

Development and evaluation of a theory- and evidence-based smartphone app to help reduce excessive alcohol consumption

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Thesis submitted for the Degree of Doctor of Philosophy

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Declaration

I, Claire Garnett, confirm that the work presented in this thesis is my own. Where information

has been derived from other sources, I confirm that this has been indicated in the thesis.

The following work was carried out at the Department of Clinical, Educational and Health

Psychology, University College London, under the supervision of Prof Susan Michie, Dr Jamie

Brown and Prof Robert West. This thesis has not been submitted, in whole or in part, for any

other degree, diploma or qualification at any other University.

My work was funded by the UK Centre for Tobacco and Alcohol Studies.

This thesis does not exceed the limit of 100,000 words specified by the Degree Committee.

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Abstract

This PhD research programme aimed to develop and evaluate a smartphone app to reduce excessive alcohol consumption and used the theoretical framework of the Behaviour Change Wheel to guide its development and evaluation. There are many different factors influencing alcohol consumption that can be targeted in an intervention to reduce excessive alcohol consumption. This thesis focuses on the cognitive and motivational factors affecting alcohol consumption.

The thesis involves three stages: i) work informing intervention content to prioritise for inclusion; ii) the development of the app; and iii) evaluation of the app. The first stage involved four studies about who uses apps to reduce excessive alcohol use; how theory is currently used in existing digital alcohol interventions; people's knowledge about how their drinking compares with others, and experts' opinions on modules likely to be most effective in apps for reducing excessive alcohol consumption.

Initial development and the first version of the app was based on pragmatic considerations as to how to deliver the intervention content, app developers' opinion based on previous experience, previous delivery of similar intervention content, and frameworks for engagement and design. A person-based approach was taken in two usability studies conducted to inform further iterations and the final version. The app was evaluated using a factorial RCT to assess which intervention modules were most effective. The results of the trial relating to the cognitive and motivational factors suggest that the normative feedback and cognitive bias re-training modules may assist with drinking reduction and are worthy of including in an optimised app for further development and evaluation in a full-scale RCT.

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I am sincerely grateful to Prof Susan Michie, Dr Jamie Brown and Prof Robert West for being excellent supervisors and inspiring mentors. It has been an honour and a joy to work with and learn from such outstanding leaders in this field of research. I have learnt so much from their expertise, writing style and approach to problem solving that has shaped me as a researcher. I am deeply grateful for their guidance and encouragement as well as their endless patience throughout my PhD. I feel incredibly lucky to have spent these last three years learning from and working with them all, and I hope to continue this in the years to come. I would also like to thank the UK Centre for Tobacco and Alcohol Studies for funding my PhD and the app development.

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To all of these people and many others besides, thank you – I would not have enjoyed the experience of doing a PhD half as much without you in my life.

Dedication

This thesis is dedicated to Ailish Sheehan; a friend that words cannot do justice to. My life is better for having known her.

 3^{rd} January 1993 – 9^{th} September 2016

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List of Abbreviations

App - Application (software)

APEASE - 'acceptability', 'practicability', 'effectiveness and cost-effectiveness', 'affordability',

'side-effects and safety', 'equity'

ATS - Alcohol Toolkit Study

AUDIT - Alcohol Use Disorders Identification Test

BCT - Behaviour Change Technique

BCW - Behaviour Change Wheel

COM-B - 'Capability' 'Opportunity' 'Motivation' - 'Behaviour'

DBCI - Digital Behaviour Change Intervention

GP - General Practitioner

MOST - Multiphase Optimisation Strategy

MRC - Medical Research Council

NHS - National Health Service

NICE - National Institute for Health and Care Excellence

NIHR SPHR - National Institute for Health Research, School for Public Health Research

RCT - Randomised Controlled Trial

TCS - Theory Coding Scheme

TDF - Theoretical Domains Framework

UCL - University College London

UKCTAS - UK Centre for Tobacco and Alcohol Studies

WHO - World Health Organisation

Contributions

Study 1 (reported in Chapter 3): I prepared and amended the manuscript for this study. Adam Winstock designed and developed the Drinks Meter app and collected data from this app. I designed the study with Jamie Brown, Susan Michie and Robert West. Data were analysed by Jamie Brown and myself. All authors contributed to and approved the final manuscript for the paper.

Study 2 (reported in Chapter 4): I conceived of the research questions with the co-authors of the published version of this chapter (David Crane, Jamie Brown, Eileen Kaner, Fiona Beyer, Colin Muirhead, Matthew Hickman, James Redmore, Frank de Vocht and Susan Michie). I coded the studies for their use of theory with David Crane. I conducted all the analyses related to theory reported in this chapter, with supervision from Jamie Brown and Emma Beard, and wrote up the study. All co-authors contributed to and approved the final manuscript for journal submission.

Study 3 (reported in Chapter 5): I conceived of the research questions with all the co-authors of the published version of this chapter (David Crane, Robert West, Susan Michie, Jamie Brown and Adam Winstock). Adam Winstock designed the survey and collected the data. I analysed the data, with help from Robert West and Jamie Brown, and wrote up the study. All co-authors contributed to and approved the final manuscript.

Study 4 (reported in Chapter 6): This study was conceived and designed by all co-authors. I collected and analysed the data. The summarising, combining and coding of responses was conducted by myself and Susan Michie. I drafted the first manuscript with all authors contributing to and approving the final manuscript.

The development of the app (reported in Chapter 7) was a team effort led by myself and David Crane; I led on the normative feedback, cognitive bias re-training and identity change modules, and David Crane led on the self-monitoring and action planning modules.

Study 5 (reported in Chapter 8): Myself, David Crane, Robert West, Susan Michie and Jamie Brown conceived of the study and participated in its design. David Crane and I drafted the methods section of the manuscript together. I wrote the introduction and analysis syntax, conducted the analyses and wrote up the results and discussion. David Crane led on all of the work on the self-monitoring and action planning intervention modules though I report results from these modules in this chapter for context. David Crane converted the app usage data into a useable format.

Dissemination

A version of Chapter 3 (Study 1) has been published in Translational Behavioral Medicine: Garnett, C., Crane, D., West, R., Michie, S., Brown, J., & Winstock, A. (2017). User characteristics of a smartphone app to reduce alcohol consumption. *Translational Behavioral Medicine*. *DOI:* 10.1007/s13142-017-0477-1.

A version of Chapter 4 (Study 2) has been presented at 3 conferences and is part of a Cochrane Systematic Review (registration number: CRD42015022135), the protocol for this has been published in the Cochrane Library. Details are as follows:

Garnett, C., Crane, D., Brown, J., Kaner, E., Beyer, F., Muirhead, C., Hickman, M., Redmore, J., de Vocht, F., and Michie, S. Theory content of digital interventions for reducing alcohol consumption: a systematic review. UKSBM annual conference (December 2015). Newcastle, UK.

Garnett, C., Crane, D., Brown, J., Kaner, E., Beyer, F., Muirhead, C., Hickman, M., Redmore, J., de Vocht, F., and Michie, S. Theory content of digital interventions for reducing alcohol consumption: a systematic review. In Michie, S., (Chair), *Symposium: Digital interventions to reduce harmful drinking – outcomes and mechanisms of action*. Behaviour Change Conference: Digital Health & Wellbeing (February 2016). London, UK.

Garnett, C., Brown, J., Crane, D., Kaner, E., Beyer, F., Muirhead, C., Hickman, M., Redmore, J., de Vocht, F., and Michie, S. Theory content of digital interventions for reducing alcohol consumption: a systematic review. Poster presentation. UK Centre for Tobacco and Alcohol Studies Early Career Meeting (September 2015). Bristol, UK.

Kaner, E. F., Beyer, F. R., Brown, J., Crane, D., Garnett, C., Hickman, M., Muirhead, C., Redmore, J., Michie., S., & de Vocht, F. (2015). Personalised digital interventions for reducing hazardous and harmful alcohol consumption in community-dwelling populations (Protocol). *The Cochrane Library*.

A version of Chapter 5 (Study 3) has been published in Addictive Behaviors (reported in Appendix 1) and presented at three conferences. Details are as follows:

Garnett, C., Crane, D., West, R., Michie, S., Brown, J., & Winstock, A. (2015). Normative misperceptions about alcohol use in the general population of drinkers: A cross-sectional survey. *Addictive Behaviors*, *42*, 203-206. DOI: 10.1016/j.addbeh.2014.11.010

Garnett, C., Crane, D., West, R., Michie, S., Brown, J., & Winstock, A. Normative misperceptions about alcohol use in the general population of drinkers: A cross-sectional survey. Oral and Poster presentation. Society for the Study of Addiction (SSA) Conference, York, November 2014.

Garnett, C., Crane, D., West, R., Michie, S., Brown, J., & Winstock, A. Normative misperceptions about alcohol use in the general population of drinkers: A cross-sectional survey. Oral presentation. UK Society for Behavioural Medicine (UKSBM) Conference, Nottingham, December 2014.

Garnett, C., Crane, D., West, R., Michie, S., Brown, J., & Winstock, A. Normative misperceptions about alcohol use in the general population of drinkers: A cross-sectional survey. Poster presentation. Health Behaviour Research Centre (HBRC) Conference, London, October 2014.

A version of Chapter 6 (Study 4) has been published in JMIR mHealth and uHealth (reported in Appendix 2) and presented at a conference. Details are as follows:

Garnett C, Crane D, West R, Brown J, Michie S. (2015). Identification of Behaviour Change
Techniques and Engagement Strategies to Design a Smartphone App to Reduce Alcohol
Consumption Using a Formal Consensus Method. JMIR mHealth uHealth, 3(2):e73
Garnett C, Crane D, West R, Brown J, & Michie S. Identification of behaviour change techniques
to design a smartphone app to reduce alcohol consumption using a formal consensus method.
Oral Presentation. British Psychological Society Division of Health Psychology Annual
Conference (September 2015). London, UK.

Part of Chapter 7 relating to the development work of the app have been presented at two conferences. Details are as follows:

Garnett, C., Crane, D., Brown, J., West, R., and Michie, S. Selecting intervention components for a smartphone app ('Drink Less') to help people reduce hazardous and/or harmful drinking. In Michie, S., (Discussant), *Symposium: Using smartphones to reduce harmful drinking*. Behaviour Change Conference: Digital Health & Wellbeing (February 2016). London, UK.

Garnett, C., Crane, D., Brown, J., West, R., and Michie, S. Development of a smartphone app ('Drink Less') to reduce excessive drinking: selection of intervention content. In Tombor, I., (Chair), *Symposium: Digital behaviour change interventions: design and evaluation*. EHPS/DHP Conference – Behaviour Change: Making an impact on health and health services (August 2016). Aberdeen, UK.

Study 5, as presented in Chapter 8, was pre-registered with ISRCTN (#40104069) on 10/2/2016 and a study protocol was published with BMC Public Health (see Appendix 3): Garnett, C., Crane, D., Michie, S., West, R., & Brown, J. (2016). Evaluating the effectiveness of a smartphone app to reduce excessive alcohol consumption: protocol for a factorial randomised control trial. *BMC Public Health*, *16(1)*, 536. DOI: 10.1186/s12889-016-3140-8

Thesis summary

Excessive alcohol consumption is prevalent in the UK and associated with significant health-related risks while costing the UK an estimated £21 billion annually due to healthcare, crime and lost productivity. Reducing excessive alcohol consumption is a public health priority. Evidence suggests that an app-based intervention for reducing excessive alcohol consumption has the potential to be effective, cost-effective, and to overcome a number of barriers associated with traditional, brief interventions. There are a number of smartphone apps that claim to help people to reduce their alcohol consumption but none have been evaluated to assess their effectiveness or developed based on theory and empirical evidence.

This PhD thesis aimed to develop and evaluate an evidence-based and theory driven smartphone app to reduce excessive alcohol consumption. The Medical Research Council (MRC) guidance for developing and evaluating complex interventions and the Multiphase Optimisation Strategy (MOST) were used to guide this process. As suggested by the MRC guidance and MOST, a theoretical model was used to inform the selection of potential intervention components. We used the COM-B model of behaviour ('capability', 'opportunity', 'motivation') as a broad model within which to consider the behaviour of excessive alcohol consumption and identify the factors associated with it (a behavioural analysis) that could be implemented within an app. This resulted in a number of factors that could be usefully targeted in an app; cognitive and motivational factors associated with alcohol consumption will be considered in this thesis.

This thesis involved three stages of work: firstly, studies to prioritise intervention content to include for evaluation; secondly, development of the app; and finally, evaluation of the app.

The first stage of work, related to informing the content of the intervention, involved four studies about: who uses these apps to reduce excessive alcohol use, how theory is currently

used in existing digital alcohol interventions, people's knowledge about how their drinking compares with others, and experts' opinions on modules likely to be most effective in apps for reducing excessive alcohol consumption.

Study 1 used data from an existing smartphone app for reducing alcohol consumption (the 'Drinks Meter' app) to assess the socio-demographic and drinking characteristics of users and to compare these users with the general population of drinkers in England. This study was conducted to assess who uses these sorts of apps and whether the app reaches those who need it. It found that drinkers seeking support from an app, compared with the general population of drinkers in England, report greater alcohol consumption and related harms. They appear more likely to be younger, from the South of England, not heterosexual, and of higher social grade.

Study 2 was a systematic review of how theory use has been reported in the development and evaluation of existing digital alcohol interventions, which theories were reported, and whether reported theory use was associated with intervention effectiveness. Overall, the reporting of theory use in the development and evaluation of digital alcohol interventions was very limited and it was often unclear when theory had been used. Given this, theory use is currently unable to explain the substantial heterogeneity in this literature. There was no evidence that any particular type of theory was associated with more effective digital interventions; the review therefore could not inform our theory selection.

Study 3 was a cross-sectional survey assessing the prevalence of normative misperceptions (underestimation of own alcohol consumption compared with other drinkers) in the general population of drinkers and whether there were any socio-demographic or drinking characteristics associated with these normative misperceptions. It found that normative misperceptions were common and a substantial minority of harmful drinkers believed their

consumption to be average or lower. Normative misperceptions were found to be greater in those who were younger, male, less well educated, unemployed, white, from the UK and high-risk drinkers.

Study 4 was a formal consensus building exercise with experts identifying what intervention content and engagement strategies would be the 'best bets' in terms of effectiveness and engagement for inclusion in the smartphone app. Twelve different intervention components were identified by experts to have the greatest potential; those rated most highly were self-monitoring, goal-setting, action planning and feedback in relation to goals. The strategies experts thought were most likely to engage users were ease of use, design, tailoring of design and information, and unique smartphone features.

The intervention content selected as highest priority for inclusion in the app were based on the behavioural analysis of excessive alcohol consumption using the COM-B model and the findings from the first stage of work. This content was then developed in the app.

The second stage of work consisted of development of the app which was an iterative process that involved multiple steps. The steps included defining the app content, choosing the most relevant design principles, usability testing and de-bugging the app. The app, 'Drink Less', has a set of core features and five intervention modules: normative feedback, cognitive bias retraining, identity change, self-monitoring, and action planning. Each intervention module has an 'intensive' and 'minimal' version. This thesis focuses on the results relating to the three cognitive and motivational modules: normative feedback, cognitive bias re-training and identity change.

The third stage of work involved the evaluation of the app. Study 5 was a full factorial RCT to estimate the effectiveness of the intervention modules at reducing excessive alcohol

consumption. The factorial RCT found that the intensive versions of the normative feedback and cognitive bias re-training modules may assist in reducing excessive alcohol consumption and are worth including in an optimised app for further development and then evaluation in a full-scale RCT.

A general discussion commented on these findings and discussed the limitations and implications of this thesis.

Chapter 1 - General Introduction

Chapter summary

Alcohol consumption is prevalent globally with approximately 2.1 billion adults drinking alcohol. The UK's average alcohol consumption per person is greater than both the worldwide and European averages. Excessive alcohol consumption includes drinking at levels that are defined as hazardous, harmful or at-risk of alcohol dependence. Excessive alcohol consumption is a serious problem for population health and the economy, and is responsible for about 3.3 million deaths worldwide each year and over 5% of the global burden of disease and injury. In the UK, alcohol costs about £21 billion each year in terms of healthcare, crime and lost productivity.

Interventions aimed at reducing the levels of excessive alcohol consumption are usually delivered either face-to-face or via digital technology. Face-to-face brief interventions are typically delivered by healthcare practitioners and are effective at reducing alcohol consumption in primary healthcare settings. However, there are a number of barriers to their implementation. Smartphone applications, in particular, are a promising and potentially effective way of delivering interventions that overcome a number of the barriers to implementation of brief interventions.

1.1 Excessive alcohol consumption

Excessive alcohol consumption is defined by the National Health Service (NHS) as drinking over the lower-risk guidelines for alcohol consumption [1]. These lower-risk guidelines consist of advice on weekly consumption and single episodes of drinking. The weekly guideline states that it is safest not to drink more than 14 units per week in order to keep

health risks from drinking alcohol to a low level, and that these units are best spread evenly over three days or more. The advice on single drinking episodes to keep short-term health risks to a low level is to limit the total amount drunk on any occasion, and to drink alcohol more slowly, with food and alternating with water. The short-term risks from excessive alcohol consumption are greater when the period of drinking time is shorter. Drinking below these levels, both weekly and on single episodes, is considered low-risk. These recommended drinking guidelines are a recent update to provide people with accurate and up-to-date information about the known health risks of different levels and patterns of drinking [2]. The guidelines aim to facilitate informed choice on whether to drink alcohol, and how much and how often to drink [2].

The Alcohol Use Disorders Identification Test (AUDIT) is a gold-standard tool for screening excessive alcohol consumption. It was developed by the World Health Organisation and has high internal consistency and test-retest reliability [3]. The AUDIT consists of ten questions about recent alcohol use, alcohol dependence symptoms and alcohol-related problems. The AUDIT scores range from 0 to 40 and individuals can be categorised into one of four alcohol-related risk zones based on their scores. These four alcohol-related risk zones are: 'low risk' (scores 0-7), 'hazardous drinking' (8-15), 'harmful drinking' (16-19) and 'at-risk of alcohol dependence' (20-40). Hazardous drinking is defined as a pattern of consumption that increases the risk of harmful consequences for the drinker or others. Harmful drinking is when the individual's drinking behaviour results in negative consequences to their physical, mental or social health. Alcohol dependence is a cluster of behavioural, cognitive, and physiological phenomena that may develop after repeated alcohol use [3]. Excessive alcohol consumption can be operationalised as a score of eight or above on the AUDIT and, therefore, includes hazardous drinking, harmful drinking and at-risk of alcohol dependence. Alcohol use

disorders are defined by the AUDIT questionnaire as a score of 16 or more and, therefore, include harmful drinking and at-risk of alcohol dependence.

1.2 Prevalence of excessive alcohol consumption

Approximately 2.1 billion adults, around 43% of the world's population, drink alcohol [4]. There is considerable regional variation with Western Europe having the highest proportion of adult drinkers (88.2%) and central, southern and western Asia having the lowest proportion (9.8%) [4]. Worldwide consumption of alcohol per person aged 15 years or older was equal to 6.2 litres of pure alcohol in 2010 [5]. This equates to a worldwide average of 13.5 grams of pure alcohol per person each day [5]. About 16% of these drinkers engage in heavy episodic drinking which is defined as the equivalent of 60 grams or more of pure alcohol on a single occasion each month [5].

The UK alcohol consumption per capita is the equivalent of 11.6 litres of pure alcohol per year, which is greater than the worldwide average (6.2 litres) and the average for Europe (10.9 litres) [6]. Over half (58%; 28.9 million) of people in Great Britain report drinking alcohol in the previous week [7,8]. Of those, nearly half (45%; 12.9 million) drank more than a third of the recommended weekly guideline (14 units of alcohol) on their heaviest drinking day [7,8]. The UK also has a high prevalence of heavy episodic drinking with over a quarter (28%) consuming the equivalent of at least 60 grams of pure alcohol on at least one occasion in the past 30 days [6]. A total of 2.5 million people (9%) exceed the weekly guideline in one day [7,8]. The prevalence of alcohol use disorders is higher in the UK than the European average (11.1% compared with 7.5%) [6].

Alcohol consumption, both in terms of volume and pattern of drinking, varies according to the socio-demographic characteristics of gender, age, household income and ethnicity [9,10]. Men

are more likely than women to drink alcohol, as well as to consume higher volumes of alcohol and more frequently [8]. A larger proportion of men in England had drunk alcohol in the last year (85%) than women (79%) in 2014 [9]. Men were also more likely than women to have drunk alcohol in the previous week (65% of men compared with 51% of women) and to have drunk on five or more days in the week (17% of men compared with 9% of women) [9]. Heavy episodic drinking is more prevalent in men (35.5%) than women (20.9%) [6]. Hazardous drinking, harmful drinking and risk of alcohol dependence are also at least twice as likely in men than women [6,11].

Alcohol consumption and vulnerability to alcohol-related harm vary according to gender. Women are more vulnerable to alcohol-related harm from a given level of alcohol use or a particular drinking pattern than men, despite having lower alcohol-related mortality than men [5]. The vulnerability of women may be explained by a range of factors: lower body weight, smaller liver capacity to metabolise alcohol, and higher proportion of body fat [12]. Women are also affected by interpersonal violence and risky sexual behaviour as a result of male partners' drinking problems and behaviour [13,14].

In general, the frequency of alcohol consumption increases with age but the maximum volume drunk on any one day decreases [5]. The proportion of people who drink at least once a week increases with age from 16 to 64 and then declines [9]. Hazardous and harmful drinking becomes less likely with increasing age [11]; the highest prevalence for men was in 25-34 year olds and for women in 16-24 year olds [11]. Young people were less likely to have consumed alcohol though were more likely to have consumed more than the weekly recommended limit in one day [8]. The prevalence of consuming more than the recommended weekly guideline increased with age and was most common amongst men aged 65-74 (30%) and amongst women aged 55-64 (22%) [9], although these are cross-sectional series data which do not represent the entire life course of an individual. Longitudinal data from multiple

overlapping cohorts were used to report life course trajectories of alcohol consumption in the UK [15] and these data support the findings from the cross-sectional surveys. Individuals change their drinking patterns substantially as they get older; initial increases in the volume consumed during adolescence is followed by a more stable period during mid-life which then declines in volume into older age [15].

Household income and socioeconomic status are related to both the volume and frequency of alcohol consumption. People in higher income households drink more frequently and are more likely to have consumed alcohol in the last week than those in households of the lowest income quintile [10]. Almost a fifth of higher earners drink alcohol on 5 days a week or more [7]. People of lower socioeconomic status are more likely to have abstained from alcohol in both the last week and year and were less likely to have drunk above weekly guidelines [9]. This pattern is also seen across countries with the high-income countries tending to have the highest alcohol per capita consumption and the highest prevalence of heavy episodic drinking among drinkers [5]. A typology of British drinking practices found that drinkers of lower socioeconomic status have fewer drinking occasions but consume more per occasion [16].

Alcohol-related mortality is also greater in people of lower socioeconomic status [10,17]. This inequality in alcohol-related harm has been termed the 'alcohol harm paradox', whereby people of low socioeconomic status suffer greater alcohol-related harm than those of a high socioeconomic status for the same or lower levels of alcohol consumption [10,18,19]. Drinkers of a lower socioeconomic status had an increased risk of head and neck cancer, stroke, hypertension and liver disease compared with drinkers of a higher socioeconomic status [19]. The alcohol harm paradox appears to exist across a range of measures of socioeconomic status and is more evident in younger men than in other demographic groups [20].

The proportion of adults who drink alcohol varies between ethnic groups. White men and women were most likely to drink alcohol whilst Asian men and women were least likely to [7]. Alcohol dependence is more common in white men and women than in those from minority ethnic groups and minority ethnic groups also have lower rates of hazardous drinking [11].

1.3 Consequences of excessive alcohol consumption

Excessive alcohol consumption has a significant impact on global public health and is responsible for about 3.3 million deaths each year [5]. The harmful use of alcohol ranks among the top five risk factors for avoidable disease, disability and death throughout the world [21–23]. Over 5% of the global burden of disease and injury is estimated as being attributable to alcohol [21] and an estimated 139 million disability-adjusted life years (DALYs) are attributable to alcohol consumption [5]. Alcohol ranks third in high-income countries as a leading cause of morbidity and premature death [24]. The costs associated with alcohol amount to more than 1% of the gross national product in high- and middle-income countries [23]. Excessive alcohol consumption is associated with health, social and economic consequences on both a national and an individual level [25,26].

1.3.1 National level

From a national economic perspective, alcohol costs the UK £21 billion a year, in terms of healthcare (£3.5 billion), crime (£11 billion) and lost productivity (£7.3 billion) [27,28]. Excessive alcohol consumption is also a serious problem for population health in the UK [22,29]. Of all hospital admissions, 7% are alcohol-related [29]. There were 1.1 million hospital admissions where an alcohol-related disease, injury or condition was the primary reason for admission in England in 2014/15 [7]. These alcohol-related hospital admissions have doubled in the last decade [7]. Nearly half of the alcohol-related hospital admissions

were for cardiovascular disease and nearly one fifth were for mental and behavioural disorders due to alcohol [7]. In 2014 there were 6,831 deaths related to alcohol-specific causes (1% of all deaths) in England; this is a 4% increase from 2013 and a 13% increase from 2004 [7]. In 2014/15 there were 151,000 people who presented for alcohol problems, of these 89,000 were treated for problematic drinking alone and 62,000 were treated for alcohol problems alongside other substances [7].

Excessive alcohol consumption is also associated with violence and crime. In over half of all instances of violent crime in England and Wales in 2013/14 (704,000 of 1.3 million incidents), the victim believed that the perpetrator was drunk [30]. The victim reported that they themselves were under the influence of alcohol in a fifth of violent incidents [30]. Alcohol was a particularly prevalent factor in violent incidents between strangers, 64% of which were perceived to be alcohol-related [30]. Alcohol misuse is also linked to significant indirect costs due to lost productivity because of absenteeism, unemployment, decreased output and reduced earnings potential [25,31].

1.3.2 Individual level

At the individual level, excessive alcohol consumption is associated with a number of short-and long-term effects. Short-term effects include impaired coordination and decision-making, reckless and uninhibited behaviour, nausea and dehydration. In the long term, harmful alcohol use is a risk factor for more than 200 disease and injury conditions including: neuropsychiatric conditions (e.g. depression, anxiety, epilepsy), gastrointestinal diseases (e.g. liver cirrhosis), cancers, intentional and unintentional injuries, cardiovascular diseases (e.g. hypertension, stroke), foetal alcohol syndrome, and infectious diseases [5,23,32,33]. There is strong evidence that alcohol consumption causes cancer at seven sites in the body and is

responsible for 5.8% of cancer deaths worldwide [33] though there is generally low awareness of this relationship [34].

The health harms of alcohol have often been found to be 'dose-dependent', which describes how the risk of harm increases with the amount (volume and frequency) of alcohol consumed [9]. The pattern of drinking also affects the risk of harm [35]. For example, drinking while eating seems to be associated with less harm from long-term health risks than the same pattern of drinking at other times [36]. The volume of alcohol consumed on a single occasion is also important for many short-term consequences of drinking such as alcohol poisoning, injury and violence.

The long-term social and economic consequences of alcohol use disorders include family break-up and divorce, domestic abuse, poor performance at work, unemployment and financial problems. Excessive alcohol consumption can impoverish a drinker or their family, especially if their earnings are low [37,38]. These long-term social and economic consequences of alcohol use disorders tend to occur when an individual crosses a social boundary of acceptable drinking behaviour [39]. Alcohol-related consequences also exist for individuals other than the consumer, for example, family, friends and colleagues. These alcohol-related consequences include injury, neglect or abuse, default on social role, property damage, toxic effects, loss of amenity or peace of mind [5].

1.4 Interventions to reduce excessive alcohol consumption

Reducing excessive alcohol consumption is a public health priority [40] and there are a number of policies and interventions that are aimed at reducing the levels of excessive alcohol consumption [41,42]. Interventions for excessive alcohol consumption are typically delivered face-to-face or digitally.

1.4.1 Face-to-face brief interventions

In the UK, face-to-face brief interventions are delivered by healthcare practitioners and are usually time-limited. Brief interventions are delivered to hazardous and harmful drinkers, often opportunistically, to those not seeking help but who have been identified through a screening or case-finding approach [43]. Brief interventions typically include a range of techniques that include: feedback on alcohol use and alcohol-related harm; clarification as to what constitutes low risk alcohol consumption; information on alcohol-related harms; benefits of reducing intake; motivational enhancement; analysis of high-risk situations for drinking and coping strategies, and the development of a personal plan to reduce consumption [43].

Brief interventions delivered in primary care settings lead to significant reductions in alcohol consumption [43–45] and are a cost-effective option for tackling alcohol misuse [46,47]. However, brief interventions are not delivered widely to all excessive drinkers [48,49]; in England, less than 10% report having received brief advice from their GP [48]. There are a number of barriers to the widespread implementation of brief interventions [50], both from the perspective of healthcare practitioners [51] and patients [52]. The barriers to the implementation of brief interventions by healthcare practitioners include: lack of available training; time constraints; lack of financial incentives; professionals' knowledge, attitudes or skills; lack of managerial support and supporting materials or protocols; reluctance for fear of damaging relationship with patients, and widespread uncertainty about recommended limits [50–58]. The barriers to users receiving brief interventions include: the stigma associated with receiving any support; reluctance to seek help or to discuss alcohol consumption with healthcare practitioners; fear of discrimination or job loss if detected, and perception of limited access to effective care [50–58]. These barriers mean many excessive drinkers remain unidentified and untreated [59,60].

1.4.2 Smartphone applications and other digital behaviour change interventions

Digital behaviour change interventions (DBCIs) refer to a product or service delivered via computer technology that is designed to promote behaviour change [61]. DBCIs include smartphone applications, websites, computer programmes, wearable devices, body sensors, and telecommunications [61]. DBCIs can overcome a number of the barriers associated with face-to-face brief interventions and were highlighted as providing a significant opportunity to reach at-risk populations in conjunction with brief interventions [62]. DBCIs have a broader reach than face-to-face brief interventions and the content can be accessed at any time. Digital interventions for reducing alcohol consumption are already being used amongst excessive drinkers in England who report trying to cut down on their drinking [63]. The potential of digital interventions for hazardous and harmful drinkers is being investigated in many countries across the world [64–68].

Smartphone applications or mobile applications, hereafter referred to as apps, are typically a self-contained software program designed to perform a specific function that run directly on a mobile device. In addition to the general benefits of using DBCIs, apps have features that make them a good platform for delivery. Apps are constantly available to the users and with them almost all of the time as smartphones tend to be carried by people for most of their waking lives [69]. This offers the potential for apps to engage users when they are needed and in their everyday situations. Apps also have the ability to sense and report locations [70] and events (in conjunction with the calendar function) to provide moment-to-moment support. Thus, apps offer more advanced technology than text-messaging and websites, and can take full advantages of a multi-touch interface and other functionalities [71].

There are other modes of delivery such as web-apps, software packages able to be accessed through the web browser, that can be used on a smartphone and have some advantages over

apps. Web-apps are cheaper to develop than apps, and are easier to maintain and update as they have a common code across mobile platforms. Web-apps are compatible and easily supported on both iPhones and Android phones. Whilst apps do have limitations, there are many advantages over web-apps. Apps perform faster on the device and there are fewer bugs providing a better user experience. Apps can: send notifications, either 'push' or 'in-app'; make use of device features such as the camera, microphone, accelerometer and GPS; and use advanced gestures such as 'tap', 'swipe' and 'drag'. Users can easily find and download apps from the respective app store; apps have to be approved by the app store so users are assured of the app's safety and security, which is not the case for web-apps. Apps can also work offline whereas web-apps cannot. When other phone functions (e.g. the ability to check emails) are limited, there is less competition for the user's attention who may then be more likely to use the app at that time. Data collected from the app is then sent to the server once the smartphone is online. So on balance, an app is a better mode of intervention delivery than a web-app as it can provide a good user experience, be discoverable on the app store and has the ability to work offline.

As with face-to-face brief interventions, there are also challenges involved with the design and implementation of app-based interventions that should be considered. Some of these are specific to apps and others are more general to all DBCIs. The advantages and challenges of delivering an intervention through an app will be considered using the APEASE ('acceptability', 'practicability', 'effectiveness and cost-effectiveness', 'affordability', 'side-effects and safety', 'equity') criteria in the following section. The APEASE criteria provide a structure within which to assess the suitability of modes of delivery for an intervention [72].

1.4.2.1 Acceptability

Acceptability refers to the extent to which an intervention is judged to be appropriate by relevant stakeholders [72]. The acceptability of apps is improved by a number of features, including the potential for tailoring and personalisation, reduction in possible stigma associated with help-seeking and the ability for them to be used anonymously and privately [73,74]. Apps are also flexible, both in terms of the time at which they can be accessed and the duration of use, and being constantly available. The convenience and anonymity of apps is likely to increase uptake amongst those individuals who are reluctant to receive help from health professionals [75,76].

However, apps cannot capture some of the benefits of face-to-face interventions such as the ability to respond to non-verbal cues and accountability from direct contact with a health professional in a face-to-face interaction. On the other hand, apps can provide access to an online community or provide virtual social support from family, friends and healthcare providers [77].

The development of accredited health apps is supported by the NHS [78] because the aim is for suitable apps to be acceptable to healthcare practitioners who could recommend or prescribe them to patients [79]. Apps can be used in conjunction with brief interventions delivered by healthcare practitioners as a means of monitoring and evaluating progress through regular communication and data sharing [77].

1.4.2.2 Practicability

An intervention is considered practicable if it can be delivered to the target population through the intended means [72]. Apps are likely to be a highly practicable mode of delivery as smartphones are increasingly pervasive in the UK. Two-thirds of adults own a smartphone

(36.4 million in 2014 [80]) and they are now the most widely owned internet-enabled devices [81]. Forecasts estimate that there will be 46.4 million smartphone users in the UK by 2018 [80]. Smartphones are considered the most important device for accessing the internet and almost two-thirds of users download apps on their phones [81].

There were 165,000 health-related apps listed in the two major app stores (Apple App store and Google Play) at the start of 2015 [82]. It is estimated that these will be downloaded a total of three billion times in 2015, almost double the number from 2013 [83]. Over half of mobile phone users in the US had downloaded a health-related app [84].

This prevalence of smartphone ownership and the increasing use of health-related apps means that apps have a very broad reach and can provide simultaneous access to large numbers of users. Digital technology, in general, also provides an opportunity to access hard to reach groups who tend to engage less with traditional healthcare providers [77].

Apps are able to deliver the intervention content with a higher degree of fidelity compared with face-to-face brief interventions. This means the content of the intervention is delivered more consistently. However, whilst a digital intervention like an app may be able to deliver intervention content with a higher degree of fidelity, it is possible that users would be less committed or engaged than with a face-to-face brief intervention.

Many people download and try apps, though engagement with health-related apps is not usually sustained beyond a few occasions [85] and, specifically in digital health trials, a large proportion of users drop out or stop using the intervention [86]. Adherence to an intervention and preventing disengagement is a major challenge with apps [69] as there is less control over the intervention dose and frequency of use than with face-to-face brief interventions. If

disengagement occurs, the intervention content necessary to achieve behaviour change may not be accessed or used in sufficient doses [87].

A poor user experience is likely to discourage continued use. For example, a survey of smartphone users found that 79% of users would only retry an app once or twice if it failed to live up to its promise on the first time [88] and nearly half of users (48%) would be less likely to use an app again if they were dissatisfied with its performance. Apps that are categorised as 'Medical' or 'Health & Fitness' tend to be used less frequently and have even lower retention rates than other categories of apps [89]. Over half of functionality criticisms from a focus group of young adults on popular apps to reduce harmful drinking were descriptions of software bugs [90]. These findings highlight the importance of developing an app that contains minimal software bugs and provides a good user experience.

1.4.2.3 Effectiveness and cost-effectiveness

Effectiveness refers to the effect size of an intervention in relation to its desired objectives in a real world context [72]. There are a large number of health-related behaviour change apps available but only a small number have been formally evaluated. Of these, there is some evidence to suggest that apps can help users achieve health-related behaviour change. For example, apps have been found to increase physical activity [91]; improve muscular fitness, movement skills, and weight-related behaviours [92], and improve diabetes management [93].

There is also evidence that DBCIs can be effective at reducing excessive alcohol consumption compared with waiting-list control, provision of standard health-related information and assessment-only groups [67,74,94–104]. These interventions have tended to be delivered predominantly by websites.

There are a number of available apps to help people reduce excessive alcohol consumption [90,105,106]. However, there is a lack of empirical evidence to recommend their use by the general population of drinkers [107,108]. In a recent review of apps to reduce alcohol consumption or support patients with alcohol use disorder, only six apps were identified as having been evaluated [108]. Two of these were for providing recovery support to alcohol use disorder patients. The 'A-CHESS' app (Alcohol – Comprehensive Health Enhancement Support System) was found to have a significant benefit in a randomised controlled trial (RCT) with those participants in continuing care who used the app reporting significantly fewer risky drinking days than those who only received treatment as usual [109]. In a pilot study of the 'LBMI-A' app (Location-Based Monitoring and Intervention for Alcohol Use Disorders) participants reported significant decreases in self-reported heavy drinking days and drinks per week and a significant increase in the percentage of days abstinent compared with baseline [110–113]. Another two of the six apps were targeted at risky alcohol use in university students ('Promillekoll' and 'PartyPlanner') and involved the use of blood alcohol concentration calculators [114]. Participants who used these apps reported either no effect or a negative effect on alcohol consumption compared with a no-intervention control [114]. The final two of the six apps identified by the review were 'HealthCall-S' [115] and 'Chimpshop' [116] and both had serious limitations in their preliminary investigations that meant the effectiveness of the apps were unclear [108]. The 'HealthCall-S' app was designed for alcohol dependent HIV-infected patients and a pilot study showed high rates of engagement and retention suggesting the app was acceptable to these patients [115]. The 'Chimpshop' app is a game to reduce the users' attentional preoccupation with alcohol-related stimuli; initial data suggests it is effective at reducing drinking in problematic drinkers [116]. However, findings relating to apps targeting heavier drinkers are of limited value when developing an app to reduce excessive alcohol consumption in the general population. Other population alcoholrelated apps that promote health or a reduction in alcohol consumption do not make any reference to theory and have not been evaluated [106].

Cost-effectiveness refers to the ratio of effect to cost [72]. Apps may have large initial development costs but can be delivered at a low incremental cost on a large scale. The incremental cost is primarily, but not solely, a function of the initial development costs: in a rapidly advancing digital environment, a modest on-going resource is required to host and update apps regularly [69]. Nevertheless, the development of a well-designed and evidence-based app may prove to be a cost-effective method of reducing excessive alcohol consumption.

1.4.2.4 Affordability

An intervention is defined as affordable if it can be delivered to, or accessed by, all those for whom it would be relevant or of benefit within an acceptable budget [72]. The effectiveness or cost-effectiveness of an intervention is irrelevant if it cannot be afforded. Smartphones have become increasingly affordable and are prevalent amongst the population, and particular apps could be made available free of charge at the point of delivery. Issues of equity still exist in smartphone ownership; this will be discussed in more detail below.

1.4.2.5 Side effects and safety

Issues of unintended side effects or user safety must be considered when developing any intervention. Currently, any app can be published as a 'health' app as long as it conforms to the guidelines offered by the relevant app store [117]. Health-related apps are often developed without reference to scientific evidence or theory, fail to conform to guidelines, lack evidence-based content, or provide inaccurate information or information that may encourage risky behaviour [105,118–125]. There are a large number of apps relating to

alcohol available on the app store but only a small minority promote health and the reduction of alcohol consumption [105,106]. Some of the health promoting and alcohol reduction apps involved blood alcohol concentration calculators, which were judged unreliable and inaccurate [105]. Apps related to alcohol use disorders that aim to improve care of patients had poor content quality [126].

There are also concerns with privacy, security, storage and transmission of data, third-party use of data, and obtaining informed consent [77,127]. There is often very little transparency about how personal information is used by the developer or other parties to whom these data may be sold [125] and the majority of health apps do not have privacy policies [128]. Users are sensitive to issues of privacy and invasiveness around app features such as geo-location tracking [129] and a common reason for not downloading a health-related app was the safety of data [84]. App-based interventions should have a clear privacy and data protection policy so users know how their data will be stored, used and shared.

Ideally, a formal system of regulation or endorsement of apps would guarantee minimum quality standards and minimise side effects and unintended consequences resulting from apps. A number of regulatory agencies have produced guidance and evaluative tools to assist in the regulation of health apps, both in the development of healthcare apps and in the assessment of existing apps [77]. These regulatory agencies include: the British Standards Institute [130]; the National Information Board [131]; NHS Choices Apps Library; My Health apps [132]; European Directory of Health Apps [133].

1.4.2.6 Equity

An important consideration is the extent to which an intervention may increase or decrease the disparities in standard of wellbeing or health between different sectors of society [72].

Access to digital technologies is growing worldwide although there is a 'digital divide' in that

people of lower socioeconomic status, lower income or those with medical or physical disabilities are less likely to own or have access to the necessary digital technology and are more likely to have issues of digital literacy. Smartphones tend to be owned by the more affluent. Among the 61% of people in the UK who owned a smartphone, in 2014, there was a social gradient. People of a higher socioeconomic status were more likely to own a smartphone (70%) than those of a lower socioeconomic status (47%) [134]. The difference in ownership is likely to reflect a disparity in those using smartphones to access support for health-related behaviours. This was illustrated in an assessment of a smoking cessation app, SmokeFree28, that showed a social gradient in app users exists and merits further investigation [135]. The issue of equity with app-based interventions must be considered during development so that the necessary steps can be taken to ensure that the intervention does not increase economic, social or health inequalities. These issues can be minimised by involving users of these groups in the development process and ensuring minimal cost to the end user for accessing the intervention [136]. For example, usability testing for the smoking cessation app, StopAdvisor, was conducted on disadvantaged groups as part of the development process [137] and subsequently was effective for increasing smoking cessation across the social spectrum [138].

1.5 Aims and objectives of the current thesis

Apps are likely to be a good mode of delivery for alcohol reduction interventions and have the potential to be cost-effective with a wide reach and acceptability to both individuals and healthcare providers. There are a number of features that are likely to make apps particularly acceptable: constant availability and accessibility; the ability for personalisation; interactivity; delivery of information in an engaging and rewarding manner; ability to elicit, record and use responses; and adaptable to users' needs. Most alcohol reduction apps have been developed

without reference to scientific evidence or theory and provide no direct evidence for the effectiveness of alcohol reduction apps.

Consequently, the overall aim of this thesis was to develop and evaluate an app to reduce excessive alcohol consumption based on theory and empirical evidence. The thesis involved three stages of work that are reported in this thesis: first, to prioritise intervention content for evaluation (Chapters 2 to 6); secondly, the development of the app (Chapter 7) and finally, evaluation of the app (Chapter 8).

The prioritisation of intervention content for evaluation began with a behavioural analysis of the target behaviour to understand what may need to change in order for the desired behaviour to occur [72]. Study 1 assessed who uses alcohol reduction apps and whether these apps reach those who need support. Data were used from a popular alcohol reduction app to assess the socio-demographic and drinking characteristics of users and to compare these users with the general population of drinkers in England. Study 2 was a systematic review and meta-regression assessing how theory use was reported in the development and evaluation of digital alcohol reduction interventions and whether reported theory use was associated with intervention effectiveness. Study 3 assessed whether the general population of drinkers was accurate in perceiving how personal alcohol consumption compared with others using a cross-sectional survey. Study 4 identified the intervention content and engagement strategies that experts considered the best bets for inclusion in an app as part of a formal consensus building methodology.

The behavioural analysis of alcohol consumption and the first stage of work were used to select the intervention components of the highest priority to be included in the app. The intervention components selected were taken forward into the second stage of work that developed these into intervention modules in the app (Chapter 7). The final stage of work

consisted of an evaluation using a factorial RCT to assess the effectiveness of each intervention module (Study 5 reported in Chapter 8).

Chapter 2- Developing a Digital Behaviour Change Intervention

Chapter summary

There is a need for a digital intervention for reducing excessive alcohol consumption. The Medical Research Council's (MRC) guidance on developing and evaluating complex interventions and the Multiphase Optimisation Strategy (MOST) were used to inform the development and evaluation of such an intervention. The development of a digital behaviour change intervention that is complex should be an iterative process that forms a cycle with feedback loops. This development should begin with the use of a theoretical model to inform the selection of potential intervention components.

The COM-B model of behaviour, which proposes that 'behaviour' is part of an interacting system with 'capability', 'opportunity' and 'motivation', was used as a broad model in which to consider the behaviour of excessive alcohol consumption. The Theoretical Domains Framework (TDF), which fits within the COM-B model, was used to provide a more detailed approach to understanding the behaviour.

A behavioural analysis of excessive alcohol consumption was conducted, using these theoretical models, in order to assess what factors associated with excessive alcohol consumption could be targeted by intervention components. This analysis indicated that a number of intervention components would be feasible to include in an app. These intervention components were: provision of information, normative feedback, cognitive bias modification, self-monitoring, action planning, identity change, evaluation of benefits and costs of drinking, and goal setting. The next step was to prioritise the intervention components to be included for evaluation in the app through conducting additional studies and triangulating the findings from these studies.

2.1 Guidance for Development of Digital Behaviour Change Interventions

Digital behaviour change interventions are typically considered as a complex intervention as they often i) involve interacting components, ii) target a behaviour that is difficult to change, iii) target various mechanisms of action through which intervention components can influence outcomes, iv) have a number and variability of outcomes, and v) involve tailoring of the intervention according to user characteristics [139,140]. The Medical Research Council's (MRC) guidance on developing and evaluating complex interventions and the Multiphase Optimisation Strategy (MOST) are two approaches that are relevant to the development and evaluation of a digital behaviour change intervention.

2.1.1 Medical Research Council guidance

The MRC's guidance on developing and evaluating complex interventions [139] is one of the relevant guidance documents for developing a digital behaviour change intervention. This guidance proposes that developing and evaluating a complex intervention consists of a four stage process that forms a cycle with feedback loops indicating the iterative nature of this type of development [139]. The four stages are 'development', 'feasibility and piloting', 'evaluation' and 'implementation' and the guidance highlights the importance of continuously refining the intervention before moving onto the next stage [139]. The development of a complex intervention involves identifying existing evidence, identifying and developing theory, and modelling process and outcomes. Once an initial version of the intervention has been developed, the next stage involves a series of feasibility and pilot studies to assess the acceptability and feasibility of the intervention. These include estimating recruitment and retention and determining sample size. Findings at this stage are then used to refine the intervention before the initial evaluation. This process of developing the intervention is highly iterative, particularly for digital interventions, which require continual testing at every stage

[61]. The evaluation stage is to assess the effectiveness and cost effectiveness of the intervention and to understand the change process. These three stages exist in a continual feedback loop until the intervention is deemed suitable for the final stage of implementation. Implementation involves dissemination, surveillance and monitoring and long-term follow-up.

2.1.2 The Multiphase Optimisation Strategy

The Multiphase Optimisation Strategy (MOST) shares the phased approach of the MRC guidance for the efficient optimisation and evaluation of complex behaviour change interventions [141,142]. MOST is an approach for developing and optimising multicomponent behavioural interventions [143]: using its programmatic and sequenced experimental approach enables the best intervention, that can be achieved within given constraints, to be built [144].

MOST consists of a sequence of steps with the aim of systematically optimising a multicomponent intervention that acts in a feedback loop [143], in a similar way to the MRC guidance. The first step in this sequence is establishing a theoretical model to inform the identification and selection of the intervention components which are to be examined. This theoretical model can be based on theory, scientific literature, clinical experience, results of previous data analysis, or any other relevant information.

The next step is to identify the most promising set of intervention components that are to be examined. An intervention component is "any aspect of an intervention that is of interest and can be separated out for study" (p221 [143]). Therefore, these intervention components have to be meaningful individually, distinct from one another, not involve a time-sequence, and all combinations have to be implementable. Different levels of each intervention component

need to be specified; these could be, for example, present versus absent, or included at different intensities in the intervention [143].

The third step is the optimisation stage whereby the individual intervention components selected (and their specified levels) are assembled into an optimised intervention. This optimised intervention is then screened via randomised experimentation that allows the testing of the independent effects of the intervention components simultaneously. The aim of this screening experiment is to identify the intervention components that can cause a change in the behavioural outcome, and to screen out the least effective ones [144]. The gathering of information about each component is then used to decide whether to include them in the intervention for further evaluation [143]. The assessment of the individual effects of intervention components is not meant to take-over from a full-scale RCT. According to MOST, RCTs are still essential in this process of developing and evaluating multicomponent interventions though are not conducted until a potentially optimal intervention package has been assembled through the earlier steps. Once an RCT confirms that an intervention, as a whole, is effective, then this optimised and evaluated intervention is implemented [143].

2.2 Use of a Theoretical Model to Guide Intervention Development

The MRC guidance and MOST approach have been used in a number of complex health interventions to optimise the intervention before an RCT is conducted [145]. Both highlight the importance of using a theoretical model or framework as the first step in intervention development to inform the selection of potential intervention components and to explain the mechanisms through which the intervention is predicted to act. We selected a comprehensive framework, the Behaviour Change Wheel (BCW), which has a model of behaviour within it [146]. The BCW is a synthesis of 19 frameworks of behaviour change found in the research literature [146] and is broad enough to be applied to any behaviour in any setting [72]. The

BCW was developed to assist in the design of interventions with particular emphasis on involving theory and evidence synthesis as specified by the MRC guidance [72]. The BCW consists of three layers for identifying: i) the sources of the behaviour that could be targeted by the intervention, ii) the intervention functions to choose from and iii) the types of policy that could be used to deliver these intervention functions (see Figure 2.1) [72,146]. I will focus on the first layer of the BCW, which is a model of behaviour (referred to as the COM-B model), to guide intervention development.

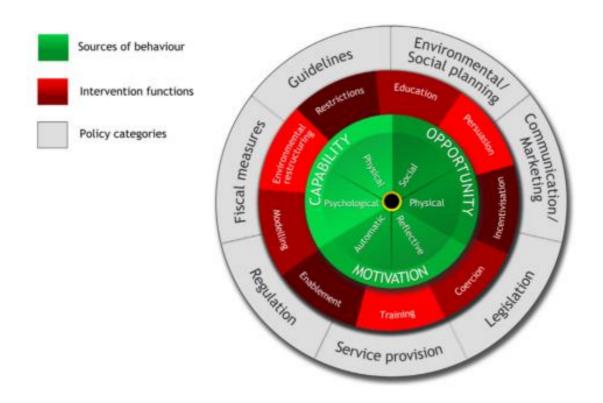


Figure 2.1: The Behaviour Change Wheel – a framework for intervention design (reproduced from Michie et al., 2011 [146])

2.2.1 The COM-B Model of Behaviour

The COM-B model conceptualises behaviour as part of a system of interacting elements that involves 'capability', 'opportunity' and 'motivation' (see Figure 2.2) [146,147]. For any behaviour to occur at a given moment, there must be the capability and opportunity to engage

in the behaviour, and the motivation to engage in the behaviour must be greater than for any competing behaviours [147].

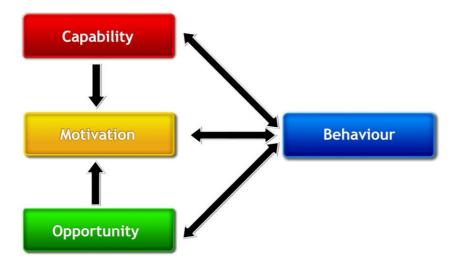


Figure 2.2: The COM-B model – a framework for understanding behaviour (reproduced from Michie et al., 2011 [146])

Each of the components of the COM-B model can be divided into two types: capability may be psychological or physical, opportunity may be social or physical, and motivation may be reflective or automatic [72,146]. Capability is conceptualised as the capacity to perform the behaviour. Psychological capability includes having the knowledge or skills to perform the behaviour, and the capacity to engage in the necessary thought processes. Physical capability includes having the necessary physical skills, strength or stamina to perform the behaviour. Opportunity is all of the external factors that prompt the behaviour or make it possible. This includes social opportunities created by the cultural environment (e.g. interpersonal influences, social cues, cultural norms) and physical opportunities created by the environment (e.g. time, resources, locations, physical barriers). Motivation is considered to be all the brain processes that energise and direct behaviour and is divided into reflective and automatic processes. Reflective processes involve self-conscious planning and evaluations

(beliefs about what is good or bad) and automatic processes involve emotional reactions, desires, impulses, inhibitions, drive states and reflex responses.

The COM-B model of behaviour provides a good theoretical model to use for designing a complex behaviour change intervention as: i) it considers all the individual determinants of behaviour which make it easier to identify appropriate interventions, ii) it can be applied at an individual, community or population level, and iii) it is applicable to all health-related behaviours.

Once the target behaviour has been determined, the COM-B model can be used to conduct a behavioural analysis to identify systematically which components of the model need to change for the target behaviour to occur [146]. This behavioural analysis is a crucial first step in designing behaviour change interventions [72]. The COM-B model is comprehensive yet simple enough to use as an over-arching model within which to consider other theories. For example, the two general types of motivation in the COM-B model reflect the different levels of the motivational system described in PRIME Theory of Motivation, a comprehensive and hierarchically structured model of the motivational influences on behaviour [148]. The components of the COM-B model of behaviour can be further elaborated by linking them with another framework, the Theoretical Domains Framework (TDF) [72,149,150].

2.2.2 Theoretical Domains Framework

The Theoretical Domains Framework (TDF) is an integrative framework consisting of 14 theoretical domains that can be relevant to intervention studies [149,150]. During the development of the TDF, an expert group identified the key influences on behaviour change described by behaviour change theories, and grouped them into 14 domains. The TDF was developed in a collaboration between psychologists and implementation researchers [149,150]. Each COM-B component [149] can be mapped onto one or more domains of the

TDF. Using the TDF in conjunction with the COM-B model of behaviour provides a more detailed structure to the behavioural analysis and, therefore, is more useful in informing behaviour change interventions [149,151]. Table 2.1 provides a list of each of the domains in the TDF, their definitions and the theoretical constructs associated with each domain.

Table 2.1: Theoretical Domains Framework (TDF) linked to COM-B components and associated theoretical constructs (adapted from [149])

COM-B	TDF domain	Definition of domain	Theoretical constructs represented within
component/s			domain
Psychological	Knowledge	An awareness of the existence of something	Knowledge (including knowledge of condition/
capability			scientific rationale); procedural knowledge;
			knowledge of task environment
	Memory, attention	The ability to retain information, focus	Memory; attention; attention control; decision
	and decision	selectively on aspects of the environment and	making; cognitive overload/ tiredness
	processes	choose between two or more alternatives	
	Behavioural	Anything aimed at managing or changing	Self-monitoring; breaking habit; action planning
	regulation	objectively observed or measured actions	
Physical	Skills	An ability or proficiency acquired through	Skills; skills development; competence; ability;
capability		practice	interpersonal skills; practice; skill assessment
Reflective	Social/ professional	A coherent set of behaviours and displayed	Professional identity; professional role; social
motivation	role and identity	personal qualities of an individual in a social	identity; identity; professional boundaries;
		or work setting	professional confidence; group identity;
			leadership; organisational commitment

СОМ-В	TDF domain	Definition of domain	Theoretical constructs represented within
component/s			domain
	Beliefs about	Acceptance of the truth, reality, or validity	Self-confidence; perceived competence; self-
	capabilities	about an ability, talent or facility that a	efficacy; perceived behavioural control; beliefs;
		personal can put to constructive use	self-esteem; empowerment; professional
			confidence
	Optimism	The confidence that things will happen for	Optimism; pessimism; unrealistic optimism;
		the best or that desired goals will be attained	identity
	Beliefs about	Acceptance of the truth, reality, or validity	Beliefs; outcome expectancies; characteristics of
	consequences	about outcomes of a behaviour (in a given	outcome expectancies; anticipated regret;
		situation)	consequents
	Intentions	A conscious decision to perform a behaviour	Stability of intentions; stages of change model;
		or a resolve to act in a certain way	transtheoretical model and stages of change
	Goals	Mental representations of outcomes or end	Goals (distal/ proximal); goal priority;
		states that an individual wants to achieve	goal/target setting; goals (autonomous/
			controlled); action planning; implementation
			intention

COM-B	TDF domain	Definition of domain	Theoretical constructs represented within
component/s			domain
Automatic	Reinforcement	Increasing the probability of a response by	Rewards (proximal/ distal, valued/ not valued,
motivation		arranging a dependent relationship, or	probable/improbable); incentives; punishment;
		contingency, between the response and a	consequents; reinforcement; contingencies;
		given stimulus	sanctions
	Emotion	A complex reaction pattern involving	Fear; anxiety; affect; stress; depression; positive/
		experiential, behavioural, and physiological	negative affect; burn out
		elements, by which the individual attempts to	
		deal with a personally significant matter or	
		event	
Physical	Environmental	Any circumstance of a person's situation or	Environmental stressors; resources/ material
opportunity	context and	environment that discourages or encourages	resources; organisational culture/ climate; salient
	resources	the development of skills and abilities,	events/ critical incidents; person x environment
		independence, social competence, and	interaction; barriers and facilitators
		adaptive behaviour	

COM-B	TDF domain	Definition of domain	Theoretical constructs represented within
component/s			domain
Social	Social influences	Those interpersonal processes that can cause	Social pressure; social norms; group conformity;
opportunity		individuals to change their thoughts, feelings,	social comparisons; group norms; social support;
		or behaviours	power; intergroup conflict; alienation; group
			identity; modelling

TDF: Theoretical Domains Framework

COM-B: 'Capability', 'Opportunity', 'Motivation', and 'Behaviour'

2.3 Behavioural Analysis of Excessive Alcohol Consumption

Excessive alcohol consumption is a complex behaviour and may involve average alcohol consumption above recommended limits, episodic alcohol consumption that exceeds a safe frequency, or episodic alcohol consumption in situations that risk significant harm. There may be a difference between the factors underpinning the first drink of a drinking session and subsequent drinks, and between different types of drinking occasion or practices such as drinking at home alone, going out for a meal, and mixed location heavy drinking [16].

This intervention is targeted at an individual level [152] as it will be delivered through a smartphone app. Despite targeting individuals, the aim of this intervention is to reduce hazardous or harmful drinking at the population level. As this intervention is targeted at individuals via an app there are some factors associated with excessive alcohol consumption that are not targeted. For example, there are factors relating to physical opportunity that act at a population level, such as affordability, availability and advertising, that have evidence for their effectiveness [41,153–159]. However, these factors acting at a population level are outside the scope of this app as they would require the support of government through fiscal or legislative measures [160].

The COM-B model of behaviour [146] and the Theoretical Domains Framework [72] provided the structure within which to conduct the behavioural analysis. The behavioural analysis involved identifying intervention components that were both likely to be effective at targeting the factors associated with excessive alcohol consumption and were feasible to include in an app. These intervention components are summarised in Table 2.2 and elaborated on below with details of the factor associated with excessive alcohol consumption that each intervention component is targeting.

Table 2.2: Intervention components and the associated TDF domain and COM-B component/s

Intervention components	Domain/s from the TDF	Component/s of the COM-B
		model
Provision of information	Knowledge	Psychological capability
Normative feedback	Knowledge	Psychological capability
	Social influences	Social opportunity
Cognitive bias modification	Memory, attention and	Psychological capability
	decision processes	
	Reinforcement	Automatic motivation
Self-monitoring	Behavioural regulation	Psychological capability
Action planning		
Identity change	Social/ professional role and	Reflective motivation
	identity	
	Optimism	Reflective motivation
Evaluation of benefits and	Beliefs about consequences	Reflective motivation
costs of drinking		
Goal setting	Goals	Reflective motivation

TDF: Theoretical Domains Framework

COM-B: 'Capability', 'Opportunity', 'Motivation', and 'Behaviour'

2.3.1 Provision of information

People may drink excessively because they do not know about the risks associated with their behaviour or are unaware of exactly how much they drink. The 2013 Health Survey for England found that people were more likely to be wrong than right about what the daily drinking limits were [161]. This suggests many people may not know they are drinking above the guidelines for low-risk drinking. The UK government guidelines for low-risk drinking have been recently updated [2]. Whilst there has been a lot of publicity surrounding this, there was a short-term increase in knowledge but not in awareness [162].

Knowledge of the associated risks of harmful health behaviours does not necessarily stop individuals engaging in them [163]. This suggests that knowledge of the risks of excessive alcohol consumption or what constitutes excessive consumption will not necessarily translate into a reduction in alcohol consumption. Whilst public information and education-type programmes have a role in providing information, education alone does not appear to reduce alcohol-related harm [41].

Many drinkers do not consider the levels of alcohol consumption associated with harmful drinking to be too heavy [164] and also underestimate their own alcohol-related risk [165]. Perceived personal relevance is considered critical to the impact of threat information [166]. This suggests that many harmful drinkers would not consider information about alcohol-related risks relevant to them, which means that simply educating people about these risks, whilst important, may not be enough to effect behaviour change. There may be some drinkers who would consider information about alcohol-related risks of personal relevance to them but then process that information defensively [167]. Defensiveness often occurs when individuals encounter information that is personally relevant and inconsistent with their self-beliefs or goals (e.g. good health) [168].

Self-Affirmation Theory proposes that information threatening an individual's self-image is processed defensively [169], and that improving someone's self-image (e.g. by reflecting on values important to them) reduces defensive processing of that threatening information [170]. This type of self-affirmation manipulation helps people process health risk information in a non-defensive manner, thereby increasing the chances that it produces a change in the target behaviour (e.g. reduction in alcohol consumption [171]).

2.3.2 Normative feedback

Norms are perceptions and beliefs about what counts as 'normal' behaviour. Most people have beliefs about how much other people drink [172] and, as a result, a belief about how their drinking compares with others.

Normative misperceptions about alcohol use refer to the phenomenon that people underestimate their own alcohol use compared with others. These normative misperceptions exist in populations of heavy drinkers [173,174] and college or university students [175–179]. Normative misperceptions about alcohol use have not been studied in the general population yet.

Evidence for the causal role of normative misperceptions in excessive alcohol consumption comes from the Social Norms Theory [180]. This theory proposes that people behave in a way that attempts to conform to the perceived norm. This can result in people behaving in ways that are not consistent with their own beliefs and values in their attempt to reach the perceived norm [181]. The theory predicts that correcting the misperceptions of these perceived norms is likely to result in a decrease of the problem behaviour.

This aspect of the theory is supported by the findings that normative misperceptions about alcohol use are predictors of higher actual alcohol use [175,178,182–184] and improving an individual's knowledge about how their alcohol use compares with others moderates their subsequent alcohol use [172–174,178,179,185–188]. Computer-delivered interventions for alcohol reduction that have used this social norms approach and provided normative information to participants were significantly better at reducing average consumption than interventions not using this approach [189]. A review on providing social norms information for alcohol misuse in university and college students found small effects on a number of alcohol-related outcomes (frequency of alcohol consumed, alcohol-related problems and

quantity of alcohol consumed when binge drinking) at a follow-up of four or more months [190].

The finding that normative feedback can reduce subsequent alcohol use indicates that normative misperceptions play a role in excessive alcohol consumption and may be a suitable target for interventions aiming to reduce alcohol consumption. As well as being a suitable target, it appears that personalized normative feedback as part of a web-based intervention may be acceptable amongst university students [191].

2.3.3 Cognitive bias modification

Behaviours can be conscious, goal-driven actions with reflective processes behind them, though they are also driven by automatic, non-conscious processes [192–194]. The PRIME Theory of Motivation and dual-process models of behaviour propose that behaviour is determined by two systems: i) a fast, impulsive, implicit automatic system and ii) a slow, controlled reflective system; and that these systems may act in conflict with one another [148,195–197]. These theories suggest that excessive alcohol consumption occurs, in part, when the automatic processes (such as the impulse to drink) overcome the inhibitory, reflective response to refrain [198].

These automatic processes include cognitive biases towards alcohol-related cues or stimuli such as those that capture attention (attentional bias), activate positive associations in memory (memory bias), or elicit approach tendencies (approach bias) [199]. The approach bias towards alcohol cues is stronger in heavier drinkers [200,201] and repeated alcohol use can result in biases in the processing of alcohol-related information [202–204]. Cues related to appetitive rewards, such as those associated with alcohol consumption, are more likely to result in an individual approaching that cue [205,206] which also increases the positive evaluations of those cues [207,208].

The reflective system involved in determining behaviour draws on the cognitive resources available [196]. If the cognitive resources are reduced or unavailable, then the automatic system gains more weight in determining behaviour [196]. Alcohol consumption can affect the availability of cognitive control resources [194,209] and can disrupt the normal self-regulation of behaviour achieved through reflective processes [210–212]. This finding is in line with the alcohol myopia theory that proposes alcohol consumption narrows focus to only the most salient and proximal cues in the environment and that reflective processes involving goals and standards are weakened [213]. Alcohol consumption is an important moderator of the relative influence of the reflective and impulsive systems on alcohol consumption itself. This highlights the fundamental importance of addressing the impulsive processes in the automatic system in behaviour change interventions in general, and particularly those aimed at reducing excessive alcohol consumption.

Cognitive biases (e.g. approach bias, attentional bias) involved in the automatic system are largely unaffected by interventions targeting conscious information or processes [214,215]. These automatic processes could explain why some individuals continue to consume alcohol at risky levels despite being aware of the negative consequences [216]. The targeting of nonconscious, automatic processes in behavioural interventions is largely untested [217]. The determinants and processes by which automatic impulses exert an influence on health behaviour have received far less attention than the models for reasoned action to engage in certain behaviours. There is both theoretical and empirical evidence to suggest that behavioural interventions targeting both the reflective and automatic systems may be more effective than either one alone [194,217–219].

There are a number of ways of addressing the automatic processes involved in alcohol consumption. Inhibitory control is the ability to stop, change or delay a behavioural response [220] and is an important part of executive functioning [221]. Deficits in inhibitory control

have been associated with increased alcohol consumption [222]. Inhibitory control training has been used in an attempt to improve cognitive control [223,224]. A small but significant effect was found on alcohol consumption in the laboratory in two meta-analyses [225,226]. Larger effect sizes for motor training were detected [226] and the authors of this meta-analysis emphasised the need for further research to translate these findings outside of the laboratory [226].

Another way to target non-conscious processes is by addressing the automatic, cognitive biases that guide alcohol use [227]. The targeting of cognitive biases is referred to as cognitive bias modification (CBM) and, when successful in changing cognitive biases, is associated with a reduction in alcohol consumption [224,228–231]. CBM has been found to be effective at altering the cognitive biases of attentional bias [230,232–235], memory bias [223,231] and approach bias [228,229,236]. Whilst the evidence is not conclusive, retraining approach biases appear to have a greater efficacy in reducing alcohol consumption [228,229,236] than retraining other cognitive biases such as attentional biases [234].

2.3.4 Self-monitoring

Self-monitoring is proposed to help individuals regulate their behaviour [149] and is recommended in the National Institute for Health and Care Excellence (NICE) clinical guidance as an effective technique for alcohol reduction [152]. Empirical evidence for the effectiveness of self-monitoring in health behaviour change has been found for controlling weight and blood-glucose levels [237–240] and improving healthy eating and physical activity [241]. Self-monitoring is also associated with up to 70% of the effect size of brief interventions to reduce excessive alcohol consumption in a review of behaviour change techniques [242].

Self-monitoring is related to core elements of Control Theory [243], which proposes that behaviour is goal-driven and that feedback enables people to assess their performance in relation to their goals and make adjustments toward it accordingly. Behaviour change interventions that use behaviour change techniques relevant to Control Theory (self-monitoring in combination with at least one other) have been found to be significantly more effective than interventions not including those techniques [241,244,245].

2.3.5 Action planning

Action planning, like self-monitoring, is proposed to help individuals regulate their behaviour [149]. The NICE clinical guidance also recommends the use or facilitation of action planning in behaviour change interventions for alcohol reduction [152]. Action planning is related to another core element of Control Theory, reducing discrepancies between goals and observed behaviour [243]. Action plans detailing the steps necessary to achieve a specific goal have been found to increase physical activity [246], enhance behaviour change in patients [247] and reduce alcohol consumption [248–250]. 'Implementation intentions', a form of action plan that enable the setting of if/then conditions for future events [251], increased goal-attainment rates for health behaviour such as regular breast examinations [252], engaging in exercise [253] and alcohol reduction [248–250].

2.3.6 Identity change

Excessive drinking is central to many peoples' sense of self or identity, particularly students [254]. The role of identity in behaviour is a key principle of PRIME theory [148], a broad model of the motivational influences on behaviour including self-conscious evaluations, plans, and motives (the reflective system) and automatic responses and impulses (the automatic system). Identity is part of the reflective system and is defined as the mental representations

(thoughts and images) of one's self as one is or aspires to be, and the feelings associated with these [148].

Identity is considered to have an important role in driving behaviour by generating strong wants and needs against the competing impulses on a moment-to-moment basis [148,255]. These wants and needs are the tendencies towards or away from particular identities and have been proposed as the mechanism by which identity drives behaviour by a number of theories, though the details differ [148,255–258].

The Social Identity Theory proposes that individuals identify themselves with their social groups and behave in a way that matches the characteristics of that group [256]. The characteristics of the social group that an individual feels part of can provide them with a definition of who they are and how they behave [259]. This theory proposes that people behave in this way to maintain a positive social identity within their group and because of perceived pressure from within the group to do so [256]. The extent the effect of these social norms has on behaviour is dependent on how much the individual identifies with the group [256].

A related theory, Identity-Based Motivation Theory, argues that people are motivated to engage in behaviours that are in line with their identity regardless of the associated benefits or costs [257]. Therefore, current or possible future identities triggered by the context at any given moment will influence an individual's self-control to engage in identity-congruent behaviour. When a behaviour becomes related to someone's identity, the behaviour is engaged in regardless of whether the health consequences are positive or negative [257].

Social Identity Theory and Identity-Based Motivation Theory both propose that identity drives behaviour. Identity-Change Theory, on the other hand, emphasises a bidirectional

nature between identity change and behaviour change with both interacting with and being dependent on each other [258]. This theory proposes that a conflict between someone's values or goals and their behaviour can initiate a step towards behaviour change. If the step towards behaviour change is successful, then this can lead to an identity change that will further strengthen the new behaviour.

Despite slight differences in the proposed mechanisms by which identity drives behaviour, these theories all propose a fundamentally central relationship between identity change and behaviour change. We will use the PRIME theory of motivation, as it is a broad structured model, to consider further the relationship between identity and behaviour change. PRIME theory proposes that identity is a source of motives, self-regulation and stability of behaviour, consisting of three elements: labels, rules and attributes [148]. Labels are the categories we think we belong to (e.g alcoholic); attributes are the features we ascribe to ourselves (e.g. good friend, responsible drinker); and the rules refer to the imperatives that govern our behaviour about what we do and do not do (e.g. don't get hangovers).

Identity change is a key starting point for deliberate behaviour change and involves creating a new label and a new set of rules governing behaviour. Identity change is an act that can occur when the desire to make the change is greater than the desire not to. Implementing behaviour change in the face of conflicting wants and urges requires self-control and consumes mental resources. New personal rules with clear boundaries, as part of an identity change, can reduce the conflict and effort required to suppress opposing desires when they occur. The new labels and attributes, and rules that govern the new behaviour provide stability to the behaviour, which can help its maintenance [148,260]. Behaviour change is maintained when the labels, attributes and rules arising from the new identity are either stronger than the desires to revert to the previous behaviour or able to overcome habitual or automatic impulses.

Behaviour change through a deliberate identity change is achieved with conscious effort involved by creating a new label or set of rules to govern behaviour [255]. Some processes involved in identity are automatic, for example, attempts to defend one's self-esteem against threats to one's identity [261]. These automatic identity processes are also important to consider when initiating a change in behaviour through identity change.

There is little research on the role of identity in relation to excessive drinking and it tends to focus on students. In two studies, the extent to which students' identity was related to alcohol was a predictor of their self-reported alcohol consumption and problematic alcohol-related behaviours [262,263]. A behaviour change intervention using an identity-change approach has been found to result in a reduction in alcohol consumption that appeared to be driven by a change in identity [264].

Evidence from smoking cessation literature supports these findings, showing that identity change may be an effective intervention technique. Strengthening an identity associated with being an ex-smoker was associated with increased four week abstinence rates (both carbon-monoxide verified and self-reported) in a systematic analysis of English Stop Smoking Services treatment manuals [265]. The nature of a smoker's identity was found to play an important role in smoking cessation [266] and a positive smoker identity predicted failure to make a quit attempt indicating this may be an important barrier to behaviour change [267]. These empirical findings support the theoretical evidence suggesting that changing the extent to which alcohol is related to identity could help to support a change in alcohol consumption.

2.3.7 Evaluation of benefits and costs of drinking

The beliefs about potential consequences of drinking in terms of the positive (benefits) and negative (costs) outcome expectancies are important in influencing drinking behaviour [268]. Alcohol expectancies are the positive (i.e. benefits) or negative (i.e. costs) beliefs about the

effects of alcohol consumption. These effects could be emotional, cognitive or behavioural. Alcohol is often considered to be a global, positive transforming agent and positive alcohol expectancies include things such as increased social confidence and relaxation. Negative alcohol expectancies are, for example, the state you anticipate being in after a heavy night of drinking, regrets about your behaviour or poor decision-making. Alcohol expectancies are strongly related to drinking patterns in the general population [269–271].

2.3.8 Goal setting

Goal setting can enhance self-regulation [272,273] through its effects on motivation, learning, self-efficacy and self-evaluations of progress [274]. Goal setting is recommended by NICE clinical guidance for its inclusion in alcohol reduction interventions [152]; it is a common strategy for health behaviour change [275] and has a broad evidence base [276,277]. Goal setting is another core element of Control Theory [243], which proposes that behaviour is goal driven and feedback allows an individual to determine their position in relation to their goal and make adjustments toward it accordingly.

2.4 Discussion

The overall approach to intervention development was that of best practice as it followed the MRC research guidance for developing complex interventions [139]. The MOST approach also guided the development and evaluation of the intervention, as this approach is more suited to digital interventions and the optimisation of an intervention through interim evaluations of modules [278]. Both of these approaches highlight the importance of using a theoretical framework.

In this context of intervention development, the COM-B model was used as the framework to conduct a behavioural analysis and guide the development of the intervention. The COM-B

model is a formal integrative theory that is part of a broader guide for intervention development that is comprehensive yet simple enough to use as an over-arching model. The COM-B model was chosen as it provides a method for understanding the target behaviour in context and considers all of the individual determinants of behaviour and their interactions [146]. Many behaviour change theories tend to focus on reflective motivation and do not consider the role of automatic motivation, or capability and opportunity in determining behaviour. As well as identifying determinants of behaviour, the COM-B model also enables the identification of levers for behaviour change – barriers or facilitators – that other theoretical frameworks, such as Intervention Mapping [279], do not include. However, the generality of the COM-B model makes it difficult to directly test as a theory of behaviour change, and may have caused a lack of domain-specific insights from more specific theories of alcohol misuse or addiction. Nevertheless, despite these limitations, the COM-B model provides a good starting point for intervention development as it allows a fairly comprehensive overview of all the relevant behavioural determinants and levers for behaviour change without focusing too early on one specific influence. Its generality also means that it can be applied to other health-related behaviours in any setting and is not limited to this particular behaviour of excessive alcohol consumption.

The COM-B model can link the behavioural analysis to the Behaviour Change Wheel and therefore to policy categories, intervention functions and specific BCTs [146]. The Behaviour Change Wheel and its accompanying guide to intervention development provide a very structured method to follow when developing any behaviour change intervention. Whilst it is useful to have a guiding approach, a rigid step-by-step method to intervention development tends not to be the way development actually occurs. Following a theoretical framework perfectly is very difficult given any time constraints as development rarely follows a smooth path. Therefore, it is usually unrealistic to follow current theoretical frameworks for guiding

intervention development exactly, which is why the guiding principles were used here, rather than the step-by-step method of the Behaviour Change Wheel.

Other specific, individual theories can be considered within the behavioural analysis based on the COM-B model and the TDF. However, a comprehensive review of all the relevant behaviour change theories was not conducted. Instead, a more time efficient method was chosen whereby relevant theories to the potential behavioural determinants or behaviour change levels identified were considered in the context of the behavioural analysis. The behavioural analysis using the COM-B model of behaviour and TDF provided a broad model within which to identify potential intervention components that were not only likely to be effective at targeting the factors associated with excessive alcohol consumption but also were feasible to include in an app as a module. A number of intervention components meeting these criteria were identified in the behavioural analysis.

Relying solely on existing empirical evidence would limit this intervention to doing what has been done before. As digital interventions for reducing excessive drinking are a relatively recent field, limiting this to intervention components with empirical evidence may miss a novel and potentially effective component that has yet to be evaluated. Therefore, it is important to use evidence from multiple sources, including the behavioural analysis, and to triangulate these findings, as there is no clear existing evidence base to start from. Each source of evidence will have its own advantages and disadvantages as a method of capturing insightful knowledge. The behavioural analysis provides a comprehensive oversight of potential behavioural determinants and behaviour change levers that are based on published theories though does have a publication bias.

Through using multiple sources, if the same intervention component arises in multiple sources then there can be increased confidence in that particular component as effective at

reducing excessive alcohol consumption. The next step in developing the app was to conduct additional studies to prioritise the intervention components to include in the app for evaluation and to ensure the identification of potentially effective intervention components was as comprehensive as possible. The additional studies that were conducted to provide an additional source of evidence for selecting the intervention components to include in the app are described in chapters 4 through to 6. The strengths and weaknesses of each of these approaches are detailed in the relevant chapter discussion.

Chapter 3 - User characteristics of a smartphone app to reduce alcohol consumption (Study 1)

Abstract

Digital interventions are available to help people reduce their alcohol consumption, but it is not known who uses these interventions and how this treatment-seeking group compares with the general population of drinkers. The objective of this study was to compare the sociodemographic and drinking characteristics of these users both with the general population of drinkers in England and with website users of the same intervention.

User data were from the 'Drinks Meter' app and website, and from a nationally representative cross-sectional survey of the general population. Participants were drinkers aged 16 and over in England. Data were collected on participants' age, gender, region, sexual orientation, social grade and AUDIT score. Regression analyses were conducted to assess differences in sociodemographic and drinking characteristics between groups.

Drinks Meter app users were younger, more likely to be from the South, not heterosexual, less likely to be of a lower social grade, and had a higher mean AUDIT score compared with drinkers of the general population. Drinks Meter app users were younger than website users of the same intervention and reported greater alcohol consumption and related harms.

The findings from this study suggest that apps for reducing alcohol consumption are being used by those who report greater alcohol consumption and alcohol-related harms than the general population of drinkers in England. Further research is needed to assess whether these findings are generalisable to other alcohol reduction apps. These results support the

development of an app to reduce excessive alcohol consumption as apps appear to be used by excessive drinkers and not just by the 'worried well'.

3.1 Introduction

As established in the general introduction (see Chapter 1), excessive alcohol consumption is a serious and prevalent problem both globally and in the UK. Approximately 43% of adults worldwide and 88% in western Europe drink alcohol [4]. The global prevalence of alcohol use disorders is 4.9% compared with a prevalence of 6.1% in western Europe [4]. In the UK specifically, the estimated annual cost to society due to health, social and criminal implications is more than £21 billion [280] and 10.8 million adults in England are at increased alcohol-related risk from their drinking behaviour [281,282]. A number of socio-demographic characteristics are related to alcohol consumption including age, gender, socioeconomic status, sexual orientation and region of England [9].

It was also established in the general introduction (see Chapter 1) that brief interventions are an effective strategy for reducing excessive alcohol consumption [43] though are rarely implemented. This is due to a number of barriers to their delivery including time constraints, lack of support and lack of training [50]. As a result, brief interventions are provided to less than 10% of excessive drinkers in England by their general practitioner (GP) [48]. The excessive drinkers who receive an intervention from their GP, compared with those who do not, are more likely to be male and have higher scores on the Alcohol Use Disorders Identification Test (AUDIT) [48], indicating that they are at a higher level of alcohol-related risk.

Digital interventions can overcome a number of barriers to the implementation of face-to-face brief interventions and have been found to be effective at reducing alcohol consumption

[283,284]. Digital technology is increasingly pervasive; two-thirds of adults in England own a smartphone, currently the most widely owned internet-enabled device, and over half of all households have a tablet computer [81]. This means digital interventions have the potential to reach a greater proportion of the population than face-to-face brief interventions. Digital interventions also have low incremental costs and avoid any stigma associated with providing or receiving help in person. Digital interventions include smartphone apps that have the additional advantage of being constantly available and accessible to the user. This means that apps have the potential to engage people in real time and in their everyday situations as almost two-thirds of smartphone users download apps [81].

A number of apps to aid drinkers in reducing excessive alcohol consumption are available for both iOS and Android smartphones [106] though none have been formally evaluated [107] and there are no reports on the characteristics of their users. However, there is literature regarding apps for more specific alcohol problems, including two for supporting individuals in the US with recovery from alcohol use disorders [109,110] and two apps targeting risky alcohol use in Swedish university students [114]. The two apps for supporting recovery from alcohol use disorders are 'A-CHESS' (Alcohol - Comprehensive Health Enhancement Support System) [109] and 'LBMI-A' (Location-Based Monitoring and Intervention for Alcohol Use Disorders) [110]. There is preliminary evidence that both are effective at supporting recovery from alcohol use disorders. The two apps appeared to be used by different groups of people. The 'LBMI-A' app users had a mean age of 34 years, about half were male (54%), half were white (50%), and the majority were employed (79%) [110]. The users of the 'A-CHESS' app had a mean age of 38 years, and the majority were male, white and unemployed [109]. This difference in user characteristics probably relates to the availability of the apps: the 'A-CHESS' app users were enrolled into the trial as part of residential treatment whilst the 'LBMI-A' app trial recruited individuals from a community. Users were only included in both trials if they

had an alcohol use disorder and both trials took place in the US so cannot indicate who in the general population of drinkers in the UK are spontaneously seeking help with reducing excessive alcohol consumption. The two apps targeted at risky alcohol use amongst Swedish university students ('Promillekoll' and 'PartyPlanner') involved blood alcohol concentration calculators. Both apps were evaluated and neither had a statistically significant positive effect on reducing alcohol use [114]. The users of these apps had a mean age of 25 and about half were female (52%) [114]. These two apps included treatment-seeking users who consumed excessive levels of alcohol though the population was limited to Swedish university students rather than the general population of drinkers in the UK.

App-based interventions are just one type of digital intervention and websites are another mode of delivery for alcohol reduction interventions. Two web-based interventions for supporting the general population of drinkers to reduce their alcohol consumption have reported their user characteristics. These web-based interventions are 'Down your Drink' and 'AlcoholScreening.org'. The Down your Drink website provides a six-week intervention for drinkers that encourages the adoption of a healthy pattern of drinking and the reduction of alcohol-associated harm [64]. The demographic characteristics for the first 10,000 users of the Down your Drink intervention were reported [285]. Down your Drink users had a mean age of 37 years, about half were female (51%), the majority were white (96%) and lived in the UK (83.9%) and reported occupations from high socioeconomic strata [285]. Users of both the Down your Drink and control website showed similar significant reductions in self-reported indicators of dependency and alcohol-related problems [285]. The AlcoholScreening.org website provides a self-screening service to assess the user's alcohol consumption and provide feedback on its consequences and norms [286]. The AlcoholScreening.org users had a mean age of 32 years and the majority were men (66%). The majority of AlcoholScreening.org users had an AUDIT score of 8 or above (65%) indicating that they were excessive drinkers.

Both the Down your Drink and AlcoholScreening.org website-based interventions reported the characteristics of a large number of users (10,000 and nearly 40,000, respectively) and both websites could be accessed for free. Thus, the user characteristics are likely to provide an accurate reflection of those drinkers who seek support with alcohol reduction from websites. However, there has been no direct assessment of whether users of the same intervention content differ as a function of the digital mode of delivery (i.e. if website users differ from app users).

There is a lack of information about the characteristics of those who download the apps that are currently available to support hazardous and harmful drinking, and whether the treatment-seeking group are in need of treatment or are the 'worried well'. If a particular socio-demographic group predominantly downloads the apps, then the design of the new app being developed should be targeted at this group. It is also not clear how this app treatment-seeking group compares with the general population of drinkers or a group seeking treatment via another digital platform such as a website. It is essential to understand whether these apps are being used by excessive drinkers, and therefore those in need of treatment, as otherwise this would be a substantial limitation to the potential usefulness of apps in delivering alcohol reduction interventions. It is also important to understand who is accessing these interventions in order to tailor materials to excessive drinkers who are likely to use apps, to highlight to healthcare providers which groups are unlikely to seek digital help unprompted and to establish whether there are differences between users of different digital interventions.

The user characteristics of apps were assessed for 'Drinks Meter', a free app that provides the user with instant feedback on their drinking and how the user compares with other users.

There are a number of apps relating to alcohol reduction available in the UK [106] though few have transparent intervention content and data openly available for analysis. However, the

Drinks Meter app has transparent intervention content and the data was available for analysis based on an existing collaboration with Adam Winstock at Kings College London. Drinks Meter also appears popular with users having a good average star rating from users on both iTunes (5/5) and Google play store (4.1/5), and it was the most highly praised app in a recent analysis of app store reviews of alcohol reduction apps [90]. The Drinks Meter intervention can also be accessed via a website which allows us to compare apps and websites to assess whether their respective treatment-seeking groups differ in terms of their socio-demographic and drinking characteristics.

The aim of this chapter was to compare the socio-demographic and drinking characteristics of users of a popular smartphone app with the general population of drinkers in England, and to compare the app users with users of a website version of the app.

3.1.1 Research questions

- 1. What are the socio-demographic and drinking characteristics of users in England of a popular app (Drinks Meter) to help reduce alcohol consumption?
- 2. How do these socio-demographic and drinking characteristics compare with the general population in England of
 - a. drinkers?
 - b. drinkers who own a smart digital device with internet access?
- 3. How do the socio-demographic and drinking characteristics differ between app and website users of the Drinks Meter intervention?

3.2 Methods

3.2.1 Design

This was an observational study involving anonymised and automated data collection from users of a popular intervention available through an app and website called Drinks Meter between November 2013 and February 2015. Drinks Meter is a free digital intervention that provides the user with instant feedback on their drinking and how the user compares with other users.

The socio-demographic and drinking characteristics of the general population of drinkers in England were assessed using the Alcohol Toolkit Study (ATS), a national monthly survey tracking alcohol consumption patterns in representative samples of adults in England [287]. The ATS is a cross-sectional, household, monthly survey of a representative sample of adults in England [287] with data collected between March 2014 and December 2015. The ATS is conducted by Ipsos Mori and uses a hybrid of random location and quota sampling [287]. England is split into 171,356 areas, each comprising about 300 households, stratified according to a geo-demographic analysis of the population [287]. Areas are then randomly allocated to interviewers, who conduct interviews within that area until the quota based on the probability of being at home is fulfilled. This sampling method is often considered superior to conventional quota sampling [287] and has been shown to result in a sample that is nationally representative in its socio-demographic composition [288].

3.2.2 Study sample

Participants were included in the analysis if they met the following criteria: aged 16 and over, lived in England, and provided complete data (9.0% of Drinks Meter data and 0.9% of ATS data had missing cases). Participants who reported 'never' to the question 'How often do you

have a drink containing alcohol?' were excluded. This resulted in a total of 27,358 participants – 818 users of the Drinks Meter app; 24,299 from the ATS (11,990 who reported owning a smart digital device with internet access), and 2241 users of the Drinks Meter website. The sample size was determined pragmatically based on the available participant data that met the inclusion criteria.

3.2.3 Measures

Socio-demographic characteristics of age (in years), gender (male/female), social grade (ABC1/C2DE), region in England (North/South), and sexual orientation (heterosexual/not heterosexual) were measured. Social grade in the ATS was assessed using the National Readership Survey social-grades system (ABC1=higher and intermediate professional/managerial, and supervisory, clerical, junior managerial/administrative/professional and C2DE=skilled, semi-skilled, unskilled manual and lowest grade workers or unemployed) [289]. Data on social grade from the Drinks Meter intervention were derived from occupation into ABC1 or C2DE classifications. Region in England was defined by government office region (North= North East, North West, Yorkshire and the Humber, East Midlands, and West Midlands; and South= London, South East, South West, and East of England). Sexual orientation was assessed by asking participants to self-identify as heterosexual, bisexual, homosexual, or prefer not to say. These responses were then dichotomised into heterosexual and not heterosexual (bisexual, homosexual, and prefer not to say).

Drinking characteristics of participants were based on the Alcohol Use Disorders

Identification Test (AUDIT) questionnaire, a gold-standard measure for assessing alcohol
consumption, harmful drinking and alcohol dependence [3]. This 10-item questionnaire
assesses alcohol consumption, alcohol dependence and harmful drinking. The possible scores

range from 0 to 40 and are categorised into four different zones indicating lower-risk drinking (0-7), hazardous drinking (8-15), harmful drinking (16-19) and at-risk of alcohol dependence (20-40). The AUDIT alcohol consumption (AUDIT-C) questionnaire consists of the first three items of the full questionnaire. The AUDIT-C assesses alcohol consumption and possible scores range from 0 to 12. For the current study, higher risk consumption was indicated by an AUDIT-C score \geq 5 [290]. The binge drinking measure was based on AUDIT question 3: "how often do you have 6 or more standard drinks on one occasion?" The possible responses of 'never', 'less than monthly', 'monthly', 'weekly', 'daily' or 'almost daily', were dichotomised into: 'less than monthly' or 'monthly or more'. Whether others had expressed concern with regard to their drinking was based on AUDIT question 10: "has a relative or friend or a doctor or another health worker ever been concerned about your drinking or suggested you cut down?" The possible responses of 'no', 'yes, but not in the last 6 months', and 'yes, during the last 6 months' were dichotomised into: 'yes' or 'no'.

The ATS assessed whether participants owned a smart digital device with internet access (if participants answered yes to owning a "web-enabled mobile or smart phone" or "tablet" and "access to internet: via a mobile terminal").

3.2.4 Intervention

On accessing the intervention, users enter their socio-demographic and drinking data. Drinks Meter then provides instant personalised feedback on the user's drinking (weekly units and calories based on their drinking data) and normative feedback on how their drinking compares with other Drinks Meter users. Users then complete a 'risk adjustor' questionnaire and are provided with the same feedback adjusted for their personal risk factors (based on personal and family medical history, if drugs are consumed whilst drinking, and pregnancy). Users then complete the AUDIT questionnaire and receive feedback on their level of alcohol-

related risk (including health risks) and some suggestions on what to do based on the reported level of risk. Both the Drinks Meter app and website provide the same intervention content and are free to access and use.

3.2.5 Analysis

Descriptive statistics were used to report the socio-demographic and drinking characteristics of the Drinks Meter app users, Drinks Meter website users, drinkers in the general population participating in the ATS, and of the subgroup of those drinkers who owned a smart digital device with internet access. Data from Drinks Meter were unweighted. Data from the ATS were weighted to match an English population profile [287] to provide an accurate comparison of the population prevalence for the Drinks Meter data. A series of separate regression analyses were conducted to assess differences in socio-demographic and drinking characteristics between the Drinks Meter app users and i) the general population of drinkers, ii) the general population of drinkers who own a smart digital device with internet access and iii) Drinks Meter website users. Unadjusted and adjusted linear regressions were conducted for continuous dependent variables (age, AUDIT score, AUDIT-C score) and logistic regressions for binary dependent variables (gender, region, sexual orientation, social grade, binge drinking, and others concerned). There was collinearity between the drinking variables. Therefore, in the adjusted models, for each socio-demographic characteristic, the other sociodemographic variables and AUDIT score were included as covariates, and for each drinking characteristic, only the socio-demographic variables were included as covariates.

3.3 Results

3.3.1 What are the socio-demographic and drinking characteristics of users in England of a popular app (Drinks Meter) to help reduce alcohol consumption?

Table 3.1 reports the socio-demographic and drinking characteristics of Drinks Meter app users. The mean age was 30.6 and the majority of app users were male (64.9%), of a high social grade (92.8%), from the South of England (71.1%), and heterosexual (83.5%). Drinks Meter app users had a mean AUDIT score of 12.3 and a mean AUDIT-C score of 6.3. The majority of app users took part in binge drinking at least monthly (63.9%) and others had not expressed concern with regard to their drinking (70.0%).

 $\label{thm:characteristics} Table~3.1: Socio-demographic~and~drinking~characteristics~of~Drinks~Meter~app~users~and~drinkers~in~the~general~population$

Variable	Drinks Meter	Drinkers	B or OR (95% CI)	Adjusted B or OR
	app users	N=24299	p-value	(95% CI) ^a
	N=818			p-value
Socio-demographic ch	aracteristics			
Gender, % (95% CI)			OR=0.58 (0.50,	OR=1.17 (1.00,
			0.67)	1.38)
			p<0.001	p=0.054
Male*	64.9 (61.6,	51.7 (51.1,		
	68.2)	52.3)		
Female	35.1 (31.8,	48.3 (47.7,		
	38.4)	48.9)		
Age, mean (SD)	30.6 (11.9)	47.8 (18.3)	B=-17.23 (-18.49,	B=-10.78 (-12.08,
			-15.97)	-9.47)
			p<0.001	p<0.001
Region of England, $\%$			OR=2.18 (1.87,	OR=2.89 (2.45,
(95% CI)			2.54)	3.40)
			p<0.001	p<0.001
North*	28.9 (25.8,	46.9 (46.3,		
	32.0)	47.5)		
South	71.1 (68.0,	53.1 (52.5,		
	74.2)	53.7)		
Sexual orientation, $\%$			OR=2.79 (2.30,	OR=2.27 (1.83,
(95% CI)			3.38)	2.81)
			p<0.001	p<0.001
Heterosexual*	83.5 (81.0,	93.4 (93.1,		
	86.0)	93.7)		
Not heterosexual	16.5 (14.0,	6.6 (6.3, 6.9)		
	19.0)			
Social grade, % (95%			OR=0.12 (0.09,	OR=0.12 (0.09,
CI)			0.15)	0.16)
			p<0.001	p<0.001

Variable	Drinks Meter	Drinkers	B or OR (95% CI)	Adjusted B or OR
	app users	N=24299	p-value	(95% CI) ^a
	N=818			p-value
ABC1*	92.8 (91.0,	60.2 (59.6,		
	94.6)	60.8)		
C2DE	7.2 (5.4, 9.0)	39.8 (39.2,		
		40.4)		
Drinking characteristi	cs			
AUDIT score, mean	12.3 (6.3)	4.9 (3.8)	B=7.38 (7.11,	B=6.46 (6.20,
(SD)			7.66)	6.73)
			p<0.001	p<0.001
AUDIT-C score, mean	6.3 (2.0)	4.1 (2.5)	B=2.17	B=1.64 (1.47,
(SD)			(1.99, 2.34)	1.81)
			p<0.001	p<0.001
Binge drinking, %			OR=6.12 (5.29,	OR=4.18 (3.58,
(95% CI)			7.08)	4.88)
			p<0.001	p<0.001
Less than monthly*	36.1 (32.8,	77.5 (77.0,		
	39.4)	78.0)		
Monthly or more	63.9 (60.6,	22.5 (22.0,		
	67.2)	23.0)		
Others concerned, %			OR=8.61 (7.34,	OR=7.58 (6.36,
(95% CI)			10.11)	9.05)
			p<0.001	p<0.001
No*	70.0 (66.9,	95.3 (95.0,		
	73.1)	95.6)		
Yes	30.0 (26.9,	4.7 (4.4, 5.0)		
	33.1)			

^{*} reference group

AUDIT: Alcohol Use Disorders Identification Test

OR: Odds ratio

B: regression coefficient

^a drinking variables adjusted for socio-demographic variables only; socio-demographic variables adjusted for other socio-demographic variables and AUDIT score

3.3.2 How do these socio-demographic and drinking characteristics compare with that of the population of i) drinkers in England?

Table 3.1 reports the results from the regression analyses. Both in the unadjusted and adjusted regression models, Drinks Meter app users were significantly younger (B_{adj} =-10.78, p<0.001), more likely to be from the South of England (OR_{adj} =2.89, p<0.001), more likely to not be heterosexual (OR_{adj} =2.27, p<0.001) and less likely to be of a lower social grade (OR_{adj} =.12, p<0.001) than the general population of drinkers. Drinks Meter app users were less likely to be female than the general population of drinkers (OR_{adj} =.58, p<0.001), but after adjusting for other socio-demographic characteristics and AUDIT score, there was no significant difference between the groups (OR_{adj} =1.17, p=0.054). Both in the unadjusted and adjusted regression models, Drinks Meter app users had significantly higher mean AUDIT (OR_{adj} =6.46, p<0.001) and AUDIT-C scores (OR_{adj} =1.64, p<0.001), and they were more likely to binge drink monthly (OR_{adj} =4.18, p<0.001), and have others who expressed concerns regarding their drinking (OR_{adj} =7.58, p<0.001) than drinkers in the general population.

3.3.3 How do these socio-demographic and drinking characteristics compare with that of the general population of ii) drinkers who owned a smart digital device with internet access in England?

Table 3.2 reports the results comparing Drinks Meter app users with drinkers of the general population who owned a smart digital device with internet access. The pattern of results remained the same as in the comparison with all drinkers. Drinks Meter app users were also younger than drinkers of the general population who owned a smart digital device with internet access, although the difference was smaller in this comparison.

Table 3.2: Socio-demographic and drinking characteristics of Drinks Meter users and drinkers in the general population who owned a smart digital device with internet access

Variable	Drinks Meter app users	Drinkers who	B or OR (95% CI)	Adjusted B or OR
	N=818	device with	p-value	p-value
		internet access	•	•
		N=11990		
Socio-demographic ch	aracteristics			
Gender, % (95% CI)			OR=0.60 (0.52,	OR=1.08 (0.91,
			0.70)	1.27)
			p<0.001	p=0.393
Male*	64.9 (61.6,	52.7 (51.9,		
	68.2)	53.6)		
Female	35.1 (31.8,	47.3 (46.5,		
	38.4)	48.2)		
Age, mean (SD)	30.6 (11.9)	40.2 (14.7)	B=-9.63 (-10.66,	B=-7.93 (-9.02, -
			-8.61)	6.83)
			p<0.001	p<0.001
Region of England, %			OR=2.32 (1.98,	OR=3.07 (2.58,
(95% CI)			2.71)	3.64)
			p<0.001	p<0.001
North*	28.9 (25.8,	48.4 (47.6,		
	32.0)	49.3)		
South	71.1 (68.0,	51.6 (50.8,		
	74.2)	52.5)		
Sexual orientation, %			OR=3.32 (2.72,	OR=2.37 (1.87,
(95% CI)			4.05)	2.99)
			p<0.001	p<0.001
Heterosexual*	83.5 (81.0,	94.4 (94.0,		
	86.0)	94.8)		
Not heterosexual	16.5 (14.0,	5.6 (5.2, 6.0)		
	19.0)			

Variable	Drinks Meter	Drinkers who	B or OR (95%	Adjusted B or OR
	app users	own a smart	CI)	(95% CI) ^a
	N=818	device with	p-value	p-value
		internet access		
		N=11990		
Social grade, % (95%			OR=0.14 (0.11,	OR=0.13 (0.10,
CI)			0.19)	0.17)
			p<0.001	p<0.001
ABC1*	92.8 (91.0,	64.8 (64.0,		
	94.6)	65.6)		
C2DE	7.2 (5.4, 9.0)	35.2 (34.4,		
		36.0)		
Drinking characteristi	cs			
AUDIT score, mean	12.3 (6.3)	5.4 (4.0)	B=6.85 (6.56,	B=6.40 (6.11,
(SD)			7.14)	6.70)
			p<0.001	p<0.001
AUDIT-C score, mean	6.3 (2.0)	4.5 (2.5)	B=1.82	B=1.63 (1.45,
(SD)			(1.64, 1.99)	1.80)
			p<0.001	p<0.001
Binge drinking, %			OR=4.54 (3.91,	OR=3.86 (3.30,
(95% CI)			5.26)	4.52)
			p<0.001	p<0.001
Less than monthly*	36.1 (32.8,	71.9 (71.1,		
	39.4)	72.7)		
Monthly or more	63.9 (60.6,	28.1 (27.3,		
	67.2)	28.9)		
Others concerned, %			OR=7.71 (6.52,	OR=7.98 (6.61,
(95% CI)			9.12)	9.62)
			p<0.001	p<0.001
No*	70.0 (66.9,	94.7 (94.3,		
	73.1)	95.1)		
Yes	30.0 (26.9,	5.3 (4.9, 5.7)		
	33.1)			

*reference group

 $^{\rm a}\,drinking\,variables\,adjusted\,for\,socio\text{-}demographic\,variables\,only;\,socio\text{-}demographic}$

variables adjusted for other socio-demographic variables and AUDIT score

AUDIT: Alcohol Use Disorders Identification Test

OR: Odds ratio

B: regression coefficient

3.3.4 How do the socio-demographic and drinking characteristics differ between app and website users of Drinks Meter?

Table 3.3 reports the results comparing app and website users of the Drinks Meter intervention. Drinks Meter app and website users did not differ in terms of gender $(OR_{adj}=0.87, p=0.110)$, region of England $(OR_{adj}=0.90, p=.225)$, sexual orientation $(OR_{adj}=1.08, p=0.503)$, or social grade $(OR_{adj}=0.85, p=0.306)$ though the app users were significantly younger than website users $(B_{adj}=-3.42, p<0.001)$.

App users' AUDIT (B_{adj} =1.16, p<0.001) and AUDIT-C (B_{adj} =0.21, p=0.021) scores were both significantly higher than website users. App users were more likely to take part in binge drinking monthly or more (OR_{adj} =1.20, p=0.033) and have others concerned with regards to their drinking (OR_{adj} =1.37, p=0.001).

Table 3.3: Socio-demographic and drinking characteristics of Drinks Meter app users and website users

W	D. J. J. M	D -! -1 - M -+	D OD (OF0/ CI)	4 d: -4 - 1 D OD
Variable	Drinks Meter	Drinks Meter	B or OR (95% CI)	Adjusted B or OR
	app users	website users	p-value	(95% CI) ^a
	N=818	N=2241		p-value
Socio-demographic cha	aracteristics			
Gender, % (95% CI)			OR=.87 (.73,	OR=.87 (.73,
			1.02)	1.03)
			p=0.088	p=0.110

V:-1-1-	D. d. l. a. M. a. a. a.	Delala Mara	D OD (OE0/ CI)	Adi arad Daro OD
Variable	Drinks Meter	Drinks Meter	B or OR (95% CI)	Adjusted B or OR
	app users	website users	p-value	(95% CI) ^a
	N=818	N=2241		p-value
Male*	64.9 (61.6,	61.5 (59.5,		
	68.2)	63.5)		
Female	35.1 (31.8,	38.5 (36.5,		
	38.4)	40.5)		
Age, mean (SD)	30.6 (11.9)	34.6 (12.3)	B=-3.99 (-4.97, -	B=-3.42 (-4.36, -
			3.01)	2.47)
			p<0.001	p<0.001
Region of England, %			OR=0.92 (0.77,	OR=0.90 (0.75,
(95% CI)			1.10)	1.08)
			p=0.346	p=0.255
North*	28.9 (25.8,	27.1 (25.3,		
	32.0)	28.9)		
South	71.1 (68.0,	72.9 (71.1,		
	74.2)	74.7)		
Sexual orientation, %	,	-	OR=1.11 (0.90,	OR=1.08 (0.86,
(95% CI)			1.38)	1.35)
(- 10 -)			p=0.336	p=0.503
Heterosexual*	83.5 (81.0,	84.9 (83.4,	1	1
	86.0)	86.4)		
Not heterosexual	16.5 (14.0,	15.1 (13.6,		
TVOC HECEF OSEMual	19.0)	16.6)		
Social grade, % (95%	17.0)	10.0)	OR=0.76 (0.57,	OR=0.85 (0.62,
CI)			1.03)	1.17)
GIJ			p=0.079	p=0.306
ABC1*	92.8 (91.0,	90.8 (89.6,	ρ-0.077	μ-0.500
VDCI	-	-		
CODE	94.6)	92.0)		
C2DE		9.2 (8.0, 10.4)		
Drinking characteristics				

Variable	Drinks Meter	Drinks Meter	B or OR (95% CI)	Adjusted B or OR
	app users	website users	p-value	(95% CI) ^a
	N=818	N=2241		p-value
AUDIT score, mean	12.3 (6.3)	10.8 (6.6)	B=1.44 (0.92,	B=1.16 (0.64,
(SD)			1.96)	1.67)
			p<0.001	p<0.001
AUDIT-C score, mean	6.3 (2.0)	6.0 (2.3)	B=0.27 (0.09,	B=0.21 (0.03,
(SD)			0.44)	0.38)
			p=0.003	p=0.021
Binge drinking, %			OR=1.35 (1.15,	OR=1.20 (1.02,
(95% CI)			1.59)	1.43)
			p<0.001	p=0.033
Less than monthly*	36.1 (32.8,	43.2 (41.2,		
	39.4)	45.3)		
Monthly or more	63.9 (60.6,	56.8 (54.8,		
	67.2)	58.9)		
Others concerned, %			OR=1.28 (1.07,	OR=1.37 (1.14,
(95% CI)			1.53)	1.64)
			p=0.007	p=0.001
No*	70.0 (66.9,	74.9 (73.1,		
	73.1)	76.7)		
Yes	30.0 (26.9,	25.1 (23.3,		
	33.1)	26.9)		

^{*} reference group

a drinking variables adjusted for socio-demographic variables only; socio-demographic variables adjusted for other socio-demographic variables and AUDIT score

AUDIT: Alcohol Use Disorders Identification Test

OR: Odds ratio

B: regression coefficient

3.4 Discussion

The aim of this chapter was to investigate who in the general population of drinkers used a smartphone app to reduce alcohol consumption and how this group of app users compared with the general population of drinkers and users of an equivalent website-based intervention. The majority of users of the Drinks Meter app were relatively young, male, of a high social grade, from the South of England, and heterosexual. The mean AUDIT score of the app users was 12.3 and the mean AUDIT-C score was 6.3 indicating hazardous drinking and higher risk alcohol consumption, respectively. The majority of Drinks Meter app users engaged in binge drinking at least once a month. This suggests apps are reaching those in need of support – excessive drinkers – but that there is not a clear socio-demographic group which is the predominant users of alcohol reduction apps.

Compared with the general population of drinkers, Drinks Meter app users were younger, more likely to be of a higher social grade, from the South of England and not heterosexual, when adjusting for other characteristics. There was no significant difference in gender after adjustment for other socio-demographic characteristics and AUDIT score. Drinks Meter app users reported greater alcohol consumption and more alcohol-related harms than the general population of drinkers in England. This pattern of results was the same when comparing Drinks Meter app users against only those drinkers who were digitally engaged. The age gap between groups was attenuated when comparing Drinks Meter app users with drinkers who were digitally engaged, which reflects younger age groups being more likely to own a smartphone and download apps [81]. Users who accessed the Drinks Meter intervention through the app were more likely to be younger and report greater alcohol consumption and harms than those who accessed the intervention via the website.

Only a small proportion of excessive drinkers receives a brief intervention from their GP [48] and digital interventions offer an opportunity to reach a greater proportion of excessive drinkers. However, users typically self-select to use a digital intervention and it was not known whether digital interventions such as apps only reach the 'worried well' and not those individuals who need help. The current findings suggest that individuals who are at higher levels of alcohol-related risk than the general population of drinkers, seek alcohol reduction apps to use even after accounting for socio-demographic characteristics and ownership of a digital device with internet access. Drinks Meter app users also had higher AUDIT scores than the website users suggesting that user characteristics differ between types of digital technology. In summary, these findings suggest that digital interventions, and apps more so than websites, are indeed being used by individuals who consume excessive levels of alcohol and not just by the 'worried well'.

The users of the Drinks Meter app were also not representative of the general population of drinkers, but do reach a wide range of demographics, and were less likely to be used by those who were older, from the North of England, heterosexual and of a lower social grade. This is an important point to consider in terms of providing digital interventions equitably to excessive drinkers. Smartphone ownership is more likely among younger age groups [81] and people of a higher socioeconomic status [134] though the difference between app users and the general population remained when selecting only those who owned a smart digital device with internet access. This suggests that it is not simply ownership of a suitable device that is driving these differences between users of the Drinks Meter app and the general population of drinkers.

Other studies have found that mobile phone users in the United States were more likely to use health apps if they were younger, had higher incomes and were more educated [84] and that users of a smoking cessation app, SmokeFree28, were more likely to be younger, female, have

a non-manual occupation and higher daily cigarette consumption than smokers in England who try to quit [135]. Although the proportion with a non-manual occupation was higher than in the general population of smokers trying to stop, the difference was small and the authors noted that social gradient in app usage merited further investigation [135]. Unlike users of the SmokeFree28 app, there was no difference in gender after adjusting for other factors between Drinks Meter app users and the general population of drinkers in England. The findings from the current study and previous research suggest that users of apps for changing health behaviours tend to be more dependent, younger and of a higher social grade. However, there are limited data available on user characteristics of apps aiming to change health-related behaviours and the extent to which these findings generalise to other apps is an empirical question requiring research.

A strength of this study is that it is the first, to the authors' knowledge, to assess the user characteristics of an alcohol reduction app for the general population and to compare them with a representative sample of the general population of drinkers. Four previous studies of alcohol-related apps have reported user characteristics but have targeted a specific user group (e.g. individuals with alcohol use disorders, university students) and none have compared user characteristics with the general population of drinkers. This study is also the first to the authors' knowledge to assess whether users of the same digital intervention for reducing alcohol consumption differ according to the type of digital technology used.

This study has limitations. It relied on data from a single app and so these findings are not necessarily generalisable to users of other alcohol reduction apps. The Drinks Meter app focuses on providing feedback on behaviour and normative feedback, but it does not include a number of intervention techniques known to be used frequently in other popular alcohol reduction apps such as facilitating self-monitoring [106]. Some apps use daily self-monitoring to promote alcohol reduction [107] though none of these, or any other alcohol reduction apps,

have been formally evaluated. Future research should assess the extent to which these results generalise to other alcohol reduction apps, ideally those that have been empirically evaluated. Another limitation of this study was that the measure for social grade was not identical between the groups of the Drinks Meter users and the general population of drinkers.

To conclude, drinkers seeking alcohol reduction support through an app compared with the general population of drinkers in England report greater alcohol consumption and alcohol-related harms. These drinkers were also more likely to be younger, of a higher social grade, from the South of England and not heterosexual. These differences still existed when the general population of drinkers was selected for owning a smart digital device with internet access. Drinkers using an app-based intervention differed from drinkers using the same intervention through a website with the app users being younger and reporting greater alcohol consumption and harms. The results from this study suggest alcohol reduction apps are being used by excessive drinkers and not by the 'worried well'. Therefore, it is of value to systematically develop and evaluate an app to help drinkers reduce excessive alcohol consumption as these apps are being used by those individuals in need of support. Future research should investigate whether these findings are applicable to alcohol reduction apps more generally. This would allow healthcare providers to be informed about which groups use apps for support and which might need more prompting to seek digital help for reducing alcohol consumption.

Chapter 4- Reported theory use by digital interventions for alcohol reduction and association with intervention effectiveness: a meta-regression of a Cochrane Systematic Review (Study 2)

Abstract

Applying theory to the design and evaluation of interventions is likely to increase effectiveness and improve the evidence base from which future interventions are developed. The aim of this study was to assess how digital interventions to reduce hazardous or harmful alcohol consumption report theory use in their development and evaluation; and whether reporting of theory use is associated with intervention effectiveness.

Randomised controlled trials were extracted from a Cochrane review on digital interventions for reducing hazardous and harmful alcohol consumption. Reporting of theory use within these digital interventions was investigated using an amended Theory Coding Scheme (TCS). The TCS was used to calculate composite scores for six categories of theory use and a total theory use score. Reported theory use was analysed by frequency counts and descriptive statistics. Associations were analysed with meta-regression models.

Of 41 trials involving 42 comparisons, half did not mention theory (50%, n=21). The mean score for total theory use was 4.4 (SD=5.43) out of a possible score of 22. Significant heterogeneity existed between studies in the effect of interventions on alcohol reduction ($I^2=77.6\%$, p<0.001). No significant associations were detected between reporting of theory use and intervention effectiveness in unadjusted models though the meta-regression was under-powered to detect moderate or small associations.

The reporting of theory use in the development and evaluation of digital alcohol interventions is extremely limited with only a third using theory to develop the intervention. Digital interventions offer a unique opportunity to refine and develop new dynamic, temporally sensitive theories, yet none of the studies in this review reported refining or developing theory. Clearer selection, application and reporting of theory use are needed to assess accurately how useful theory is in this field and to advance the field of behaviour change theories.

4.1 Introduction

As established in the general introduction (see Chapter 1), excessive alcohol consumption is a serious problem for population health [22,29] and is estimated to cost the UK £21 billion each year. Digital interventions are a cost-effective method to help people reduce their alcohol consumption and a number of reviews have found that digital interventions can be effective [67,74,94–101,189]. However, there is substantial heterogeneity between the effectiveness of the different interventions that is unexplained [94,96,97,99,100].

Behaviour change theories "explain why, when and how a behaviour does or does not occur, and the important sources of influence to be targeted in order to alter the behaviour" (p22 [147]). A good theory should have a "parsimonious, coherent explanation of phenomena" (p23, [147]) that is comprehensible, internally consistent, generates testable predictions and is not contradicted by observations [148]. Theories often lack specificity and so fail to generate hypotheses that can be tested in the real world [291]. Testable predictions can and should be used as a basis to refine and improve theories [150] or to 'retire' those that consistently fail to explain or predict intervention outcomes [148].

Using a good behaviour change theory in the development and evaluation of interventions has many potential benefits [292]. Theories can inform researchers about which variables might be most influential in mediating the effects of an intervention on the target behaviour, thereby providing a systematic method for selecting and refining appropriate intervention techniques [293–295]. Using a theoretical framework for data collection means that evidence of effectiveness can be accumulated across different contexts, populations and behaviours [292,296] and the process of adapting and refining interventions is more efficient [294]. Theory-based interventions can reveal what makes an intervention effective by allowing empirical tests of theoretical propositions. In turn, these can provide a basis for refining theory [150,297] and future theory-based interventions are likely to be improved [298]. This illustrates the concept of a 'virtuous spiral' between theory and intervention development whereby theory can inform intervention development and interventions can test and refine the underlying theory [61]. These benefits suggest that systematic use of a high quality behaviour change theory in intervention development may result in a more effective intervention [292,299–301] and be able to inform future interventions [298].

A tool for describing and reliably assessing the theoretical basis of interventions is the Theory Coding Scheme (TCS) [292]. The TCS has 19 items that can be grouped into six categories of theory use. Composite scores for the six categories and a total score can provide an estimate of the extent of reported theory use which also facilitates the assessment of whether an association exists between the extent of theory use and intervention effectiveness.

The extent to which theory is used may explain some of the substantial heterogeneity found between the effectiveness of different digital alcohol reduction interventions. Mixed evidence exists with both positive [244,295,302–307] and negative associations [308–310] being found between theory use and the effectiveness of behaviour change interventions. There are a number of factors that may contribute to this pattern of results [311]. The value of theory

depends on using a 'high quality' and appropriate theory that is relevant to the behaviour [147]. Many studies do not report theory use in intervention development or evaluation [244,301,303,312–316]. If interventions are described as having a theoretical basis, this description is often unclear or partial [300,307]. For example, a review of physical activity and dietary interventions found only half reported using theory [307] and, of those, only a small proportion reported systematically applying theory [292,299,301]. These issues delay the development of interventions and the underlying theories.

The association between theory use in computer-delivered interventions and alcohol-related outcomes in the general population has been assessed in a literature review using meta-regression [189]. This review found no association between the extent of theory use in intervention development and effectiveness but did find that the use of a particular theory – the Social Norms approach [180] – was associated with improved outcomes [189]. The current study will investigate whether these findings generalise to populations of hazardous or harmful drinkers. This population is of particular interest because they experience more economic, health and social costs compared with low-risk drinkers [9,161,317]. There is also a need for replication of studies, including meta-analyses, to confirm initial findings and build a strong evidence base [318,319].

The current study reports a theoretical analysis of interventions in a Cochrane review of the effectiveness of digital interventions for reducing hazardous and harmful alcohol consumption in community-dwelling populations (systematic review registration number: CRD42015022135) [284]. This study aims to inform this thesis and the intervention development by capturing the existing knowledge of how digital alcohol interventions currently use theory in their development and evaluation, and whether there is an association between reported theory use, and the way theory has been used, and intervention effectiveness.

4.1.1 Research questions

This study will address the following research questions:

- 1. How is theory use reported in the development and evaluation of digital alcohol reduction interventions?
 - a. Which items and categories of theory use are used most frequently?
 - b. What is the extent of reported theory use (mean total theory use score)?
- 2. Is there an association between intervention effectiveness and reported theory use?

4.2 Methods

4.2.1 Search strategy and study selection

Studies for inclusion in the systematic review were identified through a broad search of databases (e.g. MEDLINE, Cochrane library, CINAHL, PsycINFO, Clinicaltrials.gov) and relevant websites (e.g. International Alcohol Information Database, Beacon 2.0, Drug and Alcohol Findings). The reference lists of all included studies and relevant reviews were checked. The search combined terms for hazardous or harmful alcohol consumption (e.g. alcohol, drinking, alcohol use, risks) with terms for computer-assisted therapy or digital interventions (e.g. internet, computers, smartphone). Full details of the search strategy are reported in the protocol in the Cochrane Library [106].

4.2.2 Inclusion criteria

Studies were RCTs with the outcome measure of quantity of alcohol consumed (in grams per week), which could be reported in standard drinks, alcohol units or similar. Participants were community-dwelling individuals who could have been recruited in a range of settings (e.g. primary healthcare, social care, educational, work-place) and were under no obligation to complete the intervention (e.g. mandated college students). Participants were screened and

identified as hazardous or harmful drinkers typically via completing short online questionnaires such as the AUDIT or quantity-frequency measures. The intervention had to target alcohol consumption or alcohol-related problems in the drinker and be delivered primarily through a digital device. A comparator condition must have been included (e.g. no intervention, usual care, feedback or general health advice or health information via printed leaflets or booklets). Full details of the inclusion criteria are in the protocol [106].

4.2.3 Review procedure

The review procedure consisted of two phases to identify relevant studies using the inclusion criteria detailed above. Studies were initially reviewed based on their title and abstract by two researchers. This was done independently and Endnote was used to promote consistency. A conservative approach was taken so that studies were included if their relevance to the review was uncertain. In the second phase, two researchers independently reviewed the full research paper of any studies identified as potentially eligible. Any discrepancies were resolved by discussion and by consulting a third researcher if necessary. The inclusion criteria were amended to reflect any clarifications that occurred during the discussion of discrepancies.

4.2.4 Data extraction

A standardised data extraction form was developed and piloted which two researchers used to independently carry out data extraction of all included studies. Data was extracted about the following: details of the intervention (e.g. setting, duration, size and characteristics of sample), baseline and follow-up data for the primary outcome measure (grams of alcohol, converted from quantity of alcohol consumed reported in standard drinks, alcohol units, or similar).

A theoretical analysis of the studies was conducted using the TCS [292]. Two researchers independently coded a sample of five studies using the TCS. Differences were resolved through discussion and a third researcher was consulted if agreement was not reached; the coding guidelines were amended accordingly. Inter-rater reliability (IRR) was assessed with the PABAK statistic, which accounts for researchers agreeing on the presence or absence of codes [320]. Further rounds of testing were performed until the inter-rater reliability (IRR) reached a substantial level of agreement (PABAK statistic greater or equal to 0.70 [320,321]). After this level of agreement was achieved, one researcher coded the remaining studies. The PABAK statistic was 0.84 across the five rounds of IRR checking which reflects a substantial level of agreement.

An amended version of the TCS was used; two items ('quality of measures' and 'randomisation of participants to condition') were excluded because they related to methodological issues rather than informing whether or how theory was used in an intervention. Each study was dummy coded for the 22 items (17 items, three of which had sub-items) as present (1) or absent (0). If any theory was mentioned (TCS item 1), then the relevant name was documented, regardless of whether empirical support for the theory existed. If a protocol or other paper was referenced as describing the intervention, then that paper was also coded for those items relating to intervention development (TCS items 1-11).

The Theory Coding Scheme specifies theory use in six categories: reference to underpinning theory; targeting of relevant theoretical constructs; using theory to select recipients or tailor interventions; measurement of constructs; testing of theory: mediation effects, and refining theory [292]. Composite scores were calculated for the six categories of theory use and a total use of theory score (sum of all TCS items) [292]. These composite scores were used as a crude estimate of the extent of theory use in specific categories, or in total, and the relationship between that and the effect size of the intervention.

For the composite scores, any item detailing "all" (TCS items 7 & 8) that was coded as present was also coded as present for the equivalent item detailing "at least one" (TCS items 10 & 11) (as in a previous systematic review and meta-analysis [299]). This was to ensure that the composite scores of theory use were representative of the studies and studies credited with linking 'all' theoretical constructs (for example) are also credited as linking some. Otherwise, linking one theoretical construct would give same contribution towards the 'total use of theory' score as linking all the constructs.

4.2.5 Analysis

Frequency counts and descriptive statistics were used to describe the theoretical basis to digital alcohol reduction interventions. The range and frequency of the theories mentioned were tabulated.

The meta-regressions were conducted in Stata (version 14) using the 'metareg' command. A random effects model was used because the intervention effects were likely to have residual heterogeneity not modelled by the covariates. The dependent variable in these models was the mean difference in grams of alcohol consumed per week between the digital intervention and control arms at the longest follow-up time point. The I^2 statistic was used to assess the magnitude of heterogeneity and the statistical significance of this heterogeneity was assessed using p-values derived from χ^2 tests [322]. The weighted mean difference method was used to estimate pooled effect sizes and 95% confidence intervals (CIs). Previous simulation studies have found that for accurate estimates in meta-regression at least 40 studies are required [323], and that more than 200 studies are required for 80% power to detect modest associations [324].

A series of unadjusted random effects meta-regression analyses were conducted to examine the association between the TCS covariates (individual theory items (included by at least 10%).

of studies), the categories of theory use, and total use of theory) with intervention effectiveness and the percentage of the between-study heterogeneity (adjusted R²) explained by each predictor. In these analyses, the regression coefficient (B) represented the mean of the unstandardised effects between trials that differentially included each theory item. Each unstandardised effect was the mean difference in quantity of alcohol consumption, in grams per week, between intervention and control. A negative coefficient for a covariate indicated studies reporting that theory item, or with higher composite scores for the categories of theory use and total use of theory, were associated with a larger reduction in alcohol consumption between the intervention and control than studies that did not.

To investigate the independent associations, an adjusted meta-regression analysis was conducted including all of the variables that had a meaningful association with intervention effectiveness in the unadjusted models. A meaningful association was defined as B>23, based on the lower boundary of a 95% confidence interval for the effect found in a systematic review of brief alcohol interventions [44].

In the event of a 'non-significant' result, a Bayes factor was calculated to establish the relative likelihood of the null versus the experimental hypothesis given the data obtained. Using Bayes factors when analysing data for hypothesis testing can provide important information that leads to more precise conclusions than using the traditional frequentist approach alone [325,326]. The experimental hypothesis was that the TCS covariate was associated with intervention effectiveness and the null hypothesis was that there was no association. The Bayes factors were calculated with the alternative hypotheses conservatively represented in each case by a one-tailed, non-uniform distribution using the online calculator associated with Dienes (http://www.lifesci.sussex.ac.uk/home/Zoltan_Dienes/inference/Bayes.htm). The mean was specified as 0 and the standard error was specified as the expected effect size (i.e. 23). This means plausible values have been effectively represented between zero and twice the effect

size, with smaller values more likely. Bayes Factors allow the distinction between two interpretations of a null result: there is evidence for the null-hypothesis or that the data are insensitive in distinguishing an effect. Bayes Factors vary from 0 to ∞ : values of 3-10 indicate moderate evidence for the experimental hypothesis over the null, whilst values greater than 10 indicate strong evidence; values of 1/10 to 1/3 indicate moderate evidence for the null over the alternative, whilst values less than 1/10 indicate strong evidence; and values between 1/3 and 3 indicate that the data are insensitive in distinguishing an effect [327].

Sensitivity analyses for the series of unadjusted models and the adjusted model were conducted using a standardised version of the primary outcome measure to facilitate wider comparison with other behavioural domains. Hedges' g was used to calculate the standardised effect sizes; the difference between two means divided by their pooled standard deviation, with correction for small sample size [328]. The same covariates that were included in the adjusted model using the unstandardized effect size were included for this sensitivity analysis.

4.3 Results

4.3.1 Study selection

Studies were selected for this meta-regression if they were included in the primary metaanalysis of the Cochrane review [284]. 5928 records were identified through database
searching and through other sources, with 3165 records remaining after duplicates were
removed. Records were then screened by their title and abstract (with 2477 excluded) before
the full text was screened (633 excluded) (see Figure 4.1 for a flow chart showing the
identification of the studies included and reasons for exclusion). Forty-one trials compared a
digital intervention (one contained two digital arms) with a control (these included
assessment only, waiting list control groups and provision of standard health-related

information) and reported appropriate information for inclusion in the primary metaanalysis. Seven trials compared a digital intervention with a face-to-face intervention, of
which only five reported appropriate information for a meta-analysis that was not sufficient
to be included in the primary meta-analysis of the Cochrane review. This resulted in 42 digital
intervention arms being included in this review and coded for their reporting of theory use.

See Appendix 4 for the list of references for these studies.

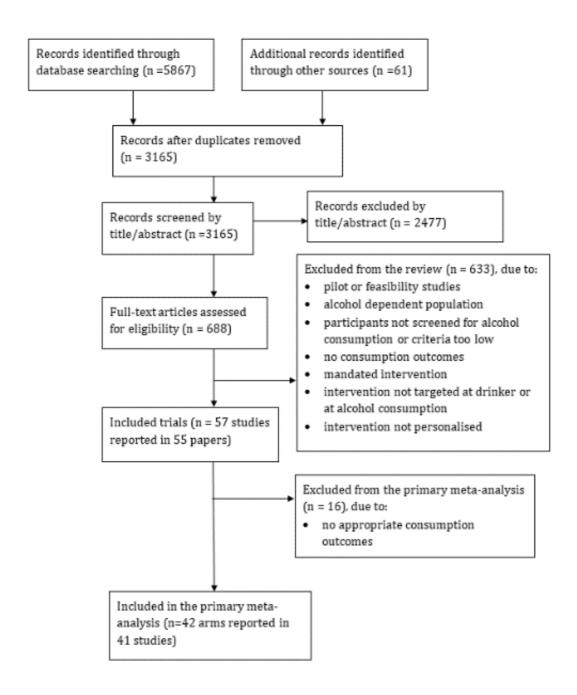


Figure 4.1: Flow chart showing identification of included trials (reproduced from the main Cochrane review [283])

4.3.2 Study characteristics

The 42 digital intervention arms included 19241 participants (9631 randomised to a digital intervention, 9610 randomised to a control condition). The longest period of follow-up ranged from one month (n=8) to 12 months (n=7). Interventions were web-based in 34 studies, comprised a stand-alone computer programme in six studies and a smartphone app in one study. Twenty-four studies focused on students or younger adults (less than 25 years old), whilst the others recruited adults of any age. Use of the intervention was restricted to a specific location (e.g. primary care clinic or psychology lab) in ten studies, and 30 trials allowed participants to use the intervention at the location of their choice. The majority of the studies (n=23) took place in North America, nine took place in continental Europe, four in Scandinavia, two in the UK, two in New Zealand and one in Australia.

4.3.3 How is theory use reported in digital interventions?

Table 4.1 reports the frequency of reporting in studies for the TCS items and Table 4.2 reports the composite scores for the six categories of theory use and the total use of theory. The most frequently reported theory items were: 'theory or model mentioned' (n= 21, 50%), 'targeted constructs mentioned as a predictor of behaviour' (n=17, 40%) and 'theory or theoretical predictors used to select or develop intervention techniques' (n=16, 38%). Twenty-one interventions (50%) made no mention of theory at all. No intervention reported refining theory, either by adding or removing theoretical constructs or by specifying that the interrelationships between theoretical constructs should be changed. The mean total use of theory score was 4.4 (SD=5.43) out of a possible 22, which indicates that typically studies are not extensively reporting theory use in intervention development and evaluation.

Table 4.1: Number of studies reporting digital alcohol reduction interventions in which items on the Theory Coding Scheme (TCS) are present

Theory Coding Scheme item description (item number)	Studies where
	item coded as
	present, n (%)
Theory/model of behaviour mentioned (I1)	21 (50%)
Targeted construct mentioned as predictor of behaviour (I2)	17 (40%)
Intervention based on single theory (I3)	9 (21%)
Theory/predictors used to select recipients for the intervention (I4)*	0 (0%)
Theory/predictors used to select/develop intervention techniques (I5)	16 (38%)
Theory/predictors used to tailor intervention techniques to recipients (I6)*	3 (7%)
All intervention techniques are explicitly linked to at least one theory-relevant construct/predictor (I7)	6 (14%)
At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/predictor (I8)	11 (26%)
Group of techniques are linked to a group of constructs/predictors (I9)*	2 (5%)
All theory-relevant constructs/predictors are explicitly linked to at least one intervention technique (I10)	7 (17%)
At least one, but not all, of the theory-relevant constructs/predictors are explicitly linked to at least one intervention technique (I11)	10 (24%)
Theory-relevant constructs are measured: post-intervention (I12a)	12 (29%)
Theory-relevant constructs are measured: post- & pre-intervention (I12b)	10 (24%)
Changes in measured theory-relevant constructs/predictor (I13)	8 (19%)
Mediational analysis of constructs/ predictors: mediator predicts the	6 (14%)
dependent variable (I14a) Mediational analysis of constructs/ predictors: mediator predicts dependent variable, controlling for the independent variable (I14b)*	3 (7%)

Theory Coding Scheme item description (item number)	Studies where
	item coded as
	present, n (%)
Mediational analysis of constructs/ predictors: intervention does not	4 (10%)
predict the dependent variable when controlling the independent variable	
(I14c)	
Mediational analysis of constructs/ predictors: mediated effect is	6 (14%)
statistically significant (I14d)	
Results discussed in relation to theory (I15)	12 (29%)
Appropriate support for theory (I16)	7 (17%)
Results used to refine theory: adding/removing constructs to the theory	0 (0%)
(I17a)*	
Results used to refine theory: specifying that the interrelationships	0 (0%)
between the theoretical constructs should be changed (I17b)*	

^{*}not present in >10% of studies so not included in the meta-regression analyses

Table 4.2: Descriptive statistics for categories of theory use

Theory Coding Scheme (TCS)	Items included	Maximum	Mean (SD)	Studies
Categories (category number)		score		scoring >=1, n
Reference to underpinning	1, 2, 3	3	1.1 (1.23)	20
theory (C1)				
Targeting of relevant	2, 5, 6, 7, 8, 9,	8	2.0 (2.43)	17
theoretical constructs (C2)	10, 11			
Using theory to select	4, 6	2	0.1 (0.26)	2
recipients or tailor				
interventions (C3)				
Measurement of constructs	12a, 12b	2	0.5 (0.86)	11
(C4)				
Testing of theory: mediation	12a, 12b, 13,	9	1.6 (2.83)	14
effects (C5)	14a, 14b, 14c,			
	14d, 15, 16			
Refining theory (C6)*	17a, 17b	2	-	-
Total use of theory	All items	22	4.4 (5.43)	20

^{*}no score >0 for any studies so not included in the meta-regression analyses

Table 4.3 reports the 18 different theories or models mentioned and by which studies. The most frequently mentioned were Motivational Interviewing theory (8/21), Transtheoretical model (6/21) and Social Norms Theory (6/21). Studies ranged from mentioning a single theory (n=8) to five different theories (n=2).

Table 4.3: Matrix of which theories mentioned (TCS item 1) for each study (n=21)

First author & year of publication Brendryen 2013	ω No. of theories	o Total theory use score	Motivational Interviewing Theory	Social Norms Theory	\times Transtheoretical Model	I-change Model	Social Comparison Theory	Social Impact Theory	Theory of Planned Behaviour	× Self-Regulation Theory	× Social Cognitive Theory	Social Identity Theory	Social Learning Theory	Theory of Social Influence	Cognitive-Behavioural Theory	Decision-Making Theory	Expectancy Theory	Health Belief Model	Problem Behaviour Theory	Social Determination Theory
Collins 2014 DBF	3	6	X		X											X				
Collins 2014 PNF	1	6											X							
Doumas 2010	1	15		X																
Gajecki 2014	1	7							X											
Geisner 2015	1	8		X																
Hansen 2012	1	8								X										
Kypri 2014	1	1										X								
LaBrie 2013	3	12		X			X	X												
Lewis 2007a	4	16		X			X	X				X								
Lewis 2007b	3	14		X			X	X												
Lewis 2014	2	15		X									X							
Murphy 2010	1	12	X																	
(study 2)																				
Neighbors 2006	1	16																		X
Postel 2010	2	4	X		X															
Schulz 2013	5	9			X	X			X		X							X		

First author & year of publication	No. of theories	Total theory use score	× Motivational Interviewing Theory	Social Norms Theory	Transtheoretical Model	I-change Model	Social Comparison Theory	Social Impact Theory	Theory of Planned Behaviour	Self-Regulation Theory	Social Cognitive Theory	Social Identity Theory	Social Learning Theory	Theory of Social Influence	Cognitive-Behavioural Theory	Decision-Making Theory	Expectancy Theory	Health Belief Model	Problem Behaviour Theory	Social Determination Theory
Sugarman 2009	3	6	X												X				X	
Voogt 2013a	3	5	X			X								X						
Voogt 2013b	5	8	X		X	X			X					X						
Wallace 2011	2	7	X		X															
Weaver 2014	2	2	X														X			
Number of studie	s:		8	6	6	3	3	3	3	2	2	2	2	2	1	1	1	1	1	1

4.3.4 Association between reporting of theory use and intervention effectiveness

The primary meta-analysis in the Cochrane review found that participants randomised to a digital intervention drank 22.8 (95% CI= 15.36, 30.31) grams of alcohol per week less than controls [283], the equivalent of about 3 standard UK units of alcohol or 1.7 standard drinks in the USA . There was a significant proportion of the residual variation attributable to between study heterogeneity ($I^2=77.6\%$, p<.001) (see Figure 4.2), which could potentially be explained by study-level covariates.

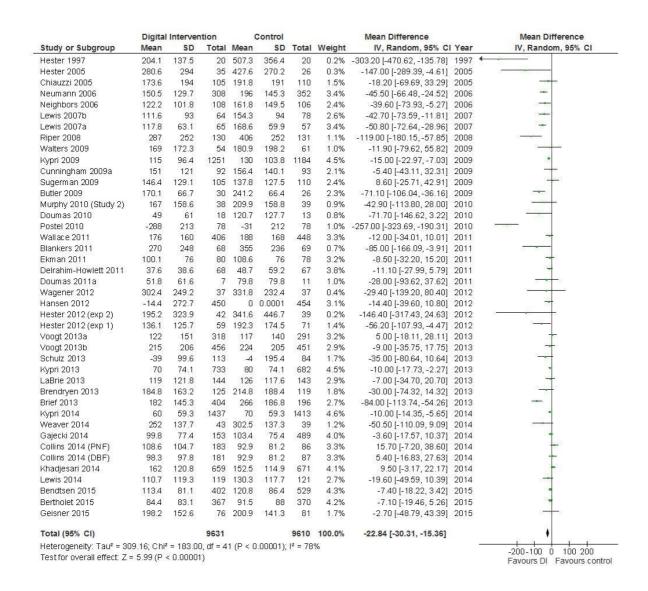


Figure 4.2: Digital intervention versus control- quantity of drinking (g/week), based on longest follow-up (reproduced from the main Cochrane review [283])

4.3.4.1 Unadjusted associations between reporting of theory use and intervention effectiveness

The unadjusted associations between reported theory use and intervention effectiveness are reported in Table 4.4. Seven TCS covariates were not included in these analyses as they were either not present in >10% of studies or had a composite score of 0. The results indicated that the TCS covariates explained little of the heterogeneity and no significant associations with intervention effectiveness were detected (all p-values>0.076).

The Bayes factors derived from the reported theory use are reported in Table 4.4 and indicated that the majority of these data were insensitive to detect an effect. The TCS item of

'Changes in measured theory-relevant constructs/predictor' had a Bayes factor greater than 3 (BF=3.50) which indicates moderate evidence for an association with intervention effectiveness. Seven TCS covariates had a Bayes factor of less than 0.33 indicating moderate evidence for no association between the item and intervention effectiveness ('targeted construct mentioned as predictor of behaviour' BF=0.22; 'theory/predictors used to select/develop intervention techniques' BF=0.27; 'at least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/predictor' BF=0.23; 'at least one, but not all, of the theory-relevant constructs/predictors are explicitly linked to at least one intervention technique' BF=0.30; 'reference to underpinning theory' BF=0.12; 'testing of theory: mediation effects' BF=0.24; 'total use of theory' BF=0.05). One TCS covariate had a Bayes factor of less than 1/10 indicating strong evidence for no association between the item and intervention effectiveness ('targeting of relevant theoretical constructs' BF=0.06).

Table 4.4: Unadjusted meta-regression analyses for the individual TCS items, six categories of theory use scores and total use of theory score

TCS covariates (item/category number)	B (SE)	p	95% CI	Adj. R ²	I ²	Bayes
						factor
Theory/model of behaviour mentioned (I1)	9.73 (14.63)	0.510	-19.84, 39.31	-4.90%	78.09%	0.36
Targeted construct mentioned as predictor of	24.17 (14.09)	0.094	-4.30, 52.64	2.27%	78.13%	0.22
behaviour (I2)						
Intervention based on single theory (I3)	12.92 (17.60)	0.467	-22.64, 48.49	-4.44%	78.08%	0.40
Theory/predictors used to select/develop	18.25 (14.57)	0.218	-11.20, 47.69	-3.43%	78.15%	0.27
intervention techniques (I5)						
All intervention techniques are explicitly linked	-3.73 (19.91)	0.852	-43.98, 36.51	-4.86%	76.50%	0.73
to at least one theory-relevant						
construct/predictor (I7)						
At least one, but not all, of the intervention	26.39 (15.34)	0.093	-4.60, 57.39	10.54%	77.49%	0.23
techniques are explicitly linked to at least one						
theory-relevant construct/predictor (I8)						
All theory-relevant constructs/predictors are	8.53 (19.81)	0.673	-31.60, 48.46	-5.82%	78.14%	0.51
explicitly linked to at least one intervention						

TCS covariates (item/category number)	B (SE)	p	95% CI	Adj. R ²	I ²	Bayes
						factor
technique (I10)			<u> </u>			
At least one, but not all, of the theory-relevant	18.79 (15.99)	0.247	-13.54, 51.11	-3.45%	78.15%	0.30
constructs/predictors are explicitly linked to at						
least one intervention technique (I11)						
Theory-relevant constructs are measured: post-	-14.67 (15.81)	0.359	-46.62, 17.28	1.42%	76.37%	1.18
intervention (I12a)						
Theory-relevant constructs are measured: post-	-13.78 (16.88)	0.419	-47.90, 20.33	-1.67%	76.94%	1.09
& pre-intervention (I12b)						
Changes in measured theory-relevant	-33.04 (17.48)	0.066	-68.37, 2.28	16.92%	74.82%	3.50
constructs/predictor (I13)						
Mediational analysis of constructs/ predictors:	-7.77 (20.24)	0.703	-48.68, 33.15	-3.13%	76.43%	0.84
mediator predicts the dependent variable (I14a)						
Mediational analysis of constructs/ predictors:	-21.88 (24.11)	0.370	-70.61, 26.86	4.48%	75.41%	1.29
intervention does not predict the dependent						
variable when controlling the independent						
variable (I14c)						
Mediational analysis of constructs/ predictors:	-7.77 (20.24)	0.703	-48.68, 33.14	-3.13%	76.43%	0.84

TCS covariates (item/category number)	B (SE)	p	95% CI	Adj. R ²	I^2	Bayes
						factor
mediated effect is statistically significant (I14d)			<u> </u>			
Results discussed in relation to theory (I15)	1.59 (16.08)	0.922	-30.91, 34.08	-6.81%	77.35%	0.54
Appropriate support for theory (I16)	-8.73 (19.43)	0.656	-48.01, 30.55	-2.11%	76.33%	0.87
Reference to underpinning theory (C1)	7.19 (5.89)	0.230	-4.72, 19.10	-1.55%	78.08%	0.12
Targeting of relevant theoretical constructs (C2)	3.94 (2.97)	0.192	-2.06, 9.93	-4.08%	78.12%	0.06
Using theory to select recipients or tailor	13.30 (27.27)	0.628	-41.81, 68.42	-7.21%	77.67%	0.60
interventions (C3)						
Measurement of constructs (C4)	-7.58 (8.41)	0.373	-24.58, 9.42	0.19%	76.61%	0.79
Testing of theory: mediation effects (C5)	-2.09 (2.53)	0.413	-7.20, 3.02	2.29%	75.71%	0.24
Total use of theory	0.39 (1.37)	0.778	-2.38, 3.15	-7.46%	77.58%	0.05

4.3.4.2 Adjusted associations between reporting of theory use and intervention effectiveness

An adjusted model was conducted entering the covariates that had a modest (albeit non-significant) association with effect size (B>23) in the unadjusted models (item 2, item 8 and item 13) and are reported in Table 4.5. The adjusted model had little effect on the degree of heterogeneity identified in the primary meta-analysis ($I^2 = 74.3\%$, $R^2_{adj} = 32.93\%$, p = 0.007). The adjusted model produced two significant associations between TCS covariate and intervention effectiveness (item 2: 'targeted construct mentioned as predictor of behaviour' (B=50.82, 95% CI= 8.31, 93.34, p=0.020) and item 13: 'changes in measured theory-relevant constructs/predictor' (B=-61.41, 95% CI= -100.71, -22.10, p=0.003)). However, these are difficult to interpret in the absence of any significant associations in the unadjusted models and that the pattern of results is not robust to standardised effect sizes or slight changes to the inclusion of studies.

Table 4.5: Adjusted meta-regression analysis for the covariates with a meaningful association with effect size in unadjusted models

TCS covariates (item number)	B (SE)	р	95% CI	Bayes
				factor
Targeted construct mentioned as predictor	50.82	0.020	8.31, 93.34	0.24
of behaviour (I2)	(21.00)			
At least one, but not all, of the intervention	-12.19	0.560	-54.12,	0.98
techniques are explicitly linked to at least	(20.71)		29.74	
one theory-relevant construct/predictor				
(18)				
Changes in measured theory-relevant	-61.41	0.003	-100.71,	23.71
constructs/predictor (I13)	(19.42)		-22.10	

4.3.4.3 Sensitivity analyses with standardised effect sizes

The sensitivity analysis using a standardised (Hedges' g) effect size showed a similar pattern of results for the primary meta-analysis; there was a standardised mean difference of 0.20 (95% CI= 0.27, 0.14) and a significant level of heterogeneity ($I^2=73.5\%$, p<0.001).

The unadjusted models showed a different pattern of results with two Theory Coding Scheme items having a significant association with intervention effectiveness: 'at least one of the intervention techniques are explicitly linked to at least one theory-relevant construct/predictor' (item 8, B=.22, 95% CI= 0.04, 0.40, p=0.020) and 'mediational analysis of constructs/predictors: intervention does not predict the dependent variable when controlling the independent variable' (item 14c, B=-.35, 95% CI= -0.66, -.03, p=.034).

In the adjusted model with standardised effect sizes, there was an overall significant association (I^2 =68.05%, R^2 _{adj}=44.29%, p<0.001). This adjusted model had the same pattern of results as the model using unstandardized effect sizes. See Appendix 5 for the results tables of the sensitivity analysis for the series of unadjusted models and the adjusted model.

4.4 Discussion

This literature review showed limited reporting of theory use in the development and evaluation of digital interventions to reduce harmful or hazardous alcohol consumption. Half of the studies in this review did not refer to a theory or model of behaviour. and a third of studies reported using theory to develop the intervention. No study reported using their results to refine the theory.

No significant associations were detected between the reporting of theory use and intervention effectiveness. However, the meta-regression had limited power to detect modest associations [324] and any associations were likely to be small given the substantial

heterogeneity in this literature. The data underlying the majority of null findings were found to be insensitive to distinguish an effect (through the calculation of Bayes factors). There was moderate or strong evidence that eight TCS covariates (of the 22 TCS covariates included in the unadjusted model) were not associated with intervention effectiveness. Insofar that a researcher believed smaller effect sizes were important then it is likely that the Bayes factors calculated for these data would indicate the findings as insensitive rather than supporting the null hypothesis. Despite failing to find evidence of a significant association, there was moderate evidence from the Bayes factor calculation that the item 'changes in measured theory-relevant constructs/predictor' is associated with intervention effectiveness; this warrants further investigation. Whilst no significant associations were found in the unadjusted models, three TCS covariates were included in an adjusted model due to a modest association with effect size and two had a significant association. However, these results are difficult to interpret in the absence of significant results in the unadjusted models and that the pattern of results was not robust to standardised effect sizes.

The current findings differ from the Black et al. review [189] of studies assessing the association between theory use and effectiveness of computer-delivered alcohol interventions in the general population [189]. The difference in findings is probably due to the different study populations, with the population of the current review being those with excessive or problematic drinking. In addition, the current review searched more databases whilst also excluding a greater number of studies. For example, studies were excluded if the follow up was less than one month or participants were not screened into the intervention and so were not necessarily a hazardous or harmful drinker. This resulted in both reviews including unique studies as well as some that were present in both reviews. Only one third of the study references listed in the Black et al. review [189] were also included in the current review though the large majority of references not included in this review were identified through

the search strategy. Another potential reason for the difference in findings is the way in which the TCS was used. In the current review, all of the items related to the reporting of theory use in intervention development and evaluation were used (excluding two relating to methodological issues) whilst the Black et al. review [189] only used items relating to intervention development and participant selection (the first 11 items). We used all the items of the TCS to assess how theory had been used not just in the intervention development but also in the interpretation of the findings and refining the relevant theory. We also assessed the TCS in terms of the categories of theory use to account for differences between intervention development or evaluation and the association with intervention effectiveness.

Our study built on the Black et al.'s review [189] by having a population of more clinical relevance, a more comprehensive use of the TCS, and a broader search strategy. We are unable to tell whether the differences in findings are due to variations in the studies included, the way in which the TCS was implemented or a lack of power to detect an effect in our meta-regression. The importance of independently replicating findings is highlighted by the different results reported by the two reviews. It is clearly an emergent evidence base and these review results should be treated with caution.

Another systematic review investigated use of theory in computer-based interventions to reduce alcohol use was conducted amongst adolescents and young adults [329]. This review found that the primary theories mentioned by the studies were Social Cognitive Theory, Social Learning Theory, Theory of Planned Behavior, Transtheoretical Model, Health Belief Model and Social Norms Theory – all of which were mentioned in the current review. Less than half of the studies used theory to select or develop intervention techniques but only a few provided detailed information about how the theory was applied to the computer based intervention. This systematic review categorised use of theory with Painter et al.'s classification system [301] which involves three stages: whether theory was mentioned, how

it was applied, and if it was tested or theoretical constructs were measured. This system is less comprehensive than the TCS and does not allow for direct comparisons between results.

The results from the current review should be treated cautiously as the majority of null findings were insensitive to distinguish an effect, which is a function of the available literature and methodology. Previous simulation studies have found that for accurate estimates in meta-regression at least 40 studies are required [323] and, as a rule of thumb, more than 200 studies are required for 80% power to detect modest associations [324]. The meta-regression conducted for this study was underpowered due to the small sample size, which was a function of the available literature. However, it is important to have a starting point for collating evidence and this study can be updated as new literature emerges. The composite scores calculated were crude measures that gave all items in the TCS equal weight and therefore were not necessarily the most accurate representation of theoretical application. However, the methodology used was the best tool currently available for assessing the reporting of theory use and quantifying its extent.

A systematic review and meta-regression can capture the existing knowledge on a topic of interest though cannot consider any novel intervention strategies or components. Meta-regression analyses have some limitations: they are susceptible to reporting bias, with quantitative methods in particular being subject to the risk of data dredging and false positive findings [330,331]. Meta-regression analyses are also subject to the risk of ecological fallacy, as they attempt to make inferences about individuals using study-level information [330]. Results from meta-regressions can be biased if the model is underpowered, and there is a practical limitation in that published papers may not always appropriately report the necessary information about the model's covariates [330,331]. There was some evidence of a publication bias with an under-reporting of results that showed little or no evidence of an effect of a digital intervention on alcohol consumption [283]. Authors were contacted where

possible to obtain missing data and every effort was made to locate all eligible trials through searching a wide range of databases and sources in an attempt to minimise publication bias. Sensitivity analyses with imputed missing values (conducted in the main Cochrane review [283]) indicate that the statistically significant effect of digital interventions on reducing excessive alcohol consumption is robust.

A limitation of the available literature was that only the *reporting* of theory use could be assessed. This makes our findings difficult to interpret, as a lack of reporting of theory use in the published study does not necessarily equate to a lack of theory use. Therefore, any inconsistent reporting of theory use between studies could have led to misclassification of studies, which cannot be addressed. This highlights the need for improvement in the way in which theory use is currently reported. The TCS may provide a useful basis as a checklist for researchers to use when reporting how theory was used. The use of the TCS in this way would help to clarify whether theory had not been used or not been reported. The TCS also enables clearer comparisons between interventions that differ in their use of theory which could provide stronger tests of theory and a firmer basis for their refinement [311].

A large number of behaviour change theories exist [147] and the null findings could suggest a poor choice of theory in this literature. For example, the Stages of Change model was used though lacks empirical support [332] and many other theories have remained popular despite little empirical support [333–336]. Some interventions based on specific theories – Social Cognitive Theory, Health Belief Model or Theory of Planned Behaviour – achieve effects on behaviour though there is limited evidence that these effects are explained by changes in the relevant theoretical constructs [337–339]. A number of studies used the same intervention component – personalised normative feedback – though there were different theories reported as the basis for this intervention (e.g. Self-Regulation Theory, [340,341], Social Norms Theory [342], Motivational Interviewing Theory [343]). The reference to different

theories with respect to the same intervention component makes it difficult to compare the effectiveness of interventions using different theories and is likely to delay the development of both theories and interventions.

Theory can be used to guide intervention development and provides the researcher with a number of benefits. However, this review identified an absence of studies using their results to refine theories and, therefore, contribute to theory development. This delays the development of theories and interventions that have the potential of achieving significant changes in behaviour [311]. Using data to test and refine theory in the evaluation of an intervention requires measurement of theoretical constructs that may create issues with user engagement if this is not automated. This issue could explain why so few of these interventions use their findings to test theory. Behaviour change theories have the potential to generate explanations and predictions at both the group- and individual-level [344–346]. However, they have tended to be drawn from cross-sectional comparisons of groups rather than within individual change over time meaning that theories tend to generate explanations and predictions about average group-level changes in outcomes [347]. Digital behaviour change interventions have the potential to provide support at the moment when a person has either the opportunity to engage in the desired behaviour or the vulnerability to engage in a negative behaviour. This 'just-in-time' support requires theories that account for variations in individual characteristics and contexts, and recognise that these variations change over time [348]. The technology underpinning digital interventions can also collect comprehensive data on an individual's behaviour over time and in different settings and contexts reflecting withinperson variation [347,349–353]. Behaviour change theories thus need to capture individual variation and temporal changes to be suitable for informing the development of digital interventions.

Recommendations for the development of theories that are informed by, and can inform, digital behaviour change interventions have been provided by a group of international experts, including behavioural, computer, and health scientists and engineers [354]. A framework was proposed that uses a 'state-space representation' to define when, where, for whom and in what state for that individual, an intervention will and will not produce an effect [354]. This requires precise specification within theories of the dynamics of the relationship (i.e. anticipated timescale of an effect, response patterns, latency and decay) and the dimensions along which contextual factors may vary to influence the intervention's effect size.

The 'state-space representation' can be used to help identify methodological strategies for improving measurement, experimental design and analysis that could feasibly match the complexity of behaviour change. The paper proposes three steps for clearer specification within theories [354]. Firstly, increased theorising about the dynamics and dimensions along which contextual factors may vary. Secondly, transdisciplinary research is needed to advance the understanding and quality of measures of the theoretical constructs in context and the dynamics of the relationship between theoretical constructs. Opportunities for this exist in the realm of digital traces, wearable technologies, and ecological momentary assessment. Thirdly, increased exploration and use of research methods and analytic techniques that can support more detailed study is warranted for both the dynamic relationships between constructs and the dimensions along which contextual factors vary. Behaviour change theories can become more precise, and theory-driven interventions more effective, if these steps are followed and emphasis is put on defining when, where and for whom an intervention will and will not produce an effect [354].

This study did not directly inform intervention development, as no main effects were detected. However, it still contributed to my thesis in that it demonstrated the importance of clearly reporting theory use and the issues associated with using theory throughout

intervention development and evaluation. It also provided me with experience of conducting a systematic review and meta-regression as part of a large team across different universities. The systematic review in general provided evidence that digital alcohol interventions can be effective compared with control groups. David Crane conducted a parallel study assessing the intervention components of these interventions and whether an association existed between individual components and intervention effectiveness. However, this systematic review and meta-regression took a long period of time and the intervention components to include in the app had already been selected before the study was completed. This highlights the issues with conducting a comprehensive and thorough development where time constraints exist.

In conclusion, a lack of evidence was found in this review that the reporting of theory use was associated with the substantial heterogeneity in effect size between digital interventions for alcohol reduction. Limitations render the data and literature insensitive to answer the more general and important question of whether systematic use of a good and appropriate theory improves intervention effectiveness. Digital interventions provide an excellent opportunity for collecting comprehensive data sets on a moment-to-moment basis by continuously observing behaviour in context [350]. This will help to develop behaviour change theories that can capture individual variation and changes over time [354] and are better suited to informing digital behaviour change theories [347,349–351]. However, no existing studies reported using their results to refine theory. This review highlights the need for clearer selection, application and reporting of theory use in the development and evaluation of digital behaviour change interventions.

Chapter 5 - Normative misperceptions about alcohol use in the general population of drinkers: a cross-sectional survey (Study 3)

Abstract

Underestimating one's own alcohol consumption relative to others ('normative misperception') may contribute to excessive drinking; it has been documented in heavy-alcohol users in Canada and college students in the US and New Zealand. The study reported in this chapter aimed to assess i) whether this phenomenon extends to the general population of drinkers in four English-speaking countries and ii) associations with socio-demographic and drinking variables.

A cross-sectional online global survey (Global Drugs Survey-2012) was completed by 9,820 people aged 18+ from Australia, Canada, the UK and the US who had consumed alcohol in the last year. The survey included the Alcohol Use Disorders Identification Test (AUDIT), which assesses alcohol consumption, harmful drinking and indicators of alcohol dependence, and questions assessing socio-demographic characteristics and beliefs about how one's drinking compares with others. Associations were analysed with linear regression models.

Underestimating one's own alcohol consumption relative to other drinkers is common in Australia, Canada, the UK and the US (46.9%; 95% CI= 45.9%, 47.9%), with a substantial minority of harmful drinkers (AUDIT score>=16) (36.6%) believing their consumption to be at or below average. This normative misperception is greater in those who are younger (16-24; p<0.003); male (p<0.001); from the UK (versus the US; p<0.001); less well educated (p=0.003); white (p=0.035), unemployed (versus employed; p<0.001) and high-risk drinkers

(ps<0.001). These findings suggest that targeting normative misperceptions using normative feedback warrants further research and may be a suitable intervention strategy for the general population of drinkers.

5.1 Introduction

'Normative misperception' about alcohol use refers to the underestimation of one's own alcohol consumption relative to others. The presence of normative misperceptions in heavy drinkers was identified in a behavioural analysis (see Chapter 2) as a potential barrier to behaviour change. A theoretical explanation for how normative misperceptions can affect drinking behaviour is the Social Norms theory [180]. This theory proposes that people behave in a way that attempts to conform to their perceived norm (i.e. heavy drinking) even if this results in behaviour that is inconsistent with their own beliefs and values (i.e. being a responsible drinker) [181]. The Social Norms theory is one of the more commonly reported theories in the development and evaluation of digital alcohol interventions (see Study 2, Chapter 4) [355]. Computer-delivered interventions using a Social Norms approach have also been found to be significantly better at reducing average alcohol consumption than interventions not using this approach [189].

Despite an understanding of how normative misperceptions affect drinking behaviour, it is unclear how they are formed. One explanation is that excessive drinking on social occasions is a salient activity and easily remembered [356]. Subsequently, perceptions of typical alcohol use develop that are unreliably based on this salient information [175]. Another potential explanation is that people adjust their beliefs about what is normal alcohol use to justify their own alcohol use. This is known as social norm calibration and allows people to view their own alcohol use as normal rather than unusual [172] and excuses their behaviour if others' alcohol

use is seen as more severe [175]. These exaggerated social norms could then be used as a guideline for alcohol use and what is considered acceptable in different situations [179].

There is empirical evidence to suggest that the existence of normative misperceptions is associated with excessive alcohol consumption. Normative misperceptions about alcohol use are predictors of higher alcohol consumption [175,178,182–184]. Studies have found that improving an individual's knowledge about their alcohol use compared with that of others can reduce subsequent alcohol consumption [172–174,178,179,185–188]. A systematic literature review on providing social norms information for alcohol misuse in students found small but significant effects on a number of alcohol-related outcomes [190]. Though not all studies have found a positive effect, one RCT amongst UK students found no effect of normative feedback on reducing alcohol consumption [357]. There also appears to be a negative effect of normative feedback on participants who perceived themselves as having no alcohol-related risk [174].

The current empirical evidence suggests that correcting normative misperceptions by providing normative feedback may be effective for reducing alcohol consumption, though more research is needed to confirm this claim. There is evidence that one's perception of personal alcohol-related risk moderates the relationship between correcting normative misperceptions and reducing alcohol consumption; this may explain the mixed results.

However, research documenting the existence of normative misperceptions has been limited to college and university students in the US and New Zealand [175,176,178,179,358] or heavy drinking samples in Canada [173,174]. These groups tend to underestimate their alcohol consumption relative to other people. It is not clear whether this normative misperception exists in the general population of drinkers. It is important to determine whether normative feedback has the potential to be effective amongst this general population of drinkers and not

just the heavy drinkers or students at whom the current interventions are targeted. If normative misperceptions do exist in the general population then normative feedback may be a promising component to include in future alcohol reduction interventions.

There is very little research on associations between normative misperception and sociodemographic or drinking characteristics. Two studies have found that women perceived larger differences between their own and others' drinking behaviour [359,360] but another study found no effect of gender on perceived norms for quantity or frequency of alcohol consumption [361]. Knowledge of associations could be used to inform the targeting of interventions, which could potentially enhance the effectiveness of the intervention.

The app-based intervention was targeted at reducing excessive alcohol consumption in the general population of drinkers, not just in heavy drinkers or students. Correcting normative misperceptions is the proposed mechanism of action for normative feedback to cause a change in behaviour. Therefore, it was important that this study assessed whether normative misperceptions exist in the general population of drinkers to inform whether to include normative feedback in the app. This study aimed to establish how widespread normative misperceptions are in the general population of drinkers and to assess associations with socio-demographic and drinking characteristics.

5.1.1 Aims and research questions

This study aimed to assess the prevalence of normative misperceptions in the general population of drinkers spanning four English-speaking countries, and to examine associations between normative misperceptions and socio-demographic and drinking variables.

This study addressed the following research questions:

- 1. What is the prevalence of normative misperceptions about alcohol use in the general population of alcohol users from the UK, US, Australia, and Canada?
- 2. To what extent are normative misperceptions about alcohol use associated with a range of socio-demographic and drinking variables?

5.2 Methods

5.2.1 Study design

This study used an anonymous cross-sectional online survey that was conducted in 116 countries (Global Drugs Survey (GDS) -2012). Sample sizes for four English-speaking countries were sufficiently large to provide useful data and these formed the basis for the study. The GDS was developed by an expert advisory group and an academic network, and captures information to monitor the use of drugs and identify emerging trends in drug use [362–365]. Participants were recruited using a purposive sampling strategy [362].

5.2.2 Participants

This study draws on GDS data obtained from Australia, Canada, the UK and the US (n=12,309). Participants who were 18 years old or over, had answered "yes" to whether they had used alcohol within the last 12 months and had no missing data for any of the variables, were included in this study. This resulted in 9,820 participants whose socio-demographic and drinking characteristics are shown in Table 5.1. The majority of participants were aged between 16-24, male, white, from the UK, had post-16 qualifications, and were employed.

Table 5.1: Socio-demographic and drinking characteristics of the Global Drugs Survey sample

Variable	n=9,820
Mean (SD) AUDIT score	10.5 (6.2)
AUDIT risk zone (%)	

Variable	n=9,820
1	36.8
2	43.4
3	10.8
4	9.0
Age (%)	
16-24	44.9
25-34	36.8
35-44	12.2
45-54	4.4
55+	1.6
Gender (% male)	68.7
Ethnicity (% white)	92.0
Country of origin (%)	
Australia	3.1
Canada	6.5
UK	63.9
US	26.5
Qualifications (% post-16)	95.8
Employment status (%)	
Employed	49.3
Student	27.7
Unemployed	23.0

5.2.3 Measures

Alcohol use and alcohol-related problems were assessed using the Alcohol Use Disorders Identification Test (AUDIT) [3]. The full 10-item AUDIT questionnaire assesses alcohol consumption, harmful drinking and alcohol dependence. The possible scores range from 0 to 40 and are categorised into four AUDIT risk zones: Zone 1 (0-7) refers to low-risk drinking or abstinence; Zone 2 (8-15) refers to hazardous drinking; Zone 3 (16-19) refers to harmful

drinking, and Zone 4 (20-40) identifies those who are at risk of alcohol dependence and warrant further assessment and investigation [3]. The AUDIT alcohol consumption (AUDIT-C) questionnaire consists of the first three-items of the full 10-item AUDIT questionnaire.

Normative perceptions about alcohol use were assessed by the question: "How do you think your use of alcohol compares to other people who have used that substance recently?" Participants selected one of nine categories or 'Don't know': 1=Lowest 10%, 2=Very low, 3=Low, 4=Low-average, 5=Average (middle 20%), 6=High average, 7=High, 8=Very high, 9=Top 10%.

Socio-demographic information on age, gender, ethnicity, country of origin, employment status and highest qualification level attained was collected.

5.2.4 Procedure

The GDS (https://www.globaldrugsurvey.com) was actively promoted as an anonymous, online survey about drug use through social networking sites (e.g. Twitter, Facebook) for five weeks from 16th November 2011. The promotions invited people to take part in a study investigating drug use and related attitudes and included a link to the study hosted on the GDS website. Those interested in participating after reading the study information were asked for informed consent prior to submission of their completed questionnaire. Respondents were offered no incentive for participation. The average time for completion was approximately 35 minutes. Ethical approval was granted by the Joint South London and Maudsley, and Institute of Psychiatry Ethics Committee (reference number 141/02).

5.2.5 Analysis

The AUDIT-C was used to calculate the normative misperception score because it focuses on alcohol consumption (both the frequency and quantity of alcohol use). The middle two deciles of AUDIT-C scores were combined into one category so that the AUDIT-C score deciles could be directly compared with the nine-item scale of normative misperception, which was anchored on the lowest 10%, the middle 20% and the highest 10% (see above). This yielded an AUDIT 'position' from 1 to 9 (1=0-10%, 2=10-20%, 3=20-30%, 4=30-40%, 5=40-60%, 6=60-70%, 7=70-80%, 8=80-90%, 9=90-100%). The 'normative misperception score' was calculated as the difference between each participant's actual AUDIT-C position and their rating, and could range from -8 to +8. A positive score indicates an individual underestimated their alcohol use compared with others whilst a negative score corresponds to an overestimation. The magnitude of the normative misperception score corresponds to the extent of discrepancy between the individual's actual and perceived position in the AUDIT-C distribution. This method operationalises normative misperceptions for the purposes of assessing associated factors and the magnitude of the normative misperceptions.

The prevalence of normative misperceptions for different AUDIT risk zones was assessed through cross tabulation. A series of simple linear regressions was used to investigate the unadjusted associations between the normative misperception score and the sociodemographic and drinking variables. A fully adjusted regression model, including all the sociodemographic and drinking variables, was used to investigate which of the factors had a unique association with the normative misperception score.

5.3 Results

5.3.1 Prevalence of normative misperception

The mean normative misperception score was 0.20 (SD=1.85) which was significantly greater than 0 ($t_{(9819)}$ =10.443, p<0.001). This means that people have a small but significant tendency to underestimate one's alcohol consumption relative to others. Nearly half of the sample (46.9%, 95% CI=45.9%, 47.9%) underestimated the proportion of other people who consume less alcohol than themselves whilst 38.6% (95% CI=37.6%, 39.5%) overestimated it and 14.5% (95% CI=13.8%, 15.2%) were accurate in their perception.

5.3.2 Unadjusted associations between normative misperception score and sociodemographic variables

Country of origin, age, gender, ethnicity, employment status and qualification level were all associated with normative misperception (see Table 5.2). Respondents from the UK had significantly greater mean normative misperception scores (indicating an underestimation of own alcohol consumption relative to others) compared with those from Australia, Canada or the US. Larger normative misperceptions were more likely in participants who were younger (16-24), male, categorised themselves as 'white' compared with all other ethnicities, unemployed and whose highest level of qualification was attained pre-16.

5.3.3 Unadjusted associations between normative misperception score and AUDIT risk zone

AUDIT risk zone was associated with normative misperception; lowest risk drinkers have the lowest mean misperception score (see Table 5.2). The mean normative misperception scores for those participants who were classified as hazardous alcohol users (AUDIT risk zone 2), harmful alcohol users (risk zone 3) or at risk of alcohol dependence (risk zone 4) were

significantly greater than 0 (hazardous: mean=0.5, SD=1.73, $t_{(4257)}$ =20.17, p<0.001; harmful: mean=1.1, SD=1.74, $t_{(1060)}$ =20.64, p<0.001; at risk of dependence: mean=1.4, SD=1.69, $t_{(885)}$ =24.18, p<0.001) indicating an underestimation of their alcohol consumption relative to others. Low-risk drinkers had a normative misperception score of significantly less than 0 (mean=-0.8, SD=1.60, $t_{(3614)}$ =-28.67, p<0.001) indicating an overestimation of their alcohol consumption relative to others. The tendency for individuals at higher levels of alcohol-related risk to have higher mean normative misperception scores was also illustrated by an examination of the data by AUDIT risk zone: 25.4% of alcohol users at risk of alcohol dependence and 36.6% of harmful alcohol users believed their alcohol use to be average or less than average.

5.3.4 Fully adjusted model

In a fully adjusted model, normative misperceptions were more likely among participants who were younger, male, from the UK compared with the US, without post-16 qualifications, white, and unemployed compared with employed (see Table 5.2). Those with lower levels of alcohol use (AUDIT risk zone 1) had significantly lower normative misperception scores than those who used alcohol more heavily (AUDIT risk zones 2, 3 & 4, ps<0.001).

Table 5.2: The effect of socio-demographic variables and AUDIT risk zone on normative misperception score

			Mean normative	Unadjusted simple line	ar regression	Adjusted multiple reg	ression
			misperception			(with all variables as o	covariates)
		N	score (SD)	B (95% CI)	p	B _{adj} (95% CI)	p
Country of	United	6273	0.4 (1.78)				
origin	Kingdom*						
	Australia	306	0.2 (1.95)	-0.25 (-0.46, -0.04)	0.021	0.03 (-0.16, 0.22)	0.779
	Canada	641	0.1 (1.92)	-0.36 (-0.50, -0.21)	< 0.001	-0.02 (-0.16, 0.11)	0.753
	United States	2600	-0.3 (1.90)	-0.70 (-0.78, -0.61)	< 0.001	-0.29 (-0.37, -0.21)	< 0.001
AUDIT risk	1 (0-7)*	3615	-0.8 (1.60)				
zone (AUDIT	2 (8-15)	4258	0.5 (1.73)	1.40 (1.33, 1.47)	<0.001	1.29 (1.21, 1.36)	<0.001
score)	3 (16-19)	1061	1.1 (1.74)	2.04 (1.92, 2.16)	<0.001	1.90 (1.77, 2.02)	<0.001
	4 (20-40)	886	1.4 (1.69)	2.19 (2.03, 2.34)	< 0.001	2.00 (1.85, 2.16)	< 0.001
Age/ years	16-24*	4407	0.5 (1.88)				
	25-34	3615	0.0 (1.80)	-0.44 (-0.52, -0.36)	< 0.001	-0.28 (-0.36, -0.20)	< 0.001
	35-44	1201	0.0 (1.79)	-0.50 (-0.62, -0.38)	< 0.001	-0.22 (-0.34, -0.11)	< 0.001
	45-54	436	-0.2 (1.77)	-0.67 (-0.86, -0.49)	< 0.001	-0.26 (-0.43, -0.09)	0.003

	55+	161	-0.6 (1.71)	-1.04 (-1.33, -0.76)	< 0.001	-0.47 (-0.73, -0.21)	< 0.001
Gender				0.47 (0.39, 0.55)	< 0.001	0.34 (0.27, 0.41)	< 0.001
	Male	6750	0.3 (1.84)				
	Female	3070	-0.1 (1.84)				
Qualification				-0.44 (-0.62, -0.26)	< 0.001	-0.25 (-0.41, -0.08)	0.003
level	Pre-16	412	0.6 (1.91)				
	Post-16	9408	0.2 (1.85)				
Employment	Unemployed*	2256	0.4 (1.91)				
status	Student	2718	0.3 (1.87)	-0.13 (-0.23, -0.02)	0.018	-0.09 (-0.18, 0.00)	0.056
	Employed	4846	0.1 (1.80)	-0.36 (-0.45, -0.26)	< 0.001	-0.20 (-0.29, -0.11)	< 0.001
Ethnicity				-0.27 (-0.40, -0.13)	< 0.001	-0.13 (-0.25, -0.01)	0.035
	White	9037	0.2 (1.85)				
	Non-white	783	-0.1 (1.82)				

^{*}reference group for the categorical variable

5.4 Discussion

There was evidence of a small but significant tendency to underestimate one's alcohol consumption relative to others in a large sample of drinkers from four English-speaking countries. This tendency was greatest amongst those who were: young (16-24), male, from the UK compared with the US, without post-16 qualifications, classifying themselves as white, and unemployed compared with employed. This normative misperception about alcohol use was greater among those with higher AUDIT scores; a quarter of the drinkers at risk of alcohol dependence and over a third of harmful drinkers considered that their alcohol consumption was average or below average. However, there was no significant difference between the normative misperception scores for hazardous and dependent alcohol users. This suggests that the relationship between normative misperception and alcohol use is not a simple positive linear relationship that other studies have suggested [175,178,179,358]. There is potentially some threshold level of alcohol use above which normative misperceptions do not continue to increase.

The findings of this study assessing normative misperceptions have implications for developing an app-based intervention to reduce excessive alcohol consumption. The current findings show that normative misperceptions exist in the general population of drinkers, particularly among heavier drinkers. There is also existing evidence to suggest that normative feedback acts by reducing normative misperceptions, which in turn reduces alcohol consumption [172–174,178,179,185–188]. Therefore, providing normative feedback to a population of heavy (but not necessarily harmful or dependent) drinkers may be effective at reducing alcohol consumption and warrants inclusion and evaluation in the app.

The findings also have broader implications: they confirm and extend previous research on the existence of normative misperceptions about alcohol use in students and heavy drinkers to the general population of drinkers in four English-speaking countries. These findings also show that the phenomenon is broadly restricted to heavier drinkers and that light drinkers typically over estimate their drinking relative to others. Therefore, it is important to only highlight negative misperceptions (believing one drinks the same as or less than others) when providing normative feedback. This is to avoid the possibility of a light drinker who over estimates their drinking relative to others drinking more as a result of normative feedback that informs them their drinking is below average. A Cochrane review of evaluations of interventions correcting normative misperceptions concluded that such interventions could lead to a small reduction in alcohol misuse [366]. However, it was not clear whether the interventions worked through the intended mechanism of correcting normative misperceptions. Future research should examine potential mediators and the effects of targeting according to significant socio-demographic and drinking characteristic moderators. Such targeting of interventions could potentially enhance the effectiveness of population-wide interventions to reduce alcohol consumption and misuse.

One study limitation was that the distribution of AUDIT scores was derived from the GDS-2012 sample, which is unlikely to be representative of the general population [367]. The 2007 Adult Psychiatric Morbidity Survey (APMS-2007) is considered representative of the English general population and respondents were found to have a lower mean full AUDIT score (mean=4.7, SD=4.69) than in the current study (mean=10.5, SD=6.16). However, it is also possible that the APMS-2007 underestimated alcohol consumption as it involved face-to-face interviews, which could result in less honest reporting of drinking habits compared with the anonymous, online GDS-2012. Insofar as the GDS-2012 sample was biased towards a heavy drinking sample, the results of this study are likely to be an overestimate of the overall population prevalence of normative misperceptions because the consumption comparator

(from which the misperceptions were calculated) would be higher than from the general population.

A second limitation of this study was that all four countries were used to create the nine-point scale of AUDIT-C scores. People may have answered the comparison question in relation to people in their own country or even their own acquaintances, as this is the most salient information to them. However, a sensitivity analysis using only the larger UK or US subsamples showed similar patterns of results compared with the analysis for all four countries.

A third limitation relates to the way the misperception score was derived. There are different ways in which it could have been approached. The chosen method was considered the best compromise between precision in terms of intended meaning and using language that respondents would understand. The extremes and the middle of the response options for the question assessing perceptions about alcohol use were anchored with deciles and linguistic terms were used for the other response options. It is possible that different choices would result in different estimates.

This particular focus on normative misperceptions (and therefore, the potential role of normative feedback) was the result of its identification in the behavioural analysis and the existence of a large data set available for secondary analysis – the Global Drugs Survey – which had measures assessing an individual's drinking characteristics and their normative misperceptions. There was evidence from other digital interventions using normative feedback that indicated this may be an important focus for determining which intervention content to include in the app. Whilst a lot of these studies show a small effect of normative feedback, digital interventions can have a very broad reach so even a small effect could have a significant effect at the population level. This study directly informed the intervention content, though it had a very specific focus and was not a source of evidence for prioritising

intervention content more generally. The focus on normative misperceptions and normative feedback subsequently influenced the development of the app as it was decided to include normative feedback as part of registration in a tunnelled approach, to ensure all users completed this section.

In conclusion, normative misperceptions about alcohol use are common in the population of alcohol users in four English-speaking countries (the UK, the US, Australia and Canada). These normative misperceptions are most prevalent in the UK. It is common for harmful alcohol users and those at risk of dependence to believe that they drink at or less than average.

Normative misperceptions about alcohol use tend to be greater in those who are younger, male, less well educated, unemployed and white. The widespread existence of normative misperceptions about alcohol use among the drinking population provides support for the inclusion and evaluation of normative feedback in our app-based intervention.

Chapter 6 - Identification of behaviour change techniques and engagement strategies to include in a smartphone app to reduce alcohol consumption using a formal consensus method (Study 4)

Abstract

Digital interventions to reduce excessive alcohol consumption are effective, can be costeffective and have the potential to have a broader reach than brief face-to-face interventions.

However, there is not yet a strong evidence base on the effective behaviour change techniques

(BCTs) to reduce alcohol consumption or how best to 'engage' users. This study aimed to
identify the highest priority BCTs and engagement strategies for evaluation by inclusion in an
app to reduce excessive alcohol consumption, using a formal expert consensus method.

The first phase of the study consisted of a Delphi exercise of three rounds with seven international experts in the field of alcohol or behaviour change. In the first round, experts identified BCTs most likely to be effective at reducing alcohol consumption and strategies most likely to engage users with an app. These BCTs were rated in the second round; and those rated as effective by at least four out of seven participants were ranked in the third round. The rankings were analysed using Kendall's W coefficient of concordance, which indicates consensus between participants. The second phase involved a new, independent group of experts (n=43) ranking the BCTs that were identified in the first phase. The correlation between the rankings of the two groups was assessed using Spearman's rank correlation coefficient.

Of the possible BCTs identified, twelve were rated as likely to be effective. There was moderate agreement among the experts over their ranking of these BCTs (W=.465, $\chi^2(11)=35.77$, P<.001). The BCTs receiving the highest mean rankings were self-monitoring, goal setting, action planning, and feedback in relation to goals. There was a significant correlation between the ranking of the BCTs by the original group of experts who identified them and a second independent group of experts (Spearman's rho=.690, P=.010). Seventeen strategies likely to engage users were rated likely to be effective by the experts. There was moderate agreement among experts on the ranking of these engagement strategies (W=.563, $\chi^2(15)=59.16$, P<.001) and those with the highest mean rankings were ease of use, design – aesthetic, feedback, function, design – ability to change design to suit own preferences, tailored information, and unique smartphone features.

The BCTs with greatest potential to reduce alcohol consumption through an app were judged by experts to be: self-monitoring, goal setting, action planning and feedback in relation to goals. The strategies most likely to engage users were: ease of use, design, tailoring of design and information, and unique smartphone features. These results will be used to inform the intervention components to include in the app to reduce excessive alcohol consumption.

6.1 Introduction

Digital interventions to reduce excessive alcohol consumption are more effective than control groups such as assessment only, waiting list control groups and provision of standard information (see Chapter 4, [283]). Previous chapters have outlined that there is not yet an evidence base on effective intervention content (i.e. behaviour change techniques (BCTs)) to draw on when developing an app to reduce excessive alcohol consumption. A behavioural analysis analysed the potential intervention content that could be included in an app to reduce excessive alcohol consumption (see Chapter 2). In order to maximise the coverage of

available evidence, expert opinion was also canvased. Formal consensus methods were used to gather expert opinion on potentially effective intervention content to either confirm what we had already found or to identify any potentially effective intervention content we had missed. Formal consensus methods are widely used to guide action in areas of research where there is a lack of, inconsistent, or contradictory scientific evidence [368,369], as in this context.

BCTs included in digital behaviour change interventions (DBCIs) need to be appropriate and effective; in addition, the target population must use the apps. Usage involves both uptake and engagement [61]. Uptake refers to the prevalence of at least some level of exposure to a DBCI, whilst engagement is the "amount and manner of use of, or interaction with, an intervention among people who use it at least to some degree" (p31 [61]). DBCIs are assumed to have greater reach than brief face-to-face interventions, which means that there is a greater potential for uptake of the intervention. DBCIs also avoid any potential stigma associated with help-seeking in person [74], which can be a substantial barrier to the uptake of interventions. The delivery of digital interventions also requires less time, training and financial resources, which makes them a potentially cost-effective method of delivering behaviour change interventions. Apps have the additional advantage of being with the individual almost all of the time, which offers the potential to engage users in real time and in their everyday situations. Smartphones are increasingly pervasive; two-thirds of adults in England own a smartphone and almost two-thirds of smartphone owners use their phones for downloading apps [81].

The fact that apps can reach a large number of people is self-evidently not sufficient for an app-based intervention to be effective. Continued usage, i.e. engagement, may also be needed for an intervention to be effective [87], so that users can be exposed to its active BCTs. It has been found that many people download and try DBCIs, though engagement with the

intervention is not usually sustained beyond a few occasions [85] and a substantial proportion of users in digital health trials drop out before completing the intervention or stop using it [86]. This degree of attrition undermines the potential for apps to be effective and generalisable evaluation is made difficult when a large proportion of users cannot be contacted due to disengagement with the intervention [370]. Engagement in internet-based interventions is increased by the inclusion of prompts [371–373], peer support [371], counsellor support [371], and the combination of tailored communication with the use of reminders and incentives [374]. However, these engagement strategies appear to have been examined only in the context of websites. A recent systematic review of engagement literature has made a useful contribution to conceptualising engagement with DBCIs more broadly and has created a framework within which to consider features associated with engagement [375]. Two studies have considered engagement strategies used in behaviour change apps specifically, for smoking cessation [376] and alcohol reduction [377]. The smoking cessation apps were coded for the presence of engagement strategies [376] whilst a content analysis of user reviews on iTunes of alcohol behaviour change apps was conducted to highlight design recommendations from users [377]. However, these two studies did not assess whether the engagement strategies identified were effective at sustaining usage with the apps. There is a need to identify the strategies for engagement with apps that are most likely to be effective.

The study reported in this chapter set out to directly inform the content of the app-based intervention by identifying the intervention components judged to be 'best bets' to reduce alcohol consumption and strategies to maintain engagement with an app. It used a formal consensus building methodology with a small group of international experts in the field of alcohol or behaviour change. A second phase of the study compared the ranking of the intervention components by the original group of experts with a new, broader expert review.

6.1.1 Aims and research questions

The aim of this study was to build consensus amongst experts in alcohol or behaviour change

as to what intervention components and engagement strategies were most likely to be

effective based on the existing research literature, relevant theories and the experts' clinical

experience.

This study addressed the following research questions:

1. What BCTs do experts in the field of alcohol research agree are most likely to be

effective in general, and when delivered by an app?

2. What engagement strategies do experts believe are most likely to be effective initially

and over time?

6.2 Methods

6.2.1 First phase: 3-round consensus exercise

6.2.1.1 Study design

A Delphi-style methodology was used to generate consensus among experts about what

intervention components are likely to be the most effective at reducing alcohol consumption,

and what strategies are most likely to improve engagement with an app. Experts were asked

to generate a list of 'best bet' intervention components and engagement strategies which were

subsequently rated and ranked.

The Delphi method of generating consensus was selected as a formal, systematic and

reproducible method of arriving at a consensus. It was conducted anonymously to avoid

biases produced by perceived authority, persuasion or bandwagon effects [368,378].

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6.2.1.2 Participants

Seven international academic experts (six male) were purposively identified from a range of scientific networks and backgrounds (health psychology, biological psychology, developmental psychopathology and addiction research) on the basis of their knowledge of the alcohol literature, or experience of designing or delivering behaviour change interventions. Seven participants are considered sufficient for reliable group judgement [369,378]. None of the experts were identified based on any user experience expertise. The authorship team used their experience to judge the suitability of invited experts. Once the experts were identified, each was formally approached by an email invitation. All the experts who were approached agreed to take part. Experts were from the UK (n=6) and the Netherlands (n=1). Six were professors and one was a senior research fellow.

6.2.1.3 *Measures*

6.2.1.3.1 Round 1

Participants were asked to provide between three and five responses to each of three questions:

- 1. What intervention components do you believe would be the best bets for helping people reduce their alcohol consumption?
- 2. What intervention components do you believe would be the best bets for helping people to reduce their alcohol consumption when delivered by a smartphone app?
- 3. What do you think are the best strategies or techniques for maintaining engagement with an app aiming to help people reduce their alcohol consumption?

Each question was preceded by the statement: "Please answer the following questions based on your knowledge of the research literature, relevant theory and your clinical experience.

Please also provide the reason behind your choice." For question 2, participants were given the option to indicate that their answers were the same as for question 1.

6.2.1.3.2 Round 2

Participants were provided with an alphabetical list of the responses generated in the first round for each of the questions. They were instructed "Please rate your agreement with each of these techniques for the three different questions on the five-point Likert scales provided". The scale ranged from 1 (*strongly disagree*), 2 (*disagree*), 3 (*neither agree nor disagree*), 4 (*agree*) to 5 (*strongly agree*). Participants were given the option to make comments on their rating.

6.2.1.3.3 Round 3

The *n* responses were listed alphabetically with the mean agreement rating and rationale provided for each response. Participants were asked to rank the *n* responses from 1 (*most likely to be a best bet*) to *n* (*least likely to be a best bet*) for each of the questions. At this stage, participants were only asked to rank responses about which there had been broad agreement in the previous round, defined as a minimum of four out of seven of the participants agreeing (i.e., rating of 4 or above) that the technique was likely to be either effective or engaging (depending upon the question) [368]. The reason for removing responses about which there was little agreement was to improve responding by minimising the time required to complete the survey [368]. There was the option to make any final comments at this point.

6.2.1.4 Procedure

This study was conducted using the online survey tool Qualtrics. A link to the survey for each of the three rounds was emailed to the participants and they were given between one and two weeks to complete it. Non-responders were sent reminders until all participants had completed each round. Participants provided informed consent.

6.2.1.5 Analysis

6.2.1.5.1 Round 1

For each question, similar responses were summarised and combined. For question 1, a BCT was selected from one of two taxonomies [242,379] to describe each response for the intervention components, where appropriate.

6.2.1.5.2 Round 2

The mean, standard deviation (SD), and mode of the agreement ratings for each response to each of the three questions were calculated.

6.2.1.5.3 Round 3

The final rankings were analysed by calculating Kendall's W coefficient of concordance [380], which measures the extent to which judges agree on their rankings of items. The value of W ranges from 0 (indicating no consensus) to 1 (indicating perfect consensus) between participants. A value of 0.1 corresponds to very weak agreement, 0.3 to weak agreement, 0.5 to moderate agreement, 0.7 to strong agreement and 0.9 to unusually strong agreement [381]. The Kendall's W statistic uses the χ^2 test to test the independence of the ranking of the components.

6.2.2 Second phase: External validation

6.2.2.1 Study design

The intervention components generated and ranked in the first phase of the study were also ranked by a second group of experts in the field of alcohol.

6.2.2.2 Participants

Assistant and Senior Editors from the journal Addiction (n=179) were invited to take part in the study if they considered that they had sufficient expertise in terms of having 'an opinion on interventions that might help people who drink more alcohol than is good for them to reduce or quit'. A total of 43 participants participated.

6.2.2.3 Measures

Participants were asked to rank from 1 (*highest*) to 12 (*lowest*), a list of 12 responses generated in the first phase of the study by the original group of experts to the question "What intervention components do you believe would be the best bets for helping people reduce their alcohol consumption?"

6.2.2.4 Procedure

An e-mail was circulated to all the assistant and senior editors at the journal of Addiction with an alphabetical list of the 'best bet' intervention component responses. If they wished to take part in the study, they were asked to reply (via e-mail) with a ranking for each of the intervention components. Participants were given one week to reply before the study closed.

6.2.2.5 Analysis

The correlation between the rankings of the original and the new independent group of experts was assessed using Spearman's rank correlation coefficient. The new rankings were also analysed using Kendall's W coefficient of concordance [380] to assess the extent to which this second group agreed with each other.

6.3 Results

6.3.1 First phase: 3-round consensus exercise

Twenty-four responses were recorded in round 1 to the question of what intervention components are likely to be the most effective at reducing alcohol consumption. Eighteen of these responses were similar to at least one other, resulting in a total of 12 distinct components (see Appendix 6), of which 11 corresponded directly with a BCT (see Table 6.1). Six of the seven participants thought that intervention components likely to be effective in general would be the same as in an app. The other participant generated one suggestion to do with the intervention modality itself and how to present the intervention in a unique way. The response did not meet the intervention component definition and, therefore, was included with the responses to the question regarding engagement strategies.

Four of the 12 components, self-monitoring, goal setting, action planning, and feedback in relation to goals, had a mean ranking score greater than the average rank (6 out of 12) and the lowest mean agreement rating for these four BCTs was 4.3 (see Table 6.1). Overall the original group of experts displayed moderate agreement (Kendall's W=0.465) in their ranking of intervention components ($\chi^2_{(11)}=35.77$, p<0.001).

Table 6.1: Responses generated by the expert group on effective behaviour change techniques to reduce alcohol consumption

Responses	Equivalent	BCT definition	Agreer	nent rat	ing	Rankin	ıg
generated	BCTs					score	
			Mean	Mode	Agree:	Mean	Mode
			(SD)		Disagree	(SD)	

Responses	Equivalent	BCT definition	Agreen	nent rat	ing	Rankin	g
generated	BCTs					score	
			Mean	Mode	Agree:	Mean	Mode
			(SD)		Disagree	(SD)	
Self-	Self-	Establish a method	4.6	5	7:0	2.4	1
monitoring	monitoring of	for the person to	(0.54)			(1.81)	
	behaviour ^a	monitor and record					
		their havior(s) as part of a behaviour					
		change strategy					
Goal setting	Goal setting	Set or agree on a	4.7	5	7:0	2.6	1, 2
_	(behaviour) ^a	goal defined in	(0.49)			(1.51)	
		terms of the					
		behaviour to be					
A -4:	A -+:	achieved Prompt detailed	4.2	4	7.0	4.2	4
Action	Action	planning of	4.3	4	7:0	4.3	4
planning	planning ^a	performance of that	(0.49)			(0.95)	
		behaviour					
Feedback in	Provide	Provide feedback on	4.6	5	7:0	4.43	3
relation to	feedback on	the outcome of	(0.54)	.54)		(2.70)	
goals	performanceb	performance of the					
Behaviour	Behaviour	behaviour Prompt substitution	4.1	4	7:0	6.3	5, 7
substitution	substitutiona	of the unwanted	(0.38)	Т	7.0	(2.06)	3, 7
Substitution	Substitution	behaviour with a	(0.30)			(2.00)	
		wanted or neutral					
		behaviour					
Environmental	Advise on	Advise to change the	3.9	4	5:2	7.3	2, 9
triggers and	environmental	physical or social environment in	(0.69)			(4.07)	
drivers re	restructuring ^b	order to facilitate					
		performance of the					
		wanted behaviour					
		or create barriers to					
		the unwanted					
		behaivour					

Responses	_		Agreen	Agreement rating			Ranking	
generated	BCTs					score		
			Mean	Mode	Agree:	Mean	Mode	
			(SD)		Disagree	(SD)		
Provide	Provide	Provide information	4.0	4	6:1	7.4	12	
information	information	(e.g. written, verbal, visual) about health	(0.58)			(4.47)		
	on	consequences of						
	consequences	performing the						
	of excessive	behaviour						
	alcohol							
	consumption							
	& reducing							
	excessive							
	alcohol							
	consumption ^b							
Feedback in	Provide	Provide feedback on	4.0	4	6:1	8.4	7	
relation to	normative	other's behaviour and experiences	(0.58)			(1.90)		
people	information	and experiences						
	about others'							
	behaviour and							
	experiences ^b							
Motivational	Conduct	Advise on, arrange,	3.9	4	5:2	8.4	12	
interviewing	motivational	or provide emotional social	(1.07)			(3.41)		
	interviewing ^b	support						
Inhibition			3.6	4	4:3	8.4	10	
training			(0.54)			(3.51)		
Reward	Provide	Arrange felivery of a	3.9	4	5:2	8.9	11	
	rewards	reward if and only if	(0.69)			(2.12)		
	contingent on	there has been						
	successfully	effort and/or progress in						
	reducing	performing the						
	excessive	behaviour						
	alcohol							
	$consumption ^{b} \\$							

Responses	Equivalent	BCT definition	Agreen	nent rat	ing	Rankin	g
generated	BCTs					score	
			Mean	Mode	Agree:	Mean	Mode
			(SD)		Disagree	(SD)	
Habit reversal	Habit	Prompt rehearsal	3.4	4	4:3	9.1	10
	reversala	and repetition of an	(0.79)			(1.68)	
		alternative					
		behaviour to replace					
		an unwanted					
		habitual behaviour					

Notes: Responses ordered in terms of mean ranking score (from round 3). Agreement rating (1: *strongly disagree*, 5: *strongly agree*). Ranking score (1: *highest*, 12: *lowest*). Agree:Disagree (ratio of (*agree/strongly agree*): (*neither/disagree/strongly disagree*) used as inclusion criteria for round 3.

- a) BCTs as referred to in the 93-item BCT Taxonomy v1 (13)
- b) BCTs as referred to in the 42-item excessive alcohol reduction specific taxonomy (24)

Of the 20 engagement strategies generated, six were similar to at least one other and thus were combined, which resulted in 17 unique strategies (see Appendix 7 for the rationale for each of the 17 responses). Seven strategies (ease of use, design-aesthetic, feedback, function, design-ability to change design to suit own preferences, tailored information and unique smartphone features) had a mean ranking score greater than average rank (8 out of 16) and the lowest mean agreement rating for these strategies was 3.6 (see Table 6.2). Overall, the experts showed a moderate degree of consensus in their ranking of the strategies (Kendall's W=0.563, $\chi^2_{(15)}=59.16$, p<0.001).

Table 6.2: Responses generated by the expert group on engagement strategies

Responses	Agreement rat	ting	Ranking score	
	Mean (SD)	Mode	Agree:Disagree	Mean (SD) Mode
Ease of use	4.9 (0.38)	5	7:0	1.4 (0.79) 1

Responses	Agreement rat	ing		Ranking sco	re
	Mean (SD)	Mode	Agree:Disagree	Mean (SD)	Mode
Design – aesthetic	4.6 (0.54)	5	7:0	3.1 (1.57)	2, 5
Feedback	4.6 (0.54)	5	7:0	3.9 (1.68)	4
Function	4.0 (0.82)	4	5:2	6.6 (3.60)	11
Design – ability to change design to suit own preferences	3.6 (0.79)	4	5:2	6.9 (4.74)	3
Tailored information	4.3 (0.76)	4, 5	6:1	7.9 (3.39)	6, 7
Unique smartphone features	4.4 (0.54)	4	7:0	7.9 (5.79)	6
Prompts	4.1 (0.38)	4	7:0	8.4 (2.44)	8
Graded tasks	4.0 (0.82)	4	5:2	8.7 (3.50)	12
Gamification	4.1 (0.69)	4	6:1	8.9 (5.30)	10
Social-	3.9 (0.69)	4	5:2	10.4 (3.36)	9
comparison					
Reward type-	4.0 (0.82)	4	5:2	11.6 (2.23)	12
Novelty					
Reward type-	3.7 (0.49)	4	5:2	11.9 (2.97)	11, 15
Games					
Reward type-	4.0 (0.58)	4	6:1	12.1 (2.79)	8, 10, 11,
Positive messages					12, 13, 15,
					16
Reward type-	3.6 (0.98)	4	4:3	12.3 (1.98)	13
Financial					
Social- connectivity	4.0 (0.58)	4	6:1	14.1 (1.95)	15, 16

Responses	Agreement rating			Ranking score	
	Mean (SD)	Mode	Agree:Disagree	Mean (SD) Mode	
Reward type- cue	3.4 (0.98)	3	3:4	-	
signalling rewarda					

Notes: Responses ordered in terms of mean ranking score (from round 3). Agreement rating (1: *strongly disagree*, 5: *strongly agree*). Ranking score (1: *highest*, 16: *lowest*). Agree:Disagree (ratio of (*agree/strongly agree*): (*neither/disagree/strongly disagree*) used as inclusion criteria for round 3.

a) This response was not included in round 3 because there was not substantive agreement that it would be an effective engagement strategy in round 2 (defined as a minimum of 4 out of 7 of the participants agreeing (i.e., rating of 4 or above) that the technique was likely to be engaging).

6.3.2 Second phase: External validation

The ranking of the BCTs by the original group was validated by an independent group of experts: there was a significant correlation between their two rankings (Spearman's rho=0.690, p=0.010). Table 6.3 shows the ranking by the independent group of experts in phase 2 of the intervention components generated and agreed by the original group. There was modest but significant agreement amongst the broader group of experts (Kendall's W=0.320, $\chi^2_{(11)}$ =151.52, p<0.001).

Table 6.3: Comparison between rankings of phase 1 and phase 2 expert groups of effective behaviour change techniques for alcohol use reduction

Responses	Phase 1 experts	Phase 2 experts
	N=7	N=43
	Mean Rank (SD)	Mean Rank (SD)
Self-monitoring	2.4 (1.81)	3.4 (2.88)
Goal setting	2.6 (1.51)	3.8 (3.00)

Responses	Phase 1 experts	Phase 2 experts
	N=7	N=43
	Mean Rank (SD)	Mean Rank (SD)
Action planning	4.3 (0.95)	6.4 (2.72)
Feedback in relation to goals	4.4 (2.70)	4.1 (2.28)
Behaviour substitution	6.3 (2.06)	7.6 (2.51)
Environmental triggers and drivers	7.3 (4.07)	5.1 (2.72)
Provide information	7.4 (4.47)	9.5 (2.87)
Feedback in relation to people	8.4 (1.90)	7.4 (3.27)
Motivational interviewing	8.4 (3.41)	7.2 (2.82)
Inhibition training	8.4 (3.51)	8.8 (2.15)
Reward	8.9 (2.12)	6.8 (3.44)
Habit reversal	9.1 (1.68)	7.9 (2.69)

Notes: Responses ordered in terms of mean ranking score (from round 3) for the original, phase 1 expert group

6.4 Discussion

This study aimed to build a formal consensus amongst international experts in the field of alcohol or behaviour change about what intervention components and engagement strategies were most likely to be effective for reducing excessive alcohol consumption in an app-based intervention. The BCTs of self-monitoring, goal setting, action planning, and feedback in relation to goals were ranked most likely to be effective for reducing alcohol use. This finding was also validated by a larger independent group of alcohol experts. None of the experts thought that the BCTs likely to be effective in general would differ from those in an app, though one participant suggested presenting information in a way that was unique to an app. The most highly ranked engagement strategies were ease of use, design (both aesthetic and

the ability to change design to suit own preferences), feedback, function, tailored information and unique smartphone features.

The findings from this study identified potentially effective BCTs to use as the intervention components in an app to reduce excessive alcohol consumption. The majority of these BCTs identified by experts had been considered as a possible intervention component within the behavioural analysis (see Chapter 2), which strengthened the argument for the inclusion of those BCTs as an intervention component in the app. The intervention components that were identified in both this study and the behavioural analysis were: self-monitoring, goal setting, action planning, feedback in relation to people (i.e. normative feedback), provide information, inhibition training and habit reversal (which were both broadly covered by 'unconscious processes' in the behavioural analysis). Feedback in relation to goals was not directly listed in the behavioural analysis though was considered within goal setting and self-monitoring. This strengthens the argument for the inclusion of the following intervention components as they were also identified in the behavioural analysis: goal setting, action planning, normative feedback, targeting of unconscious processes, feedback in relation to goals, and provide information. Whilst these intervention components were all considered high priority for inclusion in the app, not all were necessarily included for evaluation. For example, 'provide information' was identified in the behavioural analysis though not considered sufficient as an effective intervention component when delivered alone (see Chapter 2).

A strength of this study for informing the intervention content is that is does not rely on published evidence to identify potential intervention components for the app. Relying solely on published empirical evidence has a number of drawbacks as highlighted by the Reproducibility Project – a large-scale replication attempt of 100 studies published in top psychology journals – that found a lack of reproducibility [382]. Only 39% of studies could be unambiguously reported, which may stem from methodological factors and the incentive

structures to publish novel positive results [382]. The use of experts in a series of prediction markets, where participants can bet on whether the key original result would replicate, found that experts predicted the outcome of the replications well [383]. This suggests that experts have a good understanding of how robust the findings from individual studies are, perhaps as a result of knowing their own 'desk drawers' of null results. Therefore, this expert consensus study has the benefit of being able to overcome potential issues of publication bias from empirical studies.

The experts did generate some intervention components that were not identified within the behavioural analysis in Chapter 2: behaviour substitution, environmental triggers and drivers, motivational interviewing, and reward. Motivational interviewing was also found as one of the most commonly reported theories in digital alcohol interventions (see Study 2 reported in Chapter 4). These differences between the intervention components generated by experts and the results from the behavioural analysis highlights that this evidence base is not clear. Therefore, a systematic approach to development is crucial for optimising interventions. The factorial evaluation of the app that will be conducted to determine the main and interactive effects of the intervention components will inform both optimisation of the alcohol reduction app and future behaviour change interventions.

This study has provided a list of engagement strategies believed to be effective to include in an alcohol reduction app. The highest priority engagement strategies of prompts, social connectivity and tailored information have previously been shown to result in increased use of website-based interventions [371–374].

The use of a Delphi approach to selecting intervention components or engagement strategies is clearly not guaranteed to result in the best choices, but on *a priori* grounds it seems preferable to the more usual practice of drawing on expertise and interest within a single

research team. The level of agreement within each group of experts was modest. However, the fact that the aggregate rankings of the two expert groups showed a high level of concordance was reassuring that the study tapped into a shared perspective on the existing evidence.

It is possible that the results of the Delphi exercise were biased by choosing an expert group with similar backgrounds to those of the research team. Therefore, the use of a second group of experts to validate the rankings of the intervention components provided important reassurance that this was not the case. The journal Addiction has a large pool of international experts on its editorial team and arguably includes most of the leading researchers in the field covering a wide range of expertise. As shown in this study, experts in the academic field of research did not identify any intervention components as being specifically effective for an app compared with a face-to-face intervention. This may be because they were not aware of the additional functions that an app can provide in terms of a behaviour change intervention. Future research should compare the views of experts in the relevant academic field with that of user experience experts to examine if there are any discrepancies between these groups and if so, how their opinions differ.

The results of this study will inform the intervention components included for evaluation within an app to reduce excessive alcohol consumption and contribute to the building of an evidence base for other research teams to use when developing similar apps. The findings strengthen the argument for inclusion of certain intervention components that were identified in the behavioural analysis and through the other studies conducted (e.g. Study 3 reported in Chapter 5). This study also provides a list of engagement strategies to use when designing an alcohol reduction app.

Chapter 7 - Development of 'Drink Less' Intervention Content

Chapter summary

The development of intervention content for the app, '*Drink Less*', was iterative and involved a number of steps. These steps included defining the app content, choosing the design principles, usability testing and de-bugging of the app.

The Drink Less app includes a set of core features and five intervention modules (normative feedback, cognitive bias re-training, identity change, self-monitoring and action planning).

Each intervention module has two versions delivering either 'intensive' or 'minimal' support.

This chapter outlines the rationale for the selected intervention content, the specific content, the development and the design of the app.

7.1 Introduction

As described in Chapter 1, excessive alcohol consumption is a serious problem for population health [22,29] and delivering an intervention through an app has the potential to be effective [283] whilst overcoming a number of barriers associated with brief interventions. Apps to help people reduce their excessive drinking are available. An analysis of user characteristics of a popular alcohol reduction app found that users reported greater alcohol consumption and related harms than the general population of drinkers in England, and that they were more likely to be younger, from the South of England, not heterosexual, and of a higher social grade (see Study 1 in Chapter 3). This suggests that apps to help users reduce their alcohol consumption are reaching those who need support and not the 'worried well'. None of the apps currently available appear to have been empirically evaluated or clearly developed based on theory or evidence.

The Drink Less app was developed and evaluated following the MRC guidance [139] for developing and evaluating complex interventions and the MOST framework [142] for optimising complex interventions. This approach for developing and optimising a multicomponent intervention involves a number of iterative phases and evaluations [143]. The approach starts with the use of a theoretical model to guide intervention development within the context of considering implementation issues. Using a theoretical model as the basis for intervention development provides an explanation for the mechanisms of action underlying the effect of the intervention on behaviour change. The COM-B model of behaviour [72,146] and TDF framework [72,149,150] were chosen as the theoretical model for this app and provided an over-arching structure within which to conduct a behavioural analysis to identify potential intervention components (see Chapter 2).

There is no clear existing evidence base from which to select intervention components for an app to reduce excessive alcohol consumption. Therefore, it is important to use multiple sources of evidence and triangulate these findings. The triangulation of findings is a strength of this development process and whilst each method has its own advantages and disadvantages, increased confidence can be given to intervention components that arise in multiple sources. The prioritisation of intervention components for inclusion in the app came from evidence about the effectiveness of the components used in other types of intervention, specific theories of relevance and additional exploratory studies that were conducted to inform development of the app.

A systematic review of digital interventions to reduce excessive alcohol consumption found that digital interventions were more effective than controls [283]. Only one of these digital evaluations involved apps thereby underlining the need to evaluate an app-based alcohol intervention. How the use of theory was reported in the development and evaluation of these digital interventions and whether that was associated with intervention effectiveness was

assessed in Study 2 [355] (see Chapter 4). This study established that theory was rarely used to inform digital interventions and there was no evidence that any particular way of using theory was associated with more effective digital interventions. This review, therefore, did not inform our specific theory selection.

A cross-sectional survey (Study 3) was used to assess whether excessive drinkers were accurate in their perception of how their alcohol consumption compared with others (normative misperceptions) (see Chapter 5) [384]. This study found that normative misperceptions were common amongst drinkers with a substantial minority of harmful drinkers believing their consumption to be average or lower. This suggests that providing normative feedback within the app may be effective at reducing alcohol consumption, as normative misperceptions exist in the general population of drinkers.

A formal consensus building exercise (Study 4) with alcohol- and behaviour-change experts was conducted to identify both the intervention components believed to be the highest priority for evaluation and also the engagement strategies thought most likely to be effective (see Chapter 6) [385]. Twelve intervention components and 17 engagement strategies were identified as likely to be effective. These findings directly informed the selection of content for the Drink Less app and the design principles of the app (see 7.2.5).

Alongside these studies, findings from an analysis of the content of the most frequently used components included in popular alcohol reduction apps [106]; and the behaviour change techniques (BCTs) used, and their associations with effectiveness, in digital alcohol interventions [386], informed the selection of the intervention content.

The behavioural analysis using the COM-B model and additional exploratory studies formed the first stage of development, namely informing selection of the intervention content for evaluation based on theory and evidence.

The app was targeted at all adults who consume excessive levels of alcohol as the findings from Study 1 (reported in Chapter 3) indicated that there was no particular sociodemographic group that used a popular alcohol reduction app more than others. Therefore, it was considered important to provide support to anyone who might want to use the app.

Based on this finding and the multiple potential intervention components identified, it was decided that the app should be a multi-component intervention that could be used as a 'toolbox' with users able to choose the components of the app that suited them best. Five components were chosen that targeted a range of factors: motivational, cognitive and self-regulatory. The self-regulatory factors are detailed in a separate thesis by David Crane (a fellow PhD student) who led the work on the core module of goal setting and the intervention components of self-monitoring and action planning. I led the work relating to the motivational and cognitive targets and the related intervention components of normative feedback, cognitive bias re-training and identity change.

The cognitive target of normative feedback – improving an individual's knowledge about how their alcohol use compared with others through feedback – is associated with the psychological capability component of the COM-B model. Normative feedback was identified in the behavioural analysis and the expert consensus study. Normative feedback was also an intervention strategy used by many existing studies, particularly those using digital interventions [172–174,178,179,185–188]. This led to a focus on this intervention component and a study was conducted that found that normative misperceptions – incorrect beliefs about how one's alcohol use compares with others – exist in the general population of drinkers. As the proposed mechanism of action for normative feedback is by correcting normative

misperceptions, normative feedback was considered an important intervention component to include in the app.

Motivation can act through a reflective and an automatic process in determining behaviour and there is evidence to suggest that targeting both systems may be more effective than either one alone [194,217–219]. Most existing interventions do not target the automatic process to enact behaviour change and it is not a standard intervention strategy, as illustrated by there being no equivalent BCT in the current BCT Taxonomy (version 1) [379]. Therefore, it was deemed important to have intervention modules that targeted both reflective motivation and automatic motivation. Cognitive bias re-training is typically a computerised task that aims to re-train automatic biases, such as approach and attentional, away from alcohol-related cues or stimuli. Cognitive bias re-training was identified as an intervention strategy to target automatic motivation in the behavioural analysis and inhibition training, a type of cognitive bias re-training, was identified in the expert consensus study. Approach-avoidance training (AAT) is one type of cognitive bias re-training that aims to re-train biases to alcohol-related stimuli from approach to avoidance that has evidence for its efficacy in reducing alcohol consumption [228,229,236].

Identity change was selected as an intervention component to target reflective motivation. Identity change is the principle of adopting an identity that is incongruent with an undesired behaviour – in this case excessive alcohol consumption. Identity is defined as the mental representations (thoughts and images) of one's self as one is or aspires to be, and the feelings associated with these [148]. Identity change is a key starting point for intentional behaviour change and a change in identity can help provide stability to the new behaviour, aiding maintenance of that behaviour [148,260]. Identity change was identified in the behavioural analysis and there are studies indicating that identity change can drive changes in alcohol consumption [264] and smoking cessation [265–267].

The next stage of intervention development involved implementing and designing the selected intervention content into the Drink Less app. A more detailed description of the theoretical and empirical rationale for selection of these intervention components is included in the relevant results section of this chapter. The selected intervention components were developed into app modules with each module being a distinct section of the app that delivered the specified intervention component. This chapter describes the different steps taken in the design phase of the app development.

7.2 Methods

7.2.1 Step 1: Choosing a delivery platform

There are two primary delivery platforms for apps: the Android operating system and the Apple operating system. It is necessary to focus on a single platform when financial resources are limited [387]. The Apple and Android operating systems each have their own advantages and disadvantages. Fragmentation within operating systems is when a variety of operating system versions combined with a mixture of devices result in the inability to run certain apps properly. The Android operating systems have a high level of fragmentation [388] compared with the number of device types using an Apple operating system, which means there are fewer debugging and compatibility issues with iPhones. iPhones have also been found to have a greater retention rate for their apps than Android [389], perhaps due to a lower level of fragmentation or the socio-demographics of the users.

On the other hand, more people use android phones than iPhones (three Android users for every iPhone user). Users of Android phones represent a wider socio-demographic range than iPhone users, particularly amongst less affluent groups as Android is available on relatively affordable devices [390]. Apple's operating system (iOS) is the more popular among affluent

groups and consumers in markets such as the UK, US, Australia and Canada [390]. In 2012, the total sales of Android phones were higher than iPhones (375 million sales for Android compared with 209 million for iPhones) though had half the number of app downloads (15 billion downloads for Android compared with 30 billion for iPhones) [88]. Apple's App Store tracked one billion downloads a month in 2012 and has the steepest increase in mobile app downloads over time compared with Android and other smart phones, along with the largest total of apps available [88].

We chose to develop our app on Apple's operating system (iOS) primarily to avoid issues of fragmentation and also because there is a greater use and retention of apps amongst iPhone users (despite a greater total of Android phone owners). This iPhone app will be evaluated and, if effective, can be taken as a proof of concept and potentially developed on Android to reach a larger proportion of smartphone users. The coding for the app will be open source and therefore available for other developers to use. The aim of open source is to accelerate the development of future interventions.

7.2.2 Step 2: Defining the app content

The content of the app consists of core features and intervention modules. Core features were included due to a pragmatic and methodological need to structure the app around a set of features that would promote engagement for all users and allow experimental manipulation of the intervention modules to which users would be randomly allocated. The core features were chosen either based on evidence for their effectiveness from other types of interventions or theoretical reasoning that the feature was necessary to facilitate the use of intervention modules. The intervention modules that were prioritised for inclusion and evaluation in the app were selected based on the behavioural analysis, exploratory studies conducted, specific theories of relevance and existing evidence for the effectiveness of components used in other

types of intervention. For each intervention module, content of both the intensive and minimal version was specified. The minimal version acted as a control so that each intervention module could be independently evaluated as part of a factorial experimental approach, as suggested by the MOST framework [143]. The aims of using a minimal version for each intervention module were to i) minimize confounding factors, differences in experience, attrition, engagement and exposure to non-assigned treatment; ii) improve blinding to allocation, data collection, understanding of behaviour and app usage and trial management, and iii) enable recruitment of the target population.

7.2.3 Step 3: Selecting BCTs to deliver the intervention modules

The BCT Taxonomy version 1 [379] and the alcohol-specific BCT Taxonomy [242] were used to specify the intervention content and to design the intervention in a systematic, replicable and comparable manner.

7.2.4 Step 4: Translating specified intervention content into app features

There were multiple discussions between members of the research team and the app developers (Portable Pixels - http://portablepixels.com/) to ensure that the app delivered the specific content whilst also being feasible to implement. The app developers were provided with a detailed description of the intervention content, both in terms of the text and graphics to be used, as well as the functionality of specific features within the app. Multiple iterations of Drink Less were produced until agreement was reached.

7.2.5 Step 5: Design principles

A number of design principles, including those identified in the expert consensus study [385], were followed as the design of an app is an important consideration [387]. It is important that users find the app easy to use and engage with as at least some usage is necessary for an

intervention to be effective [87]. The app structure was consistent throughout with each page titled to ensure easy navigation between features [376]. A menu bar at the bottom enabled users to move easily between sections of the app. In-app notifications were used: both appdetermined prompts and reminders set by the user [375,376,385]. The app was interactive for the user with a bidirectional flow of information. Gamification, the incorporation of game design features into cognitive tasks, was used in one of the intervention modules [375,376,385] as gamified training appears to boost user motivation and is highly engaging [391]. The app was designed to look visually appealing and professional [375,376,385]. The app clearly showed that it was developed by researchers at UCL with the aim of demonstrating a credible source and being trusted by users [375,376,386]. The language used was simple with no scientific jargon and visual cues were used where possible to minimise the amount of text used [376].

7.2.6 Step 6: Usability testing

Usability testing was conducted in parallel work to understand users' impressions of the app [392]. This parallel work consisted of two studies: i) a think aloud study [393] to understand users' first impressions of the app, and ii) semi-structured telephone interviews to investigate users' impressions of the app after two or more weeks of use in naturalistic settings. This person-based approach to intervention development and design places an emphasis on user involvement throughout and can help ensure that an app is easy to use [394,395]. The think-aloud study identified issues associated with first use, which was important to minimise the proportion of users who immediately disengage with an app [392]. The semi-structured telephone interviews identified issues with repeated use that were crucial to improve sustained engagement with the app [392]. Issues common to both studies were identified and given priority in making changes to the app. Issues that arose amongst multiple participants were also given priority.

7.2.7 Step 7: Initial assessment of eligibility and retention rates

Eligibility and retention rates of existing users of the app were assessed to provide an estimate of the total number of users needed to achieve the necessary sample size. The existing users were any of those who had downloaded the app since the initial version was launched on 30th July 2015 up until the 13th March 2016 when the assessment of eligibility and retention rates was conducted. The proportions were calculated for the users who downloaded the app but either declined to give consent, did not complete the AUDIT or sociodemographic assessment, or did not meet each of the inclusion criteria. The follow-up questionnaire was sent to the app users who had met the inclusion criteria to assess the retention rate.

7.2.8 Step 8: De-bugging

All of the app functions and features were tested to check for any programme bugs. The content of each app screen was checked against the full content specification to ensure that it had been implemented accurately and as planned. These checks were also done for each of the different intervention modules and versions. Tests were also conducted to ensure that the block randomisation was working. This involved checking that users were only randomised to one of the experimental conditions if they met all of the inclusion criteria and that the correct versions of the intervention modules were displayed. All of these tests were also conducted in a piece of parallel work to ensure the de-bugging process was as comprehensive as possible [392].

7.3 Results

The outline of the Drink Less app is shown in Figure 7.1 and sample screenshots are available in Appendix 8.

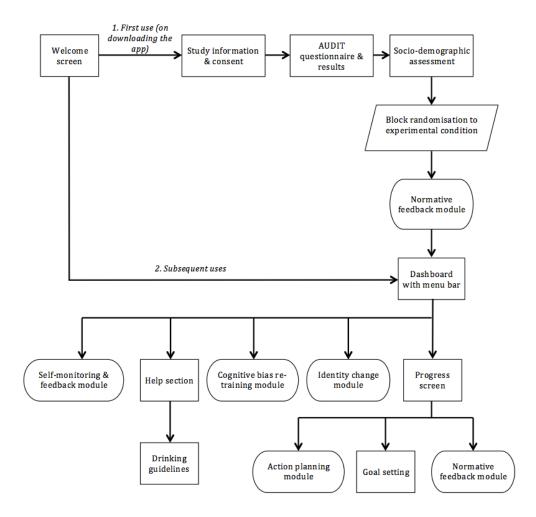


Figure 7.1: Outline of the Drink Less app

7.3.1 Registration

The process of registration during first use and subsequent logins for the Drink Less app is shown in Figure 7.1. A detailed description of the content of the app relating to this registration procedure is reported in Appendix 9 and described in more detail in the procedure section of Chapter 8.

Users completed the AUDIT questionnaire, received feedback on their AUDIT results and completed a socio-demographic assessment during the registration process. The AUDIT questionnaire is a validated measure used to assess alcohol consumption and alcohol-related harm [3]. Any reference to 'unit/s' in the AUDIT questionnaire linked to a pop-up screen that

indicated how many units were in typical drinks. Users had to confirm that they wanted to submit their answers as they could not go back and change any of their responses.

All users then received feedback on their AUDIT results with the colour of the text indicating their AUDIT risk zone (green indicating low-risk drinking; yellow, hazardous drinking; orange, harmful drinking; and red, possibility of dependence). No specific reference to AUDIT risk zone labels was made as users did not understand their meaning and reported off-putting 'scare-mongering' during informal, conceptual user testing. The emphasis was placed on the effect their drinking could be having on them based on the AUDIT risk zone they fell into as this was thought to be more salient to users. Users were told their AUDIT score though this was placed below the effect of their drinking and in smaller font as few users understood the relevance or meaning of this score.

The socio-demographic assessment measured: gender, year of birth (to determine age), ethnicity, educational level, employment status, smoking status and country. Users were asked to provide their email address (an inclusion criterion for the trial) and were informed of a prize (£500 Amazon voucher) if they did so. If the user clicked 'continue' without having entered anything into the email field, a pop-up appeared reminding them of the opportunity to win a prize by entering their email address. This was in an attempt to improve eligibility rates.

7.3.2 Core app features

The Drink Less app contained features that were core to the app and available to all users: information accessed through a 'Help' section and a goal-setting section. The full content of these core features is reported in Appendix 10.

7.3.2.1 Help section

A dashboard with a menu bar along the bottom was the main screen and is where users were taken when opening the app on their second and subsequent uses. This dashboard contained: users' achievements and active goals, a list of quick links, and daily suggestions for within-app activities. Some features on the dashboard were specific to intervention modules and did not appear for all users (e.g. a more detailed graph for the self-monitoring intensive version). The bottom menu bar included links to the 'progress screen' and the cognitive bias re-training (labelled 'Game') and identity change (labelled 'Drink + Me') intervention modules. A 'help' link in the top bar of the app took all users to a screen with three sections: 'about alcohol', 'app settings' and 'about the app'. The 'about alcohol' section included useful information such as 'drinking guidelines', 'harms of drinking', 'good goal setting' and advice for users who think they might have a serious problem with their drinking. It was deemed important to provide everyone with information on the risks associated with different levels of alcohol consumption so the 'drinking guidelines' page was included as a core feature. The text on this screen was a shortened and simplified version based on government guidelines. The 'app settings' allowed users to change the time at which they received a reminder to complete their drinking diary and enabled the user to turn this reminder on or off. The 'about the app' section included information on the team who developed the app, contact details for the team, relevant references, the information sheet for the trial, a privacy policy, the ability to 'opt-out' of the trial and a link to 'rate this app' on the app store.

7.3.2.2 Goal setting

Goal setting was included for all users as the main feature that the app was structured around to promote engagement and to facilitate the use of the intervention modules. Experts in alcohol and behaviour change identified goal setting as a best bet for an intervention component in an app [385]. Goal setting was also used in a number of existing digital alcohol

interventions [283] and popular alcohol reduction apps [106] suggesting it is feasible for an app-based intervention. Goal setting also has evidence for its effectiveness across many different behaviours and contexts [272,276,277]. This evidence for the inclusion of goal setting was considered sufficiently robust to warrant inclusion in a future evaluation of an optimised app without support from a factorial screening experiment.

Users were prompted to set a 'drinking reduction' goal/s after completing the registration process. Goals could be set based on units, spending, alcohol free days or calories. Some advice was provided on the best way to set good goals. The self-monitoring module involved providing feedback based on these user-set goals.

7.3.3 Intervention modules

Five intervention modules were selected as highest priority for evaluation in a factorial design: normative feedback, cognitive bias re-training, identity change, self-monitoring and action planning. These intervention modules are strategies designed to produce a specific outcome (e.g. re-train an 'approach' bias to alcohol) which can produce most distal outcomes (e.g. reduce excessive alcohol consumption) and can be combined with other modules [348]. This PhD thesis focuses on the intervention modules of normative feedback, cognitive bias retraining and identity change. Figure 7.2 shows the structure of the intervention modules in the Drink Less app and the full content specification of the intervention modules is reported in the appendices (see Appendix 11 for the normative feedback intervention module, Appendix 12 for cognitive bias re-training, and Appendix 13 for identity change). A separate PhD thesis by David Crane focuses on self-regulatory factors and the intervention modules of action planning, and self-monitoring (and feedback).

The results are presented in two parts: i) the theoretical and empirical rationale for selection, and ii) the specific content used to deliver the intervention strategy. Table 7.1 summarises the

intervention modules with the mechanisms targeted (the COM-B model component and TDF domain), the BCTs used and the rationale for selection.

Table 7.1: Details of the intervention modules: mechanisms targeted, BCTs and rationale for selection

Intervention	COM-B model	TDF	Behaviour Change Techniques (definition)	Rationale for selection
module	component			
Normative	Capability	Knowledge	Social comparison (draw attention to others' performance to	Social Norms theory
feedback	(psychological)		allow comparison with the person's own performance)	Identified by experts (see Chapter
			Provide normative information about others' behaviour and	6)
			experiences (provide normative information about others'	Existence of normative
	Motivation	Reinforcement	behaviour and experiences)	misperceptions (see Chapter 5)
	(automatic)	remore comenc	Feedback on outcomes of behaviour (monitor and provide	Empirical evidence of effectiveness
	(datomatic)	c)	feedback on the outcome of performance of the behaviour)	in interventions
				Face-to-face
				Digital

change (reflective) professional pehaviour may be an example to others) Resociation between alcohol- role and incompatible beliefs (draw attention to discrepancies between identity and alcohol consumption identity current or past behaviour and self-image) Valued self-identity (advise the person to write or complete rating scales about a cherished value or personal strength as a means of affirming the person's identity) Identity associated with changed behaviour (advise the person to ensure the new self-identity as someone who 'used to engage with the unwanted behaviour') Pros and cons (advise the person to identify and compare reasons for wanting and not wanting to change the behaviour) Framing/reframing (suggest the deliberate adoption of a new perspective on behaviour in order to change congitions/emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of future regret about performances of the unwanted behavior)	Identity	Motivation	Social/	Identification of self as role model (inform that one's own	PRIME theory
identity current or past behaviour and self-image) Valued self-identity (advise the person to write or complete rating scales about a cherished value or personal strength as a means of affirming the person's identity) Empirical evidence of effectiveness in smoking cessation interventions to construct a new self-identity as someone who 'used to engage with the unwanted behaviour') Pros and cons (advise the person to identify and compare reasons for wanting and not wanting to change the behaviour) Framing/reframing (suggest the deliberate adoption of a new perspective on behaviour in order to change congitions/emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of	change	(reflective)	professional	behaviour may be an example to others)	Association between alcohol-
Valued self-identity (advise the person to write or complete rating scales about a cherished value or personal strength as a means of affirming the person's identity) Identity associated with changed behaviour (advise the person to construct a new self-identity as someone who 'used to engage with the unwanted behaviour') Pros and cons (advise the person to identify and compare reasons for wanting and not wanting to change the behaviour) Framing/reframing (suggest the deliberate adoption of a new perspective on behaviour in order to change congitions/ emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of			role and	Incompatible beliefs (draw attention to discrepancies between	identity and alcohol consumption
rating scales about a cherished value or personal strength as a means of affirming the person's identity) Identity associated with changed behaviour (advise the person to construct a new self-identity as someone who 'used to engage with the unwanted behaviour') Pros and cons (advise the person to identify and compare reasons for wanting and not wanting to change the behaviour) Framing/reframing (suggest the deliberate adoption of a new perspective on behaviour in order to change congitions/emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of			identity	current or past behaviour and self-image)	Limited empirical study of
Identity associated with changed behaviour (advise the person in smoking cessation interventions to construct a new self-identity as someone who 'used to engage with the unwanted behaviour') Pros and cons (advise the person to identify and compare reasons for wanting and not wanting to change the behaviour) Framing/reframing (suggest the deliberate adoption of a new perspective on behaviour in order to change congitions/emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of				Valued self-identity (advise the person to write or complete	effectiveness in alcohol
Identity associated with changed behaviour (advise the person to construct a new self-identity as someone who 'used to engage with the unwanted behaviour') Pros and cons (advise the person to identify and compare reasons for wanting and not wanting to change the behaviour) Framing/reframing (suggest the deliberate adoption of a new perspective on behaviour in order to change congitions/emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of				rating scales about a cherished value or personal strength as a	interventions
to construct a new self-identity as someone who 'used to engage with the unwanted behaviour') Pros and cons (advise the person to identify and compare reasons for wanting and not wanting to change the behaviour) Framing/reframing (suggest the deliberate adoption of a new perspective on behaviour in order to change congitions/ emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of				means of affirming the person's identity)	Empirical evidence of effectiveness
With the unwanted behaviour') Pros and cons (advise the person to identify and compare reasons for wanting and not wanting to change the behaviour) Framing/reframing (suggest the deliberate adoption of a new perspective on behaviour in order to change congitions/ emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of				Identity associated with changed behaviour (advise the person	in smoking cessation interventions
Pros and cons (advise the person to identify and compare reasons for wanting and not wanting to change the behaviour) Framing/reframing (suggest the deliberate adoption of a new perspective on behaviour in order to change congitions/ emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of				to construct a new self-identity as someone who 'used to engage	
Optimism Praming/reframing (suggest the deliberate adoption of a new perspective on behaviour in order to change congitions/ emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of				with the unwanted behaviour')	
Optimism Framing/reframing (suggest the deliberate adoption of a new perspective on behaviour in order to change congitions/ emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of				Pros and cons (advise the person to identify and compare	
optimism perspective on behaviour in order to change congitions/ emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of				reasons for wanting and not wanting to change the behaviour)	
perspective on behaviour in order to change congitions/ emotions) Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of			Ontimism	Framing/reframing (suggest the deliberate adoption of a new	
Salience of consequences (emphasise the consequences of performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of			Optimism	perspective on behaviour in order to change congitions/	
performing the behaviour with the aim of making them more memorable) Anticipated regret (induce or raise awareness of expectations of				emotions)	
memorable) Anticipated regret (induce or raise awareness of expectations of				Salience of consequences (emphasise the consequences of	
Anticipated regret (induce or raise awareness of expectations of				performing the behaviour with the aim of making them more	
				memorable)	
future regret about performances of the unwanted behavior)				Anticipated regret (induce or raise awareness of expectations of	
				future regret about performances of the unwanted behavior)	

Cognitive	Motivation	Reinforcement	No individual BCTs are directly relatable to this intervention	PRIME theory & Dual Process
bias re-	(automatic)		module. In combination the following are of relevance:	models of addiction
training			Associative learning (present a neutral stimulus jointly with a	Identified by experts (see Chapter
			stimulus that already elicits the behaviour repreatedly until the	6)
			neutral stimulus elicits that behaviour)	Cognitive biases predict alcohol
			Behavioural practice/rehearsal (prompt practice/rehearsal of	use
	Capability	Memory,	the performance of the behaviour one or more times in a	Effective at altering cognitive
	(psychological)	attention and	context or at a time when the performance may not be	biases
		decision	necessary)	Some evidence for reduction on
		processes	Habit formation (prompt rehearsal and repetition of the	subsequent alcohol consumption
			behaviour in the same context repeatedly so that the context	
			elicits the behaviour)	

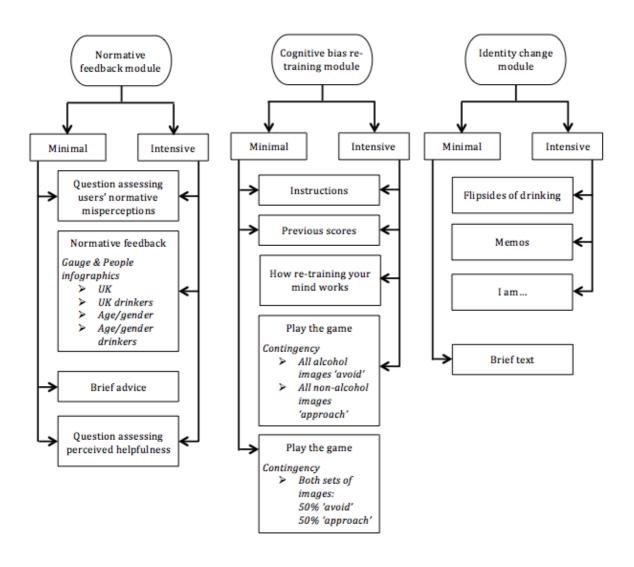


Figure 7.2: Structure of the intervention modules

7.3.3.1 Normative feedback module

Normative feedback is personalised feedback on how an individual's behaviour compares with the behaviour of other people. Normative feedback targets the components of psychological capability and automatic motivation in the COM-B model [146] and addresses lack of knowledge about how one's alcohol consumption compares with others.

7.3.3.1.1 Rationale for selection

Normative misperceptions, the underestimating of one's own alcohol use compared with others, were found in excessive drinkers in Study 3 [384]. Alcohol or behaviour-change

experts identified normative feedback ("providing feedback in relation to people") as an intervention component in an app likely to be effective at reducing excessive alcohol consumption [385]. The BCTs of 'social comparison' and 'feedback on outcomes of behaviour' (two that are appropriate for a normative feedback intervention) were amongst the most frequently used in these interventions (80.5% and 65.9%, respectively) [386]. A content analysis of popular alcohol reduction apps found that the BCT 'provide normative information about others' behaviour and experiences' was rarely used by these apps (only present in about 5% of apps) [106]. These findings demonstrated an opportunity to add to current evidence by developing and evaluating a normative feedback intervention in an app and that it would be appropriate for the general population of drinkers.

7.3.3.1.2 Designing the app content

The intensive version of this module provided users with feedback on how their drinking compared with other people and highlighted how this differed from what they believed (the users' normative misperceptions). It used BCTs identified as appropriate for a 'normative feedback' based behaviour change module: 'social comparison', 'provide normative information about others' behaviour and experiences' and 'feedback on outcomes of behaviour'. The normative feedback was provided in the form of the user's percentile in a distribution of population drinking levels in England and what that meant for their alcohol-related risk relative to others. Normative feedback that ranks individuals amongst a population was found to be more effective than comparing users with an average [396].

The users' normative misperceptions were assessed using two questions: 'how do you think your drinking compares with i) others in the UK and ii) other [women/men] aged [16-24/25-34/35-44/45-54/55+]?' The wording of these questions was based on the equivalent questions in the Global Drugs Survey, the cross-sectional survey used to assess normative

misperceptions in the general population [384]. This will allow a direct comparison between the two samples to be made and the existing sample of data can be built on.

Both the users' reported drinking levels and normative misperceptions were represented visually. A visual representation was selected to minimise the text and to make the screens more aesthetically pleasing. A 'gauge' and a 'people infographic' were chosen. Using two separate visual representations of this data increased the dose of the normative feedback. An information icon ('i') was included in the top menu bar that included an explanation on the gauge and people infographic and what they represented.

Users were compared against four samples: i) the general population, ii) the general population of drinkers, iii) people of the same gender and age group and iv) drinkers of the same gender and age group. These specific age and gender group samples were included to increase the salience of the information. The comparison sample of drinkers was included as participants in the usability studies often disregarded the normative feedback based on the inclusion of all non-drinkers in the sample.

The samples with which each user was compared was based on a representative sample of the general population in England from the Alcohol Toolkit Study (ATS). The data used were collected between March 2014 and October 2015 (the data tables used for this are shown in Appendix 14). The user's percentile was calculated by comparing the user's AUDIT score with that of the relevant ATS sample. The 'drinkers' sample removed any participant from the ATS sample who answered 'never' to 'how often do you have a drink containing alcohol?' (question 1 on the AUDIT).

The majority of participants in the usability study found the normative feedback surprising, reacted defensively to it and questioned the validity of the information provided. A screen of

text before the normative feedback was added in an attempt to manage the user's expectations and prepare them for the normative feedback. In addition, details about the source of the data were provided. After the normative feedback, some text was included that aimed to increase the user's self-efficacy by reassuring them that it was common to find the results surprising and that the Drink Less app could help.

The minimal version of this module included the questions in the intensive version assessing the user's normative misperceptions. No normative feedback was provided. Brief advice in plain text was provided as this is the usual control in similar interventions. This text came from the 'Brief Advice Tool' (2010) on the Public Health England website.

Both the intensive and minimal versions of this normative feedback module could be accessed in two ways. First, all users were taken through the module in a tunnelled approach as part of the initial registration process. Secondly, users could access the intervention module again through the progress screen under "Review your drinking". The intensive version was labelled 'comparison' and the minimal version was labelled 'alcohol advice'. Both versions also included the user's responses to the AUDIT questionnaire and their AUDIT results. At the end of both versions of this module, users were prompted as to how to access this information again and were asked whether they found the information helpful. This was used as a secondary outcome measure to assess whether users appreciated this sort of normative feedback or brief advice.

Any user who had an AUDIT score below average would not have met the inclusion criteria for the trial and would therefore have received the intensive version of every module in a separate, non-experimental condition. However, these users did not receive personalised normative feedback on their AUDIT score to avoid the possible 'boomerang effect' [397] of below average drinkers increasing their drinking to reach the social norm. Users with a below

average AUDIT score were provided with social norms information emphasising that light drinking is normal. Social norms information has been found to have a better preventative effect on alcohol consumption amongst light and non-drinking students than personalised normative feedback [398]. This information was also based on data from the ATS. Whilst these users were not the targets of this intervention, it was ethically important that using this app did not have negative consequences for any users.

7.3.3.2 Cognitive bias re-training module

The cognitive bias re-training module targets the component of automatic motivation in the COM-B model [146].

7.3.3.2.1 Rationale for selection

Inhibition training, a type of intervention targeting non-conscious processes, was identified by experts as a potential "best bet" for inclusion in an app to reduce alcohol consumption by alcohol and behaviour change experts [385]. Previous studies of digital alcohol interventions have not yet made use of theories relating to the importance of the impulsive system in guiding behaviour [355].

No BCTs are directly related to cognitive bias re-training. Though there are three BCTs that are relevant when combined: 'associative learning', 'behavioural practice/rehearsal' and 'habit formation'. The combination of these BCTs is similar to the concept of cognitive bias retraining: re-training a particular behaviour (i.e. approach alcohol stimuli) so that the newly trained behaviour (i.e. avoid alcohol stimuli) is the one elicited in a particular context or setting (i.e. alcohol stimuli).

7.3.3.2.2 Designing the app content

The intensive version of this module used a form of cognitive bias re-training (approach avoidance training (AAT) [399]) to re-train approach biases to alcohol cues using a game. The game aimed to change the 'approach bias' towards alcohol cues to an 'avoid bias'. The AAT retrains approach biases by changing the contingencies of the proportion of alcohol or non-alcohol images presented in the format to approach or avoid. This game was called "Yes please, No thanks". Alcohol images were always associated with 'avoid' ("No thanks") and non-alcohol images with 'approach' ("Yes please") [199].

The instructions about whether users should 'approach' or 'avoid' images was based on the format of the image (landscape/portrait), which was unrelated to the content of the images (alcohol/non-alcohol). Instructions for the AAT that are based on irrelevant features (e.g. image format) are suitable for modifying alcohol approach biases though are not considered reliable or valid tools for the assessment of cognitive biases [400]. In the usability studies, users preferred the use of landscape/portrait to wide/tall in the instructions and some did not find the instructions completely clear so graphics were included to illustrate how the game worked. When the user responded correctly a corresponding sound was played and the screen flashed green; when an incorrect response was made, the screen flashed red and a sound indicating an error was made. This was to provide both visual and auditory feedback to the user on their response.

Users allocated to the intensive version were counterbalanced with 50% being instructed to say "Yes please" (i.e. approach) to portrait images and to say "No thanks" (i.e. avoid) to landscape images, and the other 50% of users being instructed to say "Yes please" to landscape images and "No thanks" to portrait images. This counterbalancing was random and occurred when a user first played the game.

An existing feature of apps was implemented to create the sense of avoiding or approaching images: a finger is used to swipe the screen to move the image rather than other options such as tapping arrows. The user would swipe the image down the screen for 'approach' and swipe the image up for 'avoid'. As the user moved the image either up or down, a zooming effect occurred whereby the image increased or decreased in size as it moved to generate a strong and clear sense of approach or avoidance [199,236,401,402].

The images used in the game were selected from the Amsterdam Beverage Picture set, which is a validated picture set for cognitive bias modification paradigms [403]. A total of 40 images were used with 20 alcohol images and 20 non-alcohol images. The game lasted for one minute as this was considered an appropriate length of time for the game during informal, conceptual user testing. Experimental studies in the laboratory using AAT usually include a greater number of trials [236,404] though this was deemed off-putting as a result of usability testing and likely to result in the user not playing the game again or not completing it.

Users were provided with a graph showing their previous scores. This was to create a sense of competition, a principle of gamification, to encourage users to keep playing in an attempt to improve their score and, thereby, to enhance engagement with the intervention module. Each correct response scored '+1' and each incorrect response scored '-2' to incentivise attempting to respond correctly rather than randomly.

Findings from the usability studies showed that users wanted to know why and how the game worked, and liked the idea of "re-training your mind" when it was explained to them.

Therefore, on the main 'game' screen a sentence was included to emphasise the game's purpose and a separate sub-section was included on "how re-training your mind works" explaining the proposed way in which it worked, avoiding scientific jargon.

The minimal version of this module still had the game, instructions and graph of previous scores. The game in the minimal version involved different contingencies to those in the intensive version. Half of the 'avoid' trials had alcohol images and the other half had non-alcohol images. For the 'approach' trials, half had alcohol images and the other half had non-alcohol images. In the same way as in the intensive version, users with the minimal version were counterbalanced in terms of the orientation of the images and the approach/avoid instructions [199].

An information screen indicated by an 'i' icon in the top menu bar provided additional information explaining the game (which differed depending on version) and included details on the licensing of the ABPS images (a condition of using them in the Drink Less app).

7.3.3.3 Identity change module

Identity change is the principle of adopting an identity that is incongruent with the undesired behaviour – in this case excessive alcohol consumption – and targets 'reflective motivation' within the COM-B model [146].

7.3.3.3.1 Rationale for selection

A meta-regression assessing the BCTs used in digital alcohol interventions found that only one BCT associated with identity ('framing/reframing') was present and only in one intervention (2.4%) [386]. Other BCTs that could support identity change but were not directly related to identity were more frequently used, such as 'pros and cons' (36.6%) and 'salience of consequences' (51.2%) [386]. The part of this systematic review assessing reporting of theory use in digital alcohol interventions found that the Social Identity theory [256] was only mentioned by two studies (out of 41) [355]. Identity change was not directly identified by experts as a best bet for inclusion in an app for alcohol reduction [385], possibly because of a lack of direct evidence available. However, Motivational Interviewing (MI) was

identified in the consensus exercise [385] and a key principle of MI is to develop discrepancy between goals or values and current behaviour [405]. Moreover, there were theoretical reasons for believing identity change could be an effective component.

The following BCTs were identified as being appropriate for inclusion in an identity change module: 'identification of self as role model', 'incompatible beliefs', 'valued self-identity', 'identity associated with changed behaviour', 'pros and cons', 'framing/reframing', 'information about health/social/emotional consequences', 'salience of consequences', and 'anticipated regret'.

7.3.3.3.2 Designing the app content

The intensive version of this module aimed to help users foster a change in their identity so that users did not see being a 'drinker' as a key part of their identity. This module was named "Drink + Me" as participants in the usability studies found the name "Identity" confusing and expected a section based on a profile. The main menu screen explained the general purpose of the module and listed the three different strategies included in the module i) 'Flipsides of drinking', ii) 'Memos', and iii) 'I am...' An information button, accessed via an 'i' icon in the top menu bar provided a brief explanation about what each section of "Drink + Me" aimed to do so the user knew what to expect and its intended benefit. This was a request from a number of participants in the usability studies.

The 'Flipsides of drinking' section provided pairs of alcohol-related outcome expectancies: each pair consisting of a positive expectancy and a negative 'flipside' that may be less frequently considered. Positive and negative outcome expectancies are important in influencing drinking behaviour [268]. This section balanced each positive or benefit of drinking with a negative or cost of drinking with the aim of highlighting both the pros and cons of excessive drinking and re-framing previously considered positive effects with a potential negative. There was no definitive list of positive and negative alcohol outcome

expectancies to use so items were collated from different studies [406] and scales [407,408] and paired up. This resulted in ten flipsides/pairs of alcohol-related outcome expectancies.

Users were encouraged to write their own 'flipsides' to make the section more personal and salient to them and could either use the default images or their own (from their phone camera or photo library).

The 'Memos' section allowed users to record video messages to watch at a later date and to set reminders to either record or watch these memos. Users were prompted to record memos at different times, such as whilst sober, during drinking or after drinking. For example, the 'sober' memo could be a message of why they don't want to drink more than they planned and could be watched before going on a night out as a salient reminder. The 'during drinking' memo could be a video of the user recorded whilst drunk allowing the user to see the next day what they were like in reality rather than how they recalled the situation. The 'after drinking' memo could be of the morning after a night out if the user is hung-over as a salient reminder of the negative consequences of excessive drinking and potentially to induce 'anticipated regret' before they go out drinking the next time. The reminders were provided so that users could prompt themselves to record or watch these memos at the most salient times. The memos were automatically saved as "[date] [time]" to help the user remember the content of the memo. Users could edit the default name for each recorded memo.

The 'I am...' section aimed to get users to identify the values of importance to their identity or sense of self and consider whether their behaviour after excessive drinking was inconsistent with those values. This section was based around the Self-affirmation Theory which proposes that focusing on 'values of importance' makes an individual less defensive to threatening information [409–413]. Generally, a self-affirmation manipulation is achieved by providing values or positive characteristics in a short list to the user for them to select [409,410,413] or the user recalls and generates their own list [409,411,412]. Users were provided with both

these options in the 'I am...' section. The list provided to the users was based on those most commonly used in different studies [414] and of greatest relevance to the Drink Less app. The purpose of this section was briefly explained to users before they were prompted to either add their own photo (allowing the user to personalise this section) or use a default image of a smiley face. The subsequent screen involved the self-affirmation manipulation and users were asked to list their personal 'values of importance' or select some from a list of examples. The users' photo or the default image then appeared with these values surrounding it and the user was prompted to consider which of these values they struggled to reconcile when drinking too much. The section ended with some examples of common 'values of importance' to people, and possible ways in which someone's behaviour could be inconsistent with those values. On subsequent uses of the 'I am...' section, users were given the choice of reviewing their previous entry or completing the section again.

The minimal version of the identity change module was plain text describing the role of identity in behaviour change and maintenance, though this version does not help the user foster an identity change.

7.4 Discussion

The Drink Less app was developed based on theory and evidence, following the MRC complex interventions guidance and MOST strategy, to help users reduce excessive alcohol consumption and to evaluate which intervention modules were the most effective for this purpose. The development process involved a number of steps that considered the implementation and design of the scientific content alongside a person-based approach. Five intervention modules were designed to target a broad range of factors influencing excessive alcohol consumption: normative feedback, cognitive bias re-training, identity change, self-monitoring, and action planning. Each intervention module has two versions delivering either

intensive or minimal support. A set of core features was also included in the app to promote engagement.

These intervention modules were selected for evaluation based on theory and relevant empirical evidence. The use of both theory and empirical evidence means these intervention modules have a strong rationale for inclusion in the app. There is no direct evidence for their effectiveness in an alcohol reduction app though these intervention modules will be evaluated to build an evidence base as to what is effective. This can inform future interventions for behaviour change and the theories that have been used to inform these intervention modules.

Apps have a number of benefits over other types of digital intervention such as web-apps.

Apps have fewer bugs and perform faster, which results in a better user experience. Apps can also make use of device features, send notifications and use advanced gestures, whereas web-apps cannot. Users can easily find and download apps from the app stores, which have all been approved for the app's safety and security by the app store. Apps can also be used offline when other phone functions are limited. Whilst web-apps are cheaper to develop, and easier to maintain and update across multiple platforms and devices, an app was chosen because of the importance of having an intervention that provided a good user experience, could be discoverable on the app store, and be used offline.

The person-based approach is a systematic way of addressing the user experience of the intended intervention and can enhance the use of theory- and evidence-based approaches to intervention development [394]. The development process should involve qualitative research with the users at every stage, from planning to feasibility testing and implementation [394]. This is done primarily to modify the intervention to make it more persuasive, feasible and relevant to users [394]. However, this approach has a couple of potential limitations. First, the approach involves a longer development process and digital

technology already advances more rapidly than the speed at which interventions are typically developed and evaluated [69]. The person-based approach could delay the process of development and increase the likelihood of the app becoming obsolete. Second, what users report they like best in terms of design and functionality is not necessarily the same as what is the most effective for prolonged engagement with the intervention.

The importance of iterative development is highlighted by both the MRC guidance on complex behaviour change interventions [139] and the MOST strategy [141]. This is a strength of this development process though the necessary checks of the app following these iterations were time consuming. If this process was to be repeated, paper prototypes could be used for usability testing earlier on in the development process. This would mean that the time-consuming full checks of the app would need to be conducted less frequently making the development process quicker. Due to time constraints, the person-based approach was only used to assess the initial version of the app, not the final one, in terms of its acceptability to users. The vast majority of changes made were suggested by the users so it seems likely that the final version of the app would have been considered acceptable by the users.

The iterative development process using a person-based approach resulted in an app to reduce excessive drinking that is both considered acceptable by users and has a strong theory and evidence base for its content. The Drink Less app was the first to take a systematic and transparent approach to development using both theory and evidence. A strength of the Drink Less app is that it will be evaluated for its effectiveness at reducing alcohol consumption. The evaluation of the app will use a factorial screening experiment to assess the individual and interactive effects of the intervention modules.

Chapter 8 - Evaluation of the effectiveness of the Drink Less app to reduce excessive alcohol consumption: a factorial randomised control trial (Study 5)

Abstract

The Drink Less app was developed based on theory and empirical evidence to help reduce alcohol consumption in excessive drinkers. A systematic review, amongst other methodologies, identified promising modular intervention content that could be delivered by an app: normative feedback, cognitive bias re-training, identity change, self-monitoring (and feedback), and action planning. The app was freely available on the iTunes app store for users to download and did not require any input from a healthcare practitioner. The aim of this study was to assess the comparative potential of the five intervention modules to reduce excessive alcohol consumption in a between-subject factorial randomised control trial.

Participants were recruited online and were eligible for the trial if they were: excessive drinkers (AUDIT>=8), aged 18 or over, from the UK, making a serious attempt to reduce their drinking, and provided their email address. Eligible users were randomised to one of 32 (2⁵) experimental conditions (intensive and minimal versions for each of: normative feedback, cognitive bias re-training, identity change, self-monitoring, and action planning) after downloading the Drink Less app. This study focused on the evaluation of three intervention modules: normative feedback, cognitive bias re-training, and identity change.

Participants completed baseline measures on downloading the app and were contacted via e-mail after one-month with a follow-up questionnaire. The primary outcome measure was self-reported change in past week consumption of alcohol. Secondary outcome measures were

change in AUDIT score, app usage data and usability ratings for the app. A factorial between-subjects ANOVA was conducted to assess the main and interactive effects of the five intervention modules for the primary and secondary outcome measures. An intention-to-treat approach was used with those lost to follow-up assumed to have continued drinking at baseline level.

672 participants were included and 27% (n=172) responded to follow-up. At baseline, their mean past week alcohol consumption was 39.9 units and mean AUDIT score was 19.1, indicating that the sample was, on average, drinking at harmful levels. There was an overall decline in alcohol consumption averaging 3.8 units per week. There were no main effects of the intervention modules on past week alcohol consumption though there were numerically larger decreases in the intensive versions of normative feedback and cognitive bias retraining. There was a significant two-way interaction between the normative feedback and cognitive bias re-training modules on past week alcohol consumption with the maximal effect occurring when both modules were in the intensive version. Participants rated the app significantly above neutral on ease of use and satisfaction, and were thoroughly engaged with the app (for example a mean of 11.7 log-ins) but there was no evidence this depended upon the module content.

This study established the extent to which five intervention modules offered in the Drink Less app, developed based on theory and empirical evidence, could help reduce excessive alcohol consumption. The study suggested that a version of the Drink Less app that includes the normative feedback, cognitive bias re-training, self-monitoring and action planning intervention modules may assist with drinking reduction, and that such a version merits further optimisation and, depending on the results, evaluation in a full trial against a minimal control with long-term outcomes.

8.1 Introduction

The need for the rigorous development and evaluation of a new app-based intervention for reducing excessive alcohol consumption is highlighted by: the problem of excessive alcohol consumption, the potential of apps to help people manage their behaviour, the limited evaluation of the effectiveness of such apps, and the tendency for these apps to be developed without reference to scientific evidence or theory [106].

As established in Chapter 7, five intervention modules were selected for evaluation within the Drink Less app. These were: normative feedback, cognitive bias re-training, identity change, self-monitoring (and feedback), and action planning. This selection was based on different sources of evidence including a behavioural analysis (see Chapter 2), a formal consensus-building study with alcohol or behaviour-change experts to identify the behaviour change techniques thought most likely to be effective (see Chapter 6), a systematic review of the effectiveness of digital alcohol reduction interventions [283,284], and a content analysis of the behaviour change techniques within existing popular alcohol reduction apps [106]. Each of the intervention modules contained a number of relevant behaviour change techniques. The details of the intervention content for each module are summarised in Appendix 15. This chapter focuses on the evaluation of normative feedback, cognitive bias re-training, and identity change modules though it reports all five intervention modules.

A factorial experimental approach was chosen whereby an intensive or minimal version of each intervention module was randomly allocated to a given participant. The intensive version of each module contained the intervention component hypothesised to be effective at reducing excessive alcohol consumption. The minimal versions of each intervention module were designed to provide some support to the participants (important for ethical reasons) whilst not including the potentially active ingredients of the intensive version being assessed.

A factorial experimental approach is suggested by the MOST framework for optimising a multicomponent intervention [141,143] and allows the identification of the most promising intervention modules given funding and practical constraints. A factorial design has two main practical advantages: it saves time, by being able to evaluate all the intervention modules simultaneously, and it requires a smaller sample size than individual experimental designs whilst maintaining the same power. A factorial design was chosen over a treatment package approach with usual care or nothing as a control group so that the independent effect of each intervention module and their interactions could be assessed. This factorial evaluation screens the intervention modules selected on the basis of theory and evidence to identify those warranting further investigation [144,278]. The MOST approach recommends that promising intervention modules are included in an optimised intervention to be evaluated as a treatment package in a full RCT at a later date.

The aim of this study was to evaluate the effectiveness of the five intervention modules at reducing excessive alcohol consumption and investigate their interactions.

8.1.1 Research questions:

- 1. What are the main effects of, and interactions between, each intervention module on:
 - a) Change in past week consumption of alcohol
 - b) Change in AUDIT score
 - c) App usage
 - d) Usability ratings for the app

8.2 Methods

8.2.1 Design

A between-subject factorial randomised controlled trial was used to evaluate the effectiveness of five intervention modules (normative feedback, cognitive bias re-training, identity change, self-monitoring, and action planning). Each intervention module had two versions (intensive and minimal) yielding 32 experimental conditions (see Appendix 16 for matrix).

8.2.2 Intervention

Drink Less was designed to support adults drinking excessively and interested in drinking less alcohol.

The development process of the Drink Less app and its final content is described in detail in Chapter 7 and Appendix 15. The Drink Less app was freely available on the iTunes store for all iOS smartphones and tablets (version 1.0.7; https://itunes.apple.com/gb/app/drink-less-get-help-reducing/id1020579244). The content of the app did not change during the trial.

The app is interactive and provides automatic support to users (it involves no human input to its functionality or delivery). The app delivered daily reminders at 11am (BST) to complete the 'drinking diary' (i.e. what alcohol the user had consumed the previous day) though this function could be switched off or the time changed. Users could choose to set reminders relating to the identity change intervention module.

Two core features – 'goal setting' and 'help' – were included as there was a pragmatic, methodological need to structure the app around an activity that would engage all users and allow experimental manipulation of other supporting modules. Thus, the app asks all users to set a goal – the level to which they would like to reduce their alcohol consumption.

In addition to the core features, there were five intervention modules with intensive and minimal versions that were tested experimentally. This resulted in 32 experimental conditions to which eligible users were randomly allocated. The intensive version contained the intervention component hypothesised to be effective at reducing excessive alcohol consumption. The minimal versions of each intervention component did not include the potentially active ingredients of the intensive version being assessed. If a minimal version lacking the potentially active ingredients was not possible for an intervention module, then the minimal version was based on controls used in equivalent studies (e.g. standard brief advice in the normative feedback module [185]).

8.2.3 Participants

Participants were included in the analysis if they had: downloaded the app onto an iOS smartphone or tablet, were 18 years of age or over, lived in the United Kingdom, had an AUDIT score of 8 or above (indicative of excessive alcohol consumption warranting intervention [415,416]), had confirmed that they were making an attempt to reduce their drinking (responded 'Interested in drinking less alcohol', not 'Just browsing' to the question "Why are you using this app?"), and provided an email address as a contact point for the one-month follow-up questionnaire. The issue of multiple identities was addressed by collecting the device ID of each download. Any duplicate device IDs or email addresses were removed with the first case of download remaining in the trial.

The sample size for this trial was 672 to have more than 80% power (with alpha at 5%, 1:1 allocation and a two-tailed test) to detect a mean change in alcohol consumption of 5 units between the intensive and minimal version for each intervention module [417]. This assumed a mean of 27 weekly units at follow-up in the control group, a mean of 22 units in the intervention group and a SD of 23 units for both (d=0.22), and rounds up the sample size to

the nearest multiple of 32 to ensure the experimental conditions are balanced. The estimated effect size is large, comparable with that of a face-to-face brief intervention [44], and may be considered somewhat unrealistic for a module within a digital intervention. However, in the event of a 'non-significant' result, a Bayes factor would be calculated to establish the relative likelihood of the null versus the experimental hypothesis given the data obtained, see 'Analysis' section below for more details [326].

Participants were recruited online through a number of methods. The app was listed in the iTunes Store. The most commonly used method of finding news apps is through searching an app store [418] and so the listing was optimised according to best practices for app store optimisation [419,420]. These best practices include: ensuring the keywords are carefully selected, that the description is well written and that screenshots display the aspects of the app that users are most interested in [419–422]. Existing users were encouraged to leave reviews, which also helps persuade other users to download an app [422,423].

A number of organisations, research groups, academic networks and alcohol-reduction online forums helped to promote the app through blog posts, emails, web pages and twitter. These included: Public Health England, Alcohol Concern, Society for the Study of Addiction, National Institute of Health Research – School for Public Health Research, UK Centre for Tobacco and Alcohol Research, Institute of Alcohol Studies, Alcohol Academy, Cancer Research UK, Centre for Behaviour Change, UCL Institute of Digital Health, One Year No Beer, Club Soda and Soberistas. Facebook and Google adverts were also used to promote the app for trial recruitment. See Appendix 17 for example screenshots of these promotions.

Recruitment for the trial continued until 672 eligible users (21 per experimental condition) were obtained after excluding duplicate sign-ups.

8.2.4 Procedure

Each user was provided with a participant information sheet and asked to provide consent for participating in the trial on opening the app after downloading it (see Appendix 9). Users could contact a member of the research team with any questions or concerns regarding the trial.

Users were then asked to complete the full AUDIT questionnaire and a socio-demographic assessment, indicate their reason for using the app (interested in drinking less alcohol or just browsing) and provide their email address. All users were provided with their AUDIT score and informed of their 'AUDIT risk zone'. At this point, all users who met the inclusion criteria became trial participants and were randomised to one of 32 unique experimental conditions (see Appendix 16) in a block randomisation method, with a block size of 32. From this point onwards, the app differed for the different experimental conditions. Users who did not meet all of the inclusion criteria could still use the app and were allocated to a separate, non-experimental condition that had the intensive version of each intervention module for engagement, ethical and app rating purposes.

One month (28 days) after downloading the app, participants were emailed the follow-up questionnaire through Qualtrics (preview of questionnaire:

https://eu.qualtrics.com/jfe/preview/SV_0lamLX51zSxpVrL). If this was not completed, Qualtrics automatically sent two additional reminders one day later (29 days after download) and one week later (35 days after download). The follow-up questionnaire was also delivered within the app one calendar month (31 days) after download. A reminder to complete this remained on the app dashboard until it was completed. The follow-up questionnaire consisted of the AUDIT questionnaire and questions regarding usability. The data in Qualtrics from the follow-up questionnaire was matched to the participants' data in the app by using the user's

unique identifier. If the follow-up questionnaire was completed on Qualtrics and within the app then the earliest complete record was used.

8.2.5 Measures

The baseline measures were the AUDIT questionnaire and a socio-demographic assessment: age, gender, ethnicity, level of education, employment status, and current smoking status.

The primary outcome measure was the self-reported change in past week alcohol consumption. Past week alcohol consumption was calculated as the product of two questions in the AUDIT-C relating to alcohol consumption [417]. AUDIT 1 related to the frequency of alcohol consumption and was recoded into drinking days per week. AUDIT 2 related to the quantity of alcohol consumed and was re-coded into the average units of alcohol consumed on a typical drinking day. The change in past week alcohol consumption was calculated as the difference between past week alcohol consumption at follow-up and baseline. The full AUDIT also assesses harmful drinking and indicators of alcohol dependence [3] and has high test-retest reliability when completed online [424].

The secondary outcome measures were: self-reported change in full AUDIT score, usage data collected from the app, and self-reported app usability measures. Two indicators of usage were collected from the app: number of sessions per user and length of time per session. The usability measures were helpfulness, ease of use, satisfaction and likelihood of recommendation to a friend. These usability measures were all assessed using a five point Likert-type scale ('not at all', 'slightly', 'somewhat', 'very' and 'extremely').

8.2.6 Analysis

Descriptive statistics were used to report the socio-demographic and drinking characteristics of the participants. To investigate differences between participant characteristics by intervention module, one-way ANOVAs were conducted for continuous variables and 2-sided chi-squared tests for categorical variables.

A factorial between-subjects ANOVA was conducted to assess main and interactive effects of the intervention module version on the primary and secondary outcome measures. ANCOVAs were conducted to investigate whether usage data (number of sessions) accounted for treatment effects. In a sensitivity analysis, ANCOVAs were also conducted to adjust for any chance imbalances in user characteristics (gender, age, ethnicity, level of education, employment status, baseline AUDIT score).

An intention-to-treat approach was used for the change in past week alcohol consumption and change in AUDIT score such that those who were lost to follow-up (non-responders) were retained in the primary analysis and assumed to be drinking at baseline levels. The intention-to-treat principle is often used in the evaluation of digital public health interventions [136,425,426] and is a conservative approach to ensure effect sizes are not over-estimated as participants who respond well to the intervention are more likely to be retained. Sensitivity analyses were conducted among only those who completed the follow-up questionnaire (responders) to examine the robustness of the results to assumptions made in the primary analysis. The analysis of the usability ratings only involved complete cases.

The usage measure – time per session – may be biased by any participants who only used the app once and were likely to spend more time exploring the app during the first use. Therefore, a sensitivity analysis was conducted with the number of sessions as a covariate to address this potential bias.

In the event of a non-significant main effect of an intervention module, Bayes factors were calculated to establish the relative likelihood of the experimental versus the null hypothesis given the data obtained. The use of Bayes factors when analysing data from randomised trials provides important information about whether the data are insensitive to detect an effect or support the null hypothesis [325]. These can lead to more precise conclusions than are typically obtained using only traditional null hypothesis testing [325]. The Bayes factors were calculated with the alternative hypotheses conservatively represented in each case by a half-normal distribution (online calculator:

http://www.lifesci.sussex.ac.uk/home/Zoltan_Dienes/inference/Bayes.htm). In an alternative hypothesis represented by a half-normal distribution, the standard deviation of a distribution can be specified as an expected effect size, which means plausible values have been effectively represented between zero and twice the effect size, with smaller values more likely. The expected effect size for the primary calculation of Bayes factors will be the same as for the power calculation, reflecting a reduction of 5 units per week (d=0.22). In a sensitivity analysis, Bayes factors were also calculated for a smaller effect (reflecting a reduction of 3 units per week, d=0.13). This Bayes Factor analysis permits a relative judgment for the purposes of screening about whether the inclusion of the module in a future app would be more likely than not to have an effect on alcohol consumption.

8.2.7 Ethical approval

This trial has ethical approval from the UCL Ethics Committee under the 'optimisation and implementation of interventions to change health-related behaviours' project (CEHP/2013/508). See Appendix 18 for the approved ethics amendment forms.

8.2.8 Availability of data and material

The anonymised dataset is available on the Open Science Framework (https://osf.io/q8mua/) and the app code is available on request.

8.3 Results

8.3.1 Participants

Participants for this trial were recruited between 18th May and 10th July 2016. Follow-up data was collected between 16th June and 28th August 2016. Trial recruitment ended after each of the 32 conditions had 21 eligible users after accounting for duplicate cases.

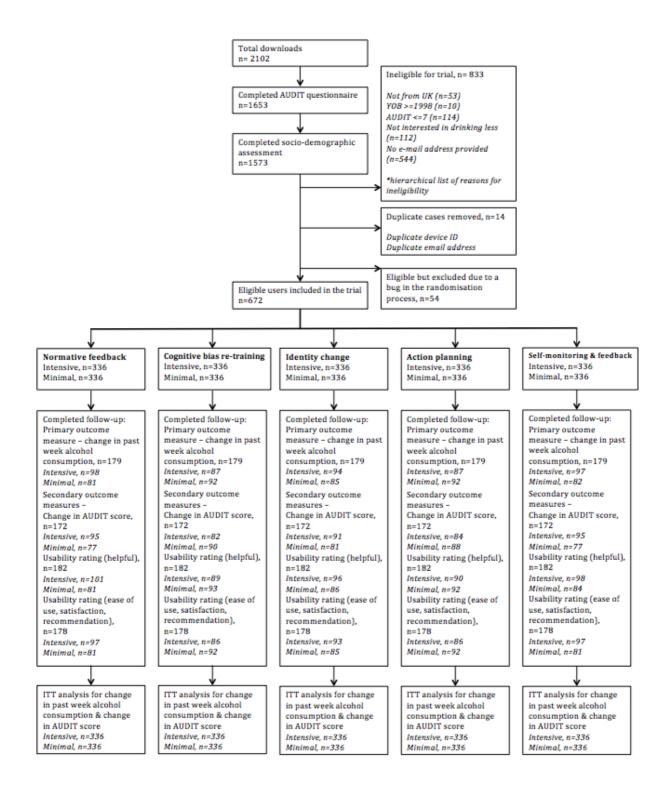


Figure 8.1: Flow chart of users

Figure 8.1 shows a flow chart of users from the trial. Of the 672 eligible users included in this trial, 179 completed the primary outcome measure at follow-up. This equates to a 27% retention rate; there were no significant differences in retention rate between versions of the intervention modules.

8.3.1.1 Baseline characteristics

The socio-demographic and drinking characteristics of participants in the trial are reported in Table 8.1. Their mean age was 39.2 years and the majority were women (56.1%), white (95.2%), had post-16 qualifications (72.0%), and were employed (86.5%). About a quarter were current smokers (24.6%), a higher prevalence than in the general population of the UK (which is 20% [48]). The mean past week alcohol consumption was 39.9 units and the mean AUDIT-C score of participants was 9.4. The mean AUDIT score was 19.1, compared with 4.9 for the general population in England (see Chapter 3). The majority of participants had an AUDIT score of 16 or above indicating they were harmful drinkers or drinkers at-risk of alcohol dependence (66.7%).

Participants' characteristics by intervention module are shown in Table 8.1. In general, the user characteristics were similar for the intensive and minimal versions of each intervention module. There were three small but significant differences: users receiving the minimal version of normative feedback were older (F=4.233, p=0.040), and those receiving the minimal version of self-monitoring (χ^2 =4.588, p=0.042) and action planning (χ^2 =6.72, p=0.013) were more likely to be employed.

Participants, on average, significantly underestimated their alcohol consumption compared with others in the UK (t=57.404, p<0.001) and others of their age group and gender (t=56.252, p<0.001). Full details of how the normative misperception scores were calculated, the analysis and results are reported in Appendix 19.

Table 8.1: Socio-demographic and drinking characteristics of trial participants

	All trial	Normative	feedback	Cognitive l	oias re-	Identity ch	ange	Self-monitoring		Action planning	
	participants			training							
		Intensive	Minimal	Intensive	Minimal	Intensive	Minimal	Intensive	Minimal	Intensive	Minimal
% Women (N)	56.1 (377)	55.1	57.1	56.3	56.0	53.3	58.9	59.2	53.0	57.1	55.1
		(185)	(192)	(189)	(188)	(179)	(198)	(199)	(178)	(192)	(185)
Age, mean (SD)	39.2 (10.92)	38.3*	40.0*	39.4	39.0	39.9	38.4	39.4	38.9	39.4	39.0
		(10.14)	(11.60)	(10.92)	(10.93)	(11.02)	(10.78)	(11.46)	(10.36)	(11.44)	(10.39)
% White (N)	95.2 (640)	95.5	94.9	95.2	95.2	95.2	95.2	94.6	95.8	95.2	95.2
		(321)	(319)	(320)	(320)	(320)	(320)	(318)	(322)	(320)	(320)
% Post-16	72.0 (484)	72.0	72.0	72.6	71.4	72.0	72.0	72.6	71.4	72.0	72.0
qualifications		(242)	(242)	(244)	(240)	(242)	(242)	(244)	(240)	(242)	(242)
(N)											
% Employed	86.5 (581)	86.9	86.0	87.5	85.4	86.9	86.0	83.6*	89.3*	83.0*	89.9*
(N)		(292)	(289)	(294)	(287)	(292)	(289)	(281)	(300)	(279)	(302)
% Current	24.6 (165)	25.0 (84)	24.1	24.4 (82)	24.7	23.2 (78)	25.9	24.4 (82)	24.7	22.6 (76)	26.5
smokers (N)			(81)		(83)		(87)		(83)		(89)

	All trial participants	Normative	feedback	Cognitive b	oias re-	Identity change		Self-monitoring		Action planning	
		Intensive	Minimal	Intensive	Minimal	Intensive	Minimal	Intensive	Minimal	Intensive	Minimal
Past week	39.9 (27.34)	39.1	40.7	40.3	39.6	39.0	40.8	39.9	39.9	39.0	40.9
alcohol		(25.97)	(28.66)	(28.23)	(26.45)	(26.62)	(28.05)	(27.09)	(27.63)	(26.46)	(28.20)
consumption/											
units, mean											
(SD)											
AUDIT-C score,	9.4 (1.85)	9.4 (1.77)	9.4	9.4 (1.95)	9.4	9.4 (1.76)	9.4	9.4 (1.86)	9.4	9.4 (1.78)	9.4
mean (SD)			(1.92)		(1.74)		(1.93)		(1.84)		(1.92)
AUDIT score,	19.1 (6.56)	19.2	18.9	19.2	18.9	19.0	19.2	18.9	19.2	19.0	19.1
mean (SD)		(6.49)	(6.63)	(6.75)	(6.37)	(6.35)	(6.77)	(6.44)	(6.69)	(6.68)	(6.45)
% AUDIT ≥16	66.7 (448)	67.6	65.8	68.2	65.2	66.7	66.7	67.3	66.1	66.1	67.3
(N) ^a		(227)	(221)	(229)	(219)	(224)	(224)	(226)	(222)	(222)	(226)

^a indicates harmful drinkers and drinkers at-risk of alcohol dependence as defined by the AUDIT

 $^{^*\} indicates\ cases\ where\ there\ was\ a\ significant\ difference\ in\ a\ user\ characteristic\ between\ versions\ of\ an\ intervention\ module$

8.3.2 Outcomes

8.3.2.1 Primary: Change in past week alcohol consumption

A between-subjects ANOVA was conducted to assess the main and interactive effects of the intervention module version on change in past week alcohol consumption. The main effects and Bayes factors are reported in Table 8.2 and the full results of all main and interactive effects for the five intervention modules are reported in Appendix 20.

There were numerically larger decreases in alcohol consumption for the intensive versions of normative feedback, cognitive bias re-training and self-monitoring intervention modules but there were no significant main effects (see Table 8.2).

Table 8.2: Primary outcome: main effects of intervention modules on change in past week alcohol consumption

	Mean change	in past week	F	F p-value		ctors
	alcohol consu	mption, units				
	per week (SD)					
	Intensive	Minimal	_		5 units	3 units
Normative	-4.1 (14.93)	-3.5 (12.87)	0.297	0.586	0.34	0.54
feedback						
Cognitive bias re-	-4.1 (13.92)	-3.5 (13.95)	0.393	0.531	0.37	0.58
training						
Identity change	-3.0 (13.13)	-4.6 (14.66)	2.160	0.142	0.09	0.15
Self-monitoring	-4.3 (13.37)	-3.3 (14.48)	0.781	0.377	0.49	0.76
Action planning	-3.6 (12.22)	-4.0 (15.48)	0.135	0.714	0.16	0.26

There was a significant two-way interaction between the normative feedback and cognitive bias re-training module on past week alcohol consumption (F=4.676, p=0.031). The simple

main effects of these intervention modules indicated that the intensive version of the normative feedback module lead to a significant reduction in past week alcohol consumption only when combined with the intensive version of the cognitive bias re-training module (see Table 8.3).

Table 8.3: Simple main effects of two-way interaction between cognitive bias re-training and normative feedback module on change in past week alcohol consumption

		Change in past	F	p-
		week alcohol		value
		consumption,		
		mean (SD)		
Cognitive bias re-training	Normative feedback			
Intensive	Intensive	-5.6 (16.27)	3.69	0.055
	Minimal	-2.7 (10.95)		
Minimal	Intensive	-2.6 (13.34)	1.32	0.252
	Minimal	-4.3 (14.53)		
Normative feedback	Cognitive bias re-training			
Intensive	Intensive	-5.6 (16.27)	3.91	0.048
	Minimal	-2.6 (13.34)		
Minimal	Intensive	-2.7 (10.95)	1.19	0.277
	Minimal	-4.3 (14.53)		

8.3.2.1.1 Sensitivity analyses

The sensitivity analysis amongst responders-only is reported in Appendix 21 for the main effects. This sensitivity analysis showed a similar pattern of results with the significant two-way interaction between normative feedback and cognitive bias re-training remaining (F=7.553, p=0.007). One difference was that the identity change module had a significant main effect with the minimal version (mean=-18.2) showing a greater decrease in past week's

alcohol consumption than the intensive version (mean=-10.8) (F=4.261, p=0.041). However, this is difficult to interpret given the result was not identified in the primary analysis.

The sensitivity analyses adjusting for app usage (number of sessions) and user characteristics (age, gender, education level, ethnicity group, employment status, smoking status, and baseline AUDIT score) showed the same pattern of results.

8.3.2.1.2 Bayes Factor analysis for main effects

The Bayes factors (BF) calculated for the main effects of these intervention modules are reported in Table 8.2. The data were insensitive to distinguish an effect for the normative feedback (BF=0.34) and cognitive bias re-training (BF=0.37) modules. For the identity change module, there was strong evidence for the null hypothesis that there was no effect between versions of the identity change module on change in past week's alcohol consumption (BF=0.09). A sensitivity analysis with the Bayes factors using a smaller expected effect size of a difference of 3 units showed a similar pattern of results of data insensitive to detect an effect for the normative feedback (BF=0.54) and cognitive bias re-training (BF=0.58) modules. Even when specifying a smaller effect, there remained moderate evidence for the null hypothesis of no difference between the intensive and minimal versions of the identity change module (BF=0.15).

8.3.2.2 Secondary: Change in AUDIT score

A between-subjects ANOVA was conducted to assess the main and interactive effects of the intervention module version on change in AUDIT score. The main effects are reported in Table 8.4 and the full results of all main and interactive effects for all the intervention modules are reported in Appendix 22.

There were numerically larger decreases in AUDIT scores for the intensive versions of normative feedback, cognitive bias re-training, self-monitoring and action planning but there were no significant main effects (see Table 8.4). There was a significant two-way interactive effect between self-monitoring and action planning modules on change in AUDIT score (F=5.818, p=0.016) with the maximum effect occurring when both where in the intensive versions.

Table 8.4: Secondary outcomes: main effects of intervention modules on change in AUDIT score

	Mean change in A	AUDIT score (SD)	F	p-value	Bayes
	Intensive	Minimal	_		factor
Normative feedback	-0.9 (2.68)	-0.6 (2.54)	1.600	0.206	0.54
Cognitive bias re-	-0.8 (2.37)	-0.7 (2.84)	0.105	0.746	0.18
training					
Identity change	-0.7 (2.71)	-0.8 (2.51)	0.087	0.769	0.11
Self-monitoring	-0.8 (2.66)	-0.7 (2.56)	0.346	0.557	0.23
Action planning	-0.9 (2.71)	-0.6 (2.51)	1.752	0.186	0.59

8.3.2.2.1 Sensitivity analyses

The sensitivity analysis amongst responders-only is reported in Appendix 23 for the main effects. This sensitivity analysis showed the same pattern of results as for the intention-to-treat approach. Sensitivity analyses adjusting for app usage and for participant characteristics showed the same pattern of results.

8.3.2.2.2 Bayes Factor analysis for main effects

Bayes factors were calculated for the main effects of intervention modules on change in AUDIT score (see Table 8.4). The Bayes factors indicated that the different versions of the

cognitive bias re-training (BF=0.18) and identity change (BF=0.11) intervention modules cause no change to the AUDIT score with an expected effect size of d=0.22 modelled using a half-normal distribution. The Bayes factor for the normative feedback module indicated that the data are insensitive to detect this effect (BF=0.54).

8.3.2.3 Secondary: Usage data

Overall, participants used the app for a mean of 11.7 sessions (SD=13.73) and the mean length of time per session was 4:23 (SD=4:19). Participants used the app on a mean of 8.0 separate days (SD=8.11) across a mean period of 11.0 days (SD=10.92).

A between-subjects ANOVA was conducted to assess the main and interactive effects of the intervention module version on participants' app usage data. The main effects are reported in Table 8.5 and the full results of all main and interactive effects for all the intervention modules are reported in Appendix 22. There was a significant main effect of the intensive self-monitoring version on the mean number of sessions (F=12.728, p<0.001), but no other main effects of intervention module version or two-way interactions on number of sessions. There were no main or interactive effects between intervention module versions on the length of time per session.

A sensitivity analysis adjusting for number of sessions when assessing length of time per session had the same pattern of results. Adjusting for socio-demographic and drinking characteristics of the participants did not affect the pattern of results for usage data.

Table 8.5: Secondary outcomes: main effects of intervention modules on usage

	Mean number of		F	p-	Mean leng	th of time	F	p-
	sessions (SD)			value	per session (SD)			value
	Intensive	Minimal	_		Intensive	Minimal	_	
Normative	12.3	11.0	1.643	0.200	4:34	4:11	1.359	0.244
feedback	(14.40)	(13.02)			(4:39)	(3:58)		
Cognitive	11.8	11.5	0.051	0.821	4:21	4:25	0.044	0.833
bias re-	(14.36)	(13.1)			(4:21)	(4:19)		
training								
Identity	12.1	11.2	0.855	0.356	4:36	4:10	1.736	0.188
change	(13.71)	(13.76)			(4:41)	(3:56)		
Self-	13.5	9.8	12.72	< 0.00	4:23	4:23	< 0.00	0.993
monitoring	(15.33)	(11.66)	8	1	(4:34)	(4:05)	1	
Action	11.4	11.9	0.167	0.683	4:36	4:09	1.785	0.182
planning	(12.79)	(14.63)			(4:33)	(4:05)		

8.3.2.3.1 Cognitive bias re-training module – "Yes please, no thanks" game

Participants played the game a mean of 1.9 times (SD=4.01) and there was no difference in the number of times played between versions (t=0.385, p=0.701). Of the 429 participants who played the game at least once, the game was played 2.9 times (SD=4.70) on average. Full details of all the measures and results relating to the "Yes please, no thanks" game (number of times played, average score, average successes, average errors) are reported in Appendix 24.

8.3.2.4 Usability ratings

A between-subjects ANOVA was conducted to assess the main and interactive effects of the intervention module version on usability ratings with complete cases for these measures. The main effects are reported in Table 8.6 and the full results of the main and interactive effects for all the intervention modules are reported in Appendix 25.

The intensive version of self-monitoring had a significantly higher rating for 'helpfulness' (F=4.388, p=0.038), 'recommendation' (F=5.023, p=0.027) and 'satisfaction' (F=6.598, p=0.011). There were no significant main effects between intervention module versions of normative feedback, cognitive bias re-training, identity change or action planning on the usability ratings.

Sensitivity analysis adjusting for participant characteristics found a very similar pattern of results for all of the usability ratings. When adjusting for app usage, there was the same pattern of results for 'ease of use', 'recommendation' and 'satisfaction' though there was no main effect of self-monitoring module version on 'helpfulness' (F=2.138, p=0.146).

Table 8.6: Secondary outcomes: main effects of intervention modules on usability

	Mean helpfulness rating (SD) N=182		an helpfulness F		Mean ease of use		F	p-	Mean	F		p-	Mean satisfaction		F	p-
				value	rating (SD)			value	recommendation rating (SD)			value	rating (SD)			value
					N=178								N=178			
									N=178							
	Intensive	Minimal	_		Intensive	Minimal	-		Intensive	Minimal	=		Intensive	Minimal	=	
Normative	3.0 (0.88)	3.0	0.015	0.903	3.5	3.6	0.723	0.397	3.0	3.1	0.282	0.596	3.2	3.2	0.167	0.683
feedback	N=101	(1.05)			(0.97)	(1.06)			(1.23)	(1.22)			(0.95)	(1.02)		
		N=81			N=97	N=81			N=97	N=81			N=97	N=81		
Cognitive	3.0 (0.98)	3.1	0.031	0.861	3.5	3.6	0.217	0.642	2.9	3.2	1.071	0.302	3.2	3.2	0.031	0.860
bias re-	N=89	(0.94)			(0.97)	(1.05)			(1.23)	(1.21)			(0.97)	(1.00)		
training		N=93			N=86	N=92			N=86	N=92			N=86	N=92		
Identity	3.1 (0.97)	3.0	0.174	0.677	3.6	3.5	0.020	0.886	3.2	2.9	0.399	0.529	3.2	3.1	0.003	0.953
change	N=96	(0.94)			(1.00)	(1.02)			(1.16)	(1.28)			(0.95)	(1.01)		
		N=86			N=93	N=85			N=93	N=85			N=93	N=85		
Self-	3.2 (0.94)	2.9	4.388	0.038	3.6	3.5	1.109	0.294	3.2	2.8	5.023	0.027	3.4	3.0	6.598	0.011
monitoring	N=98	(0.96)			(1.00)	(1.03)			(1.22)	(1.19)			(1.00)	(0.92)		
		N=84			N=97	N=81			N=97	N=81			N=97	N=81		
Action	3.0 (1.02)	3.0	0.007	0.932	3.6	3.5	0.473	0.493	3.1	3.0	0.330	0.566	3.3	3.1	1.298	0.256
planning	N=90	(0.90)			(1.07)	(0.96)			(1.23)	(1.22)			(1.00)	(0.97)		
		N=92			N=86	N=92			N=86	N=92			N=86	N=92		

8.3.2.5 Unregistered analyses

8.3.2.5.1 Overall effect of app

One sample t-tests were conducted to assess the overall effect of the app on the outcome measures for participants, regardless of their experimental condition. These results are reported in Table 8.7. There was a significant decrease in past week alcohol consumption of 3.8 units (t=-7.086, p<0.001) and AUDIT score of 0.7 points (t=-7.356, p<0.001) from baseline to follow-up. Participants rated the app significantly above neutral (a score of '3') on 'ease of use' (t=6.980, p<0.001) and on 'satisfaction' (t=2.676, p=0.008). Ratings for 'helpfulness' (t=0.620, p=0.536) and 'recommendation' (t=0.429, p=0.668) were not significantly different from average.

Table 8.7: Overall effect of Drink Less app on outcome measures

Outcome measure		N	Mean score	t	p
			(SD)		
Change in past week	ITT	672	-3.8 (13.93)	-7.086	<0.001
alcohol consumption,	approach				
units per week	Responders	179	-14.3	-7.936	< 0.001
	only		(24.10)		
Change in AUDIT	ITT	672	-0.7 (2.61)	-7.356	< 0.001
score	approach				
	Responders	172	-2.9 (4.53)	-8.388	< 0.001
	only				
Helpfulness rating	182	3.0 (0.96)	0.620	0.536	
Ease of use rating		178	3.5 (1.01)	6.980	< 0.001
Recommendation ratio	ng	178	3.0 (1.22)	0.429	0.668
Satisfaction rating	178	3.2 (0.98)	2.676	0.008	

8.3.2.5.2 Effect of overall app 'intensity'

The effect of app 'intensity' on outcome measures was assessed in a one-way ANOVA. 'High intensity' participants were those receiving four of the intensive versions of intervention modules or all five intensive versions (n=126). The 'low intensity' participants were those receiving none or only one intensive version (n=126). There was only one significant main effect of app 'intensity' on outcome measures; participants with a 'high intensity' app rated their 'satisfaction' with the app significantly higher than 'low intensity' (F=2.676, p=0.008). The full results table is reported in Appendix 26.

8.3.2.5.3 Evidence of harm from intensive versions

Bayes Factors were calculated to assess whether there was any evidence that the intensive versions of intervention modules actually caused harmful outcomes (an increase of 3 units per week), see Table 8.8. There was moderate evidence that the intensive versions of the normative feedback, cognitive bias re-training or self-monitoring intervention modules did not cause any increase in alcohol consumption. The Bayes factors for the identity change and action planning modules indicate that the data are insensitive to distinguish an effect of a 3 unit increase in alcohol consumption.

Table 8.8: Bayes factors for assessing evidence of harm for modules in the Drink Less app

	Mean change	in past	F p-value		Bayes factors		
	week alcohol						
	consumption	ı, units per					
	week (SD)						
	Intensive	Minimal	_		5 unit	3 unit	
					decrease	increase	
Normative	-4.1 (14.93)	-3.5	0.297	0.586	0.34	0.24	
feedback		(12.87)					
Cognitive bias re-	-4.1 (13.92)	-3.5	0.393	0.531	0.37	0.22	
training		(13.95)					
Identity change	-3.0 (13.13)	-4.6	2.160	0.142	0.09	1.62	
		(14.66)					
Self-monitoring	-4.3 (13.37)	-3.3	0.781	0.377	0.49	0.20	
		(14.48)					
Action planning	-3.6 (12.22)	-4.0	0.135	0.714	0.16	0.46	
		(15.48)					

8.4 Discussion

This study assessed the effectiveness of five intervention modules (normative feedback, cognitive bias re-training, identity change, self-monitoring, and action planning) delivered within an app to reduce excessive alcohol consumption. By intent to treat, there was a significant overall reduction in alcohol consumption averaging 3.8 units per week and in AUDIT score of 0.7 points. There were numerically, but not significantly, larger decreases in alcohol consumption and AUDIT score for intensive versions of normative feedback, cognitive bias re-training and self-monitoring. There were significant two-way interactions between normative feedback and cognitive bias re-training on past week alcohol consumption and between self-monitoring and action planning on AUDIT score. Both interactions were in the

direction of the maximum reduction occurring when participants received the intensive versions of both modules. Overall, participants used the app for a mean time of 4:23 minutes each session and for an average of 11.7 times, compared with 8.5 times for the SmokeFree 28 app [135]. In general, participants rated the app significantly above neutral on ease of use and satisfaction measure. Participants receiving the intensive version of the self-monitoring module used the app significantly more times, and rated the app more highly on 'helpfulness of the app', 'likelihood to recommend the app to a friend' and 'satisfaction with the app'.

The significant two-way interaction suggests a synergistic interaction between the normative feedback and cognitive bias re-training modules on past week alcohol consumption, which is supported by empirical evidence suggesting that interventions targeting both the reflective and automatic motivational systems are more likely to be effective than either one alone in achieving behaviour change [194,217,218]. This finding is in line with the dual-process models of behaviour and the PRIME Theory of Motivation that propose that behaviour is determined by motivation and its two systems [148,195–197]. The normative feedback module targeted reflective motivation and the cognitive bias re-training module targeted automatic motivation. There was also a two-way interaction between self-monitoring and action planning on AUDIT score. This interaction is consistent with previous findings from alcohol interventions [242], other behavioural domains [241], and is consistent with Control theory [243].

No main effects of the intensive versions of intervention modules were detected; however, this study was powered to detect large effects comparable with those of a brief intervention. Although this could be considered an unrealistic effect size for a module within a digital intervention, the calculation of supplementary Bayes factors in the event of null results was planned. The Bayes factors were to supplement the inferential statistics and to provide useful information on the relative likelihood of a smaller, more realistic effect size (a decrease of

three units of alcohol). However, the Bayes factors indicated that the data were not sensitive enough to distinguish a smaller effect for the normative feedback and cognitive bias retraining modules whilst the identity change module had evidence for no difference between module versions.

The lack of main effects meant that it was not possible to reach a conclusion as to whether the intensive and minimal module versions were equally helpful or unhelpful. It may have been that the minimal versions were as effective as the intensive versions or that the intervention content was equally ineffective at reducing alcohol consumption regardless of module version. Assessment reactivity, whereby the simple act of asking participants about their drinking reduces subsequent alcohol consumption, may have been sufficient regardless of experimental condition [427,428]. Participants in this trial had to be 'interested in drinking less' and so assessment reactivity may have been accentuated in this sample.

An overall significant reduction in alcohol consumption of nearly 4 units was found though this may have been unrelated to the use of the app. Another possible explanation is regression to the mean which describes how observations that differ substantially from the true mean tend to be followed by observations closer to the true mean [429]. Regression to the mean may account for some within-participant variation in alcohol consumption over time [430]. The mean decrease in AUDIT score over time increases as the AUDIT score required for inclusion increases [431]. Participants in this trial had a high mean baseline AUDIT score of 19.1 (although the selection criterion was 8).

8.4.1 Practical implications

One of the purposes of this study was to optimise the next iteration of the app. The study did not provide definitive evidence for effectiveness of specific intervention modules of the Drink Less app. However, the overall picture indicates that an app that retains the intensive versions

of the normative feedback, cognitive bias re-training, self-monitoring and action planning intervention modules may assist with drinking reduction.

Additional unregistered analyses were conducted for the purpose of informing the next iteration of the app – an optimised treatment package version. First, the effect of the availability of intensive modules on outcome measures was assessed to determine whether to include intensive module versions without clear evidence for their effectiveness. Participants with four or five of the intensive module versions used the app for a greater number of sessions and reported greater satisfaction with the app thought there were no effects on alcohol-related outcomes. This indicates it is worth retaining four or five intensive intervention modules to improve app usage and user satisfaction. Secondly, it was crucial to assess whether any intervention modules had evidence of a harmful effect of an increase in alcohol consumption of 3 units. The Bayes factors that were calculated showed that the identity change module tended towards evidence of a small harmful effect. Based on these two analyses and the previous finding that internet-based interventions that take less time to understand and use are also more likely to be effective [432], it was decided not to include the current identity change module in any future versions of the app.

This study has practical implications for public health in terms of the implementation of an optimised app for excessive drinkers in healthcare settings. Healthcare practitioners could play an important role in offering or recommending digital behaviour change interventions such as the Drink Less app and in reaching those excessive drinkers not seeking help. Future research should establish whether implementing an optimised version of the Drink Less app in healthcare settings is feasible with healthcare practitioners and patients. If found to be feasible, then the optimised Drink Less app should be evaluated to assess whether it would have an additive effect on usual care. The app could also be promoted through different

organisations, such as educational institutions and employers, to target excessive drinkers who are not treatment seeking.

8.4.2 Future research

A key aim of this study was to screen the intervention modules, as emphasised by the Multiphase Optimisation Strategy (MOST) [143,144], with the aim of optimising the next version of the app as a treatment package. The optimised version of the app will also be informed by a further content analysis of user feedback that was received during the trial via emails to the research team and reviews left in the app store. The aim of such content analysis would be to understand users' experiences of the intervention better to improve the acceptability and feasibility of the Drink Less app. Future research is needed to conduct a definitive randomised control trial with long-term outcomes for the optimised version of the app against a single control group. A suitable control group for this trial will require careful consideration; possible options include a control app, usual care in the context of existing digital support and a brief intervention.

8.4.3 Strengths and Limitations

To our knowledge, this was the first study to examine the effectiveness of a smartphone app to reduce excessive alcohol consumption. The design of the trial and its analysis also allowed each intervention module and its interactions with other modules to be assessed independently. The study provides an important starting point for building an evidence base on which intervention components are effective in what context. This trial provides preliminary findings that, in the context of a modular app-based intervention, there is support for the role of normative feedback, cognitive bias re-training, self-monitoring and action planning in reducing excessive alcohol consumption. The factorial design of this evaluation comparing intensive and minimal versions enabled the individual effect of each module to be

estimated. However, there was an absence of a clear comparator group such as a wait list control group, which might have provided a better idea of whether the overall reduction was natural 'remission' or an artefact of regression to the mean. The choice of a comparator group for the evaluation of a digital behaviour change intervention is a major consideration with multiple options, each with their own advantages and disadvantages, and no ideal option [61]. The minimal version of each module was a minimal credible intervention – the digital behaviour change intervention equivalent of a placebo [61] – which was in effect the control group for each intensive module. These minimal versions contained enough features to be judged effective by the users but without including the key active ingredients.

The other options for a control group are no intervention or an active comparator. A comparator of no intervention, such as a wait list control group, is suitable for estimating the effect of a digital intervention when there is nothing else that users could access to perform the function although it can lead to a higher rate of drop-out [61]. However, this means that recruitment for the trial could not be done 'naturally' through the app store, which is a strength of the current study. A wait list control group would also result in differential uptake and attrition, and the use of non-assigned support would be an uncontrolled factor. An active comparator would have involved testing Drink Less against another intervention. This provides an estimate of relative effectiveness compared with an existing app, best practice or usual care. Using an existing app as the comparator would need a large sample, as the effect is likely to be small, and would also require choosing a suitable app and collaborating with its developers to gain access to the necessary data. Best practice or usual care as a comparator group would mean recruitment could not be done 'naturally' as with the 'no intervention' control group.

Therefore, a minimal credible intervention was chosen as it had the major advantage over an active or no intervention comparator group that it is suited to assessing the independent and

interactive effects of multiple intervention modules within the same app. The aims of using a minimal credible intervention are as follows: to minimise differences in experience, attrition rates, engagement and exposure to non-assigned treatments; to improve blinding to allocation, data collection, understanding of app usage, and trial management; and to enable recruitment of the target population – individuals seeking an app to help them reduce their drinking. Some limitations of using a minimal credible intervention include: the additional challenge of developing two versions for each module, user expectations of the app, and potentially negative comments and ratings for the 'minimal' versions. However, all comparator groups have some limitations and using a minimal credible intervention was the best option for the specific aims of this study.

The decision of what constitutes a minimal credible intervention is clearly difficult and another limitation of this trial was that the minimal versions of the intervention modules (i.e. the control conditions for each module) were possibly too active as there was a trade-off with retention and credibility. Most popular alcohol reduction apps include almost no behaviour change techniques [106]. This indicates that the participants in the current study who received the minimal versions were effectively receiving 'usual care' in the context of digital support. Therefore, the estimates of effectiveness are likely to be conservative compared with a more basic control group. This will be addressed in future research by a definitive randomised control trial with a suitable control.

A major strength of this study is that it is in accordance with the principles of Open Science, which is important for efficient scientific progress [318]. The trial protocol, full analysis plan and outcome measures were all pre-registered on ISRCTN and published in a peer-reviewed journal, BMC Public Health. The trial data will be published on Open Science Framework (https://osf.io/q8mua/). In addition to this, the source code for the app is open access and

will be shared on request with other researchers who wish to develop similar apps, which will reduce development costs for other researchers [61].

This trial was designed to minimise the high attrition rate which is usually a major limitation of digital trials by having a short follow-up period [433] and reminding participants of the monetary incentives and their agreement to be contacted. Regular reminders (up to five) were sent via email so that participants who had stopped using the app could still be contacted [434]. There was also an in-app option to complete the follow-up questionnaire. Despite the attempts to limit attrition, the completion rate for the primary outcome measure was only 27%. A high attrition rate results in the methodological problem of how to measure the effectiveness of digital trials accurately [370] and the problem of missing outcome data undermines the credibility and validity of inferences from trial findings [433]. The intention-to-treat approach, whereby non-responders were assumed to be drinking at baseline levels, was used for the main analysis to deal with missing outcome data and provided a conservative estimate of intervention effectiveness [434], particularly given there was no evidence of differential attrition between intensive and minimal versions of the modules.

In an attempt to keep the participant burden to a minimum and increase engagement with the app, only critical measures were included. Measures to assess potentially mediating variables, fidelity of delivery and theoretical constructs were not included. For example, there was no 'testing' phase in the cognitive bias re-training module. Theory was used to inform the development of Drink Less though the results of the trial cannot inform or refine theory. Therefore, we could not determine the mechanism of action behind the lack of detected main effect; the module may have failed to alter existing cognitive biases or altered cognitive biases but had no effect on subsequent alcohol consumption. This limited the inferences that could be made and our understanding of the mechanism of actions of effects [435]. This is a limitation of conducting the trial in the 'real world' rather than in an experimental laboratory

study. One option for future research is to test a single module app in an experimental laboratory study to assess whether the module is changing the predicted mediator. It is important to use controlled experimental studies to establish whether the predicted theoretical constructs are mediating the effect of the intervention as this is an important part of accumulating a strong evidence base for behaviour change interventions [436].

The AUDIT questionnaire is a good alcohol-related outcome measure as it is reliable and has been validated internationally as a screening test, which allows for direct comparisons between studies from any country [3]. It also identifies hazardous and harmful alcohol use, and possible dependence, in line with the definitions from the International Statistical Classification of Diseases and Related Health Problems (ICD) 10th revision [32]. However, the AUDIT questionnaire does have a number of limitations. The AUDIT cannot establish past week alcohol consumption despite it having a focus on recent alcohol use. Certain items within the AUDIT can be misinterpreted by specific populations [437]. Tertiary students indicated that AUDIT items 5 and 9 had ambiguous meanings and when these items were more specifically defined, there was a markedly different response distribution to that item though no change in the total AUDIT score [437]. This suggests that caution is necessary when using any individual AUDIT items as measures of alcohol-related consequences in certain populations. However, no single items were used as measures in this trial and the Drink Less users did not appear to be a student population as there was a mean age of 39.2 years and the majority were employed.

As it was delivered by smartphone, there were few issues of availability or accessibility for the participants. The app could be used fully at any time with no need for an internet connection.

The data were stored on the phone until an internet connection was available and then the data were sent to the server.

8.4.4 Conclusions

This study evaluated the extent to which an app could help reduce excessive drinking and estimated the independent and interactive effects of five intervention modules. The findings warrant the inclusion of the intensive versions of the normative feedback, cognitive bias retraining, self-monitoring and action planning intervention modules in an optimised version of the app. This optimised version of the Drink Less app may assist with a reduction in excessive drinking and merits further optimisation and, depending on the results, evaluation in a full RCT with long-term outcomes.

Chapter 9 - General Discussion

In this final chapter, the key findings across all the studies will be summarised, the main strengths and limitations of the thesis will be considered, future research will be suggested, and the implications of this thesis will be discussed in a broader context.

9.1 Summary of findings

The objective of this thesis was to develop and evaluate a smartphone app to reduce excessive alcohol consumption, based on theory and scientific evidence. The process followed the principles outlined by the Medical Research Council (MRC) guidance on developing and evaluating complex interventions [139] and the Multiphase Optimisation Strategy (MOST) [141,142]. The work was conducted in three stages: the selection of intervention content, the development of the app and its evaluation.

The selection of intervention content was based on a number of sources of evidence including a behavioural analysis of excessive alcohol consumption and four studies conducted as part of this thesis. The behavioural analysis was conducted using the COM-B model of behaviour [146,147] and Theoretical Domains Framework (TDF) [72,149,150] in order to assess not only what factors were associated with excessive alcohol consumption but also those which were feasible to target through an app-based intervention. The behavioural analysis identified a number of possible intervention components: provision of information, normative feedback, cognitive bias modification, self-monitoring, action planning, identity change, evaluation of benefits and costs of drinking, and goal setting.

Study 1 assessed the user characteristics of a popular alcohol reduction app, Drinks Meter, in order to compare app users with the general population of drinkers in England. The users of this app reported greater alcohol consumption and alcohol-related harms compared with the general population of drinkers. Users were also younger, more likely to be from the South, and of a higher social grade. This study established that excessive drinkers in need of support, as opposed to the 'worried well', were using a popular alcohol reduction app. This finding supported the development of an app to reduce excessive alcohol consumption.

Study 2 investigated how theory use was reported by digital interventions for alcohol reduction and used a meta-regression to assess whether there was an association with intervention effectiveness. Randomised controlled trials (RCTs) from a Cochrane Systematic Review on digital interventions for reducing hazardous and harmful alcohol consumption were coded for their reported theory use with an amended Theory Coding Scheme. The findings of Study 2 showed that the reporting of theory use in the development and evaluation of digital alcohol reduction interventions was limited. Half of the studies included in the metaregression did not mention theory and only a third used theory to develop the intervention. None of the included studies used their results to refine theory. This highlighted a missed opportunity to use digital interventions and their trial results to inform the refinement of existing theories or to develop new, dynamic, temporally sensitive theories. No significant associations were found between the reporting of theory use and intervention effectiveness. However, the meta-regression was underpowered to detect modest associations, and limitations in the available literature meant no strong conclusions could be made regarding the usefulness of theory in intervention development. Study 2 highlighted the need for clearer selection, application and reporting of theory use to assess accurately how useful theory is and to advance theory development.

Study 3 assessed whether the phenomenon of normative misperceptions – the underestimation of one's own alcohol consumption compared with others – extended to the general population of drinkers, and whether it was associated with any socio-demographic or drinking characteristics. A cross-sectional online global survey was used to collect data from four English-speaking countries: the UK, the US, Australia and Canada. Normative misperceptions were found to be common in these four countries and a substantial minority of harmful drinkers believed their alcohol consumption to be average or lower than average. The normative misperception score was associated with a number of socio-demographic and drinking characteristics. Normative misperceptions were greater in those who were younger, male, from the UK (compared with the US), less well educated, white, unemployed (compared with employed), and who were high-risk drinkers. These results indicated that targeting normative misperceptions through normative feedback may be a suitable intervention component for the general population of drinkers in the UK.

Study 4 aimed to identify the highest priority intervention components to reduce excessive alcohol consumption and engagement strategies for an app using a formal expert consensus method. This study used a Delphi exercise consisting of three rounds with international experts in the field of alcohol or behaviour change. The first round involved the experts generating their initial responses to the question regarding which intervention content and engagement strategies were "best bets". The second and third rounds involved the rating and ranking, respectively, of the responses generated in the first round. Twelve intervention components and 17 engagement strategies were identified by experts as "best bets" to reduce alcohol consumption and promote engagement via an app. The intervention components considered to have the greatest potential were: self-monitoring, goal setting, action planning and feedback in relation to goals. The strategies considered most likely to engage users were: ease of use, design, tailoring of design and information, and unique smartphone features.

These results were used to inform the decision of what intervention components to include for evaluation in the app.

These four studies constituted the first stage of the thesis and together contributed to the selection of intervention content for evaluation in the app, as well as advancing understanding of who uses alcohol reduction apps and how theory is being used. The five intervention components selected as high priority for inclusion and evaluation in the app were: normative feedback, cognitive bias re-training, identity change, self-monitoring, and action planning.

The second stage involved development of the app and translation of the selected intervention components into modules. The development followed an iterative process and involved: defining the app content; choosing the design principles; usability testing, and debugging of the app. Both the implementation and design of the scientific content were considered in the development process together with using a person-based approach to improve the usability of the app.

The final stage involved estimating the independent effectiveness of each intervention module of the app at reducing excessive alcohol consumption. A factorial randomised control trial was conducted amongst excessive drinkers who were aged 18 and over, from the UK, and interested in reducing their alcohol consumption. A between-subjects ANOVA was conducted to assess the main and interactive effects of the five intervention modules on the outcome measures using an intention-to-treat approach. The primary outcome measure was change in past week alcohol consumption and secondary outcome measures were change in AUDIT score, usability ratings and app usage data. There was an overall decline of 3.8 alcohol units per week and of 0.7 AUDIT points, although no main effects of intervention modules on alcohol-related outcomes were detected. There were numerically larger decreases in alcohol

consumption and AUDIT score for intensive versions of normative feedback, cognitive bias retraining and self-monitoring. There were significant two-way interactions between normative feedback and cognitive bias re-training on past week alcohol consumption, and between self-monitoring and action planning on AUDIT score. These interactions were both in the direction of the largest effect occurring when participants received intensive versions of both intervention modules. Participants rated the app significantly above neutral on ease of use and satisfaction, and were engaged with the app (for example a mean of 11.7 log-ins) but there was no evidence that this depended upon the module content. This study suggests that a version of the Drink Less app that includes the normative feedback, cognitive bias re-training, self-monitoring and action planning intervention modules may assist with drinking reduction, and should be evaluated in a full-scale RCT with long-term outcomes.

This thesis reports (i) the systematic development of an alcohol reduction app, drawing on theory and empirical evidence that informed the app and (ii) the evaluation of the app.

Recommendations are made for how to optimise the app based on these findings.

9.2 Strengths

This thesis clearly reports the development process of an app-based alcohol intervention along with the theories and sources of evidence used to inform its content. Drink Less is the first alcohol reduction app, to our knowledge, that has been systematically developed based on theory and evidence. The transparent reporting of the development process may provide a good example to other researchers developing health-related behaviour change apps. The development of the app involved a person-based approach consisting of a think-aloud study with new users of the Drink Less app and interviews with regular users of the app. This allowed us to increase user engagement with the app, which was reflected in the high usability ratings from participants and the app usage data.

'Open science' – making materials, data, results and publications freely available – is important for efficient scientific progress [318]. A major strength of the development and evaluation of Drink Less is that it is in accordance with the principles of Open Science. The intervention content and development has been reported fully and in a transparent manner, which may provide a helpful example to other researchers developing behaviour change apps. The trial protocol, including analysis plan and outcome measures, were pre-registered on ISRCTN and published in a peer-reviewed journal, BMC Public Health. The data are freely available on the Open Science Framework (https://osf.io/q8mua/), and the results and publications will be made available in open access journals. In addition to this, the source code for the Drink Less app will be shared on request with other researchers who wish to develop similar apps. The coding of the app and the use of modules not only meant that development was more efficient, but also that modules can be shared across interventions. This will help to accelerate the development of this scientific field as well as reducing development costs for other researchers [61].

Another strength of the research reported in this thesis is that the Drink Less app was evaluated for its effectiveness at reducing excessive alcohol consumption, to our knowledge the first reported evaluation of an app for excessive drinkers in the general population. The design of the trial meant that each intervention module could be evaluated independently. Therefore, the findings from the factorial RCT can inform which intervention modules of the Drink Less app should be retained in a future, optimised version of the app, or potentially included in other alcohol reduction interventions.

9.3 Implications

The general population of drinkers underestimate their alcohol consumption. These normative misperceptions were found in a sample of the general population in four English-

speaking countries and in the trial participants. Research prior to that presented in this thesis had only assessed normative misperceptions amongst heavy drinkers and students, and it was not known whether they were limited to these populations. The presence of normative misperceptions in the general population of drinkers suggests that correcting these misperceptions might be effective, as part of interventions targeted at this population. It also has implications for any campaigns that are targeted to 'at-risk' drinkers as they may be ignored on the basis that these drinkers do not know they are considered 'at-risk'.

This thesis reports the user characteristics of alcohol reduction apps for the general population. Our examination of the data from two alcohol reduction apps – Drinks Meter and Drink Less – show that users drink at higher levels than in the general population of drinkers. Drinks Meter users were also younger than drinkers in the general population, more likely to be female, and of a higher socioeconomic status. The user characteristics of the Drink Less app, when users were not selected based on the trial inclusion criteria, show that users had a mean AUDIT score of 17.9 which is substantially higher than the general population of drinkers. These findings indicate that users of alcohol reduction apps are excessive drinkers and not just the 'worried well'. This is important as it provides support for apps as a mode of delivery for alcohol interventions since individuals in need of support are using them.

This thesis highlights the need for clear reporting of whether and how theories are used in interventions. Reporting of theory use is extremely limited in the development and evaluation of digital alcohol interventions and the results from interventions are not being used to develop or refine theories. Digital technology offers an opportunity to collect context-specific data that would aid the development of new dynamic, temporally sensitive theories that are better suited to informing DBCIs. The findings from this thesis emphasise the need to be clearer in the selection, application and reporting of theory use, and to prioritise data

collection of hypothesised mediators and moderators within theories so that results can be used to develop the relevant theories.

The findings from the screening experiment with the Drink Less app suggest that an app with normative feedback, cognitive bias re-training, self-monitoring and action planning intervention modules may assist with reducing excessive alcohol consumption. Whilst these findings are not conclusive, they provide guidance as to which intervention modules are worth including in future alcohol reduction apps and developing further, before being evaluated in a full-scale RCT with longer-term outcomes. More broadly, the screening experiment suggested that apps are a feasible method of delivering alcohol interventions and that a wide range of people seek them out. However, this is a passive approach to implementation that relies on excessive drinkers seeking digital support. Many people underestimate their alcohol consumption so a new approach is needed for reaching excessive drinkers who do not consider their alcohol consumption as excessive.

9.4 Limitations

A limitation of the factorial RCT was that the alcohol-related outcome measures were self-reported. However, it was not feasible to use biochemical verification and most major alcohol intervention trials rely on self-reported measures. There is evidence that people under-report their alcohol consumption but we attempted to minimise this effect by using an outcome measure based on the change between two time points and comparing randomly allocated individuals with no reason to suspect systematic differences in under-reporting between them.

The generalisability of the findings from the factorial trial is limited to the UK as an inclusion criterion was for participants to be from the UK. This was necessary because the differences

between countries in the standard definition of units would require the programming of the Drink Less app to change based on the country in which the app was downloaded.

The intervention content for Drink Less was selected based on the best available sources including relevant behaviour change theories and empirical evidence. However, the final decision for inclusion in the app drew on researcher judgement. The development process and rationale for selection was clearly reported and the factorial RCT allowed us to assess the effectiveness of the selected intervention modules. As there was no evaluation of intervention modules that were not selected there was no way of determining whether researcher judgement was empirically 'correct'. Goal setting was included in the app in all of the experimental conditions as there was good evidence for its effectiveness and there was a pragmatic need to provide a basic structure to the app to which other intervention modules could be linked. However, this precluded evaluating its absolute or relative effectiveness so have not provided evidence for inclusion in future interventions.

9.5 Reflections

This thesis constituted the preparation and screening stages described in MOST. The goals of these stages were to select intervention modules most likely to be effective to include in the first version of the intervention and to assess the main effects of and interactions between individual intervention modules. The COM-B model proved a useful model of behaviour to use as the starting point for developing a behaviour change intervention and selecting intervention components. It was feasible and informative to use evidence from qualitative studies with users, including those of lower socioeconomic status, to inform the content and design of the app. Initial development costs of apps depend on their complexity and can be expensive. The development of Drink Less, which is a complex app, cost approximately £40,000. However, there are no additional costs to deliver the intervention to the target

population as intended; the only additional costs would be associated with further development or changes to the app. The app development process was lengthy due to a number of small iterations and changes made to improve the app. Whilst this was crucial to the development, it meant there was less time for checks and small changes to the design of the app version evaluated in the factorial RCT. On reflection, it would have been preferable to conduct the usability studies with a less than perfect version of the app to allow more time and budget to develop the version that was evaluated in the factorial trial.

Apps, and digital interventions more generally, are particularly suitable for conducting a factorial experiment. They allow a straightforward random allocation of users to a large number of experimental conditions whilst simultaneously testing these conditions. With the Drink Less app, two versions of five intervention modules were developed resulting in 32 experimental conditions and users were allocated to one of these conditions in a block randomisation process. However, this complexity with development incurs additional costs. Factorial trials, in turn, are suited to digital technologies; undertaking independent assessment of each intervention component in simultaneous RCTs would have taken considerably more time. The app and the trial findings would have become obsolete due to the rate of technological development. Therefore, the use of digital technologies can help to accelerate the development and evaluation of behaviour change interventions. Despite the development of these alternative, more suitable evaluation methodologies for digital interventions, the vast majority of existing mHealth evaluations still use the traditional RCT [438]. In a scoping review of optimisation strategies for health interventions, only two studies used factorial or fractional factorial trials for evaluating individual intervention components [145], and these studies were both conducted by the same research group [142,143].

The factorial trial of Drink Less has shown encouraging indications that apps can live up to their promise of interventions with a broad reach that are accessible and available to a large numbers of users, and are great tools for research. The Drink Less trial has high ecological validity as recruitment was conducted "in the wild" and therefore mirrors the real-world situation for most behaviour change apps. Participants were not recruited for a trial and then provided with an app, but instead it was individuals who sought out an app and then were recruited into the trial. The recruitment of almost 700 eligible participants was achieved in two months, which is promising as participant recruitment can often be a lengthy process. This recruitment was achieved by promoting the app through relevant organisations, which resulted in the app becoming self-sustaining as more users downloaded it. Drink Less now consistently appears near the top of alcohol-related searches in the App Store and there are around 50 new downloads a day without any active promotion. This makes Drink Less a very useful tool for further research as there is a large existing user base that have consented to have their anonymous data used in academic research.

This PhD thesis is one of two written following a team science approach to the development and evaluation of Drink Less. Two students, David Crane and myself, both worked on the app and conducted complimentary PhDs separately, but in parallel. We each took a different focus: myself on motivational and cognitive factors, and David on self-regulatory factors. This approach had a great number of benefits, the main one being that we were able to conduct a more thorough and in-depth development of the app within the time-constraints, which resulted in a far better app than either one of us could have achieved alone. Our expertise differed so we were each able to each bring our own strengths to the project and, when necessary, supported the other's weaknesses. The team science approach highlighted the importance of interdependence when conducting research as part of a team, and also meant we each had another researcher to provide advice and comments on drafts of work, and to help with data collection and coding. However, it was important to keep each thesis as an independent piece of work and not to duplicate any effort. This resulted in a slight narrowing

of focus for each thesis as there were studies that were of relevance for both theses but were only included in one. Therefore, there may appear to be obvious studies or steps missing from this thesis; for example, assessing the intervention content of the digital alcohol interventions (in Chapter 4) or conducting a usability study with the developed app. Despite this narrowing of focus, I believe this approach is hugely beneficial in terms of the quality of the intervention that can be developed and for learning about the importance of interdependence when working in a team.

Theory played an important part in the development of Drink Less by providing an overarching framework. The COM-B model and TDF were used to conduct a behavioural analysis, and the COM-B model fits within a larger framework for designing behaviour change interventions, the Behaviour Change Wheel. The guiding principles that the Behaviour Change Wheel provided enabled a thorough and systematic development process to be conducted. However, it was not possible to follow the step-by-step method exactly as pragmatic issues, such as time constraints and existing intervention requirements, also shaped the development process. Therefore, using the findings from additional studies and triangulating the evidence was well suited to intervention development, particularly as there was no conclusive evidence base from which to begin development.

The use of theory in this thesis was limited to the development of the app and did not play a part in the final stage of evaluation. Measures to assess theoretical constructs were not included in the app in an attempt to minimise participant burden and increase engagement with the app. Therefore, there was no way in which to use the data from the Drink Less trial to inform or refine the theories related to each app module. The problem of participant burden highlights the issues of using a digital intervention to test and refine theory. Incorporating measures to assess the proposed theoretical constructs is likely to increase the participant drop-out rate. This is an issue that needs consideration before beginning the development

process. One option would be to conduct separate parallel studies in a laboratory to test whether the relevant app module changes the proposed theoretical mediators of behaviour change. This could then support findings from a "real world" trial without the issue of increased participant burden from assessing theoretical mediators as part of that trial. Using trial data to inform and refine theory is important for improving behaviour change theories and also because the conclusions that can be made are limited without knowing whether theoretical constructs mediate behaviour change.

9.6 Future research

Future research should continue iterative development to optimise and evaluate the Drink
Less app in line with the MOST approach. An additional intervention module worth including
in the next version of the app is behavioural substitution as there is good empirical evidence
for its effectiveness. This intervention component was identified in the expert consensus
study [385] and found to be associated with effectiveness of digital alcohol reduction
interventions [386]. There was also evidence for an association between 'credible source' and
the effectiveness of digital alcohol reduction interventions [386]. The current version of the
Drink Less app makes it clear that the app was developed by a team of researchers indicating
it comes from a credible source: this could be emphasised in the next version of the app.

Further research is required to understand the processes underpinning the effects of the intervention and n-of-1 studies are a suitable methodology for exploring this [439]. Apps are also suited to providing time-varying adaptive interventions and future research should investigate whether varying the content and intensity of support based on user characteristics is feasible. The Sequential Multiple Assignment Randomized Trial (SMART) is a research framework suited to developing time-varying adaptive interventions that could be used to

identify the best tailoring variables and decision rules for an adaptive version of the Drink Less app [141].

The Drink Less app is currently designed as a stand-alone intervention that does not require face-to-face support. There is the potential for the Drink Less app to be used by healthcare practitioners to deliver on-going support alongside usual care. Apps provide a reliable method for screening excessive drinkers that minimises data entry errors and increases the accessibility of the survey [424]. About 80% of people who downloaded the Drink Less app completed the AUDIT, which suggests that Drink Less may be a feasible screening tool for alcohol consumption and alcohol use disorders. Apps could provide an easy and cost-effective way for healthcare practitioners to monitor and evaluate their patients' progress. The effects of brief interventions diminish with time [440] and an app could be used to highlight when support was needed from a healthcare practitioner again, for example, if a patient's drinking reached hazardous levels. This method of monitoring progress is likely to save the healthcare practitioner time and cost less per patient. The implementation of the app from a healthcare practitioner removes the need for an individual to choose from a plethora of apps with little quality assurance, and may give the app greater credibility and feelings of accountability to the patient.

The success of any intervention is dependent on its feasibility and acceptability. The use of digital technology in primary care has demonstrated acceptability and feasibility for obesity [441] and smoking cessation [442] interventions. The role of GPs in actively encouraging their patients to use alcohol-reduction websites is being investigated [443–445]. However, there is no research to date on the feasibility and acceptability amongst HCPs and potential users of delivering app-based alcohol interventions in healthcare settings. The acceptability of apps being delivered in this context would need to be investigated along with what proportion of people would use the app and how frequently. If the delivery of apps in conjunction with face-

to-face support was found to be both feasible and have an additive effect on usual care, then apps, such as an optimised version of Drink Less, may have a role to play in traditional healthcare settings as part of a digital-human hybrid model of support. The delivery of an app in healthcare settings would have the added advantage of reaching non-treatment-seeking excessive drinkers who are identified opportunistically as well as those who are seeking digital support.

Whilst the findings from this thesis show promise for the role of apps in delivering alcohol based interventions, it is important to rely not only on individual-level support to address the problem of excessive alcohol consumption but also to reduce the physical opportunity people have to consume alcohol. Policy-makers have a critical role to play because there is strong evidence that limiting the availability [446,447], affordability [153–156,448] and advertising [158,159] of alcohol are all effective at reducing excessive alcohol consumption. These factors are within the remit of government policy, though the UK government has weak policies, uses evidence inconsistently, and allows the alcohol industry to evaluate the success of their own actions [449–452]. As little is currently being done by policy-makers to reduce excessive alcohol consumption, it is important for academics to continue to do high-quality research that can directly inform government policy, as well as developing and optimising effective public health interventions.

9.7 Final remarks

This thesis reports the development and evaluation of a smartphone app to reduce excessive alcohol consumption. Theory and empirical evidence were used alongside a person-based approach to develop the app. Drink Less appears to be acceptable to and well used by treatment-seeking individuals who were drinking excessively and therefore in need of support. Despite a systematic approach to the development of the app using the MRC

guidance and MOST strategy, there was not conclusive evidence for main effects of intervention modules on the alcohol-related outcomes. This highlights how difficult behaviour change is to achieve [453]. However, the significant interactions between normative feedback and cognitive bias re-training, and between self-monitoring and action planning within the Drink Less app on alcohol-related outcomes illustrate the potential to aid a reduction in excessive alcohol consumption that is worthy of further research.

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Appendices

Appendix 1: Published version of Chapter 5 (Study 3) in Addicitive Behaviours

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Text

Contents lists available at ScienceDirect

Addictive Behaviors



Short Communication

Normative misperceptions about alcohol use in the general population of drinkers: A cross-sectional survey



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ABSTRACT

Introduction: Underestimating one's own alcohol consumption relative to others ('normative misperception') has been documented in some college student and heavy-alcohol using samples, and may contribute to excessive drinking. This study aimed to assess how far this phenomenon extends to alcohol users more generally in four English-speaking countries and if associations with socio-demographic and drinking variables exist.

Methods: A cross-sectional online global survey (Global Drugs Survey-2012) was completed by 9820 people aged 18+ from Australia, Canada, the UK and US who had consumed alcohol in the last year. The survey included the AUDIT questionnaire (which assessed alcohol consumption, harmful drinking and alcohol dependence), socio-demographic assessment and a question assessing beliefs about how one's drinking compares with others. Associations were analysed by linear regression models.

Results: Underestimation of own alcohol use relative to others occurred in 46.9% (95% CI: 45.9%, 47.9%) of respondents. 25.4% of participants at risk of alcohol dependence and 36.6% of harmful alcohol users believed their drinking to be average or less. Underestimation was more likely among those who were: younger (16-24; p < 0.003), male (p < 0.001), from the UK (versus US; p < 0.001), less well educated (p = 0.003), white (p = 0.035), and unemployed (versus employed; p < 0.001)

Conclusions: Underestimating one's own alcohol consumption relative to other drinkers is common in Australia, Canada, the UK and US, with a substantial minority of harmful drinkers believing their consumption to be at or below average. This normative misperception is greater in those who are younger, male, less well educated, unemployed, white, from the UK and high-risk drinkers.

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1. Introduction

'Normative misperception' about alcohol use refers to the underestimation of one's own alcohol consumption relative to others. There is a reason to believe that normative misperception may play a role in excessive alcohol consumption as studies have found that providing normative feedback can reduce subsequent alcohol use (Collins, Carey, & Sliwinski, 2002; Cunningham, Neighbors, Wild, & Humphreys, 2012; Cunningham, Wild, Bondy, & Lin, 2001; Kypri & Langley, 2003; Neighbors, Larimer, & Lewis, 2004; Wild, 2002). It is important to establish how widespread normative misperceptions are and what factors may underlie them. This paper addresses those issues

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Research on normative misperception has been limited to college and university students (Baer, Stacy, & Larimer, 1991; Kypri & Langley, 2003; Neal & Carey, 2004; Neighbors, Dillard, Lewis, Bergstrom, & Neil, 2006; Neighbors et al., 2004) or heavy drinking samples (Cunningham et al., 2001, 2012). It has been found that these groups tend to underestimate their alcohol consumption relative to other people.

There is very little research on correlates of normative misperception. Two studies (Larimer, Irvine, Kilmer, & Marlatt, 1996; Prentice & Miller, 1993) have found that women perceived larger differences between their own and others' drinking behaviour but another study (Read, Wood, Davidoff, McLacken, & Campbell, 2002) found no effect of gender on perceived norms for quantity or frequency of alcohol consumption. To our knowledge, no other correlates of normative misperception have been investigated.

This study aimed to assess the prevalence of this phenomenon in a more diverse sample spanning four English-speaking countries, and to examine associations between the phenomenon and socio-demographic and drinking variables.

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This study addressed the following research questions:

- 1. What is the prevalence of normative misperceptions about alcohol use in the general population of alcohol users from the UK, US, Australia, and Canada?
- 2. To what extent are normative misperceptions about alcohol use associated with a range of socio-demographic and drinking variables?

2. Methods

2.1. Study design

This was an anonymous cross-sectional online survey conducted in 116 countries (Global Drugs Survey (GDS) -2012). Sample sizes for four English-speaking countries were sufficiently large to provide useful data and these formed the basis for the study. The GDS has been developed by an expert advisory group and an academic network, and captures information to monitor the use of drugs and identify emerging trends in drug use (McCambridge, Mitcheson, Winstock, & Hunt, 2005; Winstock & Barratt, 2013a,b; Winstock, Griffiths, & Stewart, 2001; Winstock et al., 2011). Participants were recruited using a purposive sampling strategy (McCambridge et al., 2005)

2.2. Participants

This study draws on GDS data obtained from Australia, Canada, the UK or the US (n=12,309). Participants who were 18 years old or over, had answered "yes" to whether they had used alcohol within the last 12 months and had no missing data for any of the variables were demographic characteristics are shown in Table 1. The majority of participants were aged between 16 and 24, male, white, from the UK, had post-16 qualifications, and were employed.

2.3. Measures

Alcohol use and problems associated with it were assessed using the Alcohol Use Disorders Identification Test (AUDIT) (Babor, Higgins, Saunders, & Monteiro, 2001). The full 10-item AUDIT questionnaire

Table 1
Demographic characteristics.

Variable	n = 9820				
Mean (SD) AUDIT score	10.5 (6.2)				
AUDIT risk zone (%)					
1	36.8				
2	43.4				
3	10.8				
4	9.0				
Age (%)					
16-24	44.9				
25-34	36.8				
35-44	12.2				
45-54	4.4				
55+	1.6				
Gender (% male)	68.7				
Ethnicity (% white)	92.0				
Country of origin (%)					
Australia	3.1				
Canada	6.5				
UK	63.9				
US	26.5				
Qualifications (% post-16)	95.8				
Employment status (%)					
Employed	49.3				
Student	27.7				
Unemployed	23.0				

assesses alcohol consumption, harmful drinking and alcohol dependence. The possible scores range from 0 to 40 and are categorised into four risk zones: Zone 1 (0–7) refers to low-risk drinking or abstinence; Zone 2 (8–15) refers to hazardous drinking; Zone 3 (16–19) refers to harmful drinking; and Zone 4 (20–40) identifies those who are at risk of alcohol dependence and warrant further assessment and investigation (Babor et al., 2001). The AUDIT alcohol consumption (AUDIT–C) questionnaire consists of the first three-items of the full AUDIT questionnaire.

Normative perceptions about alcohol use were assessed by the question: "How do you think your use of alcohol compares to other people who have used that substance recently?" Participants selected one of nine categories and 'Don't know': 1 = Lowest 10%, 2 = Very low, 3 = Low, 4 = Low-average, 5 = Average (middle 20%), 6 = High average, 7 = High, 8 = Very high, and 9 = Top 10%.

Socio-demographic information on age, gender, ethnicity, country of origin, employment status, and highest qualification level attained was collected.

2.4. Procedure

The GDS (https://www.globaldrugsurvey.com) was actively promoted as an anonymous, online survey about drug use through social networking sites (e.g. Twitter, Facebook) for five weeks from November 16th 2011. The promotions invited people to take part in a study investigating drug use and related attitudes and included a link to the study hosted on the GDS website. Those interested in participation after reading the study information were asked for informed consent prior to submission of their completed questionnaire. Respondents were offered no incentive for participation. The average time for completion was approximately 35 min.

Ethical approval was granted by the Joint South London and Maudsley and Institute of Psychiatry NHS Research Ethics Committee (reference number 141/02).

2.5. Analysis

The AUDIT-C was used to calculate the normative misperception score as it focuses on alcohol consumption. The middle two deciles of AUDIT-C scores were combined into one category so that the AUDIT-C score deciles could be directly compared with the nine-item scale of normative misperception which was anchored on the lowest 10%, the middle 20% and the highest 10% (see above). This yielded an AUDIT 'position' from 1 to 9 (1 = 0-10%, 2 = 10-20%, 3 = 20-30%, 4 = 30-40%, 5 = 40-60%, 6 = 60-70%, 7 = 70-80%, 8 = 40-60%80-90%, 9 = 90-100%). The 'normative misperception score' was calculated as the difference between each participant's actual AUDIT-C position and their rating, and could range from -8 to +8. A positive score indicates that an individual underestimated their alcohol use compared with others whilst a negative score corresponds to an overestimation. The magnitude of the normative misperception score corresponds to the extent of discrepancy between the individual's actual and perceived position in the AUDIT-C distribution. This method operationalises normative misperceptions for the purposes of assessing associated factors and the magnitude of the normative misperceptions.

The prevalence of normative misperception for different AUDIT risk zones was assessed through cross tabulation. A series of simple linear regressions were used to investigate the univariate association between the normative misperception score and the socio-demographic and drinking variables. A multiple regression model, including all the socio-demographic and drinking variables, was used to investigate which of the factors had a unique association with the normative misperception score.

3. Results

3.1. Prevalence of normative misperception

The mean normative misperception score was 0.20 (SD = 1.85) which was significantly greater than 0 ($t_{(9819)} = 10.443$, p < 0.001). This means that overall there was a small but significant tendency to underestimate one's alcohol consumption relative to others. Nearly half of the sample (46.9%, 95% CI = 45.9%, 47.9%) underestimated the proportion of other people who consume less alcohol than them whilst 38.6% (95% CI = 37.6%, 39.5%) overestimated it and 14.5% (95% CI = 13.8%, 15.2%) were accurate in their perception.

3.2. Univariate associations with socio-demographic variables

Country of origin, age, gender, ethnicity, employment status and qualification level were all associated with normative misperceptions (see Table 2). Respondents from the UK had significantly greater mean normative misperception scores compared with those from Australia, Canada or the US. Larger normative misperceptions (indicating an underestimation of own alcohol consumption relative to others) were more likely in participants who were younger (16–24), male, categorised themselves as 'white' compared with all other ethnicities, unemployed and whose highest level of qualification attained was pre-16.

3.3. Associations with AUDIT risk zone

AUDIT risk zone was associated with normative misperception with lowest risk drinkers having the lowest mean misperception score (see Table 2). The mean normative misperception scores for those participants who were classified as hazardous alcohol users (AUDIT risk zone 2), harmful alcohol users (risk zone 3) or at risk of alcohol dependence (risk zone 4) were significantly greater than 0 (hazardous: mean = 0.5, SD = 1.73, $t_{(4257)} = 20.17, p < 0.001$; harmful: mean = 1.1, SD = 1.74,

 $t_{(1060)} = 20.64, p\,<\,0.001;$ at risk of dependence: mean =1.4, SD=1.69, $t_{(885)} = 24.18, p\,<\,0.001)$ whereas low-risk drinkers had a normative misperception score of significantly less than 0 (mean =-0.8, SD=1.60, $t_{(3614)} = -28.67,$ $p\,<\,0.001).$ The tendency for higher risks to have higher mean normative misperceptions was also illustrated by an examination of the data categorically: 25.4% of alcohol users at risk of alcohol dependence and 36.6% of harmful alcohol users believed their alcohol use to be average or less than average.

3.4. Fully adjusted model

In a fully adjusted model, normative misperceptions were more likely among participants who were younger, male, from the UK compared with the US, without post-16 qualifications, white, and unemployed compared with employed (see Table 2). Those with lower levels of alcohol use (AUDIT risk zone 1) had significantly lower misperception scores than those who used alcohol more heavily (AUDIT risk zones 2, 3 & 4, ps < 0.001).

4. Discussion

In a large sample of alcohol users from four English-speaking countries, there was evidence of a small but significant tendency to underestimate one's alcohol consumption relative to others. This tendency was greatest amongst those who were: young (16–24), male, from the UK compared with the US, without post-16 qualifications, classifying themselves as white, and unemployed compared with employed. It was greater among those with higher AUDIT scores; 25.4% of the drinkers at risk of alcohol dependence and 36.6% of harmful drinkers considered that their consumption was average or below.

The findings confirm and extend previous research on students and heavy drinkers but show that the phenomenon is broadly restricted to heavier drinkers and light drinkers typically overestimate their drinking relative to others. If one's judgement about how one's drinking compares with others has an influence on how much one drinks, this

Table 2The effect of socio-demographic variables and AUDIT risk zone on normative misperception score.

		N	Mean normative misperception score (SD)	Unadjusted simple linear regression				Adjusted multiple regression (with all variables as covariates)			
				В	95% CI for B		р	В	95% CI for B		p
					Lower bound	Upper bound			Lower bound	Upper bound	
Country of origin	United Kingdoma	6273	0.4 (1.78)								
	Australia	306	0.2 (1.95)	-0.25	-0.46	-0.04	0.021	0.03	-0.16	0.22	0.779
	Canada	641	0.1 (1.92)	-0.36	-0.50	-0.21	< 0.001	-0.02	-0.16	0.11	0.753
	United States	2600	-0.3 (1.90)	-0.70	-0.78	-0.61	< 0.001	-0.29	-0.37	-0.21	< 0.001
AUDIT risk zone (AUDIT score)	1 (0-7) ^a	3615	-0.8 (1.60)								
	2 (8-15)	4258	0.5 (1.73)	1.40	1.33	1.47	< 0.001	1.29	1.21	1.36	< 0.001
	3 (16-19)	1061	1.1 (1.74)	2.04	1.92	2.16	< 0.001	1.90	1.77	2.02	< 0.001
	4 (20-40)	886	1.4 (1.69)	2.19	2.03	2.34	< 0.001	2.00	1.85	2.16	< 0.001
Age/years	16-24 ^a	4407	0.5 (1.88)								
	25-34	3615	0.0 (1.80)	-0.44	-0.52	-0.36	< 0.001	-0.28	-0.36	-0.20	< 0.001
	35-44	1201	0.0 (1.79)	-0.50	-0.62	-0.38	< 0.001	-0.22	-0.34	-0.11	< 0.001
	45-54	436	-0.2 (1.77)	-0.67	-0.86	-0.49	< 0.001	-0.26	-0.43	-0.09	0.003
	55+	161	-0.6 (1.71)	-1.04	-1.33	-0.76	< 0.001	-0.47	-0.73	-0.21	< 0.001
Gender				0.47	0.39	0.55	< 0.001	0.34	0.27	0.41	< 0.001
	Male	6750	0.3 (1.84)								
	Female	3070	-0.1 (1.84)								
Qualification level				-0.44	-0.62	-0.26	< 0.001	-0.25	-0.41	-0.08	0.003
	Pre-16	412	0.6 (1.91)								
	Post-16	9408	0.2 (1.85)								
Employment status	Unemployed ^a	2256	0.4(1.91)								
	Student	2718	0.3 (1.87)	-0.13	-0.23	-0.02	0.018	-0.09	-0.18	0.00	0.056
	Employed	4846	0.1 (1.80)	-0.36	-0.45	-0.26	< 0.001	-0.20	-0.29	-0.11	< 0.001
Ethnicity				-0.27	-0.40	-0.13	< 0.001	-0.13	-0.25	-0.01	0.035
	White	9037	0.2 (1.85)								
	Non-white	783	-0.1 (1.82)								

a Reference group for the categorical variable.

suggests that it would be important, when feeding back information, only to highlight misperceptions when they go in one direction: namely believing one drinks the same as or less than others. A review of interventions correcting normative misperceptions did conclude that it could lead to a reduction in alcohol misuse (Moreira, Smith, & Foxcroft, 2010) but it is not clear whether the interventions worked through the intended mechanism. Future research should examine this moderation and whether there is more impact for interventions when they are targeted by socio-demographic and drinking characteristics associated with nomative misperception.

One study limitation was that the distribution of AUDIT scores were derived from the GDS-2012 sample and is not representative of the general population (Friedman, 2006). Insofar as the GDS-sample was biased towards a heavy drinking sample, the results of this study are likely to be an overestimate of the overall population prevalence because the consumption comparator (from which the misperceptions were calculated) would be higher than from the general population. Secondly, the nine-point scale of AUDIT-C scores was created using all four countries (Australia, Canada, United Kingdom, and United States), though people may have answered the comparison question in relation to people in their own country. However, a sensitivity analysis using only the large UK or US sub-samples showed similar patterns of results compared with the analysis for all four countries. A third limitation relates to the way the misperception score was derived. There are many different ways in which it could have been done. This method was chosen as being the best compromise between precision in terms of intended meaning and using language that respondents could understand. We considered it best to anchor the extremes and the middle with deciles and use linguistic terms for the other response options. It is possible that different choices would result in different estimates. However, we would argue that the key findings would remain.

In conclusion, normative misperceptions about alcohol use are common in the population of alcohol users in four English-speaking countries (UK, US, Australia and Canada). The UK shows this to the greatest extent. It is common for harmful alcohol users and those at risk of dependence to believe that they drink at or less than average, and normative misperceptions tend to be greater in those who are younger, male, less well educated, unemployed and white.

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Contributions

The study was conceived by all authors. The survey was designed by AW. Data was collected by AW. Data were analysed by CG, RW & JB. The manuscript was prepared and amended by CG. All authors contributed to and have approved the final manuscript.

Conflict of interest

AW is founder and director of Global Drugs Survey. JB has received an unrestricted research grant from Pfizer related to the surveillance of smoking cessation trends. RW has received research funding and undertaken consultancy for companies that manufacture smoking cessation medications. CG, DC and SM have no competing interests.

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Appendix 2: Published version of Chapter 6 (Study 4) in JMIR mHealth and uHealth

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Original Paper

Identification of Behavior Change Techniques and Engagement Strategies to Design a Smartphone App to Reduce Alcohol Consumption Using a Formal Consensus Method

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Abstract

Background: Digital interventions to reduce excessive alcohol consumption have the potential to have a broader reach and be more cost-effective than traditional brief interventions. However, there is not yet strong evidence for their ability to engage users or their effectiveness.

Objective: This study aimed to identify the behavior change techniques (BCTs) and engagement strategies most worthy of further study by inclusion in a smartphone app to reduce alcohol consumption, using formal expert consensus methods.

Methods: The first phase of the study consisted of a Delphi exercise with three rounds. It was conducted with 7 international experts in the field of alcohol and/or behavior change. In the first round, experts identified BCTs most likely to be effective at reducing alcohol consumption and strategies most likely to engage users with an app; these were rated in the second round; and those rated as effective by at least four out of seven participants were ranked in the third round. The rankings were analyzed using Kendall's W coefficient of concordance, which indicates consensus between participants. The second phase consisted of a new, independent group of experts (n=43) ranking the BCTs that were identified in the first phase. The correlation between the rankings of the two groups was assessed using Spearman's rank correlation coefficient.

Results: Twelve BCTs were identified as likely to be effective. There was moderate agreement among the experts over their ranking (W=.465, χ^2_{11} =35.8, P<.001) and the BCTs receiving the highest mean rankings were self-monitoring, goal-setting, action planning, and feedback in relation to goals. There was a significant correlation between the ranking of the BCTs by the group of experts who identified them and a second independent group of experts (Spearman's rho=.690, P=.01). Seventeen responses were generated for strategies likely to engage users. There was moderate agreement among experts on the ranking of these engagement strategies (W=.563, χ^2_{15} =59.2, P<.001) and those with the highest mean rankings were ease of use, design – aesthetic, feedback, function, design – ability to change design to suit own preferences, tailored information, and unique smartphone features

Conclusions: The BCTs with greatest potential to include in a smartphone app to reduce alcohol consumption were judged by experts to be self-monitoring, goal-setting, action planning, and feedback in relation to goals. The strategies most likely to engage users were ease of use, design, tailoring of design and information, and unique smartphone features.

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KEYWORDS

smartphone apps; alcohol consumption; consensus; Delphi technique; behavior change techniques



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Introduction

Excessive alcohol consumption is a serious problem for population health [1,2]. Brief interventions to address this are time limited interventions delivered by health care workers targeting heavier drinkers and can be effective at reducing alcohol consumption [3]. There are substantial barriers to their delivery such as lack of time, training, and financial resources. These barriers can perhaps be avoided by delivering an intervention via a digital platform. While digital interventions have not been found to be as effective as face-to-face brief interventions [4], they may be more effective than no intervention [413], and have the advantage of being cost effective, avoid the stigma associated with help-seeking in person [10], and have greater reach than traditional health services. Smartphone applications or 'apps' have the additional advantage of being with the individual almost all of the time, which offers the potential to engage users in real time and in their everyday situations. Apps also have the ability to sense and report locations and events (in conjunction with calendar function) to provide moment-to-moment support when it is needed unlike traditional interventions. Despite a large number of apps to reduce excessive alcohol consumption in the general population, none, to our knowledge, have been rigorously evaluated. There has been a recent trial of an app on the related issue of recovery from alcoholism [14] that showed a reduction in the number of risky drinking days and therefore of probable benefit to patients in continuing care for alcohol dependence.

Reviews of digital interventions (not apps) suggest they can be effective, but there is substantial heterogeneity between different interventions [4,7,8,11,12]. Moreover, interventions have many components and their evaluations have rarely specified content in a way that would allow identification of the components responsible for the variation (e.g. [4,8,11,12]). A reliable method for specifying content and evaluating the effectiveness of complex behavior change interventions is to identify behavior change techniques (BCTs) [15]. BCTs are defined as the smallest, observable, replicable components with the potential to bring about change in behavior [16].

In order for an alcohol reduction app to be effective, it must be engaging for users, thus allowing them to be exposed to its active components. It is well established that a large proportion of users of digital interventions in health trials do not maintain engagement [17]. This degree of attrition undermines the potential of apps to be effective, and generalizable evaluation is made difficult when a large proportion of users cannot be recontacted due to disengagement with the intervention [18]. Engagement in Web-based interventions is increased by use of prompts [19-21], peer support [19], counselor support [19], and the combination of tailored communication with the use of reminders and incentives [22]. However, these have only been examined in the context of websites and there is a need to identify the most effective strategies for engagement with apps.

In sum, there is not yet an established evidence base to draw on to inform the selection of BCTs or engagement strategies in developing apps aimed at reducing alcohol consumption amongst the general population. In areas of research where there is a lack of, inconsistent, or contradictory scientific evidence, formal consensus methods have been used to guide action [23,24]. This study used a formal consensus building methodology with a small group of world-class experts in the field of alcohol and/or behavior change to identify intervention components judged to be the 'best bets' to reduce alcohol consumption (in general and in the context of an app) and to maintain engagement with an app, and then compared the original expert group's ranking of intervention components with a new, broader expert review.

This study addressed the following research questions:

- 1. What BCTs do experts in the field of alcohol research agree are most likely to be effective in general and when delivered by an app?
- What engagement strategies do experts believe are most likely to be effective initially and over time?

Methods

First Phase: 3-Round Consensus Exercise

Study Design

A Delphi-style methodology was used to generate consensus among experts about what intervention components are likely to be the most effective at reducing alcohol consumption, and what strategies are most likely to improve engagement with an app. Experts were asked to generate a list of 'best bet' intervention components and engagement strategies which were subsequently rated and ranked.

The Delphi method of generating consensus was selected as a formal, systematic and reproducible method of arriving at a consensus. It was conducted anonymously to avoid biases produced by perceived authority, persuasion or bandwagon effects [23,25].

Participants

Seven international academic experts (six male) were purposively identified from a range of scientific networks and backgrounds (health psychology, biological psychology, developmental psychopathology and addiction research) on the basis of their knowledge of the alcohol literature, and/or experience of designing or delivering behavior change interventions. Seven participants are considered sufficient for reliable group judgment [24,25]. None of the experts were identified based on any user experience expertise. The authorship team used their experience to judge the suitability of invited experts. Once the experts were identified, each was formally approached by an email invitation. All the experts who were approached agreed to take part. Experts were from the UK (n=6) and the Netherlands (n=1). Six were professors and one was a senior research fellow.

Measures

Round 1:

Participants were asked to provide between three and five responses to each of three questions:

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- 1. What intervention components do you believe would be the best bets for helping people reduce their alcohol consumption?
- What intervention components do you believe would be the best bets for helping people to reduce their alcohol consumption when delivered by a smartphone app?
- 3. What do you think are the best strategies or techniques for maintaining engagement with an app aiming to help people reduce their alcohol consumption?

Each question was preceded by the statement: "Please answer the following questions based on your knowledge of the research literature, relevant theory and your clinical experience. Please also provide the reason behind your choice." For question 2, participants were given the option to indicate that their answers were the same as for question 1.

Round 2:

Participants were provided with an alphabetical list of the responses generated in the first round for each of the questions. They were instructed "Please rate your agreement with each of these techniques for the three different questions on the five-point Likert scales provided". The scale ranged from 1 (strongly disagree), 2 (disagree), 3 (neither agree nor disagree), 4 (agree) to 5 (strongly agree). Participants were given the option to make comments on their rating.

Round 3:

The *n* responses were listed alphabetically with the mean agreement rating and rationale provided for each response. Participants were asked to rank the *n* responses from 1 (most likely to be a best bet) to n (least likely to be a best bet) for each of the questions. At this stage, participants were only asked to rank responses about which there had been broad agreement in the previous round, defined as a minimum of four out of seven of the participants agreeing (i.e., rating of 4 or above) that the technique was likely to be either effective or engaging (depending upon the question) [23]. The reason for removing responses about which there was little agreement was to improve responding by minimizing the time required to complete the survey [23]. There was the option to make any final comments at this point.

Procedure

This study was conducted using the online survey tool Qualtrics. A link to the survey for each of the three rounds was emailed to the participants and they were given between one and two weeks to complete it. Non-responders were sent reminders until all participants had completed each round. Participants provided informed consent.

Analysis

Round 1:

For each question, similar responses were summarized and combined. For question 1, a BCT was selected from one of two taxonomies [15,26] to describe each response for the intervention components, where appropriate. The summarizing, combining and coding of responses was conducted by CG & SM.

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Round 2:

The mean, standard deviation (SD), and mode of the agreement ratings for each response to each of the three questions were calculated.

Round 3:

The final rankings were analyzed by calculating Kendall's W coefficient of concordance [27], which measures the extent to which judges agree on their rankings of items. The value of W ranges from 0 (indicating no consensus) to 1 (indicating perfect consensus) between participants. A value of .1 corresponds to very weak agreement, .3 to weak agreement, .5 to moderate agreement, .7 to strong agreement and .9 to unusually strong agreement [28]. The Kendall's W statistic uses the χ^2 test to test the independence of the ranking of the components.

Second Phase: External Validation

Study design

The intervention components generated and ranked in the first phase of the study were also ranked by a second group of experts in the field of alcohol.

Participants

Assistant and Senior Editors (n=179) from the journal Addiction were invited to take part in the study if they believed they had a sufficiently informed 'opinion on interventions that might help people who drink more alcohol than is good for them to reduce or quit'. This invitation yielded 43 participants.

Measures

Participants were asked to rank from 1 (highest) to 12 (lowest), the value of 12 responses generated in the first phase of the study by the original group of experts, in response to the question "What intervention components do you believe would be the best bets for helping people reduce their alcohol consumption?"

Procedure

An email was circulated to all the assistant and senior editors at the journal of Addiction with an alphabetical list of the "best bet" intervention component responses. If they wished to take part in the study, they were asked to reply (via email) with a ranking for each of the intervention components. Participants were given one week to reply before the study closed.

A nalvsis

The correlation between the rankings of the original and the new independent group of experts was assessed using Spearman's rank correlation coefficient. The new rankings were also analyzed using Kendall's W coefficient of concordance [27] to assess the extent to which this second group agreed with each other.

Results

First Phase: 3-Round Consensus Exercise

In response to the question of what intervention components are likely to be the most effective at reducing alcohol consumption, 24 responses were recorded in round 1. Eighteen

JMIR mHealth uHealth 2015 | vol. 3 | iss. 2 | e73 | p.3 (page number not for citation purposes) of these responses were similar to at least one other, resulting in 12 components (see Multimedia Appendix 1), of which 11 corresponded directly with a BCT (see Table 1). Six of the 7 participants thought that intervention components likely to be effective in general would be the same as in an app. The other participant generated one suggestion to do with the intervention modality itself and how to present the intervention in a unique way. The response was therefore included with the responses to the question regarding engagement strategies.

Four of the 12 components (self monitoring, goal setting, action planning, and feedback in relation to goals) had a mean ranking score greater than the average rank (6 out of 12) and the lowest mean agreement rating for these four BCTs was 4.3 (see Table 1). Overall the original group of experts displayed moderate agreement (Kendall's W=.465) in their ranking of intervention components ($\chi^2_{(1)}=35.77$, P<.001).

Table 1. Responses generated by the expert group on effective behaviour change techniques to reduce alcohol consumption.^a

		Agreement rating ^b		Ranking score ^c		
				Agree:		
Responses generated	Equivalent BCTs	Mean (SD)	Mode	Disagree ^d	Mean (SD)	Mode
Self monitoring	Self monitoring of behavior ^e	4.6 (.54)	5	7:0	2.4(1.81)	1
Goal setting	Goal setting (behavior) ^e	4.7 (.049)	5	7:0	2.6 (1.51)	1,2
Action planning	Action planning ^e	4.3 (49)	4	7:0	4.3 (.95)	4
Feedback in relation to goals	Provide feedback on performance ^f	4.6 (.54)	5	7:0	4.43 (2.70)	3
Behavior substitution	Behavior substitution ^f	4.1 (.38)	4	7:0	6.3 (2.06)	5,7
Environmental triggers and drivers	Advise on environmental restructuring ^f	3.9 (.69)	4	5:2	7.3 (4.07)	2,9
Provide information	Provide information on consequences of excessive alcohol consumption & reducing excessive alcohol consumption ^f	4.0 (.58)	4	6:1	7.4 (4.47)	12
Feedback in relation to people	Provide normative information about others' behavior and experiences ^f	4.0 (.58)	4	6:1	8.4 (1.90)	7
Motivational interview- ing	Conduct motivational interviewing ^f	3.9 (1.07)	4	5:2	8.4 (3.41)	12
Inhibition training		3.6 (54)	4	4:3	8.4 (3.51)	10
	Provide rewards contingent on successful- ly reducing excessive alcohol consump-					
Reward	tion ^f	3.9 (.69)	4	5:2	8.9 (2.12)	11
Habit reversal	Habit reversal ^f	3.4 (.79)	4	4:3	9.1 (1.68)	10

^aResponses ordered in terms of mean ranking score (from round 3).

Of the 20 engagement strategies generated, six were similar to at least one other and thus were combined, which resulted in 17 unique strategies (see Multimedia Appendix 2 for the rationale for each of the 17 responses). Seven strategies (ease of use, design aesthetic, feedback, function, ability to change design to suit own preferences, tailored information and unique

smartphone features) had a mean ranking score greater than average rank (8 out of 16) and the lowest mean agreement rating for these strategies was 3.6 (see Table 2). Overall the experts showed a moderate degree of consensus in their ranking of the strategies (Kendall's W=.563, χ^2_{15} =59.2, P<.001).



^bAgreement rating (1: strongly disagree, 5: strongly agree).

^cRanking score (1: highest, 12: lowest).

^dAgree: Disagree (ratio of (agree/strongly agree): (neither/disagree/strongly disagree) used as inclusion criteria for round 3.

eBCTs as referred to in the 93-item BCT Taxonomy v1 [15]

^fBCTs as referred to in the 42-item excessive alcohol reduction specific taxonomy [26]

Table 2. Responses generated by the expert group on engagement strategies.^a

	Agreement ratingb			Ranking score	1
Responses	Mean (SD)	Mode	Agree:Disagree ^d	Mean (SD)	Mode
Ease of use	4.9 (.38)	5	7:0	1.4 (.79)	1
Design – aesthetic	4.6 (.54)	5	7:0	3.1 (1.57)	2, 5
Feedback	4.6 (.54)	5	7:0	3.9 (1.68)	4
Function	4.0 (.82)	4	5:2	6.6 (3.60)	11
Design – ability to change de- sign to suit own preferences	3.6 (.79)	4	5:2	6.9 (4.74)	3
Tailored information	4.3 (.76)	4,5	6:1	7.9 (3.39)	6, 7
Unique smartphone features	4.4 (.54)	4	7:0	7.9 (5.79)	6
Prompts	4.1 (.38)	4	7:0	8.4 (2.44)	8
Graded tasks	4.0 (.82)	4	5:2	8.7 (3.50)	12
Gamification	4.1 (.69)	4	6:1	8.9 (5.30)	10
Social comparison	3.9 (.69)	4	5:2	10.4 (3.36)	9
Reward type Novelty	4.0 (.82)	4	5:2	11.6 (2.23)	12
Reward type Games	3.7 (49)	4	5:2	11.9 (2.97)	11,15
Reward type Positive messages	4.0 (58)	4	6:1	12.1 (2.79)	8, 10, 11, 12, 13, 15, 16
Reward type Financial	3.6 (.98)	4	4:3	12.3 (1.98)	13
Social connectivity	4.0 (.58)	4	6:1	14.1 (1.95)	15,16
Reward type- cue signaling re- ward ^e	3.4 (.98)	3	3:4		

^aResponses ordered in terms of mean ranking score (from round 3).

Second Phase: External Validation

The ranking of the BCTs by the original group was validated by an independent group of experts: there was a significant correlation between their two rankings (see Table 3; p=.69,

P=.01). Table 3 shows the ranking by the independent group of experts of the intervention components generated and agreed by the original group. There was modest but significant agreement amongst the broader group of experts (Kendall's W=.320, χ^2_{11} =151.52, P<.001).



^bAgreement rating (1: strongly disagree, 5: strongly agree).

^cRanking score (1: highest, 16: lowest).

 $^{{}^{}d}Agree: Disagree \ (ratio \ of \ (agree/strongly \ agree): \ (neither/disagree/strongly \ disagree) \ used \ as \ inclusion \ criteria \ for \ round \ 3.$

^eThis response was not included in round 3 because there was not substantive agreement that it would be an effective engagement strategy in round 2 (defined as a minimum of 4 out of 7 of the participants agreeing (i.e., rating of 4 or above) that the technique was likely to be engaging).

Table 3. Comparison between rankings of phase 1 expert group and larger expert group of effective behavior change techniques for alcohol use reduction.^a

Responses	Phase 1 experts	Phase 2 experts		
	N=7	N=43		
	Mean Rank (SD)	Mean Rank (SD)		
Self monitoring	2.4(1.81)	3.4 (2.88)		
Goal setting	2.6 (1.51)	3.8 (3.00)		
Action planning	4.3 (.95)	6.4 (2.72)		
Feedback in relation to goals	4.4 (2.70)	4.1 (2.28)		
Behavior substitution	6.3 (2.06)	7.6 (2.51)		
Environmental triggers and drivers	7.3 (4.07)	5.1 (2.72)		
Provide information	7.4 (4.47)	9.5 (2.87)		
Feedback in relation to people	8.4 (1.90)	7.4 (3.27)		
Motivational interviewing	8.4 (3.41)	7.2 (2.82)		
Inhibition training	8.4 (3.51)	8.8 (2.15)		
Reward	8.9 (2.12)	6.8 (3.44)		
Habit reversal	9.1 (1.68)	7.9 (2.69)		

^aResponses ordered in terms of mean ranking score for the original experts (from round 3)

Discussion

BCTs of self monitoring, goal setting, action planning, and feedback in relation to goals were ranked most likely to be effective for reducing alcohol use by a group of international experts in the field of alcohol or behavior change or both. This finding was validated by a larger independent group of alcohol experts. None of the experts thought that the BCTs likely to be effective in general would differ from those in an app, though one participant suggested presenting information in a way that was unique to an app. The most highly ranked engagement strategies were ease of use, design-aesthetic, feedback, function, design-ability to change design to suit own preferences, tailored information and unique smartphone features.

There is empirical evidence for the effectiveness of some of the BCTs identified in this study for reducing excessive alcohol consumption. Self monitoring has been found to be effective in brief interventions [26], and is also used in a number of apps to reduce alcohol consumption [29] though none of these have been evaluated. The BCT 'feedback in relation to people' is often referred to as normative feedback in the alcohol behavior change literature. There is evidence to suggest that this BCT may have a small effect by several different modes of delivery: face-to-face [30], via phone [31], mailed [32,33] and via digital platforms [30,34,35]. However, this research is often limited to college and university students [30,32,34,35]. The highest priority engagement strategies of prompts, social connectivity and tailored information have all been shown to result in increased use of Web-based interventions [19-22].

The use of a Delphi approach to selecting intervention components is clearly not guaranteed to result in the best choices, but on a priori grounds it seems preferable to the more usual practice of drawing on expertise and interest within a single research team. It may have been that no consensus would be achieved so, while the level of agreement within each group of experts was modest, the fact that the aggregate rankings of the two expert groups showed a high level of concordance was reassuring that the study tapped into a shared perspective on the existing evidence.

It is possible that the results of the Delphi exercise could have been biased by choosing an expert group with similar backgrounds to those of the research team. Therefore, the use of a second group of experts to validate the rankings provided important support for this not being the case. The journal Addiction has a very large pool of international experts on its editorial team and arguably includes most of the leading researchers in the field covering a wide range of expertise. The question regarding user engagement was included for exploratory purposes. As shown in this study, experts in the academic field of research did not identify any BCTs as being effective for an app compared with a traditional intervention. This may be because they are not aware of the additional functions an app can provide in terms of a behavior change intervention. Future research is planned to compare the views of experts in the relevant academic field with that of user experience experts to see if there are any discrepancies between these groups and if so, how their opinions differ.

The results of this study will be used to inform the building of a prototype app that will be evaluated in a field experiment. Following the principle of optimization [36] each component will be included in a full form or minimal form using a factorial design so that its effect can be assessed. The findings should also be useful to other research teams considering developing and evaluating apps in this area.



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Conflicts of Interest

JB has received an unrestricted research grant from Pfizer related to the surveillance of smoking cessation trends. RW has received research funding and undertaken consultancy for companies that manufacture smoking cessation medications. CG, DC and SM have no declared conflicts of interest.

Multimedia Appendix 1

Intervention components generated by the experts in the first round.

[PDF File (Adobe PDF File), 37KB - mhealth_v3i2e73_appl.pdf]

Multimedia Appendix 2

Engagement strategies generated by the experts in the first round.

[PDF File (Adobe PDF File), 34KB - mhealth_v3i2e73_app2.pdf]

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Abbreviations

BCTs: behavior change techniques

NIHR SPHR: National Institute of Health Research, School for Public Health Research

SSA: UK Society for the Study of Addiction

UKCTAS: UK Centre for Tobacco and Alcohol Studies

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Appendix 3: Published version of protocol for Study 5 (reported in Chapter 8) in BMC Public Health

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BMC Public Health

STUDY PROTOCOL

Open Access



Evaluating the effectiveness of a smartphone app to reduce excessive alcohol consumption: protocol for a factorial randomised control trial

Claire Garnett1*, David Crane1, Susan Michie1,2, Robert West3 and Jamie Brown1,3

Abstract

Background: Excessive alcohol consumption is a leading cause of death and morbidity worldwide and interventions to help people reduce their consumption are needed. Interventions delivered by smartphone apps have the potential to help harmful and hazardous drinkers reduce their consumption of alcohol. However, there has been little evaluation of the effectiveness of existing smartphone interventions.

A systematic review, amongst other methodologies, identified promising modular content that could be delivered by an app: self-monitoring and feedback; action planning; normative feedback; cognitive bias re-training; and identity change. This protocol reports a factorial randomised controlled trial to assess the comparative potential of these five intervention modules to reduce excessive alcohol consumption.

Methods: A between-subject factorial randomised controlled trial. Hazardous and harmful drinkers aged 18 or over who are making a serious attempt to reduce their drinking will be randomised to one of 32 (2⁵) experimental conditions after downloading the 'Drink Less' app. Participants complete baseline measures on downloading the app and are contacted after 1-month with a follow-up questionnaire. The primary outcome measure is change in past week consumption of alcohol. Secondary outcome measures are change in AUDIT score, app usage data and usability ratings for the app. A factorial between-subjects ANOVA will be conducted to assess main and interactive effects of the five intervention modules for the primary and secondary outcome measures.

Discussion: This study will establish the extent to which the five intervention modules offered in this app can help reduce hazardous and harmful drinking. This is the first step in optimising and understanding what component parts of an app could help to reduce excessive alcohol consumption. The findings from this study will be used to inform the content of a future integrated treatment app and evaluated against a minimal control in a definitive randomised control trial with long-term outcomes.

Trial registration: ISRCTN40104069 Date of registration: 10/2/2016

Keywords: Alcohol, Excessive, RCT, App, Smartphone, BCT, Digital, Drink, Digital, Intervention

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Background

Excessive alcohol consumption is responsible for approximately 3.3 million deaths each year worldwide [1]; only high blood pressure and smoking contribute more to the global burden of disease [2]. When the impact of alcohol-related crime and lost productivity is added to healthcare, alcohol consumption costs the UK economy an estimated £21bn per year [3]. Tackling excessive alcohol consumption is a public health priority [4] and there is a need for interventions to help people reduce their consumption.

In the UK, although brief interventions for excessive alcohol use are available and appear to be both effective [5] and cost-effective [6, 7], they are not widely offered; less than 10 % of those drinking excessively receive a brief intervention on alcohol from their general practitioner (GP) [8]. Digital behaviour change interventions (DBCIs) delivered on websites, by email or through mobile phones offer the potential to increase the proportion of excessive drinkers receiving an alcohol brief intervention [9]. The convenience and anonymity of DBCIs may increase uptake amongst those reluctant to receive help from health professionals [10, 11]. DBCIs have been found in meta-analyses and systematic reviews to result in small reductions in alcohol consumption across a range of populations [12-20]. A 2016 Cochrane review of 40 RCTs found that DBCIs reduced alcohol consumption by 23.6 g of alcohol per week (equivalent of 2.95 UK units) more than controls [21, 22].

The rapid development and use of health-related smartphone apps provides a new method for supporting people in their attempts to reduce their alcohol consumption. It is estimated that the 165,000 currently available smartphone apps for the practice of medicine and public health [23] will be downloaded a total of three billion times in 2015, almost double the number from 2013 [24]. Despite their proliferation, evaluation of app content has revealed they are often developed without reference to scientific evidence or theory, fail to conform to guidelines, lack evidence based-content and/or provide inaccurate information [25-31]. There has been little evaluation of app effectiveness. Reviews of mobile phone interventions to promote weight loss [32, 33], improve women's health [34], increase physical activity [35] and improve treatment adherence for chronic disease management [36], as well as a review of digital resources for mental health self-management [37], found numerous trials of text messaging but few RCTs of apps. When they have been evaluated, apps have generally been found effective. Apps have increased physical activity [38], improved muscular fitness, movement skills, and weight-related behaviours [39], reduced symptoms of depression [40, 41] and improved diabetes management [42]. Only one trial of alcohol reduction apps appears to

have been published; this evaluated two different apps aimed at Swedish university students, both allowed users to calculate their levels of blood alcohol concentration, though neither was effective at reducing consumption relative to controls [43].

The problem of excessive alcohol consumption and the potential of smartphone apps to help people manage their behaviour, as well as the limited evidence for the effectiveness of such apps and their tendency to be developed without reference to scientific evidence or theory, highlight the need for the rigorous development and evaluation of new smartphone app alcohol interventions.

Selecting modules for evaluation

The initial selection of modules for evaluation was based on four main sources of evidence: i) examination of the behaviour change techniques (BCTs) used in alcohol interventions [44]; ii) a systematic review of the evidence of the effectiveness of digital technologies for reducing excessive alcohol consumption [21, 22]; iii), a formal consensus-building study with experts in the fields of alcohol or behaviour change to identify the behaviour change techniques thought most likely to be effective at reducing alcohol consumption in a smartphone app [45]; iv), a content analysis of the behaviour change techniques within existing popular alcohol reduction apps [46]. On the basis of this systematic development work, the following five modules were selected as high priority for experimental manipulation evaluation in a factorial design: self-monitoring and feedback; action planning; normative feedback; cognitive bias re-training; and identity change. We elaborate the reasons for each selection

Self-monitoring and feedback

Self-monitoring and feedback are both recommended as effective techniques for alcohol reduction by the National Institute for Health and Care Excellence (NICE) clinical guidance [47]. They are also related to core elements of Control Theory [48], which posits that behaviour is goal-driven and that feedback enables people to assess their performance in relation to their goals and make adjustments toward it accordingly. Selfmonitoring has been found to be effective for controlling weight and blood-glucose levels [49-52]; increasing academic performance [53, 54] and improving healthy eating and physical activity [55]. In the formal consensus-building study with behaviour change or alcohol experts, self-monitoring was ranked the most likely intervention component to be effective in a smartphone app to reduce excessive alcohol consumption [45]. Behaviour change interventions which include selfmonitoring in combination with at least one of the other behaviour change techniques (BCTs) relevant to Control

Theory have been found to be significantly more effective than interventions not including those techniques [55–57]. Feedback is a key component of brief alcohol interventions [58] and is commonly included in DBCIs: 95 % of the DBCIs in the 2016 Cochrane review gave participants feedback about their drinking [59]. Feedback was also ranked highly as an intervention component likely to be effective in an app to reduce excessive alcohol consumption by alcohol or behaviour change experts in a formal consensus-building study [45].

Action planning

NICE clinical guidance recommends that providers of behaviour change interventions for alcohol reduction should facilitate action planning [47]. Action planning is also a technique related to a core element of Control Theory, reducing discrepancies between goals and observed behaviour [48]. Action plans detailing the steps necessary to achieve a specific goal have been found to increase physical activity [60], enhance behaviour change in patients [61] and reduce alcohol consumption [62–64]. Implementation intentions, a form of action plan that enable the setting of if/then conditions for future events [65], increased goal-attainment rates for health behaviours such as regular breast examinations [66], engaging in exercise [67] and alcohol reduction [62–64].

Normative feedback

Normative feedback is personalised feedback on how an individual's behaviour compares with the behaviour of other people. Providing normative feedback can reduce subsequent alcohol use [68-73] indicating that normative misperceptions (underestimating own alcohol use compared with others) play a role in excessive alcohol consumption. Research has shown that normative misperceptions exist in the general population [74] as well as in heavy drinkers [69, 70] and college/university students [71, 72, 75-77]. Theoretical evidence for the role of normative misperceptions in excessive alcohol consumption come from Social Norms theory [78]. This theory predicts that people behave in a way that attempts to conform to the perceived norm. This can result in people behaving in ways that are not consistent with their own beliefs and values in their attempt to reach the perceived norm [79]. Providing feedback in relation to people was also identified by alcohol or behaviour change experts as an intervention component likely to be effective at reducing excessive alcohol consumption in a smartphone app [45].

Cognitive bias re-training

Dual process theories of addiction [80-82] suggest that excessive alcohol consumption occurs, in part, due to automatic processes when the impulses to drink overcome the inhibitory response not to [83]. These automatic biases in information processing of alcohol-related cues or stimuli have been found to predict alcohol use [84, 85] though are largely unaffected by interventions targeting changing conscious information or processes [86, 87]. Cognitive bias re-training has been found to be effective at altering these automatic cognitive biases [88-92] and some studies have also found there are associated impacts on subsequent alcohol use [90, 91, 93, 94]. The intervention strategy chosen for this module is to re-train approach biases, with the aim of changing the tendency to approach alcohol and alcohol-related stimuli to an 'avoid' bias. Retraining these approach biases has been shown to have a greater efficacy in reducing alcohol consumption [90-92] than retraining other cognitive biases such as attentional biases [95].

Identity change

Excessive drinking is central to many peoples' sense of self, particularly students [96], and identity has been proposed as a motivational factor for behaviours by a number of theories [97-99], including the PRIME theory of motivation which proposes that identity is a source of motives, self-regulation and stability of behaviour [100]. Identity (group, social and/or individual) was also identified in a consensus approach as a theoretical domain to explain behaviour change [101]. The relationship between identity and behaviour change has not been investigated in the field of alcohol research though there is evidence from the smoking cessation literature that identity change (adopting an identity that is incongruent with the undesired behaviour) may be an effective intervention technique. A systematic analysis of English Stop Smoking Services treatment manuals found that 'strengthening an ex-smoker identity' was associated with 4-week abstinence rates (both carbon-monoxide verified and self-reported) [102]. A positive smoker identity was present in a minority of smokers in England and predicted failure to make a smoking quit attempt at 6 months and so may be an important barrier to behaviour change [103]. A meta-ethnography also found that the nature of a smoker's identity can play an important role in smoking cessation [104].

Each of the intervention modules detailed above contain a number of relevant behaviour change techniques, details of the full content of each module are summarised in Additional file 1: Table S1. To evaluate both the overall effectiveness of the app and its component modules, we will use a full factorial study design, guided by the Multiphase Optimization Strategy [105]. This uses factorial experiments to screen possible intervention components selected on the basis of theory and evidence to identify those warranting further investigation

[106], with users randomly allocated to receive either an enhanced ('high') or minimal ('low') version of each intervention module.

Methods

Aim

The aim of the study is to evaluate the effectiveness of five intervention modules at reducing excessive alcohol consumption.

Design

A between-subject factorial randomised controlled trial evaluating the effectiveness of five intervention modules (i) self-monitoring and feedback, ii) action planning, iii) normative feedback, iv) cognitive bias re-training, and v) identity change), all with a 'high' and 'low' version (see Additional file 1: Table S1) yielding 32 experimental conditions (see Additional file 2: Table S2). This factorial design was chosen over a treatment package approach with usual care or nothing as a control group so that the individual effect of each intervention module on excessive alcohol consumption can be assessed. A factorial design also requires smaller sample sizes than individual experimental designs whilst still maintaining the same power.

Intervention

Drink Less is an app available for iOS devices that is designed to support a user who is interested in cutting down their alcohol consumption. The iOS (Apple's operating system) was chosen to avoid issues of fragmentation associated with Android [107] and because there tends to be a greater retention rate for apps amongst iPhone users compared with Android [108]. There was a pragmatic, methodological need to structure the app around an activity that would engage all users and allow experimental manipulation of other supporting modules. Thus, the app asks all users to set a goal to which they would like to reduce their alcohol consumption. The app then offers them access to a variety of modules and tools to help them achieve their goal. The app was interactive though there was no human component to its functionality. The content of these five intervention modules is described in detail in Additional file 1: Table S1. The 'high' version of each intervention module contained the BCTs or intervention component hypothesised to be effective. The 'low' version of each intervention module lacked the BCTs or intervention component being assessed and, where possible, were based on controls in equivalent studies.

Study sample

Participants will be included in the analysis if they have downloaded the app onto an iOS smartphone or tablet, are 18 years of age or over, live in the United Kingdom and have an AUDIT score of 8 or above (indicative of excessive alcohol consumption), have confirmed that they are making an attempt to reduce their drinking (responded "Interested in drinking less alcohol", not "Just browsing" to "Why are you using this app?"), and provided an email address.

This study will recruit 672 participants and have more than 80 % power (with alpha at 5 %, 1:1 allocation and a two-tailed test) to detect a mean change in alcohol consumption of 5 units between the high and low condition for each intervention module [109]. This assumes a mean of 27 weekly units at follow-up in the control group, a mean of 22 units in the intervention group and a SD of 23 units for both (d = 0.22), and rounds up the sample size to the nearest multiple of 32 to ensure all cells are balanced. The estimated effect size is large (comparable with that of a face-to-face brief intervention [5]) and may be considered somewhat unrealistic for a module within a digital intervention. However, in the event of a 'non-significant' result, we plan to calculate a Bayes factor to establish the relative likelihood of the null versus the experimental hypothesis given the data obtained [110]. This will permit a relative judgment for the purposes of screening about whether the inclusion of the module in a future app would be more likely than not to have an effect on alcohol consumption.

Recruitment

Participants will be recruited through a number of methods. The app will be listed in the iTunes Store and the listing will be optimised according to best practices for app store optimisation (e.g. ensuring the keywords are carefully selected, that the description is well written and that screenshots display the aspects of the app that users are most interested in [111-114]). Users will be encouraged to leave reviews, which may persuade others to download it [114, 115]. We intend to promote the app through organisations such as the Department of Health and Public Health England, and mHealth (mobile health) directory web sites (e.g. ourmobilehealth.co.uk, myhealthapps.net), alcohol-reduction online forums (e.g. Club Soda) and the UCL App Lab service that promotes apps to all of the staff and students at UCL.

Procedure

Each participant, on downloading the app, will be asked to read the participant information sheet and provide informed consent. Before being able to access the content of the app participants are asked to provide sociodemographic data, indicate their reason for using the app (interested in drinking less alcohol or just browsing), provide their e-mail address for the 1-month follow-up questionnaire and complete the full AUDIT questionnaire. At this point, all participants who meet the inclusion criteria will be randomised to one of 32 unique experimental conditions (see Additional file 2: Table S2) in a block randomisation method. After this they are provided with their AUDIT score and informed of their 'AUDIT risk zone'. From this point onwards, the app differs for the different experimental conditions. Participants who do not meet all of the inclusion criteria can still use the app and will be allocated to a separate, non-experimental condition that has the 'high' version of each intervention module for engagement and app rating purposes.

One month after downloading the app, the app will automatically deliver a follow-up questionnaire. If this is not completed, email reminders will be sent at periodic intervals (1 day and 1 week). The follow-up questionnaire consists of the AUDIT and questions regarding usability.

Measures

Baseline measures

AUDIT score; socio-demographic assessment (age, gender, ethnicity, level of education, employment status and whether they are a current smoker).

Outcome measures

The primary outcome measure is change in past week consumption of alcohol; calculated from the AUDIT-C score at baseline and 1-month follow-up [109]. Secondary outcome measures will be i) change between baseline and follow-up on the full AUDIT score ii) app usage data (user sessions per day, screen views per day, screens per session, session duration and session instances, user retention), and iii) usability ratings for the app (a) how helpful did you find Drink Less? b) how easy did you find Drink Less to use? c) how satisfied are you with Drink Less? d) how likely are you to recommend Drink Less to a friend?). An intention-to-treat approach will be used such that those who are lost to follow-up will be retained in the primary analysis and assumed to be drinking at baseline levels. The full 10-item AUDIT assesses alcohol consumption (AUDIT-C), harmful drinking and alcohol dependence [116]. The AUDIT has been used in other trials for assessing alcohol consumption and related harms [117].

Analysis

A factorial between-subjects ANOVA will be conducted to assess main and interactive effects of the five intervention modules on the primary and secondary outcomes. In a sensitivity analysis, ANCOVAs will also be conducted to adjust for any chance imbalances in drinking and socio-demographic characteristics (gender, age, ethnicity, level of education, employment status, AUDIT score, AUDIT-C score). On the basis of the intention-to-treat principle, individuals who are not followed up (non-responders) will be retained in the analyses and assumed they drinking at same levels as baseline. Sensitivity analyses will be conducted i) among only those who completed the follow-up questionnaire (responders) and ii) by imputing missing data from baseline characteristics. The intention-to-treat principle is often used in digital public health interventions [118–120] and is a conservative approach to ensure effect sizes are not over-estimated as participants who respond well to the intervention are more likely to be retained.

In the event of a non-significant main effect of an intervention module, Bayes factors will be calculated with the alternative hypotheses conservatively represented in each case by a half-normal distribution (online calculator: http://www.lifesci.sussex.ac.uk/home/Zoltan_ Dienes/inference/Bayes.htm). In an alternative hypothesis represented by a half-normal distribution, the standard deviation of a distribution can be specified as an expected effect size, which means plausible values have been effectively represented between zero and twice the effect size, with smaller values more likely. The expected effect size for the primary calculation of Bayes factors will be the same as for the power calculation (d = 0.22). In a sensitivity analysis, we will also calculate Bayes factors for a smaller effect (reflecting a reduction of 3 units per week, d = 0.13).

Discussion

This study protocol describes the design of a factorial randomised controlled trial to determine the effectiveness of five intervention modules delivered within a smartphone app at reducing excessive alcohol consumption. To our knowledge, this will be the first study to examine the effectiveness of a smartphone app to reduce excessive alcohol consumption that has been developed based on empirical evidence and theoretical models.

This type of trial and analysis means we can independently assess each module to see which module is having the biggest effect. This also allows for on-going evaluation and optimisation of the app for future evaluation of an integrated treatment package. As each module was developed based on empirical evidence and theoretical models, the findings of this study will be able to inform behavioural science, theory and future public health interventions. The 'pure control' group in this trial was effectively those who received 'low' versions of every intervention module which lacked the BCTs or intervention component being assessed in the 'high' version. Most popular alcohol reduction apps include almost no BCTs or mentions of theory [46], therefore the users receiving the 'pure control' were effectively receiving 'usual care' in this context.

The selection process of high priority modules for evaluation was intended to be systematic and transparent. However, it is possible that other researchers could have conducted a similar process and reached a different view. For example, it may have been of interest to evaluate the individual effect of goal-setting. Goal-setting was provided to all participants for two reasons. First, from a methodological perspective, we believed there was a pragmatic need to provide engaging content to all users, particularly those receiving low versions of all the modules, and around which access to other modules could be plausibly structured. Second, we thought the evidence-base on goal-setting was sufficiently robust that it would warrant inclusion in a future evaluation of an integrated app without support from a factorial screening experiment [121-123].

Our power calculation relied on a large estimated effect size (comparable with that of a face-to-face brief intervention) and may be considered somewhat unrealistic for a module within a digital intervention. The reason is that selecting smaller effect sizes would require larger numbers of participants and more time to recruit them. The Multiphase Optimization Strategy, which guides our research, emphasises agile screening experiments before running a definitive head-to-head trial of an optimised intervention against a control [106, 124]. We deal with the limitation of a somewhat unrealistic effect size for our power calculation by planning to supplement our inferential statistics by calculating Bayes factors. Bayes factors will provide useful information on the relative likelihood of smaller (more realistic) effects compared with the null given the data we obtain.

One strength of this intervention is that it is delivered by smartphone, so there will be no issues of availability or accessibility for the participants. The app can be used fully without an internet connection. The data is stored on the phone until an internet connection is available, when the data is then sent to the server. A limitation of this type of study is high attrition. We will send regular reminders for the one-month follow-up questionnaire and remind them of the incentives offered to reduce the risk of attrition. A practical issue may be recruiting enough participants to meet the numbers sufficient to meet the power for our analysis. We have planned for this issue by using best practices for app store optimisation and by promoting the app through trusted organisations such as Public Health England and University College London.

This study will evaluate the extent to which an app containing five intervention modules (self-monitoring combined with feedback, action planning, normative feedback, cognitive bias re-training, and identity change), developed based on theory and empirical evidence, can help reduce excessive alcohol consumption. Each intervention module will be independently assessed and the findings will be used to inform the content of a future app with an integrated treatment package that will be evaluated against a minimal control in a definitive randomised control trial with long-term outcomes. As the app and its intervention modules have been developed based on theoretical models and empirical evidence, these findings will also be able to inform future behaviour change interventions, theories and behavioural science.

Additional files

Additional file 1: RCT protocol Additional file 1. Table 51. Details of intervention modules. Table detailing the full content of the five intervention modules, both the 'high' and 'low' versions. (DOCX 19 kb)

Additional file 2: RCT protocol Additional file 2. Table S2. Experimental group matrix. Table showing the 32 experimental conditions. (DOCX 56 kb)

Ab breviations

BCT, behaviour change technique; DBCI, digital behaviour change intervention; RCT, randomised controlled trial

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Availability of data and materials

The anonymised dataset will be available in the Open Science Framework (https://cxf.io/q8mua/). The app code will be available on request.

Authors' contributions

CG, DC, RW, SM & JB conceived of the study and participated in its design. CG drafted the 'normative feedback,' cognitive bias re-training' and 'identity change' parts of the background section of the manuscript. DC drafted the 'self-monitoring and feedback' and 'action planning' parts of the background section of the manuscript. CG & DC drafted the methods and discussion sections of the manuscript together. SM, RW & JB provided critical feedback. All authors approved the final manuscript.

Competing interests

JB has received an unrestricted research grant from Pfizer related to the surveillance of smoking cessation trends. RW has received research funding and undertaken consultancy for companies that manufacture smoking cessation medications.

Consent for publication

Consent for publication obtained through the information sheet and consent form.

Ethics approval and consent to participate

Ethical approval has been granted as an amendment to the existing ethics, for the optimisation and implementation of interventions to change healthelated behavious' project (CDIP/2013/500) by the UCL Ethics Committee. Participants must have lead the participant information sheet and provide informed consent before being able to take part in the trial.

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Appendix 4: References for the studies included in the meta-regression in Cochrane review reported in Chapter 4

(n=40, because 2 study reports contained 2 digital intervention arms each)

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Appendix 5: Results tables of sensitivity analyses for unadjusted and adjusted models in the meta-regression in Chapter 4 (Study 2)

Unadjusted meta-regression analyses using standardised effect sizes for the individual TCS items, six categories of theory use and use of theory scores

Theory Coding Scheme (TCS)	B (SE)	p	95% CI	Adj. R ²	I ²
covariates (item/category					
number)					
Theory/model of behaviour	0.06	0.488	-0.12, 0.24	-2.47%	73.99%
mentioned (I1)	(0.09)				
Targeted construct	0.15	0.079	-0.02, 0.32	9.86%	72.54%
mentioned as predictor of	(80.0)				
behaviour (I2)					
Intervention based on single	0.10	0.346	-0.11, 0.32	-1.17%	73.91%
theory (I3)	(0.11)				
Theory/predictors used to	0.11	0.234	-0.07, 0.28	1.74%	73.36%
select/develop intervention	(0.09)				
techniques (I5)					
All intervention techniques	-0.12 (.12)	0.352	-0.37, 0.13	1.34%	73.28%
are explicitly linked to at					
least one theory-relevant					
construct/predictor (I7)					
At least one, but not all, of the	0.22	0.020	0.04, 0.40	21.00%	71.21%
intervention techniques are	(0.09)				
explicitly linked to at least					
one theory-relevant					
construct/predictor (I8)					
All theory-relevant	0.07	0.556	-0.17, 0.31	-3.14%	74.03%
constructs/predictors are	(0.12)				
explicitly linked to at least					
one intervention technique					

(I10)					
At least one, but not all, of the	0.11	0.289	-0.09, 0.30	0.29%	73.33%
theory-relevant	(0.10)				
constructs/predictors are					
explicitly linked to at least					
one intervention technique					
(I11)					
Theory-relevant constructs	-0.12	0.233	-0.31, 0.08	1.00%	73.95%
are measured: post-	(0.10)				
intervention (I12a)					
Theory-relevant constructs	-0.10	0.336	-0.31, 0.11	-1.98%	74.11%
are measured: post- & pre-	(0.10)				
intervention (I12b)					
Changes in measured theory-	-0.28	0.013	-0.49, -0.06	20.09%	72.26%
relevant constructs/predictor	(0.11)				
(I13)					
Mediational analysis of	-0.16	0.209	-0.42, 0.10	2.94%	73.15%
constructs/ predictors:	(0.13)				
mediator predicts the					
dependent variable (I14a)					
Mediational analysis of	-0.35 (.16)	0.034	-0.66, -0.03	16.67%	71.38%
constructs/ predictors:					
intervention does not predict					
the dependent variable when					
controlling the independent					
variable (I14c)					
Mediational analysis of	-0.16	0.209	-0.42, 0.10	2.94%	73.15%
constructs/ predictors:	(0.13)				
mediated effect is statistically					
significant (I14d)					
Results discussed in relation	-0.03	0.797	-0.22, 0.17	-4.61%	74.17%
to theory (I15)	(0.10)				
Appropriate support for	-0.16	0.211	-0.40, 0.09	3.52%	73.10%
theory (I16)	(0.12)				

Reference to underpinning	0.05	0.187	-0.02, 0.12	3.49%	73.38%
theory (C1)	(0.04)				
Targeting of relevant	0.02	0.227	-0.01, 0.06	1.94%	73.37%
theoretical constructs (C2)	(0.02)				
Using theory to select	-0.01	0.973	-0.36, 0.35	-4.42%	74.16%
recipients or tailor	(0.18)				
interventions (C3)					
Measurement of constructs	-0.06	0.266	-0.16, 0.05	-0.36%	74.04%
(C4)	(0.05)				
Testing of theory: mediation	-0.03	0.107	-0.06, 0.01	7.23%	73.22%
effects (C5)	(0.02)				
Total use of theory	-0.001	0.904	-0.02, 0.02	-4.62%	74.16%
	(0.01)				

Adjusted meta-regression analysis for the covariates with a meaningful association with effect size in unadjusted models using standardised effect sizes

Theory Coding Scheme (TCS) covariates (item	B (SE)	p	95% CI
number)			
Targeted construct mentioned as predictor of	0.25 (0.12)	0.044	0.01, 0.50
behaviour (I2)			
At least one, but not all, of the intervention techniques	0.02 (0.12)	0.852	-0.22, 0.27
are explicitly linked to at least one theory-relevant			
construct/predictor (I8)			
Changes in measured theory-relevant	-0.41 (0.11)	0.001	-0.63, -0.19
constructs/predictor (I13)			

Appendix 6: Responses and rationale generated by the experts in round 1 of Study 4

(Chapter 6) to the following question: "What intervention components do you believe would be the best bets for helping people reduce their alcohol consumption?"

- 1. Action planning
- Plans for how to avoid specific triggers for drinking or cope with the motivation to drink when it occurs
- Self-monitoring is more effective when combined with action planning
- 2. Behaviour substitution
- Prompt substitution of the unwanted behaviour with a wanted or neutral behaviour
- E.g. instead of having a birthday party at a bar, doing some other activity, such as paintballing
- 3. Environmental triggers and drivers
- Identify specific triggers and drivers that generate the urge/want/need to drink
- E.g. pressure to attend pub after work regularly
- 4. Feedback in relation to goals
- Related to the one or more goals set and any cumulative goals
- Needs to give warnings as get near the limit for session, day, week, etc
- Individualised feedback and information has more relevance and salience
- 5. Feedback in relation to people
- Consistent overestimation of the drinking levels of peers
- Social norms/normative feedbacks approaches are effective in correcting
 misperceived norms to reduce alcohol consumption and alcohol-related problems
- 6. Goal-setting
- Set clear goals for a) session, b) day, c) week and cumulative goals

- Tailored to the needs of the client
- Meaningful and achievable goals
- 7. Habit reversal
- Prompt rehearsal and repetition of an alternative behaviour to replace an unwanted habitual behaviour
- E.g. have a soft drink every other round
- 8. Inhibition training
- Poor inhibitory control has been found to have a causal link with heavy drinking and alcohol problems
- Inhibitory control can be experimentally manipulated ('trained'), which results in reduced alcohol consumption
- Multiple training sessions may be a viable way to help people to reduce their alcohol consumption
- An example of inhibition training is approach-avoidance training: where participants
 are implicitly trained to avoid or approach alcohol-related stimuli
- 9. Monitoring
- People are generally unaware of the level at which they drink
- Important accompaniment to goal setting
- As easy and quick to implement as possible
- Options for different ways of doing it (e.g repeat last drink, catch-up on missed drinks)
- 10. Motivational interviewing
- Techniques involving prompting the client to provide self-motivating statements and evaluations of own behaviour to minimise resistance to change
- Proven effective in drug abuse and related problems

11. Provide information

- Raising awareness of the consequences of drinking different amounts of alcohol might prompt behaviour change
- Brief information (when given by expert/authorative figures like doctors) can be very effective to curb problem drinking and related problems
- This could include information on the alcohol related risks for different demographic groups

12. Reward

• Provide rewards contingent on successfully reducing excessive alcohol use/abstaining

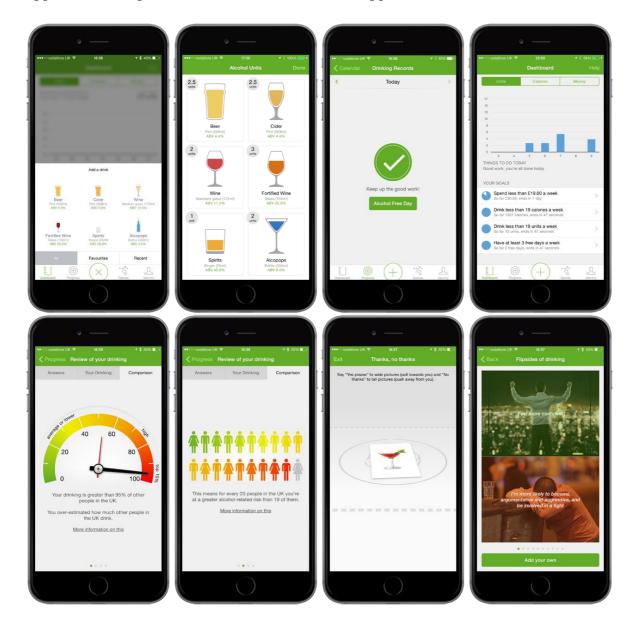
Appendix 7: Responses and rationale generated by the experts in round 1 of Study 4

(Chapter 6) to the following question: "What do you think are the best strategies or techniques for maintaining engagement with an app aiming to help people reduce their alcohol consumption?"

- 1. Design Ability to change design to suit own preferences
- Option for changing look and feel of the app when the user wants
- Tailor app to different aesthetic tastes
- 2. Design Aesthetic
- Needs to look good
- Attractive and simple design
- 3. Ease of use
- Needs to feel good/easy to use
- Intuitive user interface
- 4. Feedback
- Immediate, informative feedback
- Illustrates progress towards a goal
- Show if there is any improvement in task performance
- 5. Function
- Range of different functions
- Capture different processes (e.g. monitoring, associations)
- 6. Gamification
- Typical game elements (e.g. incremental challenges, monitoring progress, giving rewards) are used for different purposes
- Makes the intervention more persuasive

- Strategies should be tailored to fit different age groups
- 7. Graded tasks
- Motivating when you achieve a higher level
- Can help with self-efficacy
- 8. Prompts
- Can enhance interaction
- 9. Reward type Cue signalling reward
- 10. Reward type Financial
- 11. Reward type Games
- 12. Reward type Novelty
- E.g. accessing a new element/section of the app
- 13. Reward type Positive messages
- 14. Social Comparison
- Option for comparing self with others
- Anonymous unless permission granted
- 15. Social Connectivity
- Social support to achieve a certain goal
- Works well in other health behaviour apps e.g. weight loss
- 16. Tailored information
- Provide cumulative personalised information about user in relation to others
- 17. Unique smartphone features
- Use of features/functions only available on a smartphone
- For example, prompts/reminders based on location or time

Appendix 8: Sample screenshots of the Drink Less app



Appendix 9: Full content specification for registration procedure of the Drink Less app

Screen	Text
Information	Before you decide whether or not to take part in this study it is important for you to
sheet	understand why the research is being done and what it will involve. Please read the
	following information and email us if anything is unclear or if you would like more
	information.
	1. The purpose of the study and eligibility
	This study aims to evaluate a smartphone application (Drink Less) to help people
	reduce their alcohol consumption. We want to learn about the effectiveness of
	different intervention components and users' experiences with using the app. You
	must be over 18 years old to be eligible for this study.
	2. What will happen if you decide to take part?
	The programme will randomly allocate you into a group, and you will receive a
	number of different intervention components, which will be based on a combination
	of evidence-based behaviour change techniques. You will be encouraged to use the
	app daily, to use the different intervention components of the app and to monitor
	your drinking. If you provide us with your email address, we will email you to ask
	questions about the app and your drinking 3 months from today.
	3. Possible risks or discomfort
	There are no possible risks or discomfort to you for taking part.
	4. Possible benefits
	Reducing your drinking levels has a number of health and financial benefits,
	amongst others.
	5. Financial considerations
	There are no financial costs to you for taking part.
	6. Confidentiality
	All data from this study will be treated as strictly confidential and handled in
	accordance with the Data Protection Act 1998. For your protection, we will assign
	you a unique number that will be used to label all information. Results of this study
	will be written up for scientific publications, PhD thesis and conference
	presentations. Results will be available upon request via e-mail
	(c.garnett.12@ucl.ac.uk or david.crane.13@ucl.ac.uk), and through open access
	scientific literature. Any records or data obtained as a result of your participation
	may be checked by the group that oversees research to make sure that human
	participants are protected.

Screen	Text
	You are free to choose whether or not to take part in this study. You can choose to
	stop participating at any time without giving a reason.
	8. Ethics review
	This study has been approved by University College London's Psychology and
	Language Sciences Departmental Ethics Committee (Project ID: CEHP/2013/508).
	Principal Investigator: Professor Susan Michie (s.michie@ucl.ac.uk)
	9. Further information and contact details
	If you would like to receive any further information or have any questions, please
	contact Professor Susan Michie (s.michie@ucl.ac.uk), Claire Garnett
	(c.garnett.12@ucl.ac.uk) or David Crane (david.crane.13@ucl.ac.uk).
	10. Comments or concerns during the study
	If you have any comments or concerns you should discuss these with the Principal
	Investigator (s.michie@ucl.ac.uk). If you wish to complain further, you should email
	the Chair of the UCL Committee for the Ethics of Non-NHS Human Research
	(gradschoolhead@ucl.ac.uk) who will take the complaint forward as necessary.
Consent form	If you do not want to take part in this study, please close the app now. If you would
	like to take part, please indicate that you consent to do so. By tapping on the consen
	button below you are indicating that:
	You have read the information pages, had an opportunity to ask questions, and are
	happy that you understand the study and what it involves for you.
	You realise that you can withdraw from the study at any time.
	You agree that the findings of the study can be published but that you will not be
	identified.
	All the information you provide will be treated as strictly confidential and handled
	in accordance with the provisions of the Data Protection Act 1998.

handled in accordance with the provisions of the Data Protection Act 1998.

['Give consent' button]

Female

Drinking Gender assessment Male

How often do you have a drink containing alcohol?

Never/Monthly or less/2 to 4 times a month/2 or 3 times a week/4 or more times a week

How many units of alcohol do you have on a typical day when you are drinking? 1-2/3-4/5-6/7-9/10+

How often do you have six or more units of alcohol on one occasion? Never/Less than monthly/Monthly/Weekly/Daily or almost daily

Screen	Text
	How often during the last year have you found that you were unable to stop
	drinking once you had started?
	Never/Less than monthly/Monthly/Weekly/Daily or almost daily
	How often during the last year have you failed to do what was expected from you
	because of drinking?
	Never/Less than monthly/Monthly/Weekly/Daily or almost daily
	How often during the last year have you needed a first drink in the morning to get
	yourself going after a heavy drinking session?
	Never/Less than monthly/Monthly/Weekly/Daily or almost daily
	How often during the last year have you had a feeling of guilt or remorse after drinking?
	Never/Less than monthly/Monthly/Weekly/Daily or almost daily
	How often during the last year have you been unable to remember what happened
	the night before because you had been drinking?
	Never/Less than monthly/Monthly/Weekly/Daily or almost daily
	Have you or someone else been injured as the result of your drinking?
	No/Yes, but not in the last year/Yes, during the last year
	Has a relative, friend, or a doctor or other health worker been concerned about you
	drinking or suggested you cut down?
	No/Yes, but not in the last year/Yes, during the last year
Feedback on	{if AUDIT score between 0 and 7; green text}
drinking	Your results indicate you're not at risk of physical and/or psychological alcohol-
	related harm.
	Your score was X which lies in the range of 0-7 for this risk zone.
	{if AUDIT score between 8 and 15; yellow text}
	Your results indicate you're putting yourself at increasing risk of physical and/or
	psychological alcohol-related harm.
	Your score was X which lies in the range of 8-15 for this risk zone.
	{if AUDIT score between 16 and 19; orange text}
	Your results indicate you're likely to be experiencing physical and/or psychologica
	alcohol-related harm.
	Your score was X which lies in the range of 16-19 for this risk zone.
	{if AUDIT score between 20 and 40; red text}
	You results indicate the possibility of alcohol dependence. You are welcome to

further support.

continue to use this app though we strongly advise you to contact your GP for

Screen	Text
	Your score was X which lies in the range of 20-40 for this risk zone.
Socio-	Now we'd like you to answer some questions about yourself that will help us give
demographic	you more personalised feedback and it's important for us to collect this information
assessment	for our study.
	Year of birth
	Tap to select {dial with years ranging from 2000 to 1881}
	Ethnicity
	White; Black; Asian/Asian-British; Mixed; Other
	Highest qualification achieved
	GCSEs/Standard grades; A Levels/Highers; Undergraduate degree; Post-graduate
	degree
	Country
	UK; Other
	Are you a smoker?
	Yes; No
	Are you currently?
	Employed; Self-employed; Unemployed; Homemaker; Student; Retired; Unable to
	work
	Email address
	Enter {empty field for user to enter email addres}
	Win a £500 voucher simply by letting us email you
	Why are you using this app?
	Interested in drinking less alcohol; Just browsing

Appendix 10: Full content specification for core app features

Screen	Text
Create and view	Goals
goals	I want to drink less because [+]
	[Set and view goals]
	[How to set good goals]
	Set and view goals
	'Active goals'
	{list active goals set by user}
	Good goals are specific and a little challenging. Not too challenging though, because
	often the hardest thing about making a change is sticking with it. So it's important to
	keep your goals realistic. You can alter them at any time if you find they're too
	difficult or too easy.
	[Set a new goal]
	T'
	This screen lists all your active and any previous goals. If it's empty, start by tapping
	the green 'Set a new goal' button at the bottom. If you've set a goal, the white circle
	fills up as the week progresses. Tap this or the text to see your success over the
	weeks. You can amend your goal by tapping Edit (in the top right) and then the goal
	itself. Only tap the red circle if you want to delete it.
	'Previous goals'
	{list of goals set by user previously, though not currently active}
	[Set a new goal]
	ï'
	Any goals you've deleted are listed here. Tap a goal to see your success over the
	weeks. Tap Edit and then the red circle to re-activate this goal or delete it entirely.
	Set goal Set goal
	Details
	Type: Units/ Spending/ Alcohol free days/ Calories
	Max:
	Recurring: On/ Off
	[Save]
	ï'
	Type: You can set goal for how many alcohol free days you want each week, the
	maximum number of units you want to drink, the maximum amount you want to

spend or the maximum number of calories you want to consume. All relate to a

Screen

Text

week's consumption.

Max: Enter a figure for the type of goal you've set. For example: 3 alcohol free days, 14 units, £20 or 1100 calories.

Recurring: Leave this on and the goal will start again each week.

How to set good goals

Good goals are specific and a little challenging. Not too challenging though, because often the hardest thing about making a change is sticking with it. So it's important to keep your goals realistic. You can alter them at any time if you find they're too difficult or too easy.

You can set goals for:

- 1. Number of alcohol free days a week
- 2. The total amount of alcohol you drink
- 3. The number of calories you get from alcohol
- 4. The money you spend on alcohol.

We suggest you start with a couple and take it from there.

About alcohol -

Drinking guidelines

>Useful

The government's drinking guidelines have three key recommendations.

information

Limit your weekly drinking to 14 units

Whether you are a man or a woman try not to regularly drink more than 14 units of alcohol per week. If you drink as much as 14 units per week, it's best to spread this evenly over 3-5 days but keep 2-4 days alcohol free. See Help > Units guide.

Avoid drinking more than 6 units on any one occasion

Limit the amount of alcohol you drink to less than 6 units on any one occasion, if necessary by drinking more slowly, drinking with food or alternating with a soft drink

Do not drink at all if you are pregnant

Any amount of alcohol can harm your baby, so it is best not to drink at all.

You can read the full guidelines here [hyperlink to pdf of government drinking guidelines]

Harms of drinking

Harms of drinking

Alcohol increases your chance of experiencing:

Short term effects

Alcohol poisoning

Memory loss

Screen Text **Fatigue** Depression Unsafe sex **Impotence** Injury Long term effects Cancer Heart disease Liver disease Stroke High blood pressure Diabetes Reduced fertility Insomnia Social problems Causing or being the victim of violence and antisocial behaviour Problems with relationships Unplanned time off work or college Loss of personal possessions (left your phone in the pub? Again?) See here for more details [hyperlink to NHS webpage 'the risks of drinking too much'] Benefits of not drinking Benefits of not drinking Here are just some of the benefits of not drinking (or drinking less): Feel better in the mornings Get more and better quality sleep Improve your overall mood Improve your health Save money Live longer Reduce the likelihood of developing over 60 medical conditions (see *Harms of drinking* for a small sample) See here for more details [hyperlink to NHS webpage 'tips on cutting down'] Good goal setting How to set good goals

Good goals are specific and a little challenging. Not too challenging though, because

Screen	Text
	the hardest thing about making a change is often sticking with it. So it's important to
	keep your goals realistic. You can alter them at any time if you find they're too
	difficult or too easy.
	You can set goals for:
	1. Number of alcohol free days a week
	2. The total amount of alcohol you drink
	3. The number of calories you get from alcohol
	4. The money you spend on alcohol.
	We suggest you start with a couple and take it from there.
	Setting a plan for action
	Action plans
	Achieving a goal is easier when you've got a plan. Planning helps you manage
	situations when you may be tempted to drink a bit too much.
	For example, how might you plan to avoid having that drink that takes you over the
	edge? How might you plan for drinking nothing at all for a few days each week?
About alcohol -	If you find it difficult to cut down your drinking, or think you may have a problem
>Can't stop	with your drinking
drinking	The NHS has services that might help
	Or try alcoholics anonymous
	[hyperlink to relevant site]
App settings	It's a good idea to set this for the morning, at a time you'll regularly be able to fill it
->Reminders	in, and when your memory is fresh.
	[Clock dial]
	We'll help you keep a drinking diary
	[Reminder on/off]
	If this is on we'll prompt you to record your alcohol consumption each day.
About the app	Contact
	We would be delighted to help if you've got any questions about the app or the
	study
	[David Crane]
	[Claire Garnett]
	[Susan Michie] (Principal Investigator)
	{each name is a hyperlink to an email draft with their email address pre-filled}
	The team
	About us
	If you use this app to help you drink less alcohol you're in good hands.

Text

The app has been developed by a highly qualified team of experts based at University College London, with support from leading researchers from other universities. Professor Susan Michie and Professor Robert West both have extensive experience in helping people achieve behaviour change goals. Dr Jamie Brown led a successful project called StopAdvisor to help smokers quit and runs ongoing studies about alcohol use. David Crane has developed a very popular app called [Smoke Free] and Claire Garnett comes to the project as a psychologist with a Master of Science Degree from University College London.

We've developed this app to study whether it helps people drink less alcohol so we can learn how to do this better. We will publish our findings so that others can benefit. So by using the app you're not only helping yourself but are helping science too. Thank you.

This research was funded by the UK Centre for Tobacco and Alcohol Studies (UKCTAS) and the NIHR School for Public Health Research (NIHR SPHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. UKCTAS is a UKCRC Public Health Research Centre of Excellence. Funding from the Medical Research Council, British Heart Foundation, Cancer Research UK, Economic and Social Research Council and the National Institute for Health Research under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged. Dave's PhD studentship is funded by NIHR SPHR, Claire's is funded by UKCTAS.

The study and you

{same as for information sheet and consent form}

Privacy policy

All your information will be stored anonymously and securely. You are not obliged to take part in this study and you should not feel coerced. If you choose to withdraw you may do so without disadvantage to yourself and without any obligation to give a reason.

To withdraw please got to the Help tab of the app and choose "Opt out of the experiment".

Please feel free to ask us any questions on support@drinklessalcohol.com.

Opt out

Please confirm you wish to opt-out of the experiment

[Opt-out / Cancel]

Rate this app {hyperlink to app store}

Appendix 11: Full content specification for normative feedback module

Screen	Text	Additional information
Comparison	How do you think your drinking compares with	9 response options though
questions	others in the UK?	only 5 terms shown around
	Average or lower	the gauge to prevent screen
	High	looking cluttered (those in
	Top 10%	italics not placed around the
	Lowest 10%	gauge).
	Very low	Every option appears under
	Low	the gauge whenever the
	Low-average	needle is pointing to that
	Average (middle 20%)	bracket.
	High-average	
	High	The comparison question
	Very-high	relating to the user's relevant
	Top 10%	gender and age group will
	How do you think your drinking compares with	automatically select the
	other [women/men] aged [16-24/25-34/35-44/45-	relevant option based on the
	54/55+]?	socio-demographic data the
	Average or lower	user inputted.
	High	
	Top 10%	
	Lowest 10%	
	Very low	
	Low	
	Low-average	
	Average (middle 20%)	
	High-average	
	High	
	Very-high	
	Top 10%	
Normative	1) Prepare yourself! We're going to show you how	The statement about their
feedback	your drinking compares with other people and this	estimation will be based on
(Intensive)	might come as a bit of a surprise. If so, don't worry,	their answer to the
	there are plenty of things you can do about it if you	comparison questions.
	want to, and this app is here to help.	

Screen	Text	Additional information
	These data come from a large survey of adults in	A red needle on the gauge
	England called the Alcohol Toolkit Study [hyperlink	indicates their response to the
	to website http://www.alcoholinengland.info].	comparison question. A black
	The survey asks adults over 16 years old about their	needle indicates how their
	drinking – this includes people who don't drink at all	drinking actually compares
	who you may have forgotten about when answering	with the relevant comparison
	the questions on the previous screen. Remember, we	group.
	usually socialize with people who drink similar	
	amounts and so assume everyone drinks that much.	The scale on the gauge refers
	2i) {UK gauge}	to percentiles. The colour of
	Your drinking is greater than $x\%$ of other people in	the gauge indicates alcohol-
	the UK.	related risk and represents
	You [over-/under-/correctly] estimated how much	the four quartiles (0-25%-
	other people in the UK drink.	green to yellow; 26-50%-
	2ii) {UK gauge - drinkers}	yellow to orange; 51-75%-
	Your drinking is greater than $x\%$ of other drinkers in	orange to red; 76-100%- red).
	the UK.	Minimal text directly above
	You [over-/under-/correctly] estimated how much	the gauge with three labels
	other drinkers in the UK consume.	(for 0-50% - average or lower;
	3i) {UK people infographic}	70-80% - high; 90-100% - top
	This means for every 20 people in the UK you're at a	10%). The text underneath
	greater alcohol-related risk than x of them.	the needle of the gauge
	3ii) {UK people infographic – drinkers}	specifies the exact percentile
	This means for every 20 drinkers in the UK you're at	the user falls in and how
	a greater alcohol-related risk than x of them.	accurate their beliefs about
	4i) {Age/gender gauge}	how their drinking compares
	Your drinking is greater than $x\%$ of other	with others are.
	[women/men] aged [16-24/25-34/35-44/45-	
	54/55+].	People infographic:
	You [over-/under-/correctly] estimated how much	People infographic with 20
	other [women/men] aged [16-24/25-34/35-44/45-	people (each one representing
	54/55+] drink.	5% of population)
	4ii) {Age/gender gauge - drinkers}	
	Your drinking is greater than $x\%$ of other	The gauges and people
	[women/men] aged [16-24/25-34/35-44/45-	infographic have a toggle at
	54/55+] who drink.	the top of the screen allowing

Screen	Text	Additional information
	You [over-/under-/correctly] estimated how much	users to choose between
	other [women/men] who drink aged [16-24/25-	'everyone' and 'drinkers'. The
	34/35-44/45-54/55+] consume.	way in which drinkers were
	5i) {Age/gender people infographic}	defined was stated below the
	This means for every 20 [women/men] aged [16-	toggle button:
	24/25-34/35-44/45-54/55+] you're at a greater	"Drinkers includes anyone
	alcohol-related risk than x of them.	who has had a drink in the last
	5ii) {Age/gender people infographic – drinkers}	year, even if that was just
	This means for every 20 [women/men] aged [16-	one!"
	24/25-34/35-44/45-54/55+] who drink you're at a	
	greater alcohol-related risk than x of them.	
	6) As we said before, don't worry if this was a bit of a	
	surprise; it is very common for people to	
	underestimate their drinking. We've created this app	
	to help you drink a bit less. So let's go ahead and get	
	started.	
Info	This screen lets you know how your drinking	'Info' button requested by
(Intensive)	compares with other people.	users to explain the normative
	The red needle on the gauge shows what you have	feedback screens.
	said and the black needle shows how your drinking	'i' icon on the top right of the
	actually compares.	screen when showing the
	On the infographic, the people highlighted are at	normative feedback
	greater alcohol-related risk than you.	
Brief advice	Drinking too much can put you at an increased risk	
(Minimal)	of a number of things including	
	Memory loss	
	Relationship problems	
	Depression	
	Impotence	
	Injury	
	High blood pressure	
	Liver disease	
	Cancer	
	Weight gain	
Social norms	1) {UK gauge}	A black needle always
information	Your drinking is average or lower than other people	indicates 50% so the users are

Screen	Text	Additional information
(below	in the UK.	never told their drinking
average	You [over-/under-/correctly] estimated how much	levels are below average.
drinking)	other people in the UK drink.	
	2) {UK people infographic}	The text below the gauge does
	X out of 20 people in the UK drink alcohol once a	not inform the user of their
	week or less.	specific percentile. Instead
	3) {Age/gender gauge}	informs the user that "Your
	Your drinking is average or lower than other	level of drinking is average or
	[women/men] aged [16-24/25-34/35-44/45-	lower" and how accurate their
	54/55+].	estimation was.
	You [over-/under-/correctly] estimated how much	
	other [women/men] aged [16-24/25-34/35-44/45-	
	54/55+] drink.	
	4) {Age/gender people infographic}	
	X out of 20 [men/women] aged [16-24/25-34/35-	
	44/45-54/55+] drink alcohol once a week or less.	
Question	If you want to look at these screens again, you can	
assessing	find it in the progress menu.	
helpfulness	Was this information helpful?	
	Yes	
	No	

Appendix 12: Full content specification for cognitive bias re-training module

Screen	Text	Additional
		information
Yes please, no	This game aims to help you re-train your mind so you get more	The link to
thanks	used to saying "No thanks" to alcohol when you choose to.	previous scores
(Intensive)	Read the instructions below or start playing now and pick it up	appears after
	as you go.	the game has
	[Play]	been played
	[Instructions]	twice.
	[Previous scores]	
	[How re-training your mind works]	
Yes please, no	[Play]	
thanks (Minimal)	[Instructions]	
	[Previous scores]	
Instructions	i) You will see pictures in either landscape (short and wide) or	
	portrait (long and think). The key thing to remember is that it's	
	the shape of the box, not the image itself, which matters.	
	When you see a {landscape} picture use your finger to pull it	
	towards you (i.e. down). This is like saying "Yes please". When	
	you see a {portrait} picture use your finger to push it away	
	from you (i.e. up). This is like saying "No, thanks".	
	You will have 60 seconds to see how many pictures you can	
	sort. Quick is good but remember, the quicker you go, the more	
	errors you might make. You get a point for every one you get	
	right but lose two if you get it wrong.	
	ii) Say "No thanks" to [landscape] pictures by pushing them	
	away from you.	
	iii) Say "Yes please" to [portrait] pictures by pulling them	
	towards you.	
	iv) Play now! {which takes you straight to the game}	
Congratulations	Could do better! You scored [0] points.	Screen showed
	Good! You scored [2] points.	only after user
	You have finished the game. Remember practice makes perfect.	completed the
	Come back and play again to see if you are getting any faster.	game.
	On 2 nd attempt	
	Amazing! You scored 71 points. You beat your personal best!	

Screen	Text	Additional
		information
	You have finished the game. Do come back and play again to see	
	if you are getting any faster!	
	On 3 rd attempt	
	Good! You scored 3 points. You have finished the game. Do	
	come back and play again to see if you are getting any faster!	
How re-training	Research has shown that we sometimes drink but don't know	
your mind works	why this is. This is like an unconscious impulse to say "yes" to	
(Intensive)	the idea of drinking. One way to help you stick to a decision to	
	drink less is to reduce the power of that impulse, and a number	
	of studies have shown this to work.	
	This game has been designed to help you do just that, and be a	
	bit of fun too.	
	If you'd like to read more about the theories and evidence	
	showing how this works, please visit Help > References.	
Info (Intensive)	This game is a fun way to re-train your mind so it gets more	
	used to saying "No thanks" to alcohol. Follow the instructions	
	and use your finger to either pull the picture towards you	
	(swipe down) or push it away (swipe up).	
	Images are used from the Amsterdam Beverage Picture Set. To	
	find out more about their licensing please visit	
	drinklessalcohol.com	
Info (Minimal)	This is meant to be a fun and engaging game. Follow the	
	instructions and use your finger to either pull the picture	
	towards you (swipe down) or push it away (swipe up). Images	
	are used from the Amsterdam Beverage Picture Set. To find out	
	more about their licensing please visit drinklessalcohol.com	
	more about their licensing please visit drinklessalconol.com	

Appendix 13: Full content specification for identity change module

Screen	Text
Drink + Me	Building a picture of yourself that is not based around drinking is an important part of
(Intensive)	changing your drinking behaviour.
	This section will help you do that.
	[Flipsides of drinking]
	[Memos]
	[I am]
Flipsides of	1) We've heard about some of benefits of drinking. But there is often a downside, which
drinking	you may not have thought about.
(Intensive)	By not drinking too much, you can avoid these downsides and be the person you want to
	be. Have a flick through our examples that are based on what some people have said.
	To make this section more helpful for you, why don't you add your own examples of
	what you don't like about drinking too much.
	[Add your own]
	2i) Feel more confident / I'm more likely to become argumentative and aggressive, and
	be involved in a fight
	2ii) Drinking helps me forget problems at work or school / I can become depressed
	2iii) Drinking makes socialising easier / I need my friends to look after me and take me
	home, spoiling their evening
	2iv) Alcoholic drinks taste good / I can have a whole days' worth of calories just from
	drinks and feel too rubbish the following day to go out and exercise
	2v) Drinking makes me feel more romantic / I might have sex with someone who I
	wouldn't want to if sober
	2vi) Drinking helps me think better / My decision making is impaired and I spend far
	more money than I intended
	2vii) Drinking helps calm me down when I'm angry / Too much means I can become
	aggressive and argumentative, and get into fights
	2viii) Drinking is a nice way to celebrate special occasions / I might have memory lapses
	and forget the occasion
	2ix) Drinking gives me more confidence in myself / I say something inappropriate that
	ends up offending someone
	2x) Feel great and have fun / I feel awful (groggy and tired) the following day
Memos	1) This is where you can record messages to yourself to watch in the future.

Screen

Text

(Intensive)

Maybe try saying a tongue twister after you've had some drinks or a message that will persuade you not to drink more than you planned to.

[Add new memo]

[Reminders]

>>>

Reminders

Here you can set reminders to record memos. It may be helpful to set reminders to record a memo when you're out drinking or the morning after a heavy night. You can also remind yourself to watch one you've already recorded. Maybe at a time you think you're likely to start drinking.

Record memos

[Add Record memo reminder]

Watch memos

[Add Watch memo reminder]

I am...

(Intensive)

- 1) This is about thinking about what is important to YOU. And then thinking about how drinking too much can affect whether you live up to them.
- 2) Click on the icon to take a photo...
- 3) Write a list of the values that are important to you. Or select some of our examples.

[Important values to me]

Honest

Good friend

Responsible

Health conscious

Friendly

Fun

4) Sometimes drinking can mean that we behave in ways that do not fit with what we value about ourselves.

Have a think about which of these values you struggle with when you've been drinking too much. Tap to highlight them if you'd like.

5) Here are some of our examples of values that don't go with getting drunk. Obviously they won't all apply to you though...

Honest -> Exaggerate stories for 'comic' effect but take it too far

Screen	Text
	Good friend -> End up spoiling my friends' night as they need to take care of me once I've
	had too much to drink
	Responsible -> Spend more money than planned and go over your weekly budget
	Health conscious -> After drinking too much I often have an unhealthy snack, like a kebab, on my way home
	Friendly -> I can get quite argumentative once I have an excessive amount of alcohol Fun -> End up half asleep, unable to join in with what's going on
	Tap an example to find out more
	[Done]
	***Would you like to either review your previous entry or start again?
	[Review]
	[Start Again]
	[Cancel]
Info (Intensive)	Building a picture of yourself that is not based around drinking is an important part of changing your drinking.
	The 'Flipsides of drinking' provide some examples of the negatives about drinking too
	much, which you may not have thought about. By drinking less, you can avoid these and
	follow your true values.
	You can use 'Memos' to record messages to yourself in the future. This is a chance to
	record a motivational message about your true self and why you think you should limit
	your drinking.
	The 'I am' section is about thinking about what is important to YOU. And then thinking

thinking about how drinking too much can affect whether you live up to your ideals.

Drink + Me You are here because you've decided that you want to drink less.

(Minimal) Now, take a moment to imagine yourself as this person who drinks less. What would it mean for you?

> Building up a new identity as someone who does not drink excessively is an important part of drinking less.

Sometimes the consequences of drinking too much are not what you intended or wanted to happen.

It can be helpful to think about these negative consequences of drinking too much when you're trying to drink less.

Appendix 14: Alcohol Toolkit Study data tables used for normative feedback module

Above average AUDIT score

This table shows the AUDIT scores in percentiles for different groups for the English population

-		All UK	Male						Female					
	Percentile	16+	16-24	25-34	35-44	45-54	55-64	65+	16-24	25-34	35-44	45-54	55-64	65+
0-	50	0-3	0-3	0-3	0-3	0-4	0-4	0-3	0-2	0-1	0-2	0-3	0-2	0-1
50-	55	3	4	4	4	4	4	3	3	2	3	3	3	1
55-	60	4	5	4	4	5	4	4	4	2	3	3	3	2
60-	65	4	6	5	5	5	5	4	4	3	3	4	3	2
65-	70	4	7	6	5	6	6	4	5	4	4	4	4	3
70-	75	5	8	6	6	6	6	4	6	4	4	4	4	3
75-	80	6	9	7	7	7	7	5	7	5	5	5	5	4
80-	85	7	10	8-9	8	8	8	6	8	6	6	6	5	4
85-	90	8	11-12	10	9-10	9	9	7	9-10	7	7	7	6	4
90-	95	9-11	13-14	11-13	11-12	10-12	10-11	8-10	11-13	8-9	8-9	8-9	7-8	5
95-	100	12+	15+	14+	13+	13+	12+	11+	14+	10+	10+	10+	9+	6+

This table shows the AUDIT scores in percentiles for different groups for the English population of drinkers

		All UK	Male						Female					
	Percentile	16+	16-24	25-34	35-44	45-54	55-64	65+	16-24	25-34	35-44	45-54	55-64	65+
0-	50	1-4	1-6	1-5	1-5	1-5	1-4	1-4	1-5	1-4	1-4	1-4	1-3	1-3
50-	55	4	7	5	5	5	5	4	5	4	4	4	4	3
55-	60	5	7	6	6	6	5	4	6	4	4	4	4	3
60-	65	5	8	7	6	6	6	4	6	5	4	4	4	3
65-	70	6	8	7	7	7	6	5	7	5	5	5	4	4
70-	75	6	9	8	8	7	7	5	8	6	5	5	5	4
75-	80	7	10	9	8	8	8	6	9	6	6	6	5	4
80-	85	8	11	10	9	9	9	6	10	7	7	7	6	4
85-	90	9-10	12-13	11	10-11	10	10	7-8	11-12	8	8	8	7	5
90-	95	11-12	14-16	12-14	12-14	11-13	11-12	9-10	13-14	9-10	9-10	9-10	8-9	6-7
95-	100	13+	17+	15+	15+	14+	13+	11+	15+	11+	11+	11+	10+	8+

Average or lower AUDIT score

This table shows the proportion of people in the English population who only drink once a week or less

		All		Only drinkers	
		%	Out of 20	%	Out of 20
UK		67.6	14	52.9	11
Male	16-24	73.2	15	59.9	12
Male	25-34	73.8	15	58.7	12
Male	35-44	64	13	48.5	10
Male	45-54	55.3	11	43.8	9
Male	55-64	51.8	10	36.7	7
Male	65+	53.3	11	40.6	8
Female	16-24	85.1	17	71.7	14
Female	25-34	83.4	17	72.9	15
Female	35-44	75.8	15	62.1	12
Female	45-54	64.6	13	50.4	10
Female	55-64	63.3	13	50.5	10
Female	65+	72.9	15	56.6	11

Appendix 15: Intervention content for each module in the Drink Less app

Intervention	Objective	Details of module		BCTs included in 'high' version	BCTs included in
module		High	Low		'low' version
Self-monitoring	Facilitate easy and	Ability to record	Ability to record	Review behaviour goals,	Self-monitoring of
and feedback	on-going recording of	drinks, graph	drinks. No other self-	Discrepancy between current	behaviour
	alcohol consumption;	showing units	monitoring	behaviour and goal, Feedback	
	provide feedback on	consumed calories	facilitated. No	on behaviour, Self-monitoring	
	consumption,	consumed, amount	feedback provided	of behaviour, Self-monitoring of	
	consequences of	spent on alcohol.		outcomes of behaviour,	
	consumption and	Record mood,		Feedback on outcomes of	
	progress toward	productivity, clarity,		behaviour, Salience of	
	goals.	sleep quality, graph		consequences, Information	
		illustrating how they		about emotional consequences,	
		differ on mornings		Social reward, Self-reward	
		after heavy drinking			
		compared to			
		mornings after			
		light/no drinking.			
		Feedback on progress			
		towards goals:			

		cumulatively as the			
		week progresses, on			
		the past week and on			
		all previous weeks.			
Action planning	Allow users to create	Create	Gain understanding	Action planning,	None
	implementation	implementation	of why to set	Credible source	
	intentions for dealing	intentions, review	implementation		
	with difficult drinking	implementation	intentions only.		
	situations.	intentions already			
		created, gain			
		understanding of why			
		to set implementation			
		intentions.			
Normative	Inform users of the	Questions assessing	Text on risks of	Social comparison	Information about
feedback	social drinking norm	how users think they	drinking too much	Provide normative information	health consequences
	and alert them to any	compare with others.	(from PHE website)	about others' behaviour and	Information about
	discrepancy with how	Infographics		experiences	emotional
	they believe their	illustrating how			consequences
	drinking compares	user's drinking			
	with normal to how it	actually compares			
	actually compares	with other adults and			

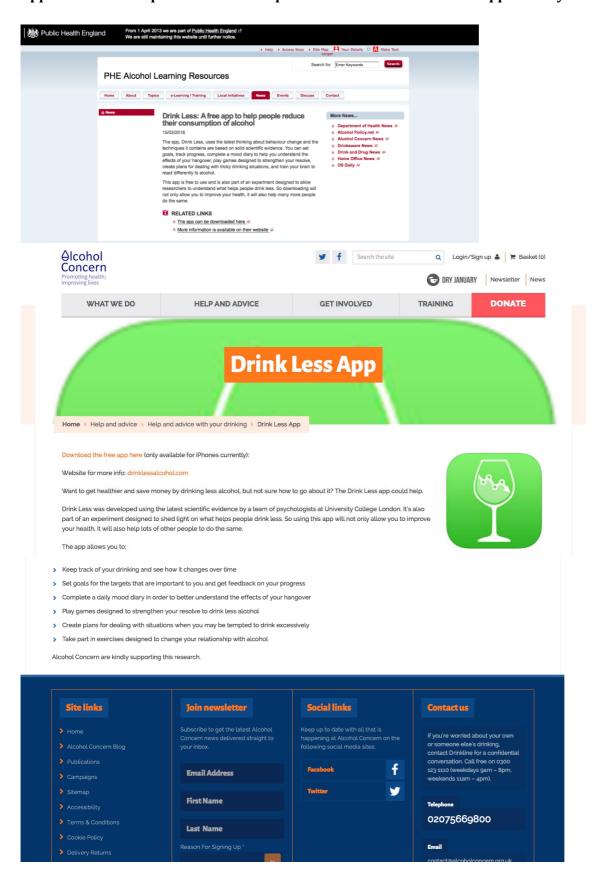
	with normal.	others of same			
		gender and age.			
Identity change	Help users foster a	Memos – record	Text on how identity	Identification of self as role	None
	change in their	messages about	is an important factor	model	
	identity so that users	drinking or when	in how we behave	Incompatible beliefs	
	do not see themselves	drunk too much to	and advise to think	Valued self-identity	
	as "drinkers" as a key	watch in the future	about the undesired	Identity associated with	
	part of their identity	"I am": identifying	consequences of	changed behaviour	
	which should aid	and considering those	drinking too much.	Information about	
	their behaviour	values that are		health/social/emotional	
	change attempt.	important to you, and		consequences	
		whether you do not		Salience of consequences	
		live up to those		Anticipated regret	
		values when you have		Pros and cons	
		drunk too much.		Framing/reframing	
		Flipsides of drinking:			
		Providing examples			
		of the negative sides			
		of positive alcohol			
		expectancies.			
Cognitive bias	Use a form of	Game with all alcohol	Game with 50% of	None	None

re-training	cognitive bias	related pictures	alcohol related
	modification to	associated with	pictures associated
	strengthen cognitive	"avoid" and all soft	with "avoid" and 50%
	control over the	drink pictures	associated with
	automatic biases to	associated with	"approach". Same for
	approach alcohol that	"approach".	soft drink pictures.
	predict alcohol use	Additional section of	
	that exist amongst	text on why and how	
	the users through an	this sort of game is	
	engaging game.	believed to work.	

Appendix 16: Matrix for experimental conditions in Study 5 (Chapter 8) I=intensive; M=minimal

Experimental	Normative	Identity	Cognitive bias	Self-	Action
condition	feedback	change	re-training	monitoring	planning
1	M	M	M	M	M
2	M	M	M	I	M
3	I	M	M	M	M
4	I	M	M	I	M
5	M	M	I	M	M
6	M	M	I	I	M
7	I	M	I	M	M
8	I	M	I	I	M
9	M	I	M	M	M
10	M	I	M	I	M
11	I	I	M	M	M
12	I	I	M	I	M
13	M	I	I	M	M
14	M	I	I	I	M
15	I	I	I	M	M
16	I	I	I	I	M
17	M	M	M	M	I
18	M	M	M	I	I
19	I	M	M	M	I
20	I	M	M	I	I
21	M	M	I	M	I
22	M	M	I	I	I
23	I	M	I	M	I
24	I	M	I	I	I
25	M	I	M	M	I
26	M	I	M	I	I
27	I	I	M	M	I
28	I	I	M	I	I
29	M	I	I	M	I
30	M	I	I	I	I
31	I	I	I	M	I
32	I	I	I	I	I

Appendix 17: Example screenshots of promotions for the Drink Less app in Study 5



Appendix 18: Approved ethics amendment forms for Study 5

Amendment Approval Request Form

1	Project ID Number:	Name and e-mail address of Principal Investigator:
CEHP/2013/508		Professor Susan Michie Research Department of Clinical, Educational and Health Psychology 1-19 Torrington Place London, WC1E 7HB
2	Project Title:	
	The optimisation and implementation of intervention	s to change health-related behaviours
3	Type of Amendment/s (tick as appropriate)	
	Research procedure/protocol (including research instrum Participant group Sponsorship/collaborators	
	Extension to approval needed (extensions are given for one Information Sheet/s x Consent form/s x Other recruitment documents	year)
	Other	
	Please specify:	
4	Justification (give the reasons why the amendment/s ar	
	This amendment is an extension of Work Package 3 interventions') in the original research project to include and therefore alcohol reduction interventions. In line with the approved proposal, the current study has for new digital alcohol reduction interventions, ii) to confeatures and iii) to estimate effectiveness of different feat. This extension falls within the original application for 'The to change health-related behaviours' though the third wo behaviour, that of smoking. This amendment will inconsumption. The main aim of Work Package 3 will still the project to include the same and the consumption.	the health-related behaviour, alcohol consumption, following aims: i) to identify highest priority features and uct user-testing with early prototype of these ares of digital alcohol reduction interventions. The eoptimization and implementation of interventions are package refers specifically to one health-related include the health-related behaviour of alcohol.
	digital interventions according to MOST'.	and the second s
	Details of Amendments (provide full details of each ame have been made and attach all amended and new docum	
5	We have developed Drink Less, an evidence-based application to help people reduce excessive alcohol consula goal related to reducing their alcohol consumption. The which information and advice relating to the health effects in alcohol reduction, self-monitoring of daily alcohol consuplanning, and feedback (both in relation to their goals and	amption. The intervention facilitates users choosing app was designed around intervention modules, in of excessive alcohol consumption, identity change amption, cognitive bias modification training, action
	To evaluate the effectiveness of individual intervention mo will recruit enough participants for 80% power to detect the	

which will be the difference in AUDIT score between baseline and a 3-month follow up and low-level interaction effects between intervention modules. This study will be powered ambitiously though in the event of a shortfall in recruitment, we will use a Bayesian analysis to detect more subtle effect sizes.

In addition, face-to-face usability testing will be carried which will provide meaningful insight into the usability of the app and the usefulness of the modules.

Participants will be recruited through self-selection by downloading the app from iTunes, free of charge. In addition, the app will be advertised online, and posters about the study will be displayed. Informed consent will be obtained from each participant. The participant will be asked to provide their email address. If given, the participant will be included in the trial and be sent the 3-month follow-up questionnaire.

Participants will be eligible for inclusion, if they are age 18 and over and score more than 8 on the AUDIT questionnaire.

Ethical Considerations (insert details of any ethical issues raised by the proposed amendment/s; in the case of adding a new researcher, please confirm in writing that you have discussed ethical issues of the project with this researcher and that you have taken them through the risk assessment form for the project, which they have signed)

Participants will be recruited remotely through online adverts. Participants on giving consent and providing their email address for the study will be entered into a prize draw for a gift voucher of a nominal value. The consent form and information sheet have been edited as users are even less likely to read long detailed information on an app screen than on an information sheet meaning it is essential to have a short and concise information sheet and consent form.

7 Other Information (provide any other information which you believe should be taken into account during ethical review of the proposed changes)

Participants will participate on a fully voluntary basis.

Declaration (to be signed by the Principal Researcher)

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendments to be implemented.

Approved 31/10/14 TAKE CETTE Ethio Chair.

Amendment Approval Request Form

Project ID Number: Name and e-mail address of Princip Investigator:	_	_		
Research Department of Clinical, Educational and Health Psychology 1-19 Torrington Place London, WC1E 7HB 2 Project Title: The optimisation and implementation of Interventions to change health-related behaviours 3 Type of Amendment/s (tick as appropriate) Research procedure/protocol (including research instruments) Participant group Participant group Sponsorship/collaborators Extension to approval needed (extensions are given for one year) Information Sheet/s Consent form/s Other Please specify: 4 Justiffication (give the reasons why the amendment/s are needed): This is an additional amendment to the approved extension of Work Package 3 (approved 31/10/2014). one-month follow-up is often used in alcohol Intervention trials and we have increased the value of the g vocucher to improve initial reference rates. Details of Amendments (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation) In the trial to evaluate the effectiveness of intervention modules in a factorial RCT, the follow-up will be conducted at one-month. Participants on giving consent and providing their email address for the study will be entered into a prid draw for a gift voucher of a sizeable value to encourage participants to take part. Ethical Considerations (insert details of any ethical issues raised by the proposed amendment/s; in the case of adding a new researcher, please confirm in writing that you have discussed ethical issues of the project with this researcher and that you have taken them through the risk assessment form for the project with this researcher and that you have taken them through the risk assessment form for the project within the properties of the project with this researcher and that you have taken them through the risk assessment form for the project with this researcher and that you have taken them through the risk assessment form for the project within the properties of the project with the researcher and that it would be reasonable f		1	Project ID Number:	Name and e-mail address of Principal Investigator:
The optimisation and implementation of interventions to change health-related behaviours Type of Amendment/s (tick as appropriate) Research procedure/protocol (including research instruments) Participant group			CEHP/2013/508	Research Department of Clinical, Educational and Health Psychology 1-19 Torrington Place
3 Type of Amendment/s (tick as appropriate) Research procedure/protocol (including research instruments) Participant group Sponsorship/collaborators Extension to approval needed (extensions are given for one year) Consent form/s Other recruitment documents Other recruitment documents Other recruitment documents Other please specify: 4 Justification (give the reasons why the amendment/s are needed): This is an additional amendment to the approved extension of Work Package 3 (approved 31/10/2014). one-month follow-up is often used in alcohol intervention trials and we have increased the value of the groundher to improve initial retention rates. Details of Amendments (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation) 5 In the trial to evaluate the effectiveness of intervention modules in a factorial RCT, the follow-up will be conducted at one-month. Participants on giving consent and providing their email address for the study will be entered into a prize draw for a gift voucher of a sizeable value to encourage participants to take part. Ethical Considerations (insert details of any ethical issues raised by the proposed amendment/s; in the case of adding a new researcher, please confirm in writing that you have discussed ethical issues of the project with this researcher and that you have taken them through the risk assessment form for the project which they have signed). No additional ethical considerations 7 Other Information (provide any other information which you believe should be taken into account during ethical review of the proposed changes) Claire Garnett and David Crane are both researchers associated with this project. Declaration (to be signed by the Principal Researcher) • Loonfirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it. • Loonsider that it would be reasonable for the proposed amendments to be implemented.	L	2	Project Title:	
Research procedure/protocol (including research instruments) Participant group Sponsorship/collaborators Extension to approval needed (extensions are given for one year) Information Sheet/s Consent form/s Other recruitment documents Other please specify: 4 Justification (give the reasons why the amendment/s are needed): This is an additional amendment to the approved extension of Work Package 3 (approved 31/10/2014). one-month follow-up is often used in alcohol intervention trials and we have increased the value of the groupher to improve initial retention rates. Details of Amendments (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation) 5 In the trial to evaluate the effectiveness of intervention modules in a factorial RCT, the follow-up will be conducted at one-month. Participants on giving consent and providing their email address for the study will be entered into a priz draw for a gift voucher of a sizeable value to encourage participants to take part. Ethical Considerations (insert details of any ethical issues raised by the proposed amendment/s; in the case of adding a new researcher, please confirm in writing that you have discussed ethical issues of the project with this researcher and that you have taken them through the risk assessment form for the project which they have signed). No additional ethical considerations 7 Other Information (provide any other information which you believe should be taken into account during ethical review of the proposed changes) Claire Garnett and David Crane are both researchers associated with this project. Declaration (to be signed by the Principal Researcher) • I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it. • I consider that it would be reasonable for the proposed amendments	Ĺ		The optimisation and implementation of interventions	to change health-related behaviours
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Other recruitment documents Other Please specify: 4 Justification (give the reasons why the amendment/s are needed): This is an additional amendment to the approved extension of Work Package 3 (approved 31/10/2014). one-month follow-up is often used in alcohol intervention trials and we have increased the value of the groucher to improve initial retention rates. Details of Amendments (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation) 5 In the trial to evaluate the effectiveness of intervention modules in a factorial RCT, the follow-up will be conducted at one-month. Participants on giving consent and providing their email address for the study will be entered into a prize draw for a gift voucher of a sizeable value to encourage participants to take part. Ethical Considerations (insert details of any ethical issues raised by the proposed amendment/s; in the case of adding a new researcher, please confirm in writing that you have discussed ethical issues of the project with this researcher and that you have taken them through the risk assessment form for the project which they have signed). No additional ethical considerations 7 Other Information (provide any other information which you believe should be taken into account during ethical review of the proposed changes) Claire Garnett and David Crane are both researchers associated with this project. Declaration (to be signed by the Principal Researcher) • I consider that it would be reasonable for the proposed amendments to be implemented. Signature:			Extension to approval needed (extensions are given for one y	voar)
Please specify: Justification (give the reasons why the amendment/s are needed): This is an additional amendment to the approved extension of Work Package 3 (approved 31/10/2014). one-month follow-up is often used in alcohol intervention trials and we have increased the value of the groucher to improve initial retention rates. Details of Amendments (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation) In the trial to evaluate the effectiveness of intervention modules in a factorial RCT, the follow-up will be conducted at one-month. Participants on giving consent and providing their email address for the study will be entered into a prix draw for a gift voucher of a sizeable value to encourage participants to take part. Ethical Considerations (insert details of any ethical issues raised by the proposed amendment/s; in the case of adding a new researcher, please confirm in writing that you have discussed ethical issues of the project with this researcher and that you have taken them through the risk assessment form for the project which they have signed). No additional ethical considerations Other Information (provide any other information which you believe should be taken into account during ethical review of the proposed changes) Claire Garnett and David Crane are both researchers associated with this project. Declaration (to be signed by the Principal Researcher) I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it. I consider that it would be reasonable for the proposed amendments to be implemented.				
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Appendix 19: Details of normative misperceptions scores for participants (Study 5): measures and results

Measures:

Normative perceptions about alcohol use were assessed by two questions: "How do you think your drinking compares with others in the UK?" and "How do you think your drinking compares with other [men/women] aged [16-24/25-34/35-44/45-54/55-64/65+]"

Participants moved a dial on a gauge to indicate their response which was categorised into nine options: lowest 10%; very low; low; low-average; average (middle 20%); high-average; high; very high; top 10%. This was recorded in the app as an exact percentile. The normative misperception score was calculated as the difference between each user's actual percentile and their belief percentile (normative perception). The normative misperception score could range from -100 to +100. A positive score indicates an individual underestimated their alcohol use compared with others whilst a negative score corresponds to an overestimation. The magnitude of the normative misperception score corresponds to the extent of discrepancy between the individual's actual and perceived position in the population.

Results:

The average normative misperception score for participants comparing themselves with the rest of the UK was 33.9 (SD=15.30) and comparing themselves with the relevant age/gender group was 34.6 (SD=15.92). Participants, on average, significantly underestimated their own alcohol consumption relative to others in the UK (t=57.404, p<0.001) and others of their age group and gender (t=56.252, p<0.001).

Appendix 20: Full results of all main and interactive effects in factorial ANOVA on the primary outcome measure (change in past week alcohol consumption) (Study 5)

	F	p-value	
Normative feedback (NF)	0.297	0.586	
Cognitive bias re-training (CBR)	0.393	0.531	
Identity change (IC)	2.160	0.142	
Self-monitoring & feedback (SM)	0.781	0.377	
Action planning (AP)	0.135	0.714	
NF x CBR	4.676	0.031	
NF x IC	0.814	0.367	
NF x SM	2.199	0.139	
NF x AP	0.081	0.776	
CBR x IC	0.939	0.333	
CBR x SM	2.799	0.095	
CBR x AP	0.007	0.933	
IC x SM	0.385	0.535	
IC x AP	0.042	0.837	
SM x AP	0.220	0.639	
NF x CBR x IC	1.864	0.173	
NF x CBR x SM	0.025	0.874	
NF x CBR x AP	4.943	0.027	
NF x IC x SM	0.025	0.874	
NF x IC x AP	0.290	0.590	
NF x SM x AP	0.139	0.710	
CBR x IC x SM	0.003	0.958	
CBR x IC x AP	0.283	0.595	
CBR x SM x AP	2.680	0.102	
IC x SM x AP	0.516	0.473	
NF x CBR x IC x SM	1.081	0.299	
NF x CBR x IC x AP	0.007	0.931	
NF x CBR x SM x AP	0.494	0.482	
NF x IC x SM x AP	0.053	0.817	
CBR x IC x SM x AP	0.852	0.356	
NF x CBR x IC x SM x AP	0.121	0.728	

Appendix 21: Sensitivity analysis on primary outcome measure (change in past week alcohol consumption): main effects of intervention modules among responders-only (Study 5)

		ean change in past week alcohol F		
	consumption, units per week (SD) Intensive Minimal			
Normative feedback	-14.1 (25.07)	-14.6 (23.03)	0.120	0.729
Cognitive bias re-training	-16.0 (23.73)	-12.7 (24.47)	0.128	0.721
Identity change	-10.8 (23.17)	-18.2 (24.65)	4.261	0.041
Self-monitoring & feedback	-14.8 (21.57)	-13.7 (26.92)	0.051	0.821
Action planning	-13.9 (20.87)	-14.6 (26.92)	0.015	0.902

Appendix 22: Full results of all main and interactive effects in factorial ANOVA on secondary outcome measures – change in AUDIT score and usage data (Study 5)

	AUDIT score		Number o	of sessions	Length per session	
	F	p-value	F	p-value	F	p-value
Normative feedback (NF)	1.600	0.206	1.643	0.200	1.359	0.244
Cognitive bias re-training (CBR)	0.105	0.746	0.051	0.821	0.044	0.833
Identity change (IC)	0.087	0.769	0.855	0.356	1.736	0.188
Self-monitoring (SM)	0.346	0.557	12.728	< 0.001	< 0.001	0.993
Action planning (AP)	1.752	0.186	0.167	0.683	1.785	0.182
NF x CBR	1.455	0.228	0.404	0.525	1.229	0.268
NF x IC	0.222	0.638	2.328	0.128	1.428	0.232
NF x SM	0.779	0.378	0.919	0.338	2.064	0.151
NF x AP	1.185	0.277	2.486	0.115	0.096	0.757
CBR x IC	0.280	0.597	0.144	0.704	3.514	0.061
CBR x SM	0.498	0.480	0.243	0.622	0.001	0.975
CBR x AP	1.600	0.206	0.261	0.610	0.158	0.691
IC x SM	0.458	0.499	0.002	0.964	0.931	0.335
IC x AP	2.340	0.127	0.191	0.662	0.545	0.461
SM x AP	5.818	0.016	0.031	0.860	0.140	0.708
NF x CBR x IC	0.014	0.906	0.855	0.356	1.570	0.211
NF x CBR x SM	0.031	0.860	< 0.001	0.995	0.956	0.328
NF x CBR x AP	0.070	0.791	0.124	0.725	0.004	0.948
NF x IC x SM	0.195	0.659	0.124	0.725	0.763	0.383
NF x IC x AP	0.031	0.860	0.278	0.598	2.615	0.106
NF x SM x AP	1.385	0.240	6.371	0.012	2.999	0.084
CBR x IC x SM	0.022	0.883	0.544	0.461	0.055	0.815
CBR x IC x AP	0.087	0.769	1.807	0.179	0.063	0.801
CBR x SM x AP	0.346	0.557	0.604	0.437	0.086	0.770
IC x SM x AP	0.541	0.462	2.934	0.087	3.848	0.050
NF x CBR x IC x SM	1.060	0.304	5.729	0.017	0.402	0.526
NF x CBR x IC x AP	1.994	0.158	1.198	0.274	0.032	0.858
NF x CBR x SM x AP	0.031	0.860	0.290	0.590	0.316	0.574
NF x IC x SM x AP	0.195	0.659	0.013	0.910	0.809	0.369
CBR x IC x SM x AP	0.541	0.462	0.479	0.489	0.015	0.902
NF x CBR x IC x SM x AP	0.312	0.576	0.238	0.626	0.080	0.778

Appendix 23: Sensitivity analysis on secondary outcome measure - change in AUDIT score: main effects of intervention modules among responders only (Study 5)

Mean change ir	n AUDIT score (SD)	F	p-value	
Intensive	Minimal	-		
-3.1 (4.34)	-2.7 (4.77)	0.693	0.407	
-3.2 (3.94)	-2.6 (5.01)	0.281	0.597	
-2.6 (4.72)	-3.2 (4.31)	1.016	0.315	
-2.8 (4.41)	-3.0 (4.70)	0.041	0.839	
-3.5 (4.51)	-2.3 (4.49)	2.667	0.105	
	Intensive -3.1 (4.34) -3.2 (3.94) -2.6 (4.72) -2.8 (4.41)	-3.1 (4.34) -2.7 (4.77) -3.2 (3.94) -2.6 (5.01) -2.6 (4.72) -3.2 (4.31) -2.8 (4.41) -3.0 (4.70)	Intensive Minimal -3.1 (4.34) -2.7 (4.77) 0.693 -3.2 (3.94) -2.6 (5.01) 0.281 -2.6 (4.72) -3.2 (4.31) 1.016 -2.8 (4.41) -3.0 (4.70) 0.041	

Appendix 24: Details of usage data for "Yes please, no thanks" game (Study 5): measures and results

Measures:

Measures relating to the "Yes please, no thanks" game in the cognitive bias re-training intervention module were collected from the app. Data were recorded for the number of times a user played and their score for each game. The score was calculated as the number of successful trials minus twice the errors made.

Results:

The descriptive statistics of the "Yes please, no thanks" game in the cognitive bias re-training intervention module are reported in the table below. Participants played the game a mean of 1.9 times (SD=4.01) and there was no difference in the number of times played between versions (t=0.385, p=0.701). The distribution of number of times the game was played was strongly positively skewed with 88% of users playing the game 3 times or less in the 28 day period after downloading the app.

The game was played at least once by 429 participants and, of these participants, the game was played a mean of 2.9 times (SD=4.70). The mean score of the participants who played the game at least once was 24.1 with the mean number of successes being 35.7 and the mean number of errors was 5.8. Of the participants who played the game at least once, 221 participants were in the intensive version and 207 were in the minimal version. Participants in the intensive version who played the game at least once had a significantly higher average score than participants in the minimal version (t=-6.927, p<0.001) though there was no difference in the number of times the game was played (t=0.834, p=0.405). Participants in the intensive version had both significantly more successes (t=-5.337, p<0.001) and fewer errors (t=6.462, p<0.001).

Descriptive statistics of "Yes please, no thanks" game in cognitive bias re-training module

	Mean (SD)	Range	Cognitive bias re-training		t	p-value
		(min,	module, mean (SD)			
		max)				
			Intensive	Minimal	_	
Number of	1.9 (4.01)	1, 62	1.8 (3.74)	1.9 (4.27)	0.385	0.701
times played						

Participants who played at least once						
Number of	2.9 (4.70)	1, 62	2.8 (4.32)	3.1 (5.09)	0.834	0.405
times played						
Average score	24.1	-42.0, 65.7	31.3	16.4	-6.927	< 0.001
	(23.48)		(18.98)	(25.34)		
Average	35.7	0, 68.5	38.9	32.2	-5.337	< 0.001
successes	(13.45)		(12.61)	(13.48)		
Average	5.8 (6.86)	0, 31.5	3.8 (5.27)	7.9 (7.70)	6.462	< 0.001
errors						

Appendix 25: Full results of all main and interactive effects in factorial ANOVA on secondary outcome measure – usability ratings (Study 5)

	Helpfuln	ess	Ease of u	ise	Recomm	endation	Satisfaction	on
	N=182		N=178		N=178		N=178	
	F	p-value	F	p-value	F	p-value	F	p-value
Normative	0.015	0.903	0.723	0.397	0.282	0.596	0.167	0.683
feedback (NF)								
Cognitive bias re-	0.031	0.861	0.217	0.642	1.071	0.302	0.031	0.860
training (CBR)								
Identity change	0.174	0.677	0.020	0.886	0.399	0.529	0.003	0.953
(IC)								
Self-monitoring &	4.388	0.038	1.109	0.294	5.023	0.027	6.598	0.011
feedback (SM)								
Action planning	0.007	0.932	0.473	0.493	0.330	0.566	1.298	0.256
(AP)								
NF x CBR	0.422	0.517	3.813	0.053	0.023	0.880	0.092	0.762
NF x IC	2.515	0.115	0.490	0.485	0.035	0.851	0.207	0.650
NF x SM	0.134	0.715	0.012	0.913	0.011	0.915	0.017	0.895
NF x AP	0.075	0.785	1.605	0.207	3.105	0.080	1.579	0.211
CBR x IC	0.726	0.395	< 0.001	0.995	0.079	0.779	0.021	0.885
CBR x SM	0.328	0.568	0.216	0.642	0.001	0.982	0.285	0.594
CBR x AP	0.025	0.873	< 0.001	0.989	0.014	0.905	0.052	0.821
IC x SM	< 0.001	0.998	0.336	0.563	0.138	0.711	0.003	0.959
IC x AP	0.009	0.925	0.214	0.644	0.005	0.944	0.003	0.958
SM x AP	0.117	0.733	0.631	0.428	0.202	0.654	0.053	0.818
NF x CBR x IC	0.180	0.672	0.677	0.412	0.249	0.618	0.109	0.742
NF x CBR x SM	1.299	0.256	1.117	0.292	0.149	0.700	0.520	0.472
NF x CBR x AP	0.928	0.337	0.513	0.475	0.876	0.351	0.153	0.696
NF x IC x SM	0.657	0.419	2.637	0.107	1.391	0.240	3.098	0.080
NF x IC x AP	1.921	0.168	0.190	0.664	1.128	0.290	0.003	0.954
NF x SM x AP	1.395	0.239	1.587	0.210	< 0.001	0.995	0.001	0.980
CBR x IC x SM	0.650	0.421	0.222	0.638	0.067	0.796	0.489	0.485
CBR x IC x AP	0.268	0.605	0.033	0.857	0.050	0.824	0.001	0.974
CBR x SM x AP	1.433	0.233	0.705	0.402	0.093	0.760	0.384	0.536
IC x SM x AP	8.439	0.004	2.495	0.116	3.605	0.060	10.621	0.001
NF x CBR x IC x	0.660	0.418	0.172	0.679	0.130	0.719	0.152	0.697

SM								
NF x CBR x IC x	2.315	0.130	0.426	0.515	3.373	0.068	0.480	0.490
AP								
NF x CBR x SM x	0.083	0.774	0.025	0.876	0.276	0.600	0.578	0.448
AP								
NF x IC x SM x AP	2.643	0.106	0.827	0.365	1.096	0.297	3.991	0.048
CBR x IC x SM x	0.626	0.430	0.371	0.543	1.528	0.218	0.945	0.333
AP								
NF x CBR x IC x	0.301	0.584	0.878	0.350	2.470	0.118	1.065	0.304
SM x AP								

Appendix 26: Results table for unregistered analysis – effect of overall app intensity on outcome measures (Study 5)

Outcome measure	N	Mean score (SD))	F	p	
		High intensity	Low intensity	_		
Change in past week	252	-4.3 (13.50)	-4.4 (16.49)	0.002	0.961	
alcohol consumption,						
units per week						
Change in AUDIT score	252	-1.0 (2.41)	-0.5 (2.58)	2.601	0.108	
Number of sessions	252	13.4 (14.46)	9.8 (13.14)	4.210	0.041	
Length of time per	252	4:35 (4:20)	3:44 (2:27)	3.832	0.051	
session						
Helpfulness rating	64	3.1 (0.97)	2.8 (1.08)	1.695	0.198	
		N=36	N=28			
Ease of use rating	62	3.5 (0.99)	3.4 (1.10)	0.025	0.875	
		N=34	N=28			
Recommendation	62	3.1 (1.23)	2.6 (1.26)	2.360	0.130	
rating		N=34	N=28			
Satisfaction rating	62	3.4 (0.95)	2.8 (1.06)	4.347	0.041	
		N=34	N=28			