Participant Information Statement

Research Study - Phase 2: HEALTH4ME Study

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1. What is this study about?

We are conducting a research study about whether a text message healthy lifestyle program (HEALTH4ME) with optional health counselling will help young people to improve their physical and mental health. We aim to test whether receiving the text message program with optional health counselling is better at improving physical and mental health outcomes, compared to receiving no text message program. Finding this out is important so we can provide programs to all young people to create healthy life-long habits and prevent chronic diseases. Taking part in this study is voluntary.

You have been invited to take part in this study because you are a young person with an active mobile phone and free from any chronic (long-term) health conditions.

Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about.

2. Who is running the study?

The study is being carried out by the following researchers:

- Dr Stephanie Partridge, Senior Research Fellow
  Engagement and Co-design Research Hub, School of Health Sciences, Faculty of Medicine and Health

Rebecca Raeside is conducting this study as the basis for the degree of Doctor of Philosophy at The University of Sydney.

This study is being funded by a Medical Research Future Fund (MRFF) Primary Care Grant (MRFF2006315).

3. Who can take part in the study?

We are looking for young people aged 12-18 years who own a mobile phone which can send and receive text messages and with sufficient English to read at a 7th grade level to take part in the study.

You are not able to take part if you:

- have a diagnosis of type 1 or type 2 diabetes mellitus;

- have a medical condition that would make you incapable of providing informed consent;
- are enrolled in an alternative randomised lifestyle management program;
- have a previous or current diagnosis of an eating disorder OR at high risk for an eating disorder as assessed in screening;
- have had recent rapid weight loss;
- have weight <25th BMI centile for their age;
- are pregnant or planning to become pregnant in the next 6-months or;
- are unable to read English at a 7th grade level

This is because people with these conditions require care above and beyond what this program is designed to offer.

4. What will the study involve for me?

Please note: this study involves no in-person activities, everything will be completed online including via phone call, text message, email or videoconference.

This study is 6 months long. Sometimes we do not know which intervention is best for helping people with improve their health. To find out we need to compare different groups. The computer system will randomly (like flipping a coin) assign you to either receive text messages right away (intervention group) or no messages until after the 6-month visit (control group). You will have a 50% chance of being in the intervention group or the control group. You will be notified of which group you are in via text message.

It is not possible for you to choose the group. Nor will you be able to change groups at any time. Our study is a single-blind randomised controlled trial. This means the researchers do not know which group you are in. So please avoid telling them. We designed the study this way to make sure the researchers interpret the results in a fair and suitable way. At the end of the study, the results are compared to see if receiving text message intervention helps improve young people's physical and mental health more than not receiving any text messages.

If you decide to take part in this study, you will be asked to:

1. Complete a short screening process online (15 minutes);
2. Sign the Participant Information and Consent Form electronically;
3. Complete enrolment online (45 minutes) which will involve:
    a. Self-reported clinical measurements including height, weight and waist circumference
    b. The following questionnaires (if needed, our research team will be available at a time suitable to you to help you complete them)

Questionnaire topic	**# Questions**	**Minutes to complete**
Demographics	11	2 min
Diet quality, food choices and food patterns	134	15 min
Physical activity levels	5	2 min
Sedentary activity	4	3 min
Sleep quality	7	3 min

Quality of life	9	3 min
Self-efficacy	16	4 min
Anxiety	7	2 min
Depression	10	2 min
Psychological distress	6	2 min
Eating disorders	6	2 min
Food insecurity	6	2 min
eHealth literacy	10	3 min
Feedback on the program*	27	10 min
Focus group*	-	45 min
Total time Enrolment	**-**	**45 min**
Total time 6-month follow-up	**-**	**55 min**
Total time focus group	**-**	**45 min**

* Only collected at 6-month follow-up

** Focus groups are optional and only for those in the intervention group

c. You will then be sent an activity tracker to wear for 7 days and then return it to the research team via a pre-paid post bag which will be provided
d. Once the research team receive the activity tracker back and all enrolment items are complete, you will be issued your first gift card as an incentive for participation

4. Approximately 1-3 days after the research team receive the activity tracker back, you will receive a "welcome to the study" text message. This will tell you which group you are in (either the intervention or control group).
    a. If you are in the intervention group, you will receive 4-5 text messages per week with positive and encouraging advice and information about keeping healthy habits including messages on healthy eating, physical activity, sleep and mental wellbeing. The messages are designed to support you and you may save, share or delete the messages, if you'd like.
    b. All text messages will be sent at appropriate times. If you are attending high school, the weekday messages will only be sent before school between 7.30am to 8.30am or after school hours from 3.30pm to 7.30pm. If you are driving, please remember that you must not read the text messages or perform any other functions while driving.
    c. Intervention participants will also have the opportunity to talk to a university qualified health counsellor once per month (6 calls in total). Each month, intervention participants will be sent a text message encouraging them to call the health counsellor and ask questions or request additional information. The health counsellor will monitor and respond to participants requests within 3 working days. The calls will allow participants to set goals, discuss challenges and their overall progress.
    d. If you are in the control group, you will not receive any text messages or health counselling calls for 6-months.

All participants will receive a text message after 6-months. This will state that someone from the research team will contact you to complete your 6-month follow up online.

5. Complete 6-month follow up (45-55 minutes) which will involve:
    a. Self-reported clinical measurements including height, weight and waist circumference
    b. The same questionnaires as the enrolment, including a feedback survey about what you liked and disliked about the study
    c. You will once again be sent an activity tracker to wear for 7 days, then return to the research team via a pre-paid post bag provided by the research team.
    d. Once the research team receive the activity tracker back and all 6-month follow-up items are complete, you will be issued your second gift card as an incentive for participation

6. Focus groups (optional): If you received the text message intervention, you will be invited to a focus group via Zoom teleconference with study researchers and other participants who received the intervention. This will be at the end of the intervention (6-months) to discuss what you liked and disliked about the text messages, so we can improve them for future use. We would like to make you aware that this session will be audiotaped for research purposes and will last about 45 minutes.

5. Can I withdraw once I've started?

Being in this study is completely voluntary and you do not have to take part if you don't want to.

Your decision will not affect your current or future relationship with the researchers or anyone else at The University of Sydney.

If you decide to take part in the study and then change your mind you can withdraw at any time by letting one of the researchers know by phone or email or by replying 'STOP' to any of the text messages. Once you reply 'STOP' your request will be processed by one of the researchers as soon as possible, usually within 72 hours. You also don't need to answer any questions that you don't want to.

If you choose to withdraw, we will not collect any more information from you. Please let us know at the time you withdraw what you would like us to do with information we have collected about you up to that point.

6. Are there any risks or costs?

We do not expect any side effects or risks by taking part in our study. However, questionnaires relating to your emotional health may be distressing and may reveal an undiagnosed eating disorder. If this happens, you will be referred to the Inside Out Institute for Eating Disorders with a letter from us. If anything you talk about during the study makes you feel upset, you may stop the study at any time, Your parents/carers will be told and you will be provided with information and contacts you can talk to, if that's what you want to do. The researcher can help you do that. Here are other contacts that you can talk to and websites you can access if you feel distressed or upset.

Kids Helpline: *T: 1800 551 800* *W: kidshelpline.com.au*

Lifeline	*T: 13 11 14*	*W: lifeline.org.au*
The Butterfly Foundation:	*T: 1800 334 673*	*W: thebutterflyfoundation.org.au*
ReachOut:		*W: au.reachout.com*
HeadSpace:		*W: headspace.org.au*

The only time the researchers would have to tell someone is if anyone hurt you or upset you in any way. The researchers would also have to tell someone if you said you might hurt yourself or someone else. If any of those things happen, they would have to call the child protection helpline run by the NSW Government Family and Community Services.

7. What happens when the study ends?

At the end of the 6-month follow-up, the text messages will be offered to those in the control group to receive free-of-charge, if they would like to receive them.

8. Are there any benefits?

This study aims to further medical knowledge about whether text message programs are helpful to young people and may improve your physical and mental health, however it may or may not directly benefit you. If all study activities and follow-ups are completed at baseline and 6-months, you will be offered a $30 voucher from JB HIFI or The Iconic at each time point as a reimbursement for your time to participate in the study ($60 total). If you choose to withdraw from the study or study activities and follow-ups are incomplete, you will not be eligible to receive the voucher.

9. What will happen to information that is collected?

By providing your consent, you are agreeing to us collecting information about you for the purposes of this study. Research staff will only collect and use personal information about you that is relevant to the study. Once you have been assigned to the intervention or control group, you will be given a study identification number which will be used on all the study documents instead of your name. Information collected from you will be stored in a secure web application called REDCap. This system is managed by the University of Sydney and will be used to send out the text messages and analyse information collected during the study. If you choose to take part in the focus groups at the end of the study, these sessions will be audio recorded and stored on secure research data stores within the University of Sydney.

Any information you provide us will be stored securely and only disclosed with your permission, unless we are required by law to disclose material. We anticipate study findings will be published and we plan to discuss the results at scientific meetings. You will not be individually identifiable in these publications.

All information collected during the study that can identify you will be treated confidential in accordance with Australian privacy laws. Confidential data will be stored for a period of 20 years from the time of the study is completed, or until the youngest child in the study turns 25 (whichever is the longest). This information will only be accessible to study investigators. After this time, computer files will be deleted, and paper files will be shredded. In accordance with relevant Australian and New South Wales privacy and other relevant laws, you have the right to request access to your

information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

This study will be conducted in compliance with all conditions of this protocol. As well as the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

10. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. We will ask a question in the consent form so you can let us know whether you'd like to receive results of the study one they are available, although this may take some time. This feedback will be in the form of a brief lay summary.

11. What if I would like further information?

When you have read this information, the following researcher/s will be available to discuss it with you further and answer any questions you may have:

- Ms Rebecca Raeside, Research Associate
  E: rebecca.raeside@sydney.edu.au
  M: +61 412 961 432

12. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney 2022/402 according to the *National Statement on Ethical Conduct in Human Research (2007).*

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager
human.ethics@sydney.edu.au

+61 2 8627 8176

This information sheet is for you to keep

Participant Consent Form

Research Study: HEALTH4ME Study

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Participant Name _____

I agree to take part in this research study. In giving my consent, I confirm that that:

- The details of my involvement have been explained to me, and I have been provided with a written Participant Information Statement to keep.
- I understand the purpose of the study is to investigate whether a text message healthy lifestyle program (HEALTH4ME) with optional health counselling will help young people to improve their physical and mental health and wellbeing.
- I acknowledge that the risks and benefits of participating in this study have been explained to me to my satisfaction.
- I understand that in this study I will be required to complete the screening, enrolment and 6-month follow up online including self-reported clinical measurements and surveys; and if selected for the intervention group, receive text messages for 6-months designed to support and improve a physical and mental health and wellbeing.
- I understand that if I participate in the focus groups the audio will be taped and stored securely.
- I understand that being in this study is completely voluntary.
- I am assured that my decision to participate will not have any impact on my relationship with the research team or the University of Sydney.
- I understand that I am free to withdraw from this study at any time and that I can choose to withdraw any information I have already provided (unless the data has already been de-identified or published).
- I have been informed that the confidentiality of the information I provide will be protected and will only be used for purposes that I have agreed to. I understand that information about me will only be told to others with my permission, except as required by law.
- I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me.

- I confirm the following:

I consent to audio recordings	Yes ☐	No ☐
I consent to being contacted for future studies	Yes ☐	No ☐
I would like feedback on the overall results of this study	Yes ☐	No ☐

If you answered **yes**, please provide your preferred contact details (email/telephone):

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- I understand that after I sign and return this consent form it will be retained by the researcher, and that I may request a copy at any time.

Participant Name _____

Participant Signature _____

Date _____