Thank the participant for their time and explain they do not meet the criteria for being in the study.* *If AUDIT score <7/8, give information packet A* *If AUDIT score >15, give information packet B* *Proceed to Section 9*	

PART 2

3. Mobile Phone Details

Q Number	Label	Field format
3.01	Mobile phone number	Numerical
3.02	Which one of these options best describes your use of your mobile phone?	-Many times per day -Once a day to once every few days -Once or twice per week or less
3.03	What do you use your mobile phone for? *Tick all that apply.*	-Texting -Phone calls -Browsing the internet -Playing games -Download apps -Other
3.04	If 'Other' *(Specify)*	Text
3.05	How often do you receive or send a text message? (*Select one)*	-Many times per day -Once a day to once every few days -Once or twice per week or less
3.06	What sort of payment plan are you on?	-Pre-paid plan

		-Monthly account plan -Other -Unknown

4. Cigarette and drug use

Q Number	Label	Field format
4.01	Are you currently a cigarette smoker?	Yes; No; Unknown/ don't recall
4.02	Do you currently use recreational drugs?	-Yes -No -Unknown/ don't recall -Refused (If No/ Unknown/Refused skip to Section 5)
4.03	How often do you use marijuana?	- Never - Less than once a month - Once a week to once a month - Several times a week - Unknown/ don't recall - Refused
4.04	How often do you use any other recreational drugs?	- Never - Less than once a month - Once a week to once a month - Several times a week - Unknown/ don't recall - Refused

5. Role of alcohol in this injury

Q Number	Label	Field format
5.01	Do you think your drinking played a role in your injury?	Yes / No
5.02	Do you think another's drinking played a role in your injury?	Yes/No

6. Employment and education information

Q Number	Label	Field format
6.01	At present are you? **Read** (*select only one*)	- Self-employed - Full-time salary or wage earner - Part-time salary or wage earner - Retired - Full-time home-maker - Secondary school student - Student other - Unemployed - Other beneficiary - Refused

6.02	For those not at secondary school or equivalent, what is your highest educational qualification? **Read if necessary** (*select one only*)	-School qualification -Trade qualification -Tertiary qualification - None - Refused -Other (specify) -Not applicable
6.03	If 'Other' *(Specify)*	Text

7. Text message service options (this question is for participants who self-identified as Māori)

Q Number	Label	Field format
7.01	If you receive text messages as part of this study, would you rather get messages in: *(Choose one option only)*	-English -Te Reo Māori - English with some Te Reo Māori words -Not applicable

Research assistant to extract the following from the medical record:

8. Admission details

Q Number	Label	Field format
8.01	Date of injury	Date DD/MM/20YY
8.02	Date of admission	Date DD/MM/20YY
8.03	Date of discharge	Date DD/MM/20YY
8.04	Mechanism of injury	Text
8.05	Mechanism of injury ICD category *(Select one)*	-Cutting piercing -Drowning -Fall -Struck by or against -Burns -Machinery -Natural Environment -Motor vehicle crash -Non-motor vehicle crash -Overexertion -Suffocation -Firearm -Poisoning -Other specified -Unspecified
8.06	Suspicion of alcohol involvement in this injury documented in the notes?	Yes / No
8.07	Blood alcohol level taken?	Yes / No
8.08	If yes to 8.07: Blood alcohol level result mmol/L	Numeric
8.09	Nature of injuries categories *(Select as many as apply)*	-fracture of skull or facial bones -fracture of upper limb -fracture of lower limb -fracture of spine or pelvis

		-other fractures -sprain/strain of neck or back -sprain/strain of upper limb -sprain/strain of lower limb -open wound of head -open wound of upper limb - open wound of lower limb -other open wounds -superficial injuries -intracranial injury -foreign body -burns -poisonings -drowning and suffocation -other injuries -unknown
8.10	Intentional injury	Yes / No / Undetermined

9. Signature of Study Researcher

Q Number	Label	Field format
9.01	Signature	Text
9.02	Printed Name	Text
9.03	Date	Date DD/MM/20YY

Notes	For updates	

10. CRF Sign-off:

Study Management: _____ Date: _____

Data Services Manager: _____ Date: _____

Biostatistician: _____ Date: _____

Appendix 7: Twelve-Month Survey Form

Participant DOB	Participant initials	Registration Number
|_|_|_|_|_1|9_|_|	|_|_|_|_|	|_|_|_|_|

Thank you for taking part in the YourCall text message study. This is the final survey of the study.

Please answer the questions below. All your responses are confidential.

0. Assessment Details (for paper forms only)

Q Number	Label	Field format
0.00	Date of assessment	Date DD/MM/20YY
0.01	Mobile Number	Numerical
0.02	Date of Birth	Date DD/MM/19YY

PART 1: AUDIT

1. Questions about alcohol use

Q Number	Label	Field format
This part is about your drinking. Please click the circle that best describes your answer to each question.		
1.01	How often do you have a drink containing alcohol?	(0) Never (Go to 1.09) (1) Monthly or less (2) 2 to 4 times a month (3) 2 to 3 times a week (4) 4 or more times a week
1.02	How many drinks containing alcohol do you have on a typical day when you are drinking? *(1 drink= 10 gm alcohol, ie 100mls wine, 330ml beer, 30 mls spirits.)*	(0) 1 or 2 (1) 3 or 4 (2) 5 or 6 (3) 7,8 or 9 (4) 10 or more
1.03	How often do you have six or more drinks on one occasion? *(1 drink= 10 gm alcohol, ie 100mls wine, 330ml beer, 30 mls spirits.)*	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily *(If 1.02 is answered 1 or 2 AND 1.03 is answered Never, go to 1.09.*
1.04	How often during the last year have you found that you were not able to stop drinking once you had started?	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily

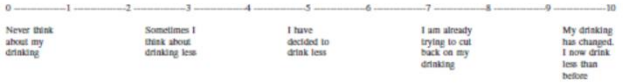
1.05	How often during the last year have you failed to do what was normally expected from you because of drinking?	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily
1.06	How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily
1.07	How often during the last year have you had a feeling of guilt or remorse after drinking?	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily
1.08	How often during the last year have you been unable to remember what happened the night before because you had been drinking?	(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily
1.09	Have you or someone else been injured as a result of your drinking?	(0) No (2) Yes, but not in the last year (4) Yes, during the last year
1.10	Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down?	(0) No (2) Yes, but not in the last year (4) Yes, during the last year
SOURCE: Babor et al. (2001)[55]		

SUBMIT POINT

PART 2: ALCOHOL-RELATED BEHAVIOUR

2. Alcohol-related health seeking behaviours and readiness to change

Q Number	Label	Field format
This part is about people you may have talked to or websites you may have looked at. In the last 12 months did you do any of the following?		
2.01	Ring the Alcohol Helpline?	Yes/No
2.02	Look at the Alcohol Helpline website?	Yes/No
2.03	Look at any other websites for information or help about alcohol?	Yes/No If No, go to 2.05
2.04	If 2.03 is yes, what websites were they?	text
2.05	Talk with a doctor or other health professional about your drinking?	Yes/No
2.06	Talk with anyone else, such as friends or family, about your or their drinking?	Yes/No

2.07	On the ruler below, please select the number that best describes how you feel ***right now***:  *SOURCE: LaBrie et al. (2005)*[190]	Visual Analogue Scale 0 to 10

SUBMIT POINT

3. Questions about alcohol-related harms

Q Number	Label	Field format
	The next part is about harms that may happen because of drinking. During the last 12 months, has your drinking had a harmful effect:	
3.01	On your work, studies or employment opportunities?	No Yes, once or twice Yes, more than twice
3.02	On your housework or chores around the house?	No Yes, once or twice Yes, more than twice
3.03	On your marriage/intimate relationships?	No Yes, once or twice Yes, more than twice
3.04	On your relationships with other family members, including your children?	No Yes, once or twice Yes, more than twice
3.05	On your friendships or social life?	No Yes, once or twice Yes, more than twice
3.06	On your finances?	No Yes, once or twice Yes, more than twice
3.07	On your physical health?	No Yes, once or twice Yes, more than twice
SOURCE: Gender, Alcohol, and Culture: an International Study (GENACIS), Expanded Core Questionnaire.[189]		

SUBMIT POINT

4. Questions about alcohol-related troubles

Q Number	Label	Field format
	In the last 12 months, have you had any of the following experiences?	
4.01	Have you had trouble with the law about your drinking and driving?	No Yes, once or twice Yes, more than twice
4.02	Have you had an illness connected with your drinking that kept you from working on your regular activities for a week or more?	No Yes, once or twice Yes, more than twice

4.03	Have you lost a job, or nearly lost one, because of your drinking?	No Yes, once or twice Yes, more than twice
4.04	Have people annoyed you by criticising your drinking?	No Yes, once or twice Yes, more than twice
4.05	Has your spouse or someone you lived with threatened to leave or actually left because of your drinking?	No Yes, once or twice Yes, more than twice
4.06	Have you lost a friendship because of your drinking?	No Yes, once or twice Yes, more than twice
4.07	Have you got into a fight while drinking?	No Yes, once or twice Yes, more than twice
SOURCE: Gender, Alcohol, and Culture: an International Study (GENACIS), Expanded Core Questionnaire.[189]		

SUBMIT POINT

5. Hangover questions

Q Number	Label	Field format
5.01	At any time in the past, have you ever had a hangover after heavy drinking? *Choose one of the following answers*	Yes *(if Yes, go to 5.02)* No *(go to 6.01)* Never ever drank heavily *(go to 6.01)* Prefer not to answer *(go to 6.01)*
5.02	During the **past 12 months**, on how many days were you kept from your usual activities because of a hangover? *Choose one of the following answers*	Never Once a month or less 2-3 times a month Once a week More than once a week Prefer not to answer
SOURCE: Verster et al. (2010)[236]		

SUBMIT POINT

PART 3: YOURCALL STUDY EXPERIENCE

6. Experience of being in the YourCall Study

Q Number	Label	Field format
	This part is about your experience of being in the YourCall Study.	
6.01	Did you share any of the text messages you received from this study with other people?	Yes/No
6.02	What were some of the good things about being in this study?	text
6.03	What did you like the least about being in this study?	text

6.04	Did anything bad happen to you (such as a car crash) when sending or receiving text messages from this study?	Yes/No
6.05	If Yes, please describe what happened.	text
6.06	Do you have any suggestions about how this study could have been improved	text
SOURCE: all questions above are novel.		

SUBMIT POINT

Thank you for doing the survey!

7. Signature of Study Researcher (for paper forms only)

Q Number	Label	Field format
8.01	Signature	Text
8.02	Printed Name	Text
8.03	Date	Date DD/MM/20YY

Notes	For updates	

8. CRF Sign-off:

Study Management: _____ Date: _____

Data Manager: _____ Date: _____

Biostatistician: _____ Date: _____

Appendix 8: Published 'Letter to the Editor'

A *Letter to the Editor* based on findings described in Chapter Seven has been accepted (in press and available online at time of thesis submission): *'Sharpe S, Kool B, Whittaker R, Ameratunga S. Hawthorne effect in the YourCall trial suggested by participants' qualitative responses. Journal of Clinical Epidemiology 2019*; *doi: https://doi.org/10.1016/j.jclinepi.2019.05.035.'*

Permission to reprint this Letter in this thesis has been granted as part of the Journal Publishing (License) Agreement.

Dear Editor,

We commend McCambridge et al[199] for their elegant trial evaluating if the Hawthorne effect influenced self-reported alcohol consumption online. They first 'dismantled' the Hawthorne effect into two components (the effect of participants' awareness that the behaviour is being monitored and the effect of participants completing behavioural assessments). The subsequent methodological experiment found no evidence supporting either of these component effects on self-reported alcohol consumption online. Importantly, the authors recommend examining the effects in contexts where interpersonal contact may be a more prominent feature of the study.

Our research group has conducted a randomized controlled trial evaluating the effect of a low intensity, automated, culturally appropriate, text message intervention (called 'YourCall') based on the Brief Intervention model[87] and designed to reduce hazardous alcohol use in injured adult patients discharged from trauma wards.[28] This involved face-to-face enrolment and baseline assessment including alcohol screening conducted by research assistants, with subsequent alcohol use data collected by text message at 3 and 6 months, and an online survey at 12 months. While the main trial finding was of a significant reduction in hazardous drinking in the intervention compared with control (usual care) group at 3 months and sustained to 12 months follow-up, we observed a substantial reduction in hazardous drinking in the control group between baseline and follow-up points.[28] As previously noted by others, this could be due to the influence of participating in a research study, i.e. the awareness that alcohol use was a focus of this study, and the repeated assessments of alcohol use (i.e. assessment reactivity).[175, 176, 199] Other explanations include regression to the mean,[179] and the effect of being unwell with an injury and/or recovering from surgery and therefore not taking part in usual activities.

In order to examine potential influences on reported alcohol use including potential 'treatment effects' in the control group, we examined the qualitative responses to two open-ended

questions in the 12-month survey which explored participants' perceptions of their research experience (Table A). Free-text responses were analysed using a general inductive approach.[155]

Overall, the majority of responses indicated positive perceptions of being involved in the study, from *both* intervention and control group respondents. Of the five main themes that emerged (Table B), the most dominant was 'contemplation about alcohol use' suggesting that respondents were prompted to think about their alcohol use.

This finding alongside more generalised positive perceptions regarding the research experience expressed by control group respondents suggest that participating in the study resulted in a beneficial effect on their alcohol use. While we cannot quantify the extent to which the observed change in alcohol use in the control group is attributable to the Hawthorne effect or determine which of the two components referred to by McCambridge et al. may be most influential, the phenomenon is likely to have underestimated the intervention effect in our study.

Table A: Participants' responses to free-text questions in 12-month survey

Characteristics	**Control group** **n (%)**	**Intervention group** **n (%)**	**Total** **n (%)**
What were some of the good things about being in this study?	167 (55.8)	163 (54.5)	330 (55.2)
Female	45 (26.9)	44 (27.3)	89 (27.0)
Māori ethnicity	37 (22.2)	30 (18.4)	67 (20.3)
Age group 16-29 years	62 (37.1)	72 (44.2)	134 (40.6)
What did you like the least about being in this study?	149 (49.8)	147 (49.2)	296 (49.5)
Female	42 (28.2)	39 (26.5)	81 (27.4)
Māori ethnicity	33 (22.1)	28 19.0)	61 (20.6)
Age group 16-29 years	56 (37.6)	66 (44.9)	122 (41.2)

Table B: Overview of upper and lower level themes from qualitative analysis

Upper level themes	Lower level themes	Dominance of theme
Contemplation about alcohol use	Learning & awareness "It made me think" Alcohol drinking habits - frequency and quantity Reminder function	The most dominant theme emerging from the free-text responses Lower level category themes appear in both treatment groups; "it made me think" was the strongest sub-theme
Examples of quotations from respondents:	*"It made me realize how much I was actually drinking, learnt what a standard drink is"* (Control, ID 10792, male, 16-19 years, Māori) *"It was a good way to make me think about drinking and its impact on both myself and those around me."* (Control, ID 11855, female, 30-34 years, NZ European.) *"Thinking about maybe I am drinking too often and sometimes too much."* (Control, ID 14133, female, 50-54 years, NZ European.) *"It's a great reminder about how to control my alcohol."* (Intervention, ID 11950, male, 30-34 years, Pacific.)	
Decision made or action taken to change behaviour	Decision to make a change A change has been made	Less dominant theme Lower level category themes appear in both treatment groups
Examples of quotations from respondents:	*"A reminder that alcohol is actually an issue, my decision to refrain from drinking was much easier having texts coming through to support me."* (Intervention, ID 11057, female, 20-24 years, Māori.) *"More self-awareness. Helped me in making a conscious decision to reduce my intake."* (Control, ID 10538, male, 35-39 years, NZ European.)	
Characteristics of text messages	Timing & frequency Relevance of content Phone credit	Dominant theme Differences between treatment groups Positive and negative perspectives related to the first two lower level themes
Examples of quotations from respondents:	*"The texts came regularly and were a gentle reminder to me."* (Intervention, ID 10239, female, 45-49 years, NZ European.) *"I started to find the regular texts quite intrusive... it just went on for so long."* (Intervention, ID 14212, male, 40-44 years, NZ European.) *"The concern and advice was timely and helpful. Kept me focused on cutting down alcohol every day."* (Intervention, ID 10678, female, 60-64 years, NZ European.) *"I never had credit to reply back to text messages"* (Intervention, ID 11057, female, 20-24 years, Māori.)	
Involvement in a research study	Helping others Appreciation of study attributes	Dominant theme Theme and sub-themes emerged more strongly in the control group
Examples of quotations from respondents:	*"I like to help progress knowledge and so am happy to help research."* (Control, ID 10165, male, 50-54 years, NZ European.) *"I like the idea of a research project to do with alcohol."* (Intervention, ID 11009, male, 40-44 years, NZ European.) *"It was simple and easy to take part in. Also liked the initial company in the hospital."* (Control, ID 10348, female, 20-24 years, NZ European.)	
"Not for me"	Not relevant "I am not a heavy drinker"	Less dominant theme Evident in intervention group only
Examples of quotations from respondents:	*"Didn't really relate to my situation."* (Intervention, ID 10249, female, 30-34 years, NZ European.) *"This study was just not for me as I'm not a heavy drinker."* (Intervention, ID 11203, female, 20-24 years, Māori.)	

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Ethics approval and consent to participate: The 'YourCall' trial was approved by the New Zealand Health and Disability Ethics Committee (12/NTB/28) and was carried out in accordance with the ethical guidelines of the National Ethics Advisory Committee (New Zealand). Written informed consent was obtained from all participants.

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