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TABLE OF CONTENTS

[Intervention Protocol]

Internet interventions for treatment of alcohol-related problems

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ABSTRACT

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

The primary objective of this review will be to assess the effect of internet and mobile phone alcohol-related interventions on reducing participants' alcohol consumption. Secondary objectives will include assessing the impact of the interventions on symptoms of alcohol-related disorders and degree of alcohol dependence, the effects on functioning, and patient acceptability. The review will also assess whether there are different outcomes for different diagnostic groups, and which intervention approaches or components (including therapeutic support) may be contributing to any positive effects.

BACKGROUND

Description of the condition

Alcohol-related problems can be broadly classed under three categories: 1) alcohol dependence, which is characterised by symptoms of tolerance and withdrawal; 2) alcohol abuse, which occurs when the criteria for alcohol dependence are not met, but the use of alcohol has caused significant distress or impairment in functioning; and 3) binge-drinking, which is characterised by heavy, episodic use of alcohol.

The challenge within the alcohol research and treatment domain is how to operationalise terms such as 'binge', 'heavy', and 'episodic' alcohol use. The qualitative and quantitative definitions of these terms vary between jurisdictions and over time. Internationally, there is no consensus on: 1) the number of standard drinks that constitute a binge; 2) the volume of alcohol in a standard drink; and 3) the duration of a drinking 'episode', occasion, or event.

Excessive alcohol use is related to a wide range of physical, psychological, and social problems (WHO 2011). Worldwide, harmful alcohol use is the third leading risk factor for premature death and disability, although in middle-income countries it is the greatest risk factor (WHO 2011). Alcohol use is a direct cause of many diseases, including alcoholic psychoses, dependence, abuse, cardiomyopathy, gastritis, and liver cirrhosis, and plays a contributory role in many other diseases such as cancer, cardiovascular disease, birth defects, and depression. It also has acute adverse health consequences, including accidental injury and poisoning, suicide,

interpersonal violence, and assaults (WHO 2011).

While alcohol use by adults appears relatively stable over time in most countries, there is an increase in heavy, episodic, and binge-drinking in adolescents and young adults in many countries (WHO 2011). Binge-drinking and its associated negative effects, including the risk of alcohol-related injury, peak in the 18- to 34-year age group. There is a differential pattern and quantity of alcohol use between males and females with men having greater mortality (6.0% vs. 1.1% of deaths attributed to alcohol) and morbidity (7.4% vs. 1.4% disability-adjusted life year (DALYs); WHO 2009).

Alcohol-related problems often co-occur with other mental health problems. The Epidemiological Catchment Area study (Regier 1990) for example, found that people with an alcohol-use disorder had an increased lifetime risk of anxiety disorder (19.4%; odds ratio (OR) 1.5), and of affective disorders (13.4%; OR 1.9). As the rates of anxiety and depression are higher among women, there is a greater likelihood that women with alcohol-use disorders will also have one of these disorders (Teesson 2000). For people with alcohol-use disorders, those receiving treatment have been found to have higher rates of co-morbid mental health disorders than those not receiving treatment (e.g. Ross 1988). The presence of co-occurring disorders substantially accentuates the functional impact of both disorders (Burns 2002), highlighting the need to address co-morbidity.

The vast majority of people with alcohol-use problems never access professional treatment services (Substance Abuse and Mental Health Admin 2007; WHO 2004). Overall, treatment rates for people with alcohol-related disorders may be as low as 15% (Cohen 2007). Treatment for alcohol problems is more common among men, in people aged 30 to 54 years, and in people with other co-occurring mental disorders (Cohen 2007). One review of 37 studies on the use of services found that, on average, those with alcohol abuse and dependence had lower treatment access rates than people with other mental health problems (WHO 2004). Israel had the highest treatment access rates (50.6%), the UK the lowest (4%), and most western countries around 25%. Barriers to help-seeking include cost, accessibility, lack of services, stigma, and lack of knowledge about the problem (WHO 2004). Sub-clinical but high-risk drinking may present even greater challenges for engagement in interventions than substance-use disorders, and, given the large numbers of affected people (Substance Abuse and Mental Health Admin 2010), it also presents acute problems for service delivery.

Together, these data suggest that innovative ways of reaching at-risk groups (e.g. young people who are heavy drinkers) and overcoming traditional barriers to treatment provision are needed. In recent years, internet-based interventions have been gaining increased attention. This approach is acceptable to at-risk drinkers, and can service greater numbers than current specialist treatment services could realistically support (Cloud 2001; Cunningham 2000).

Access to the internet is substantial and is growing rapidly. The internet is widely accessible in Western countries, with 80.6% of Australians and 70.9% of people in the UK accessing the internet regularly (Internet World Statistics 2009). Currently, North America is the region with the highest usage rate (78.6%), followed by Oceania/Australia (67.5%), and Europe (61.3%; Internet World Statistics 2011). Internationally, there was a 380% growth in internet usage between 2000 and 2009 (Internet World Statistics 2009). Much higher growth rates were seen in regions with a lower base of usage in 2000 (e.g. 1648% in the Middle East, 1392% in Africa) than those with higher initial usage (e.g. 298% in Europe) in the same time period, reflecting both the relative saturation of access in highly developed countries and the tendency for the world to trend towards parity of access. While internet adoption is higher among city dwellers (Goldfarb 2008), the disparity between urban and rural access is narrowing. For example, in 2006-2007, 57% of non-metropolitan households in Australia had internet access, compared to 67% in metropolitan areas (Australian Bureau of Statistics 2008). Even in very remote areas, 42% had internet access. Internet use is highest in the 15- to 44-year age group (Australian Bureau of Statistics 2008): the age group most at risk for heavy alcohol use and related problems. Given that young people aged 15 to 34 years are least likely to seek face-to-face treatment, internet interventions may have particular benefit in this group (Cohen 2007).

Mobile phones are an emerging medium in the treatment of alcohol-related problems. Interactive voice response, for example, has been used effectively to monitor daily stress and alcohol consumption (Andersson 2007). With the advent of mobile phones and tablets with internet capability, the increasing use of wireless access by computers, and the emergence of interventions that are tailored to mobile phone platforms, the lines between online and mobile phone interventions are blurring. While developing regions such as Africa and Asia still have low internet penetration rates (6.8% and 19.4%) (Internet World Statistics 2009), these regions are showing substantial mobile subscription rates (59.8% and 72.4%, respectively). Mobile telephone is rapidly emerging as a new platform for intervention, with potential to be used in naturalistic settings and in contexts where cable access to online treatments remains limited.

Online treatments for a range of mental health problems have been shown to overcome some of the traditional barriers to treatment access including stigma, cost, and convenience (Robinson 2009). Using the internet eliminates the stigma associated with face-to-face treatment (Gega 2004). For many people in rural and remote regions, online treatments may help to address some of the inequity of access to psychological treatments that are faced in geographically isolated areas (Abbott 2008). *MoodGYM*, an online program for the treatment of depression, has reported that 20.5% of users worldwide were from rural or remote areas (Griffiths 2007a). Online therapies enable consumers to access services at times and locations that suit them, and to eliminate travel time and associated costs (Abbott 2008; Bischoff 2004). Consumers can also avoid

delays of waiting lists and commence treatment as soon as they wish to do so (Rapp 2006). While there is a considerable economic investment in the development and maintenance of online treatment programs, there are significant potential cost savings in service delivery, which grow with the numbers serviced. Costs are also offset by reduced health and social costs of the disability associated with mental health problems. One systematic review assessing the cost effectiveness of *MoodGYM* found that costs per client were lower than either face-to-face cognitive behavioural therapy (CBT) or general practitioner (GP)-administered antidepressant medication (Griffiths 2007b).

In other treatment domains, previous reviews have found that increased adjunctive therapist contact is associated with a greater effect size (Palmqvist 2007; Titov 2011). However, comparisons of high and low therapist contact within the same randomised controlled trial (RCT) do not always find superior effects from a condition with greater therapist input (e.g. de Graaf 2009). If research on alcohol-related problems had similar results, it would have important implications, given the recurrent costs and challenges for scalability that are associated with provision of therapist support.

There have been a number of reviews on online treatment interventions both generally (Andersson 2009; Khadjesari 2011; Riper 2011; Walters 2005; Wantland 2004; White 2010) and within specific populations (Carey 2009). However, the field is rapidly evolving with the ongoing growth in technology.

Description of the intervention

Current internet programs range from user-generated content applications such as Web logs/blogs, Web-based instant messaging technologies, or discussion boards (e.g. AlcoholHelpCenter.net; Cunningham 2008), to interactive software applications. Even within interactive applications there is substantial variability, from brief normative feedback interventions (Bewick 2008) to multisession modularised programs (e.g. AlcoholEdu; Eisen 2009) and substance mediation services involving a therapist (Bickel 2009; Saitz 2004). Many of these program applications include brief intervention strategies and educational content based on a harm-reduction philosophy (Finfgeld-Connett 2006), and motivational interviewing techniques that are presented in a self-help workbook style.

How the intervention might work

One meta-analysis of computer-based treatments of common mental health problems found that the majority of published research suggests that computerised psychotherapies offer an acceptable format for care, increased access to effective psychotherapies for people suffering from anxiety and depression, reduced symptoms and problem severity, improved functioning and well-being, and reduced costs of delivering effective psychotherapy (Cavanagh 2004). Online interventions for anxiety and stress have been found to be as effective as face-to-face treatment (Barak 2008). Significant effects have also been found for depression, although effect sizes are smaller than those for anxiety (Spek 2007). Online interventions have been shown to be effective with and without therapist support, although there is some evidence to suggest that effect sizes are larger with some therapist involvement (Spek 2007).

Internet interventions have a high reliance on the existing skills of participants and primarily focus on encouraging participants to use those skills and to generalise them to new situations. The new skills taught through online interventions easily lend themselves to being either described in text or modelled in multimedia formats to demonstrate their application. Therapist involvement may contribute to higher outcomes in online interventions through a mechanism of social support, resulting in increased treatment engagement and compliance. Alternatively, it may assist in tailoring the intervention to the individual's needs.

There are some data to support the acceptability of online screening and treatment for alcohol-related problems (e.g. Cunningham 2000). Moreover, the number of users accessing online programs could exceed the capacity of face-to-face services (Saul 2007). For example, the Down Your Drink program for heavy drinkers had an average of 1039 visits per month (range 706 to 1541 visit per month) or 34 visits per day (range 25 to 49 visits per day), with 1319 people from 41 countries registering with the online program over a six-month period (Linke 2007). A number of features of the web-based modality appeal to people seeking treatment, including: 24-hour accessibility (Linke 2007); anonymity and privacy; not being limited by geographical locale; and not having to attend face-to-face meetings (Humphreys 2001; Lieberman 2008).

The avoidance of negative consequences of treatment seeking, including stigma and discrimination, and the ready access offered by internet-based interventions, makes them ideal for early intervention and for the initial step in a stepped-care approach. These interventions are not intended to replace face-to-face treatment. By providing assessment feedback, informational resources and practical coping strategies to large numbers of people, they instead potentially offer a powerful source of marketing the benefits of treatment seeking in general. They also potentially offer strategies to increase the efficiency and impact of standard services, by increasing numbers of serviced patients and freeing therapist time to address more complex problems.

In principle, internet-based interventions have limitations, particularly when offered in a totally self-guided format. Potential users report that unguided interventions would require substantial motivation to maintain engagement, and that they would miss the accountability offered by involvement of therapist (Kay-Lambkin 2011). While internet treatments can develop a strong working alliance, this alliance is not necessarily associated with better outcomes (Knaevelsrud 2007). In substance-use disorders, physical complications, including nutritional and withdrawal-related risks,

may not be addressed, and assertive interventions for suicide risk may not be offered, although there appear to be few reported problems from either issue to date. While literacy issues can partially be addressed by the use of graphics and video, thereby minimising the restriction imposed by reading age, Internet-based interventions are likely to remain more attractive to users with greater education and linguistic confidence than for people with lesser educational attainments. Both linguistic and cognitive difficulties are likely to increase the need for therapist support, although the issue requires further research.

Why it is important to do this review

Internet and mobile technologies provide a potential treatment modality for alcohol-related problems, which may help to overcome the barriers to accessing treatment that apply to traditional, face-to-face interventions. There is growing recognition of the potential of the internet for the treatment of mental health and alcohol and drug problems, and programs are rapidly proliferating. This growth is creating a demand from both consumers and practitioners for authoritative information to guide decisions about the use of these interventions, and about the choice of specific program options. Research on the efficacy and effectiveness of internet-based alcohol interventions is rapidly emerging, although it remains limited, and many questions remain unanswered. The proposed review will assist in clarifying the status of the current evidence base for these treatments, and the nature of the questions that remain.

OBJECTIVES

The primary objective of this review will be to assess the effect of internet and mobile phone alcohol-related interventions on reducing participants' alcohol consumption. Secondary objectives will include assessing the impact of the interventions on symptoms of alcohol-related disorders and degree of alcohol dependence, the effects on functioning, and patient acceptability. The review will also assess whether there are different outcomes for different diagnostic groups, and which intervention approaches or components (including therapeutic support) may be contributing to any positive effects.

METHODS

Criteria for considering studies for this review

Types of studies

We will include RCTs or cluster RCTs and associated economic evaluations.

Types of participants

Participants will be adults or adolescents with either at-risk drinking behaviours (e.g. measured in grams of alcohol above a national standard), dysfunctional drinking patterns (e.g. drink-driving), or symptoms of an alcohol-related disorder. Participants may be diagnosed with alcohol abuse and dependence, as classified by the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV), or alcohol dependence or harmful consumption levels, as classified by the International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10), but the review will not be limited to people with established disorders.

Types of interventions

To be included in the review, the intervention must have a primary focus on alcohol consumption or related problems, and involve online participant interaction and feedback. The interventions must be able to be accessed via the internet, mobile phone, or similar technologies that may emerge. To distinguish these interventions from programs that are based on the remote device alone (e.g. an electronic diary, mobile phone, or computer hard drive), there must be transmission of personal data to and from a remote mainframe computer. However, this transmission need not be in real-time (i.e. data may be stored and forwarded periodically).
Therapist support may or may not be available. If support is provided, the intervention must remain primarily internet-based, with the support having only a proportionally minor role in terms of frequency of contact, contact time, or content.
Active online intervention, involving both consumer interaction and feedback, will be compared with a no-treatment or wait-list control, with other online interventions that are also online, or with treatments using another modality (e.g. face-to-face or mailed). Studies will be restricted to those where the majority of content and interaction is internet-based. Any adjunctive therapist-assisted components (e.g. face-to-face, email, text messaging) will be of a limited nature. Interventions targeted primarily towards practitioners to either increase treatment fidelity or work through with consumers will be excluded from the study.

Types of outcome measures

Primary outcomes

Primary outcome measures must include either the number of grams of alcohol used, binges per period, or drinking or days abstinent.

Secondary outcomes

Secondary outcome measures may include general functioning, at risk behaviours, craving, mental health outcomes, program satisfaction, health service utilisation, adverse events, economic outcomes.

Search methods for identification of studies

Electronic searches

We will search following databases:

1. Cochrane Drugs and Alcohol Group's Register of Trials;
2. the Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*, most recent);
3. MEDLINE (January 1950 to present);
4. EMBASE (January 1974 to present);
5. CINAHL (1982 to present);
6. ERIC (1966 to present);
7. LISA (to present);
8. PsycINFO (1806 to present).

The literature search will be conducted in English but relevant papers will be included irrespective of the language they are published in. Searches will be included from the start date of each database. The reference lists of relevant papers, trials, and reviews will be examined to identify additional studies. Authors of included studies and other authors in the field will also be contacted to assist in locating any additional studies meeting the inclusion criteria.

The search strategy will be based on the MEDLINE strategy shown in Appendix 1 with MeSH terms and free text, adapted as necessary for use in each database. Search terms relate to the core concepts in the review question: internet, mobile phone, smartphone, alcohol, and intervention. We will combine the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying RCTs in MEDLINE: sensitivity-maximising version (2008 revision) (Lefebvre 2011). The search strategies for non-medical databases include an extra concept block to identify health-related studies.

We will also search some of the main electronic sources of ongoing trials:

- ClinicalTrials.gov (www.clinicaltrials.gov);
- WHO International Clinical Trials Registry Platform (ICTRP) (apps.who.int/trialsearch/);
- Current Controlled Trials (www.controlled-trials.com/);
- Australian New Zealand Clinical Trials Registry (www.anzctr.org.au/);
- US Clinical Trials Registry (www.clinicaltrials.gov/);
- NIH RePORTER (projectreporter.nih.gov/reporter.cfm).

Searching other resources

Personal contact

We will contact experts in the field for published and unpublished trials.

Citations

1. We will search the references of included and relevant excluded studies and previous systematic reviews for relevant citations.
2. We will undertake a citation search of each included study in the ISI Web of Knowledge.

Data collection and analysis

Selection of studies

Two review authors (HS, DK) will independently assess the eligibility of papers identified by the search strategy. The selection criteria will be applied to titles and abstracts, with decisions erring on the side of caution, that is, to include all papers potentially reporting an intervention for enhancing consumer use of online health information unless they can be definitely excluded. We will retrieve the full text of papers assessed as potentially relevant, and two review authors will assess them independently for inclusion. Disagreements about inclusion or exclusion of particular studies will be resolved by discussion between the two review authors and with another review author (AW) as necessary. Study authors will be contacted for further details in cases where it is unclear whether a study meets the inclusion criteria. Studies that appear to fulfil the inclusion criteria but are later excluded from the review will be detailed in a 'Characteristics of excluded studies' table, along with the reasons for their exclusion.

Data extraction and management

Data will be extracted from all included studies using an adaptation of the Cochrane Drugs and Alcohol Group data extraction template. Two review authors will independently extract the data from each included study, with disagreements resolved by discussion with each other and with the other review author, as necessary. The data extraction form will be pilot tested with the first five included studies and refined as necessary. The following data will be extracted onto a computer-based form:

- title, author, date of study;
- details of the study including aim, design, participant recruitment/inclusion, research ethics, use of appropriate statistical methods, consumer involvement;
- assessment of study quality (see below);
- details of participants including description (e.g. patient or carer), category of internet health seeker, location, setting,

number, socio-demographic information, health status and problems (including number and type of co-morbid health problems), and treatment;

- details of the intervention(s) including description (format, source, setting, content) and theoretical basis, control condition and any co-interventions, delivery (including stages, timing, frequency, and duration), provider, and quality. Intervention quality will be assessed with respect to 1) was the intervention delivered as intended?; 2) was the provider trained to deliver the intervention?; 3) did delivery of the intervention differ across settings or population?; 4) what was the evidence base for the intervention?;
- details of outcomes, including identification of primary/secondary outcomes, methods of assessment and follow-up, timing of assessment and adverse events; and
- results of the study, including for each outcome the timing of assessment and end-point mean, standard deviation, and number of participants in the intervention and control groups.

Extracted data will be entered into Review Manager by one review author, and the entries checked for accuracy against the original data form by a different author (RevMan 2011).

Assessment of risk of bias in included studies

The 'Risk of bias' assessment for RCTs and controlled clinical trial in this review will be performed using the criteria recommended by the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The recommended approach for assessing risk of bias in studies included in a Cochrane review 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 source 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 *Cochrane Handbook for Systematic Reviews of Interventions* 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.

In all cases, two review authors will independently assess the quality of included studies, with any disagreements resolved by discussion and consensus. If necessary we will contact study authors for additional information about the included studies, or for clarification of the study methods as required. We will incorporate the results of the quality assessment into the review through systematic narrative description and commentary about each of the quality items, leading to an overall assessment of the quality of included studies and a judgement about the internal validity of the review's results.

Measures of treatment effect

We will report the results of individual RCTs, and cluster RCTs as standardised mean differences (continuous variables) or risk ratios (dichotomous variables) with 95% confidence intervals.

Unit of analysis issues

Cluster-randomised trials

We shall use statistical methods described in Deeks 2008 if cluster-randomised trials are included in this review. If included trials are randomised by clusters and if the results have been adjusted for clustering, we will combine the adjusted measures of effects of these cluster-randomised trials. If results have not been adjusted for clustering, we will attempt to adjust the results for clustering by multiplying the standard errors of the estimates by the square root of the design effect, where the design effect is calculated as D_{Eff} = 1 + (M - 1) ICC, where M is the average cluster size and ICC is the intracluster coefficient (an estimate of the relative variability within and between clusters within the studies) (Donnor 1980). We will attempt to obtain the ICC from the article and, if not available, we will use external estimates obtained from similar studies. Subsequently, the estimates and their corrected standard errors from the cluster-randomised trials will be combined with those from parallel group designs using the generic inverse variance method in Review Manager 5 (RevMan 2011).

Cross-over trials

Data from cross-over trials will be pooled according to the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The mean of within-participants difference and standard error of the mean difference will be entered into Review Manager 5 using the generic inverse outcome

type (RevMan 2011). Where the standard error of the difference in means is not reported, the original data will be requested from study authors or the value will be imputed. Correlation coefficients will be calculated from studies where sufficient data are available and, if consistent, will be used to calculate the missing standard errors for other studies.

Dealing with missing data

We will seek to carry out an intention-to-treat (ITT) analysis where this is not reported by the study authors. If the data are available in the paper, we will carry out a full ITT analysis. If necessary, we will contact the authors to obtain the data necessary for this analysis. If sufficient data are not available, we will not impute the missing data. Instead we will carry out an available case analysis and consider the implications of the missing data in the review Discussion section.

Assessment of heterogeneity

If a meta-analysis is performed, statistical heterogeneity will be tested using the I^2 statistic. This statistic gives the percentage of the variability in effect estimates that can be attributed to heterogeneity rather than chance. A value greater than 50% will be considered substantial heterogeneity. If statistical heterogeneity is found to be present, this will be further explored using analysis of a priori subgroup and sensitivity analyses.

Assessment of reporting biases

We will include grey literature in our search strategy to minimise the effects of publication bias. We will investigate the effects of publication bias in the review using a funnel plot. We will discuss the results of the funnel plot and possible explanations for the results, which include publication bias but also other sources of bias such as diverse methodological quality.

Data synthesis

RevMan will be used to enter and report quantitative data (RevMan 2011).

Following data extraction, we will tabulate data to create a descriptive synthesis of the included studies. Data will be grouped within the tables with respect to study design and type of intervention. If there are sufficient appropriate studies they will also be categorised based on the two categories of intervention, single or multiple session. Within these categories the results will be further structured to reflect the comparisons detailed in the 'Types of participant' section. We will separately present the results of studies that compare intervention to no intervention and those that compare two or more types of online alcohol interventions. We will also present separately the results of studies exploring the immediate effects versus long-term effects. We will use this synthesis to prepare a narrative review of the results, and to examine included studies to assess clinical and methodological heterogeneity. The narrative review will present the results of the studies as relative and absolute percentage change and direction of effect for each of the outcomes.

If the studies are sufficiently homogenous with respect to populations, inclusion criteria, interventions, outcomes, or a combination of these, we will consider pooling the data statistically using meta-analysis. We will perform a formal random-effects model meta-analysis, which will report pooled mean differences (continuous variables using the same scale) or standardised mean differences (continuous variables using different scales) or ORs (dichotomous variables) and 95% confidence intervals. Numbers needed to treat for an additional beneficial outcome (NNTB) or harmful outcome (NNTH) will also be calculated if follow-up periods are comparable. If necessary, we will account for the effects of clustering in cluster randomised trials by adjusting each trial to its 'effective sample size' using ICCs where available, or external estimates from similar studies. We will analyse separately the comparisons detailed in the previous paragraph. Separate meta-analyses will be carried out for each of the five primary outcomes and for the seven categories of secondary outcomes. The decision to carry out meta-analyses will be made by consensus of all the review authors.

Subgroup analysis and investigation of heterogeneity

If a meta-analysis is performed, statistical heterogeneity will be tested using the I^2 statistic. As age is known to predict internet use and is hypothesised to affect outcomes of the intervention, we will, if possible, conduct a subgroup analysis comparing participants aged less than 30 years with those aged 30 years and over. We will conduct sensitivity analyses by excluding unpublished trials (if there are any), and by excluding studies of poor quality or less rigorous study design. RCTs will be separated into high, moderate, and low risk of bias as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), based on the number of quality criteria rated as adequate, inadequate, or unclear for each study.

Sensitivity analysis

We shall undertake sensitivity analyses if trials report drop-out rates of 10% or greater to ascertain differences in outcomes of ITT analysis (all drop-outs will be assigned to the worst outcome for dichotomous outcomes) and analysis of completers. If the results of these analyses differ significantly with relation to direction of effect, we shall perform two additional analyses:

1. a best-case scenario favouring treatment, that is, none of the drop-outs in the treatment condition had the unfavourable

outcome but all drop-outs from the control group had the outcome;

2. a worst-case scenario favouring control, that is, all the drop-outs from the treatment arm had the unfavourable outcome but none from the control group had this poor outcome. We shall report the results of all such analyses.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

1. exp Alcohol-Related Disorders/
2. Alcohol Drinking/
3. (alcohol* adj3 (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$ adj3 (heavy or hazard$ or binge or harmful)).tw.
5. 1 or 2 or 3 or 4
6. exp Internet/
7. (web$ or internet or mobile or on?line or e?therapy or e?health or phone or cellphone or smartphone).mp.
8. 6 or 7
9. randomized controlled trial.pt.
10. controlled clinical trial.pt.
11. randomized.ab.
12. placebo.ab.
13. drug therapy.fs.
14. randomly.ab.
15. trial.ab.
16. groups.ab.
17. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18. exp animals/ not humans.sh.
19. 17 not 18
20. 5 and 8 and 19

Appendix 2. Criteria for 'Risk of bias' assessment

Item	Judgement	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
	Unclear risk	• Insufficient information about the sequence generation process to permit judgement of low or high risk
2. Allocation concealment (selection bias)	Low risk	• Investigators enrolling participants could not foresee assignment because 1 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

(*Continued*)

		containers of identical appearance; sequentially numbered, opaque, sealed envelopes
	High risk	• Investigators enrolling participants could possibly foresee assignments because 1 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
	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
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
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

(*Continued*)

		influenced by lack of blinding
	Unclear risk	• Insufficient information to permit judgement of low or high risk
7. 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 • 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)
8 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 • 1 or more primary outcomes is reported using measurements, analysis methods, or subsets of the data (e.g. subscales) that were not pre-specified • 1 or more reported primary outcomes were not pre-specified

(*Continued*)

		(unless clear justification for their reporting is provided, such as an unexpected adverse effect) • 1 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
9. Other bias *	Low risk	-
	High risk	-
	Unclear risk	-

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