

Hello Change Participant Information Sheet/Consent Form

Title	An evaluation of Hello Sunday Morning’s online alcohol behaviour change programs and services for the community.
Short Title	Hello Sunday Morning Research Study
Principal Investigator	Dr Katinka van de Ven – Hello Sunday Morning, Sydney, Australia
Co-Investigator	Hannah MacRae – Hello Sunday Morning, Sydney, Australia

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, aiming to help us understand the real-world impact of an online interactive cognitive behavioural therapy Hello Change program on alcohol use and psychological wellbeing. This Participant Information and Consent Form tells you about the research project. Knowing what is involved will help you decide if you want to participate, so please read this information carefully. If you have any questions about anything that you don’t understand or want to know more about, please feel free to email the research team.

If you decide you want to take part in the research project, you will be asked for your consent by clicking “Submit”. By clicking “Submit” you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the use of your information as described.

2 What is the purpose of this research?

Hello Sunday Morning’s mission is to help people change their relationship with alcohol. We offer digital health products and services that everyone can access. The aim of this study is to understand how the Hello Change program may help people change their relationship with alcohol. We are interested in your experience of the Hello Change program and its impact on your alcohol consumption and psychological wellbeing over time.

3 What does participation in this research involve?

If you consent to participate and meet our inclusion criteria (see below), you are welcome to register for the Hello Change program via the Hello Change website.

To test whether the Hello Change program is effective, we need to divide participants into two groups. Those who will complete the Hello Change program (group 1) and those who be on the waiting list (group 2). But not to worry if you are on the waiting list group as the Hello Change program will be made available to you after 6 weeks. And you can of course use our [Daybreak app](#) for free while waiting for access to the Hello Change program.

Appendix J – Hello Change RCT Participant Information Sheet/Consent Form (PISCF) (Application ID: 2024-08-1015)

Participants will be randomly allocated to group 1 or group 2. There is a 50% chance that you will be allocated to the waitlist group. We will then be able to make comparisons between the two groups to see if the Hello Change program makes a difference.

You will have six weeks to complete the program once you receive access.

Participation will involve a brief registration survey and a survey at 6 and 12 weeks post access. Group 2 will also complete a survey at the end of the waitlist period (after 6 weeks). The survey contains questions around your alcohol consumption and psychological wellbeing and will take no more than 10 minutes to complete.

You will also be asked to fill out a feedback survey at completion of the Hello Change program.

To summarise, if you agree to participate in this research, you will be also asked to complete the following online surveys:

Survey	When is this completed?	How long will this take?
Registration survey	At registration	10 mins
End of wait list survey (group 2 only)	When the Hello Change program becomes available (after the 6 week waitlist)	10 mins
Feedback survey	Immediately following completion of the Hello Change program (or 6 weeks after accessing the program)	10 mins
6 week check-in survey	Week 6 post access	10 mins
12-week check-in survey	Week 12 post access	10 mins

As a thank you for your time and continued commitment to the research, you can enter a lottery once study recruitment is complete to win one of ten Amazon vouchers (\$150 Australian dollars each or equivalent) if you complete the 6 and 12 week check-in survey.

Criteria for participation. To participate in the research, you must (1) be 18 years or older, and (2) complete the Hello Change program, (3) provide us with your email address so we can send you your monthly check-in questionnaires.

4 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with professional staff or investigators on the project or your relationship with Hello Sunday Morning or partnering organisations.

5 What are the possible benefits of taking part?

We cannot guarantee that you will receive any direct benefits from this research. However, you will be assisting in the ongoing development of Hello Sunday Morning products and services that we hope are useful to people seeking to change their relationship with alcohol. This information will be used to improve the Hello Change program.

6 What are the possible risks and disadvantages of taking part?

Discomfort or distress

If you agree to participate in this research, you will be asked questions about your alcohol consumption and psychological wellbeing. In general, it is not anticipated that this would give rise to any negative effects. However, there may be a small possibility that these discussions may cause you to feel upset or distressed. If you do feel distressed when answering questions online, please let the research team know or consider contacting the services provided below. If you feel uncomfortable with any aspect of your participation, you are free to discontinue your participation at any time.

This program does not replace your usual medical care. Because this is an international online study, we are not able to take on the responsibility for your health care or wellbeing. There is no emergency assistance available through the Hello Sunday Morning website, which is not monitored across all the time zones that participants are coming from.

If you experience or believe you are at risk of self-harm, you should seek immediate assistance from your medical practitioner or emergency department.

If you need support, please contact (Australian participants only):

- **Counselling Online:** a free and confidential service that provides 24/7 online support <https://www.counsellingonline.org.au/how-we-can-help/chat-to-a-counsellor>
- **Alcohol and Drug Information Service (ADIS):** a free and confidential phone service available 24/7 to provide information, referrals, and counselling support. Call 1800 250 015
- **NSW Get Healthy Coaching Service:** is a free telephone based coaching service for NSW residents. The service is available Monday to Friday (8am-8pm). <https://www.gethealthynsw.com.au/> (Call 1300 806 258)

For 24/7 support you can also call **Lifeline** on 13 11 14.

If you are based overseas, please contact: <http://www.suicide.org/international-suicide-hotlines.html>

Compensation for injury

If, as a result of your participation in this study, you become ill or are injured, immediately advise the clinical contact (Hannah MacRae, see p 5) for this study. In the first instance the clinical contact will evaluate your condition and then discuss treatment with both you and your regular treating doctor. Any question about compensation must initially be directed to the clinical contact, who should advise their insurer of the matter. It is the recommendation of the independent ethics committee responsible for the review of this study that you seek independent legal advice.

7 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please email our research team. If you do not tell a member of the research team you wish to withdraw, we will continue to send you check-ins questionnaires.

If you decide to leave the research project, we will not collect additional information from you, although information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project. Requests for removal of data must be received prior to the end of the study (December 2025).

8 What happens when the research project ends?

We expect to publish the results of this study when it is completed (March 2026). Scientific findings will be published in scientific journals, presented at conferences, and disseminated via the Hello Sunday Morning website. Participants will also be emailed a summary of the study findings. In all types of publication, only group data will be presented, and no individuals will be identified.

Part 2 How is the research project being conducted?

9 What will happen to information about me?

Confidentiality. It is a requirement of your participation that you provide your email address so that we can contact you for the check-ins surveys. Any information obtained in connection with this research project that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. All participants will be identified by a code number. Only the researchers involved in the study will have access to the information.

Security. Following Australian Health Data regulations and requirements of the overseeing ethics committee, all data will be securely held by Hello Sunday Morning for 15 years following completion of the study. Whilst we endeavour to ensure that personal information is secure, it is not possible to safeguard against all possible breaches of security. Participants are advised to ensure that the device from which they participate is secure and to log out of the device after they have finished a session on it. We use Qualtrics to administer our questionnaires. Qualtrics services are protected by high-end firewall systems and scans are performed regularly to maintain security and ensure protection and reliability of data. Access to Qualtrics systems is restricted and bound by confidentiality obligations. Qualtrics uses Transport Layer Security (TLS) encryption (also known as HTTPS) for all transmitted data, and their services are hosted by trusted data centres that are independently audited using the industry standard SSAW-18 method.

Participants should also note that some of our software programs are hosted by organisations outside Australia. The regulatory regimes governing data access and use in other countries may not be the same as those that are in place in Australia. In the unlikely event that information is requested, Hello Sunday Morning is subject to Australian privacy laws and reasonable steps need to be undertaken to ensure that the overseas organisation handling the data that identifies participants, or from which their identity may be ascertained, is in accordance with any relevant Australian privacy principle (unless an exemption applies).

Publications. In any publication, information will be provided on a group level such that no individual can be identified.

Accessing information about you. In accordance with relevant Australian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please email our privacy officer if you would like to access your information.

For further information, please see our privacy policy (<https://hellosundaymorning.org/privacy-policy>)

10 Who is organising and funding the research?

Funding. Hello Sunday Morning programs are funded by the Ian Potter Foundation and the nib foundation. The research project is sponsored by Hello Sunday Morning.

Co-ordination. It is being co-ordinated by Hello Sunday Morning in Sydney, Australia.

Commercialisation. Although not planned at this time, it is possible that in the future Hello Sunday Morning may seek to commercialise intellectual property arising from this research. You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from your participation proved to be of commercial value. In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Hello Sunday Morning or the nib foundation, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than ordinary wages).

11 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the [National Statement on Ethical Conduct in Human Research \(2023\)](#). This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Director of HREC Operations, Bellberry Limited on 08 8361 3222.

12 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the following people:

Clinical Contact

Name	<i>Hannah MacRae</i>
Position	<i>Program Development Manager</i>
Email	<i>hannah.macrae@hellosundaymorning.org</i>

Research Contact

Name	<i>Katinka van de Ven</i>
Position	<i>Research Manager, Hello Sunday Morning</i>
Email	<i>Katinka.vandeven@hellosundaymorning.org</i>

Privacy Contact

Name	<i>Kate Acosta</i>
Position	<i>Privacy Officer, Hello Sunday Morning</i>
Email	<i>privacy@hellosundaymorning.org</i>

Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact: the Director of Operations, Bellberry Limited on (08) 8361 3222.

Consent Form

Declaration by Participant

1. I have read the project information above and I understand the purposes, procedures and risks of the research described in the project.
2. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
3. I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future relationship with Hello Sunday Morning or partnering organisations.
4. I am over 18 years of age and am willing to provide my email address for the purposes of being contact to complete the check-in questionnaires.
5. I understand that my involvement in this study may not be of any direct benefit to me.

By clicking “SUBMIT” I am acknowledging the above and agree to participate in the study.

Withdrawal of Participation

The participant's decision to withdraw is communicated via email, the research team must provide a brief description of the circumstances below.

The participant has provided consent for the data that they have provided to date to be used for this research study:

- Yes
- No

Declaration by research team

I have given a written explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of researcher (please print) _____

Signature _____ Date _____