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Information Statement for the Research Project:

A randomised controlled trial of the effectiveness of real-time video counselling on smoking cessation in smokers residing in regional and remote areas

The Research Team:

University of Newcastle: Dr Flora Tzelepis, Prof John Wiggers, A/Prof Christine Paul, Prof Jennifer Bowman, Ms Judith Byaruhanga, Miss Emma Byrnes

Hunter New England Population Health: Dr Elizabeth Campbell, Ms Karen Gillham

You are invited to participate in the research project identified above which is being conducted by the research team from the University of Newcastle and Hunter New England Population Health. People who smoke tobacco daily and live in regional and remote areas of New South Wales are being invited to participate in this study. This research has been funded by the Cancer Institute NSW.

Why is the research being done?

The purpose of the research is to provide support to those who are interested in quitting. Those who participate in the study will be offered either video support sessions (via Skype, Facetime or other form of video communication), telephone support calls or written materials. This will help us determine if smokers who live in regional and remote areas are willing to use these types of support during a quit attempt and the helpfulness of each of these strategies.

Who can participate in the research?

People who are able to participate in this study will:

- currently smoke cigarettes or use tobacco every day;
- be aged 18 years or older;
- have access to a telephone;
- have access to a mode of video-communication (e.g. Skype, Facetime or other form);
- have access to the internet;
- have a current e-mail address; and
- live in a regional or remote area of NSW.

What choice do you have?

Participation in this research is entirely your choice. Only those people who give their informed consent will be included in the project. Whether or not you decide to participate, your decision will not disadvantage you in any way. If you decide to participate, we will offer you assistance to help you quit smoking and ask you to complete surveys regardless of whether you quit successfully, relapse or do not quit smoking. If you do decide to participate, you may withdraw from the project at any time without giving a reason.

What would you be asked to do?

If you agree to participate, you will be asked to:

Complete a 5 minute screening survey: Potential participants will be asked to complete an online screening survey so that we can determine if you are eligible to participate or not.

10 minute baseline survey: After completing the screening survey, those who are eligible to participate will be automatically re-directed to an online baseline survey. The survey will take about 10 minutes to complete and will ask you questions about your smoking habits, previous quit attempts and intentions and confidence to quit smoking. At the end of the baseline survey the computer program will randomly allocate

you to one of the following forms of support to help you with any quit attempts you make: 1) video support sessions (via Skype, Facetime or other form of video communication); 2) telephone support sessions; or 3) written materials. Participants will only be offered the form of smoking cessation support they are randomly allocated to.

One-third of participants will receive video support sessions

If you are randomly allocated to the video support sessions you will be asked about which form of video-based communication you prefer (e.g. Skype, Facetime or other form) and to provide relevant details (e.g. Skype address) so that an advisor can contact you for the video support sessions.

You will be offered up to six video support sessions to assist you to quit smoking or move closer to quitting. Video support sessions will be offered: on the initial session, on the quit date and 3-, 7-, 14- and 30-days after the quit date. If you are not ready to set a quit date, video support sessions will be offered: on the initial session, 2-, 4- and 6 weeks later. However these sessions will be scheduled according to your availability and preference. You can use as many or as few video support sessions as you like.

One-third of participants will receive telephone support calls

If you are randomly allocated to the telephone support calls you will be asked to provide relevant details (e.g. preferred telephone number) so that an advisor can telephone you.

You will be offered up to six telephone support calls from an advisor to assist you to quit smoking or move closer to quitting. Telephone support calls will be offered: on the initial session, on the quit date and 3-, 7-, 14- and 30-days after the quit date. If you are not ready to set a quit date, telephone support calls will be offered: on the initial session, 2-, 4- and 6 weeks later. However these telephone calls will be scheduled according to your availability and preference. You can take as many or as few telephone support calls as you like.

One-third of participants will receive written materials

If you are randomly allocated to receive the written materials you will be asked to provide your postal address so that we can mail these to you. The written materials will include information about products and strategies that can help you during a quit attempt.

Complete 10 minute surveys 4-months, 7-months and 13-months later: In 4-months, 7-months and 13-months after the baseline survey, you'll be asked to complete online surveys. These surveys will ask you about your smoking and quitting behaviours and how useful you found the support you received.

How much time will it take?

Each online survey should take approximately 10 minutes to complete. For those offered the video support sessions, telephone support calls or written materials you can use these for as long as you like. Each video support session or telephone support call will take approximately 10-15 minutes.

What are the risks and benefits of participating?

We cannot promise you any benefit from participating in this research. However, the support you receive may help you improve your health. The surveys also include brief questions about alcohol consumption, financial issues and mental health. We do not expect that there will be any risks associated with participating. It is possible that participation may cause you to reflect on and raise questions about your health. If you do have questions about your health, we recommend that you discuss these with your doctor. Other sources of support also include Beyondblue (telephone 1300 22 4636) or Lifeline (telephone 13 11 14).

How will your privacy be protected?

The information that you provide will be stored securely. The contact details that you include in the online baseline survey so that we can contact you to provide the support to assist with quitting will be stored separately from your survey data. Any identifying information will be stored securely in a password protected file on the University of Newcastle server. This information will only be accessed by the researchers except as required by law. Data will be retained for at least 7 years in a locked filing cabinet and password protected files at the University of Newcastle.

How will the information collected be used?

The information that we collect will be used to identify how effective video support sessions, telephone support calls and written materials are in helping people to quit smoking. The results will also be reported in scientific journals and conference papers. Ms Judith Byaruhanga, a PhD student at the University of

Newcastle, will also report the findings in her PhD thesis. A summary of the results will also be provided to the Cancer Institute NSW.

Individual participants will not be named in any of the reports about the study. Data will only be presented in summarised form. You will be able to withdraw your data at any time.

In the final online survey in 13-months you will be asked if you would like to receive a summary of the key findings of the project. This information will be e-mailed to those who are interested in receiving a copy of the summary. You can also request a summary of the project findings via e-mail or telephone by contacting Dr Flora Tzelepis using the contact details listed below. In the 13-month survey you will also be asked if you would be interested in being asked to take part in any future studies conducted by the research team. If during the 13-month survey you agree to be contacted about future studies, this does not mean you need to participate in this future research, you would only be agreeing to be contacted and invited to any future studies.

What do you need to do to participate?

Please read this Information Statement and be sure you understand all its contents before you consent to participate. If there is anything you do not understand, or you have questions, please ask the researcher.

If you would like to take part, please complete the online screening survey by selecting this hyperlink http://newcastlebusandlaw.co1.qualtrics.com/SE/?SID=SV_5gSXDPIW1TQJ6t This screening survey will determine whether you are eligible to participate. Those who are eligible will be automatically re-directed to the online baseline survey, after completing the screening survey. If you complete the online baseline survey then this will mean that you have understood what was asked and agreed to take part.

Further information

If you would like further information please contact:

Dr Flora Tzelepis: on email flora.tzelepis@newcastle.edu.au or phone (02) 4924 6275

Thank you for considering this invitation.

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Complaints about this research

This project has been approved by the University of Newcastle Human Research Ethics Committee (Approval No. H-2016-0148).

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Office, The Chancellery, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 49216333, email Human-Ethics@newcastle.edu.au