

PARTICIPANT INFORMATION SHEET

TITLE:	The New Zealand 'Step Away' Study
PROTOCOL NUMBER:	Version 1.0
FUNDED BY:	Health Research Council of New Zealand
INVESTIGATOR:	Dr Natalie Walker
INSTITUTION:	University of Auckland
TELEPHONE:	(09) 923-9884

Kia ora ra, tenei te toonoa ki a koe.

We would like to invite you to take part in a study called 'Step Away'. If you have any questions, please feel free to ask the researcher when they contact you or call us on 09 923 8663.

Purpose of the study

The study is about testing a smartphone app called 'Step Away' to see how good it is at helping people who are drinking at harmful levels to reduce the amount of alcohol they drink, or stop drinking alcohol altogether. The app is also designed to help people connect with alcohol-related health services should they need them.

The 'Step Away' app has been developed in America and needs to be changed to suit the New Zealand culture. We have made some changes to the app and now need to test it to see how well it works. This is where we need your help.

Where will the study be undertaken?

The study will take place throughout Auckland.

About the study

We plan to recruit 200 people into the study between April and May 2018. People will be in the study for six months.

If you agree to take part in the study, you will be randomly allocated (like the toss of a coin) to one of two groups:

- **App Version 1 group:** If you are in this group you will get six months free access to Version 1 of the 'Step Away' app.
- **App Version 2 group:** If you are in this group you will get six months free access to Version 2 of the 'Step Away' app.

Both apps are designed to give you feedback, tools, and support to reduce or stop drinking alcohol. The two apps differ in that they allow access to a different number of features.

A researcher will also call you four times during the six month period (each call will last 10-15 minutes) to collect information about your drinking habits and health, and your views about the app you have been given access to.

Who can take part in this study?

You can take part in this study if you:

- Currently live in Auckland
- Currently drink alcohol
- Have had two or more occasions in the last 30 days where you have drunk six or more glasses of alcohol on one occasion
- Score 8-19 on our alcohol use questionnaire (click <here> to take the questionnaire. It will automatically create a score for you)
- Are aged 18 years or over
- Are able to provide consent
- Have access to a smartphone
- Want to reduce or stop drinking alcohol

You can't take part in this study if you are currently enrolled in an alcohol treatment programme or if you score 20 or more on our alcohol use questionnaire.

What will I be asked to do?

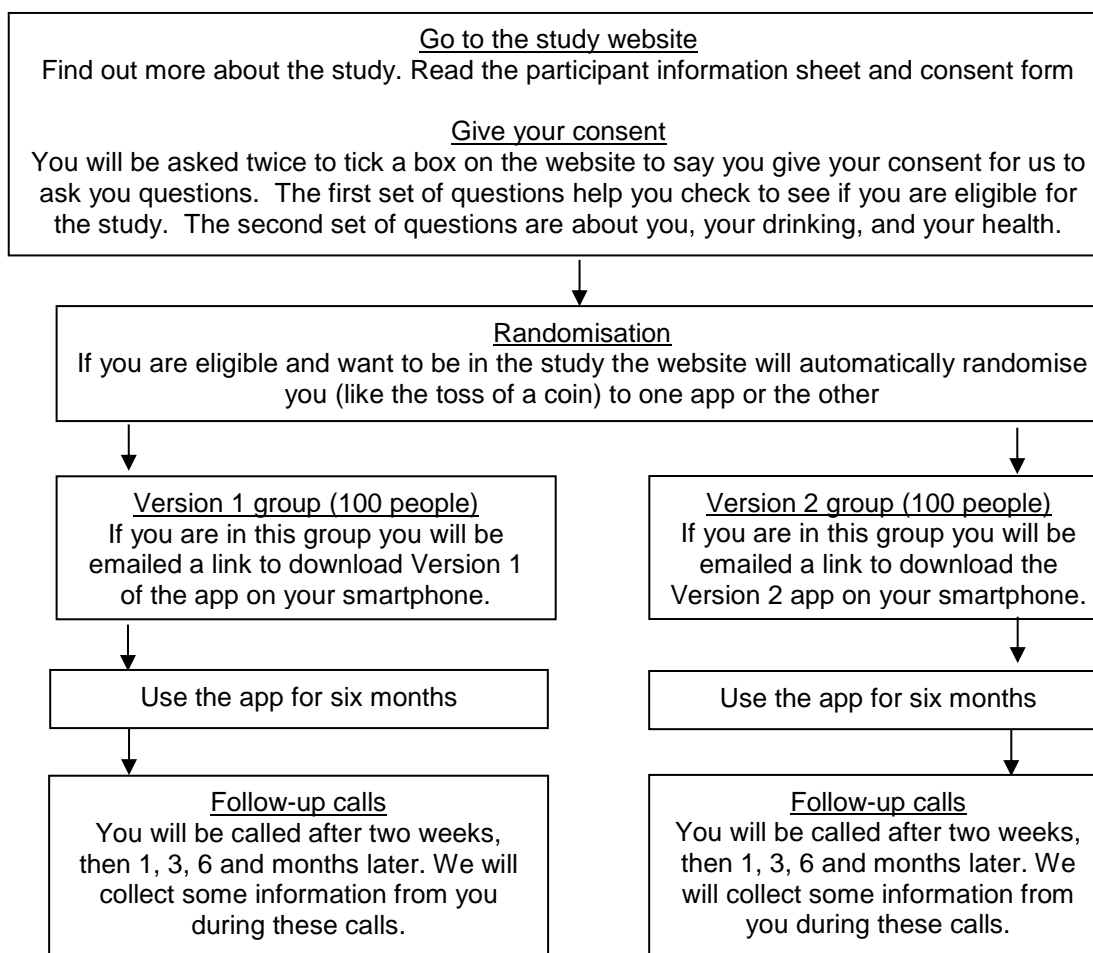
- On the study website there is further information about the study, including a copy of the participant information sheet and consent form.
- This study involves a two-step consent process. First we need your consent to ask you questions to see if you are eligible. Once this is confirmed, we need your consent to come into the study. At each stage, simply tick the 'consent' box on the website if you wish to continue.
- Once your consent has been provided a copy of the participant information sheet and consent form will be emailed to you. If you wish you can call a researcher on 09 923 8663 to discuss the study further, before you provide your consent.
- You will then need to complete a short on-line questionnaire where you will be asked questions about your age, gender, ethnicity, and education, your drinking, whether other people in your house also drink alcohol, and whether you currently have depression, anxiety and/or use other addictive drugs (such as tobacco, etc). All information will be kept strictly confidential.
- You will then be randomised by computer (like the toss of a coin) to either Version 1 of the app or Version 2 of the app.
- You will be emailed a link to your app, which you will need to download onto your smartphone. The app will be free and there are no in-app purchases required. You will need to use your app for six months. During this time, the app will be collecting data on how much you use each feature.
- Two weeks, then one, three, and six months after you have been randomised, you will be called by a researcher and asked about your drinking habits, health, and engagement with

health services. On the last call at six months the research will also ask for your views about the app.

- When a researcher calls you, you do not have to answer all of the questions, and you may stop the interview at any time. Each call will take 10-15 minutes.

Study design

The picture below will give you an idea about how the study works.



Will participating in the study affect my healthcare?

Your GP (and/or any specialist who you have been seeing) will continue to care for you during the study. We will send your GP a letter to say you are participating in the study. If you do not want us to do this, please let us know.

Will I be paid?

No, people are not usually paid for participating in clinical studies.

Will it cost me anything to be in the study?

No. The app to be used in this study will be free and there are no in-app purchases required.

Benefits

- The app may help support you to reduce or stop drinking.
- The app can connect you with support services if you need them.

'Step Away' Study, PIS and consent v1.0, 07 June 2017

- If you reduce or stop drinking alcohol your health will improve, and the risk of experiencing alcohol-related harm will reduce.
- Your input into the study will be help us refine the app for other people who want to reduce or stop drinking alcohol.

Potential risks and discomforts

- Reducing the amount of alcohol you drink, or stopping completely, may lead you to experience alcohol withdrawal symptoms, such as agitation, anxiety, and/or shakiness.
- These feelings are quite common when people reduce or stop drinking, and they will go away over time.
- The apps used in this study will help you manage these feelings.
 - If you have major changes in behaviour or thinking, anxiety, psychosis, mood swings, agitation, aggression, depressed mood, suicidal thinking and suicidal behaviour, you should contact your doctor or another health professional immediately and also ring us on 09 923 8663

What if something goes wrong?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you should check with your insurer that taking part in this study won't affect your cover.

What are my rights?

Your participation in this study is entirely voluntary (your choice). You do not have to take part. Take your time in deciding if you wish to take part in the study. You may like to talk to your whānau/ family and/or Doctor about the study before taking part.

If you agree to take part in the study, you should only use the app we have given you – not any other alcohol management app. If you choose to stop using the app before the study is over, we would still like to contact you at six months to see if you have reduced or stopped drinking alcohol. If you withdraw from the study we would like to use your information up to the point you withdraw.

All information that you provide will be strictly private. No material that could identify you will be used in any reports on this study. The information will be kept at the National Institute for Health Innovation, the University of Auckland. All computer records will be password protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act, 1994.

During the study only the 'Step Away' researchers and the study monitor will have direct access to your information. Representatives of the ethics committee may also require access. This access will only be to check the accuracy of the information collected for the study, and the information will remain confidential.

As a participant you have the right to access your information and to correct your information in the study documents. If you wish to do this, then just ask us when we contact you.

If we learn of any new information of importance to the content of the apps, that could have a positive or negative effect on your health, we will inform you as soon as possible.

What will happen when the study has ended?

We hope to finish collecting all the information for the study by December 2018. We will then analyse the data, and publish the findings in a medical journal. At the earliest, this publication will

be available mid to late 2019. We will then notify you of the results by email or post. We will keep your information for 10 years after the study is completed.

Who do I contact for more information or if I have concerns?

If you want to talk to someone who isn't working on the study, you can contact a health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

Mēnā he pakirehua tāu, whakapāngia mai a Rhys Jones
(For Māori health support, please contact Dr Rhys Jones):

Phone: 09 923 6278
Email: rg.jones@auckland.ac.nz

Step Away has received ethics approval from the Health and Disability Ethics Committee (HDEC). You can contact the Health and Disability Ethics Committee on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Thank you

Online Consent Form (Stage 1)

Step Away

A study to compare two smartphone apps that aim to support people to reduce or stop drinking alcohol.

I have read the study explanation online and I understand it.

I have been given enough time to decide whether or not to take part in this study.

I give my consent to ask me questions about my eligibility for the study.

I understand that taking part in this study is my choice, and I may withdraw from the study at any time.

I consent to the research staff collecting information about my health. I understand I have the right to access and, if needed, to correct my information.

I understand my responsibilities as a study participant.

I understand my taking part in this study is confidential and that nothing that could identify me personally will be used in any reports.

I understand that a monitor or members of the ethics committee may review my study records to check the accuracy of the information collected for the study.

I understand this study is covered under ACC compensation.

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be used.

Participant's name: _____

Date: _____

Online Consent Form (Stage 2)

Step Away

A study to compare two smartphone apps that aim to support people to reduce or stop drinking alcohol.

I have read the study explanation online and I understand it.

I have been offered the chance to talk with my whānau/ family and/or Doctor to help me ask questions and understand the study before taking part.

I have been given enough time to decide whether or not to take part in this study.

I give my consent to take part in this study.

I understand that taking part in this study is my choice, and I may withdraw from the study at any time.

I consent to the research staff collecting information about my health. I understand I have the right to access and, if needed, to correct my information.

I understand my responsibilities as a study participant and I agree to use the 'Step Away' app.

I understand that I need to download the app on my smartphone, and I will do this as soon as possible.

I agree to accept study-related telephone calls at a telephone number of my choice. If needed, researchers can leave messages about the reason for calling.

I understand the risks associated with participating in this study.

I understand my taking part in this study is confidential and that nothing that could identify me personally will be used in any reports.

I understand that a monitor or members of the ethics committee may review my study records to check the accuracy of the information collected for the study.

I understand this study is covered under ACC compensation.

If I decide to withdraw from using the study application, I agree to be contacted for the follow-up phone calls.

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be used.

I wish to receive a summary of the results from the study. I understand the results will not be available until mid to late 2019.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
I would like my usual doctor to be told I am participating in this study	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Participant's name: _____

Date: _____