

Participant Information Sheet

Study title: Natural health products (NHPs) in alcohol, tobacco, and other recreational substance use: pre-testing a data collection tool

Investigators:

Principal investigator (PI)/Supervisor:

Professor Jo Barnes, School of Pharmacy, University of Auckland

Co-investigator:

Dr Rhys Ponton, School of Pharmacy, University of Auckland

Student Researcher:

Rayna Sharma, School of Pharmacy, University of Auckland

Tēnā koe, hello, and warm Pacific greetings

This participant information sheet will help you decide if you would like to take part in this study. It explains the reasons for doing the study, what being a participant involves, outlines potential risks and benefits, and describes what will happen when the study ends.

This project is being conducted by Rayna Sharma (a PhD candidate in the School of Pharmacy, University of Auckland) as part of her PhD thesis, under the supervision of Professor Jo Barnes and Dr Rhys Ponton.

If any questions arise, please contact the study researchers (contact information at the end of this document). You may wish to discuss your involvement in this study with family, whānau, or friends. You are welcome to do this. You can forward the details of this study to any family members, whānau, or friends who may also be interested in taking part.

If you agree to participate in this study, you will be asked to complete an online consent form.

Background:

Natural health products (NHPs), (also described as complementary and alternative medicines) are used for many health reasons. Some NHPs are claimed or promoted to help prevent unpleasant effects (symptoms) and harms that some people experience from using alcohol and/or tobacco use (e.g., cure or prevent 'hangovers', to stop cravings for nicotine, and to help 'detox' the liver). Some NHPs have also been used recreationally for their psychoactive ('mind-altering') effects.

At present, very little is known about which NHPs are used in New Zealand to help with symptoms from using alcohol, tobacco and/or other recreational substances, or for psychoactive effects.

This study aims to test a questionnaire that has been designed to collect information about NHPs that are used in New Zealand to help with alcohol, tobacco and/or other recreational substance use, or for psychoactive effects. We are doing this study to improve the questionnaire, which we will then use in future studies.

About this study:

This study involves two phases:

- Phase 1 is an **online questionnaire**. You will be asked to answer questions on your:
 - Use of NHPs
 - Use of alcohol
 - Use of tobacco
 - Use of other recreational substances
 - Understanding of and views on the questions we have asked on these topics

- Phase 2 is a follow-up **online interview** (by videolink, or audio-only if preferred) to explore your understanding of the questions from Phase 1 in more detail, and for us to collect feedback on the questionnaire.

You can choose to take part in Phase 1 (questionnaire) only, or to take part in both Phase 1 and Phase 2. If you wish to take part in Phase 2 (interviews), you will be required to indicate this and provide your contact details on the study consent form.

This study is an independent study. It is a student doctoral research project at the University of Auckland. If you are a student at the University of Auckland, participation or non-participation will not impact your relationship with the University and your grades will not be impacted.

Please note: If you are a member of The University of Auckland staff and you disclose information which suggests you have violated professional and/or ethical obligations within the university, we may be required to breach confidentiality and report this to the relevant university organisations.

Study procedures:

We aim to recruit approximately 100 people in Phase 1 (online questionnaire) of the study, and up to 20 people for the interviews in Phase 2. Please note that as we can only interview up to 20 people, there is a chance that, even if you have agreed to participate in Phase 2, we may not be able to interview you.

Phase 1 (online questionnaire):

The online questionnaire will ask you to answer several questions about your use of NHPs, alcohol, tobacco, and other recreational substances. You will also be asked for your feedback on the clarity and ease of answering each question.

It will take you approximately 30 - 40 minutes to complete the questionnaire. You can complete and submit the questionnaire once only.

You can complete the questionnaire at a time and place that suits you. You may wish to complete the questionnaire in a private area, and to use a personal or secure device and internet connection, as you will be asked personal questions about your use of alcohol and/or other substances.

You will need to complete and submit the survey all in one 'go' as the website will not be set to 'save' partial responses. Before you start to complete the questionnaire, we recommend that you gather together any NHPs that you are taking to prevent interruptions while you are completing the questionnaire.

If you wish to complete a paper-based copy of the questionnaire, instead of the online version, please contact the research team (see contact details below). You will be posted a questionnaire with a unique identifier.

Participants who complete the questionnaire will be offered a \$20 shopping e-voucher. You will be asked to provide your name and email address at the end of the questionnaire to receive this. Participants who completed a paper-questionnaire will be offered a physical \$20 shopping voucher. This will be posted to you after we receive your completed questionnaire form.

Your name and email (or physical) address will be stored separately from your questionnaire responses (that is, we will not link your contact information to your answers).

You are strongly encouraged to download a copy of your questionnaire responses at the end of the questionnaire, particularly if you volunteer to participate in Phase 2 (interviews).

Phase 2 (interview):

Participation in the follow-up interview involves having an online discussion with a student researcher through a *video* communication platform, such as Zoom. You can be interviewed by telephone if you prefer. You are advised to be in a private and quiet environment to do the interview.

The interview will take approximately 30 – 45 minutes, depending on the length of your answers. The interview consists of questions about your views on the questions included in the online questionnaire.

All interviews will be video and audio-recorded by default (unless you are interviewed by telephone, as these are only audio-recorded). If you would like to be audio-recorded only, please let the research team know when you are contacted. All interviews will be transcribed verbatim (word-for-word) by the student researcher. These interviews will be conducted during working hours (9am to 5pm) from Monday to Friday.

You are welcome to have a whanau member or support person present during your interview. However, anything they say will not be included in the interview.

Participants who are interviewed will be offered a \$50 shopping voucher; this will be emailed or posted to you after the interview.

If you volunteer to be interviewed, you are strongly encouraged to download a copy of your questionnaire responses at the end of Phase 1 (you will be able to do this at the end of the questionnaire) to refer to during the interview. We can also provide you with a copy of your responses should you forget to do this.

If you volunteer to be interviewed, please indicate on the consent form if you would like to receive a copy of your interview transcript for you to check and edit if you wish. If you request this, we will send you your transcript and ask that you highlight the changes you would like to make and return it to us (by email) within two weeks of the date you receive it. If you do not return the transcript within this time, we will assume that you do not have any changes to make to its content.

Invitation to participate:

If you are aged 18 years or over AND if you have EVER used (drunk) alcohol, smoked tobacco and/or tobacco products, or used other recreational substances, we are inviting you to take part in this study.

Participation in this study is completely voluntary. If you would like to participate, you will be asked to provide your consent before completing the online questionnaire. When providing consent, you will be asked to indicate your interest and provide consent to be contacted to participate in an optional follow-up online *video* interview. You may choose to have an *audio* interview (if preferred). If you are Māori, you will be asked if you would like to be interviewed (in English) by a Māori interviewer. You are welcome to have a member of your whānau present during the interview if you wish. We are conducting up to 20 interviews, so even if you agree to be interviewed, you may not be selected. If this is the case, we will inform you of this.

If you give your consent to be interviewed, and if you are selected for the interview, the student researcher will contact you via telephone or email to arrange a suitable date and time for an interview.

Possible risks and benefits of taking part in the study:

There is no direct benefit to you if you participate in this study. You are not expected to experience any physical risks from this study.

During the study, you may share information about your use of legal (and, possibly, illegal) substances, and this may make you more aware of your current use habits. By taking part, you may also share information about your substance use behaviour that is harmful to your health, or to those living with you, or someone in your care. Disclosing this information might make you feel emotionally distressed or uncomfortable.

Please note: if you provide your information (to be interviewed) and you disclose details during the study which reveals that you, or someone you know, is at clear risk of serious harm (that is, if you express a clear intention to cause harm to yourself either directly, or by deliberately increasing your substance use, or you express a clear intention to cause harm, or are already causing harm, to others) we will be required to follow moral and legal obligations to breach confidentiality and report this risk to the appropriate authorities and/or others, where relevant.

If you are a registered health professional (or in-training to-be) and you disclose information which suggests that the health or life of any patient(s) in your care may be at risk or impacted negatively, we may be required to breach confidentiality and report this to your relevant regulatory body(ies).

If you are a member of The University of Auckland Faculty of Medical and Health Sciences staff and you disclose information which suggests you have violated professional and/or ethical obligations within the university, we may be required to breach confidentiality and report this to the relevant university organisations.

We encourage you to contact your primary healthcare provider if you have any questions or concerns about your substance use. You can also contact the Alcohol Drug Helpline (0800 787 797) or visit their website <https://alcoholdrughelp.org.nz/> for more information. Alternatively, a list of contact information for other relevant support organisations can be found in Appendix one, at the end of this document.

Data storage, retention, destruction, future use:

We recognise that the information you will share with us is sensitive and it is important that it is kept secure.

Consent forms will be stored for six years. Any paper-based study data will be stored in a locked filing cabinet in the School of Pharmacy, University of Auckland for at least six years or until the publication process is complete. Electronic files will be stored in password-protected folders on the secure University of Auckland network.

Interview transcriptions and other study data will be retained for at least six years for the purposes of writing reports and publications. Electronic study data for each participant will be stored using a unique identifier. A separate, password-protected file linking participants' details with the unique identifier will be kept. After the study is finished and the publication process is completed, all information will be destroyed by shredding (paper data) or deletion (electronic files).

Right to withdraw from participation:

Phase One (online questionnaire): You are able to withdraw your participation from the study at any time before or during completion of the questionnaire by closing your web browser. However, please note that once you complete and *submit* the questionnaire, we will not be able to withdraw your participation or your data.

Phase Two (interview): If you are selected for an interview, you can withdraw your participation before and during the interview, without giving a reason. Once you have undertaken the interview, you may choose to withdraw your information from the study up to *one week* after the date of your interview by contacting the student researcher (Rayna Sharma) or principal investigator (Jo Barnes).

Withdrawing from the study means you withdraw your participation and any information you have provided in the *interview*, without any consequences.

Anonymity and confidentiality:

Your participation in this study will remain confidential.

If you decide to participate in the study, the research processes will provide confidentiality for you. Your participation will only be known to the research team. We will write reports and publications from the data collected during the study. If the information you provide is reported or published, this will be done in a way that does not identify you. If we use quotes from your questionnaire responses and/or interviews, these will be de-identified.

Please note: if you disclose information which suggests that you, or someone you know, is at clear risk of serious harm (that is, if you express a clear intention to cause harm to yourself, either directly, or by

*deliberately increasing your substance use, or you express clear intention to cause harm, or are already causing harm, to others)) we will be required to follow moral and legal obligations to **breach confidentiality** and report this risk to the appropriate authorities and/or others, where relevant.*

You will be asked to complete a consent form before starting the questionnaire. Your contact information (name and email address) will only be collected if you choose to volunteer for the Phase Two interviews. We will collect your email address if you wish to be provided with a summary of results or a copy of your interview transcript. At the end of the Phase One questionnaire, you will be asked to provide a name and email address to receive a \$20 e-voucher (if you completed a paper-based questionnaire, we will post a physical voucher to your address).

In all these circumstances, your contact information will be collected and stored separately from your survey responses.

Study results:

If you participate in the study and wish to receive a summary of the results, please indicate this on the consent form and provide your email address. A summary will be emailed to you once it is available.

Funding:

This study is funded by a grant to Professor Jo Barnes (principal investigator) from the Health Research Council of New Zealand.

Contact details:

If you have any queries regarding the study, please contact Professor Jo Barnes (see below for contact details).

For concerns of an ethical nature, you can contact the Chair at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142. Telephone: (09) 373 7599 ext. 83711. Email: ahrec@auckland.ac.nz

If you require Māori cultural support, talk to your whānau in the first instance. If you have any questions or complaints about the study, you can contact Te Whatu Ora Te Toka Tumai Auckland and Te Whatu Ora - Waitematā Māori Research Committee or Māori Research Advisor. Telephone: (09) 486 8920 ext 3204.

<p><i>Principal Investigator:</i> Professor Joanne Barnes School of Pharmacy The University of Auckland Private Bag 92019 Auckland, New Zealand Telephone: (09) 3737599 Ext.83069 Email: j.barnes@auckland.ac.nz</p>	<p><i>Head of School:</i> Associate Professor Shane Scahill School of Pharmacy The University of Auckland Private Bag 92019 Auckland, New Zealand Telephone: (09) 3737599 Ext.85226 Email: s.scahill@auckland.ac.nz</p>
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Approved by the Auckland Health Research Ethics Committee on 08/06/2023 for three years. Reference number 25004.

Appendix one – contact information for relevant support organisations

Listed in alphabetical order

Please note: If you, a friend or whānau member needs urgent medical attention CALL 111

Alcohol Drug Helpline

0800 787 797 | <https://alcoholdrughelp.org.nz>

Alcohol Drug Helpline – Māori helpline

0800 787 798 or FREE TXT 8681 | <https://alcoholdrughelp.org.nz/contact#maori-helpline>

Alcohol Drug Helpline – Pasifika Services

0800 787 799 or FREE TXT 8681 | <https://alcoholdrughelp.org.nz/contact#pasifika-helpline>

Alcohol Drug Helpline – Youth Helpline

0800 787 984 or FREE TXT 8681 | <https://alcoholdrughelp.org.nz/contact#youth-helpline>

Are You OK (Family violence helpline)

0800 456 450 | <https://areyouok.org.nz>

Community Alcohol and Drug Services (CADS) – Auckland

0800 845 1818 | <https://www.cads.org.nz/>

Healthline

0800 611 116

Lifeline

0800 543 354 (0800 LIFELINE) or free text 4357 (HELP)

Need to talk?

Free call or text 1737

New Zealand Drug Foundation

<https://drugfoundation.org.nz>

Quit Line (Smoking cessation help)

0800 778 778 | <https://quit.org.nz>

Suicide Crisis Helpline (0508 TAUTOKO)

0508 828 865

University of Auckland Student Health and Counselling

0800 698 427