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[Intervention Protocol]

Personalised digital interventions for reducing hazardous and harmful alcohol consumption in community-dwelling populations

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The main objective is to assess the effectiveness and cost effectiveness of digital interventions for reducing hazardous and harmful alcohol consumption and/or alcohol-related problems in community-dwelling populations.

We envisage two comparator groups: (1) no intervention (or minimal input) controls; and (2) another active intervention for delivering preventive advice or counselling to reduce hazardous or harmful alcohol consumption. Specifically, we will address two questions: (1) Are digital interventions superior to no intervention (or minimal input) controls? This question is important for individuals accessing interventions through their own motivation or interest. These individuals will be unlikely to experience active practitioner input and it is important to understand whether digital interventions are better than general material they might seek out on the internet or via mobile phone-based apps etc. (2) Are digital interventions at least equally effective as face-to-face brief alcohol interventions? Practitioner delivered brief interventions are generally accepted to be the best alternative in secondary preventive care in health, workplace, educational or community settings. However, time constraints can impede face-to-face delivery of such interventions and it is important to know whether digitally provided input can yield comparable effects to interventions delivered by trained practitioners. We will also identify the most effective component behaviour change techniques of such interventions and their mechanisms of action.

Secondary objectives are as follows:

1. To assess whether outcomes differ between trials where the digital intervention targets participants attending health, social care, education or other community-based settings and those where it is offered remotely via the internet or mobile phone platforms;
2. To develop a taxonomy of interventions according to their mode of delivery (e.g. functionality features) and assess their impact on outcomes;
3. To identify theories or models that have been used in the development and/or evaluation of the intervention - this will inform intervention development work.

Personalised digital interventions for reducing hazardous and harmful alcohol consumption in community-dwelling populations (Protocol)

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BACKGROUND

Description of the condition

Excessive drinking contributes significantly to physical and psychological illness, injury and death and a wide array of social harm in all age groups (WHO 2011). Contributing to over 60 types of diseases, alcohol drinking is the leading risk factor worldwide for disease burden in middle-income countries; it is second only to tobacco use in high-income countries, and third after childhood underweight and unsafe sex in low-income countries. As well as the direct harms to health, 20% of deaths due to road traffic accidents, 30% of deaths caused by oesophageal and liver cancer, epilepsy and homicide, and 50% of all deaths caused by liver cirrhosis are attributable to alcohol (WHO 2009). Although drinking low amounts of alcohol has been shown to decrease the incidence of some diseases (particularly coronary heart disease in later life) and can have a positive social effect, the net effect of alcohol consumption is detrimental to health. The economic cost - including both health and social harm, such as property damage and domestic violence - relating to alcohol consumption tends to amount to more than 1% of gross domestic product in high- and middle-income countries (Rehm 2009).

People drinking hazardously display a repeated pattern of drinking above recommended limits and are at risk of (but not yet experiencing) physical or psychological harm, whilst those drinking harmfully are drinking above recommended limits and currently experiencing harms (WHO 1992). Hazardous or harmful patterns of alcohol consumption can involve either regular exceeding of consumption guidelines, or more infrequent but high volume binge drinking. People exhibiting hazardous or harmful drinking are more numerous than those with alcohol dependence (e.g. McManus 2009 in the United Kingdom (UK)), and at a population level the greatest impact on alcohol-related problems can be made by addressing interventions towards the former groups (McGovern 2013).

Description of the intervention

A proven strategy for reducing excessive alcohol consumption levels across the population is to offer a brief intervention in primary care provided by general practitioners, nurses or other generalist health professionals; a Cochrane review incorporating a meta-analysis of 22 randomised clinical trials found that face to face brief interventions in primary care settings were consistently effective at reducing excessive drinking, producing an average reduction of 38 grams or 4 to 5 standard drink units per week (Kaner 2007). These interventions typically comprise a conversation of anywhere between 5 and 45 minutes, include an initial screening process to identify individuals who are experiencing alcohol related risk or harm, provide personalised feedback on alcohol use

and harms, identify high risk situations for drinking and coping strategies, suggest strategies to increase motivation for positive behaviour change, and develop a personal plan to reduce drinking. Face to face brief interventions delivered by health professionals have been in use for decades (O'Donnell 2013), but more recently technological innovations have allowed people to interact directly via their computer, mobile device or smart phone with digital interventions designed to address problem alcohol consumption using some of the same ingredients (Khadjesari 2011).

How the intervention might work

Digital interventions for alcohol consumption include some of the same features as face to face interventions (e.g. personalised feedback, engaging the participant in creating coping strategies and goal-based plans) to motivate the participant to reduce their alcohol consumption over time.

Face to face brief interventions have been found to be effective on average (Kaner 2007), but various differences should be considered when translating these interventions to a digital medium:

- **Setting:** most of the cited evidence on face to face brief interventions (Kaner 2007) comes from primary care, although there is a growing literature on other health settings, such as general hospitals (McQueen 2011). However, screening for hazardous and harmful alcohol consumption may not reliably take place in busy healthcare settings or may not effectively identify all those with problems. Barriers to implementation of alcohol interventions (McAvoy 2001) include excessive drinkers not even attending primary care settings, and practitioners being too busy to engage in this work (Wilson 2011). Digital interventions have been proposed as a means of accessing 'hard to reach' groups outside health settings, and also of providing a cheaper alternative to interventions delivered within health settings (Kaner 2011).

- **Modality:** digital interventions differ considerably in their modality or delivery mechanism, which may present advantages and disadvantages. Some individuals may find disclosing excessive alcohol consumption easier if they feel anonymous but it is also possible that intervention outcomes may be due, at least in part, to therapist effects; greater outcome effects have been reported for physician delivery compared to other practitioners (Sullivan 2011). It is also plausible that a smart phone app which can be used anywhere and at any time at the owner's discretion may produce a different effect to a specific computer sited in a primary care practice, despite the actual content being very similar.

- **Timing:** published evidence suggests that alcohol intervention effects may decay over time for face to face brief interventions (Moyer 2002), which may also apply to digital interventions. Nevertheless, the scope for repeated intervention may potentiate initial effects. Whereas a face to face intervention

is often delivered as a one-off event (although there can be several sessions), digital interventions may be engaged with one-off or more frequently and regularly over an extended time period.

- Population: differences in effectiveness may arise for different population groups due to variations in enthusiasm for (e.g. technophilia versus technophobia) or access to technology, for example by age, gender, ethnicity, or socio-economic status.

Interventions aimed at reducing alcohol consumption are complex in that they are usually made up of several behaviour change techniques (BCTs) and may incorporate several stages. Most brief interventions incorporate a FRAMES approach which includes: giving Feedback on the person's intake, impressing the Responsibility for change onto them, offering Advice, listing a Menu of options, having Empathy, and building Self-efficacy (Miller 1994). In order to identify the 'active ingredients' within interventions, it is important to document the component BCTs using a reliable method. For example, an analysis of brief interventions, based on the trials in the aforementioned Cochrane review (Kaner 2007) and using a reliable taxonomy of BCTs, has recently identified self-monitoring as an effective component of these health promoting approaches (Michie 2012).

Modelling work based on published studies to date has suggested that a programme of face to face brief interventions rolled out in primary care would be cost effective compared to no programme, providing additional health benefits at reduced health service cost (Purshouse 2013). Little has yet been published on the cost effectiveness of digital alcohol interventions, although one study (Blankers 2012) suggests that internet-based therapy (including a therapist) is more cost-effective than internet self-help. A question remains on the relative cost effectiveness of digital versus face to face interventions.

Why it is important to do this review

A recent review of reviews (Kaner 2012) has identified a large and relatively well-designed research literature with around 35 published trials in this field (Carey 2009; Khadjesari 2011; Rooke 2010; White 2010). This body of work included the use of technology to deliver alcohol interventions in social care, education and other community-based settings as well as via the internet or mobile phone applications. This review will update previous reviews from a public health prevention perspective - it will focus on community-dwelling individuals who are not seeking formal treatment for alcohol-related problems but nonetheless are drinking at a level which may cause them risk or harm, who engage with any digitally delivered intervention designed to address alcohol consumption. We will not restrict by type of digital intervention so as to capture all interventions targeting this population, and so as to include interventions which take place on multiple platforms (for example text prompts to use smart phone apps). Interventions are an established part of public health policy (for example UK

Government 2012) and this is a fast-moving field, so it is crucial to keep the evidence base up to date.

OBJECTIVES

The main objective is to assess the effectiveness and cost effectiveness of digital interventions for reducing hazardous and harmful alcohol consumption and/or alcohol-related problems in community-dwelling populations.

We envisage two comparator groups: (1) no intervention (or minimal input) controls; and (2) another active intervention for delivering preventive advice or counselling to reduce hazardous or harmful alcohol consumption. Specifically, we will address two questions: (1) Are digital interventions superior to no intervention (or minimal input) controls? This question is important for individuals accessing interventions through their own motivation or interest. These individuals will be unlikely to experience active practitioner input and it is important to understand whether digital interventions are better than general material they might seek out on the internet or via mobile phone-based apps etc. (2) Are digital interventions at least equally effective as face-to-face brief alcohol interventions? Practitioner delivered brief interventions are generally accepted to be the best alternative in secondary preventive care in health, workplace, educational or community settings. However, time constraints can impede face-to-face delivery of such interventions and it is important to know whether digitally provided input can yield comparable effects to interventions delivered by trained practitioners. We will also identify the most effective component behaviour change techniques of such interventions and their mechanisms of action.

Secondary objectives are as follows:

1. To assess whether outcomes differ between trials where the digital intervention targets participants attending health, social care, education or other community-based settings and those where it is offered remotely via the internet or mobile phone platforms;
2. To develop a taxonomy of interventions according to their mode of delivery (e.g. functionality features) and assess their impact on outcomes;
3. To identify theories or models that have been used in the development and/or evaluation of the intervention - this will inform intervention development work.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials with individual, cluster, stepped wedge, and n-of-1 designs; initial scoping activity has identified a relatively large number of randomised controlled trials in this area.

Types of participants

Participants must be community-dwelling individuals who have personally sought out or been directed towards any digital intervention including web-based, mobile phone text messaging, smart phone apps, social networking, or 'stand alone' computer-based technologies (including CD-ROMs). Participants may be recruited in a range of settings, including primary health care (including emergency departments), social care, educational, workplace or community, and there is no restriction on where participants may interact with the intervention, given that it may be delivered through mobile devices. Recipients of interventions will have been identified by themselves, significant others or via a screening process as hazardous or harmful drinkers and/or have experienced problems as a result of their drinking behaviour.

Studies will be excluded if they are directed mainly towards people who are seeking specialist health or social care treatment for their alcohol consumption, or if they deliver the intervention in a secondary or tertiary care setting.

Types of interventions

- The intervention must be digital, defined as being delivered primarily through a programmable computer or mobile device (laptop, phone, or tablet), and must respond to user input and generate personalised content which aims to change the participants' alcohol-related behaviours. Interventions which do not generate feedback or other output based on the personal characteristics of the user will not be included (for example, generic educational interventions). Interventions are not restricted to those accessible online.

- The comparator condition may be no intervention, usual care (in a health or social care setting), or other digital or face to face brief intervention to reduce alcohol consumption or harm.

Types of outcome measures

Listed here are outcomes of interest; if a study contains none of these outcomes, it will be excluded. We will assess outcome on the basis of the behaviour change techniques (BCTs) incorporated in the interventions, their theoretical underpinning, and mechanisms of action as reported elsewhere (Webb 2010).

Primary outcomes

Many types of outcome measures are available in the alcohol literature. Our primary outcome will be quantity of alcohol consumed,

which may be reported in standard drinks, alcohol units or similar, and which we will convert into grams of alcohol. We will consider trials reporting outcomes at 1 month or more, but we will separate trials according to follow-up time: less than 6 months, 6 to 12 months, and more than 12 months.

Secondary outcomes

- Other measures of consumption (e.g. number of binge episodes, frequency of drinking occasions, number of participants exceeding limits as defined by study authors);
- Indices of alcohol-related harm or social problems to the drinkers or affected others;
- Cost effectiveness;
- Any reported adverse effects.

Search methods for identification of studies

The following sources of information will be used to capture studies for the review. The search will not be limited by publication status, language or date (some digital interventions, such as CD-ROMs, could go back decades).

Electronic searches

We will search the following databases. An example search strategy is given in Appendix 1.

- MEDLINE (Ovid) 1946 to present
- *The Cochrane Library* (Wiley) - including Drugs & Alcohol Group Specialised Register, CENTRAL (Cochrane Central Register of Controlled Trials), DARE (systematic reviews), HTA (health technology assessments)
- CINAHL (EBSCO) 1981 to present
- PsycINFO (Ovid) 1967 to present
- ERIC (EBSCO) 1966 to present
- SCI (Science Citation Index via Web of Knowledge) 1970 to present
- CPCI-S (Conference Proceedings via Web of Knowledge) 1990 to present
- Index to Theses
- Clinicaltrials.gov
- WHO International Clinical Trials Registry Platform (ICTRP)
- Google Scholar

We will also search relevant websites which are likely to contain evaluations of digital brief interventions, such as:

- International Alcohol Information Database (IAID) <http://www.drinksresearch.org/>
- Beacon 2.0 <https://beacon.anu.edu.au/>
- SAMHSA (Substance Abuse and Mental Health Services Administration)

- NREPP (National Registry of Evidence-based Programs and Practices) <http://nrepp.samhsa.gov/Index.aspx>
- Drug and Alcohol Findings <http://findings.org.uk/>

Searching other resources

We will check reference lists of all included studies and relevant reviews, carry out citation searches for included studies, and consult experts to confirm nothing has been missed.

Data collection and analysis

Selection of studies

Two researchers will independently screen all titles and abstracts identified, using Endnote to ensure consistency in screening approach. The full research papers of any studies identified as being potentially eligible will be reviewed by two researchers independently. Any discrepancies will be resolved by discussion and by consulting a third researcher if necessary to reach consensus. A kappa statistic will be calculated at each stage to assess agreement between researchers.

Data extraction and management

A standardised data extraction form will be developed and piloted. This will be used by two researchers independently to carry out data extraction of all included studies. Discrepancies between researchers will be resolved by a third researcher. Relevant data pertaining to patient and intervention characteristics (including mode of delivery and costs), sample sizes, outcome measures (including standard deviations or related measures of variability), and trial characteristics which allow quality assessment will be extracted from included studies onto the piloted data extraction form.

In order to identify the 'active ingredients' within interventions, we will code all interventions in terms of their component BCTs using a reliable taxonomy developed for specifying the content of brief interventions for excessive alcohol use (Michie 2012).

The mechanisms of action by which interventions have their effect will be investigated by documenting theories cited by authors as informing the interventions. Both the name of the theory and the extent to which it has been applied in designing or evaluating the intervention will be documented, and the latter will be investigated using the 19-item Theory Coding Scheme (Michie 2010). This specifies theory use in six areas: reference to underpinning theory, targeting of relevant theoretical constructs, using theory to select recipients or tailor interventions, measurement of constructs, testing of mediation effects and refining theory. This will not only illustrate the extent to which theory is applied but also associations between type of theory and theory use and the effectiveness of the intervention (its usefulness has been demonstrated in, for example, a meta-analysis investigating this in interventions

aimed at increasing physical activity and healthy eating, which found weak relationships between theory type and use and effectiveness (Prestwich 2013)). The findings from this analysis can be used to improve future interventions through a better understanding of the mechanisms of action and theoretical frameworks used in effective interventions.

Assessment of risk of bias in included studies

Methodological quality will be assessed independently by two researchers using the criteria recommended in the *Cochrane Handbook* (Higgins 2011). The recommended approach for assessing risk of bias in studies included in Cochrane reviews is a two-part tool, addressing seven specific domains, namely sequence generation and allocation concealment (selection bias), blinding of participants and providers (performance bias), blinding of outcome assessor (detection bias), incomplete outcome data (attrition bias), selective outcome reporting (reporting bias), and other sources of bias. The first part of the tool involves describing what was reported to have happened in the study. The second part of the tool involves assigning a judgement relating to the risk of bias for that entry, in terms of low, high or unclear risk. To make these judgements we will use the criteria indicated by the *Handbook* adapted to the addiction field (see [Appendix 2](#) for details).

The domains of sequence generation and allocation concealment (avoidance of selection bias) will be addressed in the tool by a single entry for each study. Blinding of participants, personnel and outcome assessor (avoidance of performance bias and detection bias) will be considered separately for objective outcomes (e.g. drop out, use of substance of abuse measured by urine analysis, subjects relapsed at the end of follow-up, subjects engaged in further treatments) and subjective outcomes (e.g. duration and severity of signs and symptoms of withdrawal, patient self-reported use of substance, side effects, social functioning as integration at school or at work, family relationship). Incomplete outcome data (avoidance of attrition bias) will be considered for all outcomes except for the drop out from the treatment, which is very often the primary outcome measure in trials on addiction.

'Risk of bias' assessments will be used to carry out sensitivity analyses (see [Sensitivity analysis](#)).

Measures of treatment effect

In the outcome assessment, for continuous variable outcomes (e.g. quantity of alcohol consumed) we will compare mean differences, and for dichotomous outcomes (e.g. participants classified as binge drinker, or drinking over set limits) we will compare proportions using relative risks. Where outcomes have been assessed at more than one time, data for each time point will be extracted. Attention is likely to be focused on outcomes at 6 months and 12 months post-intervention, although this may depend on the number of trials that have reported data at these times.

Unit of analysis issues

For trials with more than one - and very similar - control arms, the results for these arms will be combined in the meta-analysis. The same approach will be used for very similar treatment arms. If all arms in a multi-arm trial are to be included in the meta-analysis and one treatment arm is to be included more than once in some comparisons, then we will divide the number of events and the number of participants in that arm by the number of treatment comparisons made. This method avoids the multiple use of participants in the pooled estimate of treatment effect while retaining information from each arm of the trial. It compromises the precision of the pooled estimate slightly.

Cluster randomised trials will be eligible for inclusion in the meta-analysis. If the analysis in a trial report accounts for the cluster design, we will assign imputed standard deviations to the treatment and control groups such that the standard error of the treatment effect estimated by the weighted mean difference method in RevMan is the same as the standard error of the treatment effect as reported in analysis which allowed for clustering. If the analysis in a trial report does not account for the cluster design, we will add an external estimate of the intra-cluster coefficient (ICC) to estimate a design effect, thus inflating the variance of the effect estimate. Then we can enter the data into RevMan and combine the cluster randomised trials with individually randomised trials in the same meta-analysis.

Dealing with missing data

We will contact authors to try to obtain missing data. Where this is impossible, we will attempt to estimate primary outcome measures using secondary outcome measures; for example, estimating quantity of alcohol consumed using frequency and intensity of consumption. Trials with missing standard deviations will be excluded from the main analysis for the associated continuous measure, but may be included in a sensitivity analysis, using imputed values for the standard deviations.

Assessment of heterogeneity

The magnitude of heterogeneity will be assessed using the I^2 statistic, and the statistical significance of the heterogeneity will be assessed using P values derived from Chi^2 tests (Deeks 2001). Heterogeneity will be explored both narratively and using subgroup and sensitivity analyses. Clinical heterogeneity is likely, due not only to the variation in delivery methods but to aspects of content.

Assessment of reporting biases

We will note whether studies appear to have incomplete reporting bias. We will have made every effort to minimise publication bias by searching a wide range of databases and sources of grey literature and not restricting by language or publication status, but we will

use funnel plots to assess the potential for bias related to the size of the trials, which may indicate publication bias.

Data synthesis

If studies are sufficiently homogeneous to enable meta-analysis, we will pool the data for each outcome using a random-effects model in a meta-analysis that compares intervention and control arms, using mean differences for continuous variables and relative risks for dichotomous outcomes. The meta-analysis will be performed using RevMan. If meta-analysis is not feasible we will carry out a narrative summary of studies.

Where possible, analysis will consider key population groups such as men versus women, older versus younger, and different socio-economic groups.

We will estimate long-term cost-effectiveness of strategies for the use of internet, mobile phone text messaging, smart phone app interventions or computer-based technologies if data allow, by adapting the current Sheffield Alcohol Policy Model (SAPM) analysis of screening and brief interventions, which was developed to inform National Institute for Health and Care Excellence (NICE) public health guidance for England.

If there are sufficient data for analysis we can identify effective BCTs using meta-regression and theoretical combinations of BCTs using Classification and Regression Trees. This will help to identify the mechanisms of action of effective interventions to inform future development of interventions.

Subgroup analysis and investigation of heterogeneity

If there are sufficient studies, subgroup analyses will be carried out based on:

- Intervention modality (functionality and setting): to capture potential differences caused by different delivery mechanisms and settings for the intervention outside of the actual content of the intervention;
- Timing of outcomes (intermediate versus delayed): to investigate possible delay over time;
- Component BCTs (Michie 2012) as a comparison for face to face brief interventions;
- Theoretical basis of the interventions;
- Key population subgroups, such as age, gender, ethnicity, and socio-economic status.

Sensitivity analysis

We will conduct sensitivity analyses by investigating the effect of omitting studies with a high risk of bias.

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* Indicates the major publication for the study

APPENDICES**Appendix I. MEDLINE search strategy**

Proposed search strategy developed on MEDLINE (via OVID)

#	Searches
1	exp Alcohol-Related Disorders/
2	exp Alcohol Drinking/
3	(alcohol\$ adj2 (drink\$ or intoxicat\$ or use\$ or abus\$ or misus\$ or risk\$ or consum\$ or withdraw\$ or detox\$ or treat\$ or therap\$ or excess\$ or reduc\$ or cessation or intervention\$)).tw
4	(drink\$ adj2 (excess or heavy or heavily or harm or harmful or hazard\$ or binge or harmful or problem\$)).tw

(Continued)

5	("alcohol use" or alcoholic\$.tw.
6	or/1-5
7	Internet/
8	Blogging/
9	Social Media/
10	Computers/
11	exp Microcomputers/
12	Minicomputers/
13	Therapy, Computer-Assisted/
14	Computer-Assisted Instruction/
15	exp Cellular Phone/
16	Electronic Mail/
17	((email\$ or e-mail\$ or electronic mail\$ or text messag\$ or SMS or MMS or phone? or cellphone? or cell-phone? or smartphone? or smart-phone? or digital tablet? or pda or personal digital assistant? or social media or social networking or facebook or twitter or skype\$ or app?) adj3 (deliver\$ or generat\$ or based or provid\$ or facilitat\$ or support\$ or treatment? or therap\$ or intervention? or program\$ or feedback)).ti,ab
18	((Internet\$ or electronic\$ or digital\$ or technolog\$ or online or on-line or computer\$ or laptop? or software or web\$ or weblog\$ or blog\$ or CD? or CD-ROM?) adj3 (deliver\$ or generat\$ or based or provid\$ or facilitat\$ or support\$ or treatment? or therap\$ or intervention? or program\$ or feedback)).ti,ab
19	(e-BI or e-SBI or ehealth or e-health or electronic health or mhealth or m-health or mobile health or virtual health or digital health or technological aid?).ti,ab
20	or/7-19
21	6 and 20

Appendix 2. Criteria for 'Risk of bias' assessment in RCTs, CCTs and prospective observational studies

Item	Judgment	Description
1. Random sequence generation (selection bias)	Low risk	The investigators describe a random component in the sequence generation process such as: random number table; computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots; minimisation
	High risk	The investigators describe a non-random component in the sequence generation process such as: odd or even date of birth; date (or day) of admission; hospital or clinic record number; alternation; judgement of the clinician; results of a laboratory test or a series of tests; availability of the intervention Observational prospective study.
	Unclear risk	Insufficient information to permit judgement of low or high risk
2. Allocation concealment (selection bias)	Low risk	Investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based, and pharmacy-controlled, randomisation); sequentially numbered drug containers of identical appearance; sequentially numbered, opaque, sealed envelopes
	High risk	Investigators enrolling participants could possibly foresee assignments because one of the following method was used: open random allocation schedule (e.g. a list of random numbers); assignment envelopes without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure Observational prospective study.
	Unclear risk	Insufficient information to permit judgement of low or high risk This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement
3. Blinding of participants and providers (performance bias) Objective outcomes	Low risk	No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken
	High risk	No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding
	Unclear risk	Insufficient information to permit judgement of low or high risk

(Continued)

4. Blinding of participants and providers (performance bias) Subjective outcomes	Low risk	Blinding of participants and providers and unlikely that the blinding could have been broken
	High risk	No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding
	Unclear risk	Insufficient information to permit judgement of low or high risk
5. Blinding of outcome assessor (detection bias) Objective outcomes	Low risk	No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken
	High risk	No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding
	Unclear risk	Insufficient information to permit judgement of low or high risk
6. Blinding of outcome assessor (detection bias) Subjective outcomes	Low risk	No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken
	High risk	No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding
	Unclear risk	Insufficient information to permit judgement of low or high risk
5. Incomplete outcome data (attrition bias) For all outcomes except retention in treatment or drop out	Low risk	No missing outcome data; Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; Missing data have been imputed using appropriate methods

(Continued)

		All randomised patients are reported/analysed in the group they were allocated to by randomisation irrespective of non-compliance and co-interventions (intention to treat)
	High risk	Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation
	Unclear risk	Insufficient information to permit judgement of low or high risk (e.g. number randomised not stated, no reasons for missing data provided; number of drop out not reported for each group)
6. Selective reporting (reporting bias)	Low risk	The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon)
	High risk	Not all of the study's pre-specified primary outcomes have been reported; One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; The study report fails to include results for a key outcome that would be expected to have been reported for such a study
	Unclear risk	Insufficient information to permit judgement of low or high risk
7. Free of other bias: comparability of cohorts for baseline characteristics and outcome measures on the basis of the design or analysis	Low risk	Exposed and non exposed individuals are matched in the design for most important confounding factors; Authors demonstrated balance between group for the confounders; Analyses are adjusted for most important confounding factors and imbalance; Randomised controlled trial.
	High risk	No matching or no adjustment for most important confounding factor

(Continued)

	Unclear risk	No information about comparability of cohort.
8. Free of other bias: selection of the non exposed cohort	Low risk	The sample has been drawn from the same community as the exposed cohort
	High risk	The sample has been drawn from a different source.
	Unclear risk	No description of the derivation of the non-exposed cohort.
9. Free of other bias: protection against contamination	Low risk	Allocation was by community, institution or practice and it is unlikely that the control group received the intervention
	High risk	it is likely that the control group received the intervention
	Unclear risk	it is possible that communication between intervention and control groups could have occurred
10. Ascertainment of exposure	Low risk	Information in the study was obtained from a secure record (eg clinical records or structured interview)
	High risk	Self report.
	Unclear risk	No description.

WHAT'S NEW

Date	Event	Description
15 January 2015	Amended	declarations of interest

CONTRIBUTIONS OF AUTHORS

The protocol was drafted by FB, EK and SM. All authors commented on and approved the final version.

DECLARATIONS OF INTEREST

Eileen Kaner, Fiona Beyer and Colin Muirhead are authors on a related Cochrane review ([Kaner 2007](#)).

Eileen Kaner is an investigator on the ongoing SIPS Junior trial (NIHR programme grant number NIHR RP-PG-0609-10162), which will have an app component in one arm of the trial.

Jamie Brown, David Crane, Claire Garnett and Susan Michie are currently working on the development and evaluation of an app to reduce excessive alcohol consumption but have not yet published a protocol or results.

Matt Hickman and James Redmore have no interests to declare.

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