



# A randomised trial of real-time video counselling for smoking cessation in regional and remote locations: study protocol

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## ARTICLE INFO

### Keywords:

Video counselling  
Telehealth  
Telephone counselling  
Smoking cessation  
Regional  
Remote

## ABSTRACT

**Background:** Real-time video communication technology (e.g. Skype) may be an effective mode for delivering smoking cessation treatment to regional and remote residents. This randomised trial examines the effectiveness of real-time video counselling compared to: 1) telephone counselling; and 2) written materials (control) in achieving smoking abstinence in regional and remote residents.

**Design:** A three-arm, parallel group, randomised trial will be conducted with smokers residing in regional and remote areas of New South Wales, Australia. Potential participants will complete an online screening survey and if eligible an online baseline survey. Participants will be randomly allocated into: 1) real-time video counselling; 2) telephone counselling; or 3) written materials (control). In the video counselling intervention an advisor will deliver up to six video sessions (e.g. via Skype) to participants. Those who nominate a quit date within a month during the initial video session will be offered sessions on the quit date, 3-, 7-, 14- and 30-days after the quit date. Those not ready to set a quit date within a month during the initial video session will be offered sessions 2-, 4- and 6-weeks later. Other than delivery mode, the video counselling and telephone counselling will be identical in content and callback schedules. Control group participants will be mailed one-off written materials. Follow-up surveys will occur at 4-months, 7-months and 13-months post-baseline. The primary outcome will be 7-day point prevalence abstinence at 13-months post-baseline.

**Discussion:** Real-time video counselling may be an effective strategy for smoking cessation that could be integrated into quitlines globally.

## 1. Introduction

In developed countries such as the United States and Australia, adults living in rural, regional or remote locations are a priority population for smoking cessation interventions because they are more likely to smoke tobacco [1,2] and experience more difficulty accessing face-to-face smoking cessation services than those in major cities [1,3]. In a Canadian study 90% of rural or remote smokers indicated they would have to travel over 500 km to attend a face-to-face group counselling program [3]. Effective modes of delivering smoking cessation interventions that may be more easily accessible in regional and remote areas include telephone-based counselling [4,5], internet programs [6] and printed materials [7].

Real-time video communication technology (e.g. Skype, FaceTime)

could also reach smokers in regional and remote areas and consists of a video camera connected to a smart phone, tablet or computer, that transmits live, interactive, video and audio over the internet [8]. The similarities between face-to-face counselling which is one of the most effective behavioural treatments for smoking cessation [9] and virtual face-to-face communication via video software may mean that video counselling for smoking cessation may be more effective than current non-face-to-face communication modes used to deliver smoking cessation interventions.

Two randomised trials have examined the effectiveness of real-time video counselling for smoking cessation [10,11]. One trial delivered video counselling to smokers directly in their homes [10]. This trial randomly allocated Korean American women to video counselling or telephone counselling and found that 7-day point prevalence abstinence

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<https://doi.org/10.1016/j.cct.2018.10.001>

Received 29 June 2018; Received in revised form 22 September 2018; Accepted 1 October 2018

Available online 02 October 2018

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rates did not differ between the groups at 3 months [10]. However, this study included only 49 participants and therefore had limited power to detect differences in abstinence rates and the generalisability of findings to other populations may be limited [10]. Another randomised trial with U.S. rural smokers examined the effectiveness of real-time video counselling delivered to smokers in their primary care physician's office compared to telephone counselling delivered to smokers at home [11]. This trial found no significant differences in 7-day point prevalence abstinence rates at 12-months [11]. Given this trial required rural smokers to attend a primary care physician appointment to receive the video counselling intervention these results may be limited to those in this setting. Both studies were comparative effectiveness trials (i.e. video vs telephone) [10,11] and hence the effectiveness of real-time video counselling compared to a control was not determined.

No studies have examined the cost-effectiveness of individual, real-time video counselling for smoking cessation delivered directly to regional and remote smokers in their homes compared to telephone counselling or written materials. A cost study with rural smokers examined the resources required to deliver video support in their primary care physician's office compared to telephone support. This study found the mean cost for the telephone group was US\$53.25 compared to US\$47.04 for the video group [11].

This randomised trial aims to examine the effectiveness and cost-effectiveness of real-time video counselling compared to: a) telephone counselling; and b) written materials (control) in achieving smoking abstinence among regional and remote residents.

## 2. Material and methods

### 2.1. Design

A three-arm, parallel group, randomised trial will be conducted with smokers residing in regional and remote areas of New South Wales (NSW), Australia. Participants will be randomly allocated into either: 1) real-time video counselling; 2) telephone counselling; or 3) written materials (control). Given the small effect of written materials on smoking cessation [7], this group will be the control (i.e. minimal support), which is consistent with randomised trials of telephone counselling for smoking cessation [4,5]. Online surveys will be administered at baseline, 4-months, 7-months and 13-months post-baseline (Fig. 1).

### 2.2. Setting

NSW covers an area of 809,444 km<sup>2</sup> and is the most populous state in Australia with 7.7 million residents [12]. 25% of NSW residents live in inner regional, outer regional, remote and very remote locations [12]. Based on the Accessibility and Remoteness Index of Australia (ARIA+) [13], there are 1.47 million residents in inner regional locations, 445,258 residents in outer regional areas, 28,957 residents in remote and 7835 residents in very remote locations of NSW [12].

### 2.3. Participants

Eligibility requirements will be: daily tobacco use; aged 18 years or older; access to video-communication (e.g. Skype, FaceTime); internet access; telephone access; e-mail address; and residing in inner/outer regional or remote/very remote areas of NSW.

### 2.4. Recruitment and screening survey

Smokers who live in inner/outer regional and remote/very remote areas of NSW will be recruited via online (e.g. Facebook, Twitter, e-mail) and traditional strategies (e.g. newspaper, radio, posters). The ARIA+ will identify inner regional (> 0.2- ≤ 2.4), outer regional (> 2.4- ≤ 5.92), remote (> 5.92- ≤ 10.53) and very remote (> 10.53)

areas of NSW based on residential postcode [13]. ARIA+ codes are based on the accessibility to services, specifically the road distances needed to travel from the location to service centres of various population sizes [13]. Potential participants will be invited to go to a project website which describes the trial, conditions, eligibility criteria, and contains a detailed information statement. The information statement will be viewed prior to potential participants completing an online screening survey. The information statement indicates that participants should be sure they understand all its contents before they consent to participate and if there is anything they do not understand, or if they have questions, to ask the researcher. Once potential participants have read the information statement and understand its contents they will be invited to take part and complete the online screening survey. Potential participants will be able to access the hyperlink to the online screening survey via the website which will take < 5 min to complete. During the screening survey, the Qualtrics computer software will determine whether eligibility requirements are met and notify potential participants whether or not they are eligible to participate. Eligible participants will be immediately and automatically redirected to the online baseline survey. Ineligible participants will be provided with information onscreen about how to access the NSW Quitline [14] and written materials.

### 2.5. Baseline survey and randomisation

The online baseline survey will take approximately 10–15 min to complete. At the end of the baseline survey, a random number function within the Qualtrics survey software will randomly allocate the participant to either: 1) real-time video counselling; 2) telephone counselling or 3) written materials (control). The survey software will immediately notify the participant of their allocated condition. Participant blinding will not be possible because they will be aware of whether counselling is received, and if so whether by telephone or video.

#### 2.5.1. Real-time video counselling condition

The same protocol and group of advisors will be used to deliver both the video counselling and telephone counselling so only the mode of delivery differs between these groups. Smokers in the video counselling condition will receive up to six video sessions from an advisor via the participant's preferred form of video communication. To protect privacy and provide a secure connection for each session between the advisor and the participant the video software (e.g. Skype, FaceTime) uses encryption. The first video session will be scheduled within 7 days of participant enrolment on a convenient day/time as specified by the participant during the baseline survey. The content will be based on quitline protocols and the advisor will use evidence-based techniques such as cognitive behaviour therapy [15] and motivational interviewing [16] to support smokers to quit. An evidence-based schedule that accounts for the greatest probability of relapse and involves most calls being scheduled in the critical first two weeks following a quit attempt will be used [17]. For those who nominate a quit date within a month during the initial session, subsequent video sessions will be offered on the quit date and 3-, 7-, 14- and 30-days after the quit date. Those who relapse and set a new quit date within a month will restart the ready to quit callback schedule, whereas those who do not set a new quit date will be offered a call in 2 weeks time.

Those who are not ready to quit within a month during the initial session will be offered video sessions at 2-, 4- and 6- weeks. If those in the not ready to quit schedule indicate during counselling that they are now ready to quit within a month, they will begin the ready to quit callback schedule on their nominated quit date. Each video session will take on average between 15 and 20 min. The advisor will make six attempts to reach the participant for each video session.

During the first video session the advisor will assess the participant's smoking history, discuss barriers to smoking cessation, identify potential solutions for overcoming these difficulties, and provide information

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