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Real-time video counselling for smoking cessation (Protocol)

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[Intervention Protocol]

Real-time video counselling for smoking cessation

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

The objectives of this review are to assess the following, across community, healthcare or other settings.

- The effectiveness of real-time video counselling delivered individually or to a group for increasing smoking cessation.
- The effectiveness of real-time video counselling on increasing the number of quit attempts.
- The effect of real-time video counselling on intervention adherence and duration of consultations.
- The effect of real-time video counselling on satisfaction, including ease of use.
- The effect of real-time video counselling on therapeutic alliance.
- To provide a brief economic commentary of real-time video counselling.

BACKGROUND

Description of the condition

Tobacco use is a leading preventable cause of premature death and disease worldwide (Samet 2013). Globally there are an estimated 1.1 billion current tobacco smokers (World Health Organization 2015a) and tobacco use is responsible for the death of approximately 6 million people each year (World Health Organization 2015b). Compared to the general population, subgroups that are at high risk of tobacco use include: lower socioeconomic groups (Australian Institute of Health and Welfare 2016; Chahine 2011); unemployed individuals (Australian Institute of Health and Welfare 2016); adults with mental illness (Lê Cook 2014); those who reside in remote or very remote areas (Australian Institute of Health and Welfare 2016); indigenous populations (Australian Institute of Health and Welfare 2016); and ethnic groups (Chahine 2011). Current tobacco smokers are estimated to die an average of 10 years earlier than non-smokers (Banks 2015; Jha 2013). Tobacco use harms nearly every organ of the body and causes

numerous diseases including coronary heart disease, chronic obstructive pulmonary disease, stroke, cancers, respiratory diseases and adverse reproductive outcomes (U.S. Department of Health and Human Services 2014). Quitting smoking reduces the risk of tobacco-related mortality and morbidity even among long-term smokers (Peto 2000; Taylor 2002). Smoking cessation before 40 years of age reduces the risk of death associated with continued smoking by approximately 90% (Jha 2013). Effective behavioural interventions and pharmacotherapies for smoking cessation include self-help materials (Hartmann-Boyce 2014), web-based programs (Myung 2009), proactive telephone counselling (Stead 2013a), healthcare professional advice (Stead 2013b), individual counselling (Lancaster 2005), group therapy (Stead 2005), nicotine replacement therapy (Stead 2012), bupropion (Hughes 2014) and varenicline (Cahill 2016).

The global economic cost of smoking in 2012 was estimated to be US$1.4 trillion, comprised of US$422 billion in direct healthcare costs, US$357 billion for morbidity and US$657 billion for mortality (U.S. National Cancer Institute and WHO 2016). In the United States, the cost of tobacco use between 2001 and 2004 totalled US$193 billion per year, consisting of US$96 billion in direct healthcare costs and US$97 billion for productivity losses (CDC 2008). There are limited data about the economic costs of tobacco use in low- and middle-income countries, but available evidence suggests that as a percentage of the total healthcare costs, tobacco-related healthcare costs for low- and middle-income countries are comparable to those of high-income countries (U.S. National Cancer Institute and WHO 2016).

Description of the intervention

Real-time video counselling uses video conferencing technology (also referred to as telemedicine or telehealth), consisting of a video camera connected to a computer or mobile device, to securely transmit live video and audio of the counsellor and client to one another over the internet. There are more than 3 billion internet users worldwide in over 190 countries (Internet Society 2015), suggesting that real-time video counselling has the potential for widespread implementation. Freely available software such as Skype, Facetime or Google+Hangouts allows real-time, interactive video communication between users via personal computers and/or mobile devices. Real-time video counselling differs from telephone counselling because quitlines and other telephone services transmit only the sound of the counsellor's and client's voices to each other (Stead 2013a). Therefore, the Cochrane systematic review of telephone counselling for smoking cessation includes interventions that were delivered via audio only over the telephone (Stead 2013a). In contrast, real-time video counselling includes a visual mode of communication because it transmits both live video and audio of the interaction between the counsellor and client over the internet.

How the intervention might work

Healthcare providers have used video conferencing to deliver smoking cessation care (Richter 2015), as well as consultations for medical conditions including preoperative anaesthesia (Roberts 2015), ophthalmology (Johnson 2015), mental health (Saurman 2014), and remote supervision of chemotherapy administration to cancer patients (Sabesan 2012). Real-time video consultations are potentially valuable because despite the success of behavioural interventions, such as individual counselling (Lancaster 2005), group therapy (Stead 2005) and proactive telephone counselling (Stead 2013a), in increasing smokers' chances of quitting successfully, the use of in-person cessation services (Matcham 2014) and quitlines (Cummins 2007; Woods 2007) is low. Real-time video interventions allow health care to be delivered to patients who may otherwise have limited access to health care and specialist services, and thus may increase the uptake of behavioural support. For example, those who live in rural areas may not receive treatment or may delay seeking treatment because of fewer healthcare services near their home, and those with mobility problems may find it difficult to attend in-person consultations, resulting in poorer health outcomes. The evaluation of a telehealth-delivered smoking cessation support group found that 86% of rural participants were only able to take part in the program because it was offered via video-conferencing, because the distance to travel and associated costs would have been prohibitive (Carlson 2012). This may have an associated negative impact on health. In Australia the mortality rate of all cancers combined is significantly higher in very remote areas compared to major cities, with residents in very remote areas having 1.4 times the mortality rate due to lung cancer than those in major cities (Australian Institute of Health and Welfare 2017). In addition, low- and middle-income countries have experienced an increase in the use of internet technologies, with technology-enabled health programs emerging in lower-income countries (Lewis 2012). The reasons for using technology to deliver health care in low- and middle-income countries include improving access to, and the quality of, care, in diverse geographical locations where there may be a shortage of healthcare professionals, facilitating patient communications outside regular health visits and improving diagnosis and treatment (Lewis 2012). These could all lead to better health outcomes for patients.

As well as being used as an additional treatment option, real-time video counselling could also be implemented in existing community and healthcare settings, to expand their reach or reduce the burden on overstretched services. For instance, real-time video counselling could be delivered through quitline services or other smoking cessation services in settings such as general practice, hospitals or other treatment centres, to clients in their own homes. Smoking cessation counsellors and/or healthcare professionals could provide behavioural support via video sessions to assist smokers to quit as either a primary intervention or as an adjunct to other smoking cessation treatments.

Similar to face-to-face smoking cessation interventions, the live

video images transmitted during real-time video counselling sessions allow counsellors to deliver behavioural support via a visual mode and be responsive to the smoker's verbal and non-verbal cues. During real-time video counselling sessions counsellors can use evidence-based techniques, such as cognitive behaviour therapy (CBT) (Clark 1997) and motivational interviewing (MI) (Miller 1991) to support smokers to quit. As there is evidence that behavioural interventions are generally effective across a range of media (Lancaster 2005; Stead 2005; Stead 2013a), it is reasonable to assume that this may translate to the medium of real-time video counselling.

However, the limitations of real-time video counselling also need to be considered. Potential disadvantages of this approach include that the smoker and/or healthcare professional or counsellor may not feel adequately skilled to operate the video-conferencing equipment (O'Connell 2015), there may be insufficient bandwidth (Winters 2007), and low quality of the audio and video transmission may impede clear communication and produce a mismatch between the timing of the audio and video (Winters 2007). Despite the virtual face-to-face capabilities of real-time video counselling, either in-person communication or the greater anonymity of non-visual contact may be preferred by the provider and client.

Why it is important to do this review

To our knowledge, there are no systematic reviews that have examined the effectiveness of real-time video counselling for smoking cessation. Real-time video counselling is a scalable intervention that may increase access to smoking cessation services particularly for those living in regional and remote areas and individuals with mobility issues. If found to be effective, real-time video counselling for smoking cessation could be included in the suite of smoking cessation services offered by any smoking cessation service provider worldwide.

OBJECTIVES

The objectives of this review are to assess the following, across community, healthcare or other settings.

- The effectiveness of real-time video counselling delivered individually or to a group for increasing smoking cessation.
- The effectiveness of real-time video counselling on increasing the number of quit attempts.
- The effect of real-time video counselling on intervention adherence and duration of consultations.
- The effect of real-time video counselling on satisfaction, including ease of use.
- The effect of real-time video counselling on therapeutic alliance.
- To provide a brief economic commentary of real-time video counselling.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs), randomised trials (i.e. compare multiple treatment groups), cluster RCTs or cluster randomised trials that measure smoking cessation at least six months following baseline.

Types of participants

Current tobacco smokers (daily or occasional) recruited from a community, healthcare or other setting. There will be no restrictions based on age, gender, level of nicotine dependence or comorbidities.

Types of interventions

Interventions will be included where real-time video counselling is delivered by smoking cessation advisors or healthcare professionals as either the primary intervention or an adjunct to other smoking cessation treatments. Administration of the intervention may occur via telemedicine video conferencing technology and/or other platforms such as Skype, Facetime, Messages, Google+Hangouts, Talky Core, Viber, Tango or alternative forms of video communication.

The real-time video counselling intervention will be compared with either a control intervention; and/or another smoking cessation intervention. Therefore, eligible comparison arms will include: (i) no intervention control; (ii) health information or brief advice; (iii) written self-help materials; (iv) proactive telephone counselling; (v) individual face-to-face support; (vi) group face-to-face support; (vii) web-based interventions; or (viii) any other smoking cessation intervention.

Types of outcome measures

Primary outcomes

The primary outcome is smoking cessation (e.g. point prevalence, continuous or prolonged abstinence) measured at least six months

following baseline. Where a study measures cessation in a number of ways, we will use the most stringent measure for meta-analyses. The most stringent measure is the one that requires smoking cessation to have been achieved for the longest duration (i.e. prolonged abstinence is judged to be more stringent than point prevalence abstinence). Biochemically-validated cessation rates will be used where available, otherwise self-reported measures of cessation will be included in the analysis. Sensitivity analysis will be conducted to explore the impact of using verified rates, and is described in the Sensitivity analysis section below.

Secondary outcomes

The secondary outcomes are:

1. self-reported number of quit attempts (i.e. quitting smoking intentionally for one day or longer);
2. intervention adherence (e.g. number of completed sessions) and duration of consultations;
3. satisfaction, including ease of use (e.g. satisfaction with counselling, connectivity and quality of audio and video, satisfaction with usability of video conferencing equipment); and
4. therapeutic alliance (e.g. affective bond, client-therapist collaboration, mutual goals).

Search methods for identification of studies

Electronic searches

We will search the following electronic databases: the Cochrane Tobacco Addiction Group Specialised Register, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (1946-present), PubMed (1966-present), PsycINFO (1806-present) and Embase (1947-present). The search strategy, including MESH terms and keywords, for MEDLINE is presented in Appendix 1.

Searching other resources

We will check the reference lists of included articles and relevant systematic reviews to identify any additional eligible publications. We will also search the World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch/) and ClinicalTrials.gov (clinicaltrials.gov/) to identify ongoing trials. Experts who have published on the effectiveness of behavioural smoking cessation interventions will also be contacted and asked if they are aware of any randomised trials of real-time video counselling for smoking cessation.

Data collection and analysis

Selection of studies

FT will implement the search strategy and import all identified references from each electronic database into EndNote reference management software and remove duplicates. Two authors (FT, CP, TR, CW, RH or JD) will independently screen the titles and abstracts to determine if they meet the inclusion criteria. For articles that appear relevant or where we cannot determine eligibility from the title or abstract, we will obtain the full-text article. The same two authors will independently review full-text articles for possible inclusion. If there are inconsistencies, the two authors will discuss until consensus is reached. If discrepancies are unable to be resolved, a third author, who will act as an arbiter, will be consulted.

Data extraction and management

Two authors (FT, TR, CG or JD) will independently extract data from all eligible trials. We will use a standardised data collection form, adapted from the Cochrane Effective Practice and Organisation of Care (EPOC) Group's template (EPOC 2015) and tailored to this review's objectives. The data collection form will be pilot-tested and feedback incorporated. The following information will be extracted from the eligible studies: authors and year of publication; setting and location/country; population; recruitment method and consent rate; sample size and socio-demographic characteristics (e.g. age, gender, ethnicity, level of education, socio-economic status); smoking status and history (e.g. current or occasional smoker, level of nicotine dependence, interest in quitting), inclusion criteria and exclusion criteria; study design; video counselling intervention (e.g. number of contacts, duration, frequency, type of provider); comparison arm (e.g. control or other smoking cessation treatment, number of contacts/doses, duration, frequency, type of provider); biochemically-validated smoking cessation outcomes (where available) and self-reported smoking cessation outcomes; self-reported number of quit attempts; satisfaction and therapeutic alliance measures for video intervention and comparison arms; and costs.

If there are discrepancies in data extraction between the two authors they will be discussed until consensus is reached or, if required, a third author will be consulted for resolution.

Assessment of risk of bias in included studies

Two review authors (FT, CG or TR) will independently assess the risk of bias for included trials using the Cochrane Collaboration's tool for assessing risk of bias (Higgins 2011). For randomised controlled trials, the following seven study characteristics will be assessed: (i) random sequence generation (selection bias); (ii) allocation concealment (selection bias); (iii) blinding of participants and personnel (performance bias); (iv) blinding of outcome assessment (detection bias); (v) incomplete outcome data (attrition bias); (vi) selective outcome reporting (reporting bias) and (vii) other biases

(e.g. contamination, baseline imbalances, inappropriate administration of the intervention) (Higgins 2011). In addition, for cluster RCTs we will also assess the risk of: recruitment bias; baseline imbalance; loss of clusters; incorrect analysis; and comparability with individually randomised trials (Higgins 2011). Each of these features will be rated as either 'low', 'high' or 'unclear' risk using the criteria for judging risk of bias described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). If there are inconsistencies between the two review authors' ratings they will discuss to reach consensus and consult a third author if required.

Measures of treatment effect

For the dichotomous primary outcome, a risk ratio (RR) and 95% confidence interval (CI) will be calculated for each study. The RR for each study will be calculated as (number of participants that report smoking abstinence in the intervention group/number of participants randomised to the intervention group)/ (number of participants that report smoking abstinence in the control (comparison) group/number of participants randomised to the control (comparison) group). For dichotomous secondary outcomes, we will also calculate RR with 95% CI for each study. Continuous secondary outcomes will be analysed by calculating mean differences (MD) for each study.

Unit of analysis issues

For cluster RCTs, we will extract individual level data that adjust for clusters using an intracluster correlation coefficient (ICC). If clusters have not been controlled for in the analyses, the trial's authors will be contacted and the ICC information requested. If this information is unavailable, an estimate of the ICC will be obtained from similar studies where appropriate, and an approximate analysis performed.

Where RCTs or cluster RCTs include multiple arms, only the arms that meet the inclusion criteria will be included. If multiple intervention or control arms are eligible, all relevant and comparable intervention arms will be combined into a single intervention group and all relevant and comparable control arms will be combined into a single control group to create a single pair-wise comparison.

In trials with multiple follow-up points $\geq$ 6 months, the most stringent cessation outcome measured at the longest follow-up will be analysed.

Dealing with missing data

The number and percentage of participants lost to follow-up in each relevant arm will be reported, and considered in the 'Risk of bias' assessment. Where primary outcome data are missing at follow-up, a conservative approach commonly used in the tobacco control field will be used that assumes that individuals with missing data continue to smoke tobacco (Hedeker 2007). Where the trial's authors have conducted sensitivity analyses using different assumptions to deal with missing data this will be recorded. Analysis will be based on the intention-to-treat principle and participants will remain in the group they were randomly allocated to, irrespective of the extent to which they received the intervention/ comparison.

Assessment of heterogeneity

We will inspect the characteristics of included studies and consider whether there is clinical and/or methodological heterogeneity across included trials. We will also use forest plots to visually inspect statistical heterogeneity among studies. If there are sufficient homogenous studies, we will pool the data and quantify statistical heterogeneity using the I^2 statistic. The I^2 statistic is a measure of inconsistency that describes the percentage of variation between studies that is due to heterogeneity rather than sampling error (chance) (Higgins 2011). We will consider $I^2 \geq 50\%$ as representative of substantial heterogeneity (Higgins 2011), and where present will investigate the impact of using a random-effects versus fixed-effect model, and will explore reasons for such variability by conducting subgroup and sensitivity analyses.

Assessment of reporting biases

If there are at least 10 studies, we will use funnel plots to assess publication bias. Asymmetrical funnel plots may be indicative of publication bias, although other potential explanations for asymmetry in funnel plots include methodological flaws or true heterogeneity (Egger 1997). We will test for funnel plot asymmetry only if there are $\geq$10 studies in the meta-analysis, as the power would be too low to distinguish chance from real asymmetry if fewer studies were included (Higgins 2011).

Data synthesis

Where meta-analyses of outcomes is deemed appropriate, following assessment of heterogeneity, we will pool study RR, MD and standardised mean differences (SMD) for each outcome using a fixed-effect model. Continuous secondary outcomes will be analysed by calculating MD if the same method of measurement is used across trials for an outcome, or SMD if different measures are employed.

Individual-level data (adjusted for clusters) from cluster RCTs will be included in meta-analyses. For the primary outcome, a pooled RR > 1 will indicate that more participants in the real-time video counselling arm achieved tobacco abstinence than individuals in the control/comparison arm. Only studies where the isolation of the video component can be achieved (e.g. video counselling plus telephone counselling versus telephone counselling alone) will be included in the meta-analyses.

If there are insufficient homogeneous trials to permit meta-analyses, a narrative synthesis of the included studies will be presented. The narrative synthesis will categorise studies based on the intervention vs control/comparison group and the population type, and summarise the primary outcome (smoking cessation) followed by each of the secondary outcomes.

Subgroup analysis and investigation of heterogeneity

Where it is possible to carry out meta-analyses we will investigate potential heterogeneity between studies by categorising them by population for subgroup analyses (e.g., general population, type of patient population such as cancer patients or mental health patients), intensity of support (e.g. number of sessions), type of provider (e.g. healthcare provider, smoking cessation counsellor) and type of control/comparison group (e.g. no intervention control, proactive telephone counselling). We will compare pooled summary statistics across groups and run statistical tests for subgroup differences.

Sensitivity analysis

If sufficient studies are identified, we will perform sensitivity analysis to examine the impact of removing trials from the meta-analyses that are judged to be at high risk of bias (i.e. rated as high risk of bias on three or more domains). Although abstinence misreporting rates have been found not to differ significantly between intervention and control conditions (Lantini 2015), given there is often substantial non-response to biochemical validation in studies of remote interventions, we will also perform sensitivity analysis to examine the impact of using self-reported cessation rates only.

'Summary of findings' table

We will include a 'Summary of findings' table that will describe the information recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Two review authors will also assess the quality of the body of evidence for the primary outcome (i.e. smoking cessation), and for the secondary outcome 'therapeutic alliance' using the GRADE approach (Guyatt 2011). This will involve consideration of: risk of bias (methodological quality); directness of evidence; heterogeneity; precision of effect estimates; and risk of publication bias. Each outcome will be assigned a GRADE quality rating of 'very low', 'low', 'moderate' or 'high'. Any disagreements will be discussed by the two review authors until consensus is reached, and if required a third author will be consulted.

Incorporating economic evidence

We will develop a brief economic commentary based on current methods guidelines (Shemilt 2011), to summarise the availability and principal findings of trial-based economic evaluations (cost analyses, cost-effectiveness analyses, cost-utility analyses and cost-benefit analyses) that compare real-time video counselling to no intervention control or other smoking cessation treatments, among current tobacco smokers. This commentary will focus on the extent to which principal findings of eligible economic evaluations indicate that an intervention might be judged favourably (or unfavourably) from an economic perspective, when implemented in different settings. The eligibility criteria for the studies that will be included in the brief economic commentary (with respect to the population, intervention, comparator(s) and primary health outcome) will be the same as those for the main systematic review of treatment effects.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

1	exp Smoking/
2	exp Smoking Cessation/
3	exp Tobacco/
4	exp Tobacco Products/
5	exp "Tobacco Use"/
6	exp "Tobacco Use Cessation"/
7	exp "Tobacco Use Cessation Products"/
8	exp Nicotine/
9	smok*.mp
10	tobacco.mp
11	cigar*.mp
12	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11
13	exp Videoconferencing/
14	exp Remote consultation/
15	exp Telemedicine/
16	tele?health.mp
17	tele?medicine.mp
18	video*.mp
19	Skype.mp
20	Facetime.mp
21	Google+Hangouts.mp
22	Talky Core.mp

(*Continued*)

23	Messages.mp
24	Viber.mp
25	Tango.mp
26	13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
27	exp Randomized Controlled Trial/
28	exp Randomized Controlled Trials as Topic/
29	exp Clinical Trial
30	exp Clinical Trials as Topic/
31	exp Pragmatic Clinical Trial/
32	exp Pragmatic Clinical Trials as Topic/
33	exp Random Allocation/
34	random*.mp
35	RCT*.mp
36	trial*.mp
37	27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36
38	12 and 26 and 37

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