

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.

Your child has been invited to take part in this study because they are a young person with an active mobile phone and free from any chronic 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, University of Sydney

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.

Young people are not able to take part if they:

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

- have a medical condition that would make them incapable of providing informed consent;
- if they 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.

The 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 your child to either receive text messages right away (intervention group) or no messages until after the 6-month follow-up (control group). They will have a 50% chance of being in the intervention group or the control group. They will be notified of which group you are in via text message.

It is not possible for them to choose the group. Nor will they 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 they are assigned to. 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 and your child decide to take part in this study, they will be asked to:

1. Complete a short screening process online (15 minutes);
2. Co-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 your child to help them 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	-	45-55 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. Your child 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, they will be issued their first gift card as an incentive for participation

4. Approximately 1-3 days after the research team receive the activity tracker back, your child will receive a “welcome to the study” text message. This will tell them which group they are in (either the intervention or control group).
 - a. If they are in the intervention group, they 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 your child and they may save, share or delete the messages, if they’d like.
 - b. All text messages will be sent at appropriate times. If they 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.
 - 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 they are in the control group, they 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 your child 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 your child liked and disliked about the study
 - c. They 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, your child will be issued their second gift card as an incentive for participation
6. Focus groups (optional): If your child received the text message intervention, they 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 they liked and disliked about the text messages, so we can improve them for future use. We would like to make you and your child 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 your child does not have to take part if they don't want to.

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

If you and your child decide to take part in the study and then change your mind they 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 they reply 'STOP' their request will be processed by one of the researchers as soon as possible, usually within 72 hours. Your child also doesn't need to answer any questions that they don't want to.

If they choose to withdraw, we will not collect any more information from your child. Please let us know at the time they withdraw what you would like us to do with information we have collected about your child 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 child's emotional health may be distressing and may reveal an undiagnosed eating disorder. If this happens, they will be referred to the Inside Out Institute for Eating Disorders with a letter from us. If anything your child talks about during the study makes them feel upset, they may stop the study at any time, they will be provided with information and contacts they can talk to, if that's what they want to do. The researcher can help your child do that. Here are other contacts that your child can talk to and websites they can access if they feel distressed or upset.

<i>Kids Helpline:</i>	<i>T: 1800 551 800</i>	<i>W: kidshelpline.com.au</i>
<i>Lifeline</i>	<i>T: 13 11 14</i>	<i>W: lifeline.org.au</i>
<i>The Butterfly Foundation:</i>	<i>T: 1800 334 673</i>	<i>W: thebutterflyfoundation.org.au</i>

ReachOut:
HeadSpace:

W: au.reachout.com
W: headspace.org.au

The only time the researchers would have to tell someone is if anyone hurt your child or upset them in any way. The researchers would also have to tell someone if your child said they might hurt themselves 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 child's physical and mental health, however it may or may not directly benefit your child. If all study activities and follow-ups are completed at baseline and 6-months, your child will be offered a \$30 voucher at each time point from JB HIFI or The Iconic as a reimbursement for their time to participate in the study (\$60 total). If they choose to withdraw from the study or study activities and follow-ups are incomplete, they 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 your child for the purposes of this study. Research staff will only collect and use personal information about your child that is relevant to the study. Once your child has been assigned to the intervention or control group, they will be given a study identification number which will be used on all the study documents instead of their name. Information collected from your child 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 your child chooses 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 your child 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. Your child will not be individually identifiable in these publications.

All information collected during the study that can identify your child 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. In accordance with relevant Australian and New South Wales privacy and other relevant laws, you have the right to request access to your child's information collected and stored by the research team. You also have the right to request that any information

which you or your child disagrees with be corrected. Please contact the study team member named at the end of this document if you would like to access your child's 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 and your child 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 once 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 further discuss it with you and/or your child 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



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Dr Stephanie Partridge

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Participant Name _____

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

- The details of my child's 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 my child 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 my child participates 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 for my child to participate will not have any impact on my relationship with the research team or the University of Sydney.
- I understand that my child is free to withdraw from this study at any time and that we can choose to withdraw any information that has already provided (unless the data has already been de-identified or published).
- I have been informed that the confidentiality of the information my child provides will be protected and will only be used for purposes that we have agreed to. I understand that information about my child will only be told to others with our permission, except as required by law.
- I understand that the results of this study may be published, and that publications will not contain my child's name or any identifiable information about them.

- 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):

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

Participant Name

Participant Signature

Date

Parent/Guardian Name

Parent/Guardian Signature

Date
