



PARTICIPANT INFORMATION SHEET – YOUNG PERSON

Title:	TEXT message Behavioural Intervention for Teens on Eating, physical activity and Social Wellbeing
Short Title:	TEXTBITES Study
Protocol Number:	Version 4, 19 th March 2020
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PART 1: WHAT DOES MY PARTICIPATION INVOLVE?

This is a booklet that has been put together to help you decide if you would like to take part in our research study called TEXT message Behavioural Intervention for Teens on Eating, physical activity and Social Wellbeing (known as TEXTBITES study).

1. WHAT IS THE STUDY ABOUT?

We are trying to find out whether a text message healthy lifestyle program with optional health counselling will help young people, like you, to improve their health and wellbeing, and weight outcomes. The text message program is based on national guidelines for healthy eating, physical activity and wellbeing. We want to test whether getting the text message program with optional health counselling is better at reducing weight and improving health and wellbeing. Finding this out is important so we can provide programs to help create healthy life-long habits in young people and prevent chronic diseases.

About 150 young people are expected to take part in the TEXTBITES study. It will take place at Westmead Hospital, The Children's Hospital at Westmead and YMCAs.

2. WHAT WILL I HAVE TO DO IF I TAKE PART?

Young people aged 13-18 years who are well above a healthy weight and own an active mobile phone can participate. The study is 12 months long, during those 12 months you will meet with the study team 3 times in-person or over the phone.

If you decide to take part in the study, you and your parent and/or legal guardian will sign a consent form. You will then complete an enrolment visit. At this visit, we will record your preferred name, mobile number and whether you are attending school. This information will be stored in a secure Research Electronic Data Capture (REDCap) computer system. This will allow us to personalise text messages that will be sent to you. This computer system is password protected. It is only accessible to study researchers.

Sometimes we do not know which treatment is best for helping people to improve their health. To find out we need to compare different groups. The computer system will randomly (like flipping a coin) select you to either receive text messages right away (intervention group) or no messages until after the 12-month visit (control group). You will have a 50% chance of being in the intervention group or the control group. You will be told which group you fall into through a text message.

It is not possible for you or the researchers to choose the group you fall into, and you won't 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 remember not to tell them. We designed the study this way to make sure the researchers read the results in a fair and suitable way. At the end of the study, the results are compared to see if receiving the text messages helps improve young people's health and wellbeing, and weight more than not receiving any text messages.

As part of the study, one-fifth (30/150) of participants will be randomly selected to have their body composition measured. This will be done using a machine at the enrolment and 6-month visit. If you are selected, you will be told at your enrolment and 6-month visit. Another one-fifth (30/150) of participants will be randomly selected wear an accelerometer. This is a small, matchbox-sized portable device that measures your physical activity. If you are selected, you will be told at your enrolment and 6-month visit. You will then wear the device for 7 days after the enrolment and 6-month visit. Then return it to the researchers in person or by a pre-paid post bag provided by the research team. We do this to see if the way we are measuring physical activity in a questionnaire is accurate or not.

We recommend that you tell your local doctor of your decision to participate in this study.

If you are eligible and you agree participate in this 12-month study, the first steps will be:

1. A short screening process with study researchers (15 minutes) where they will ask you some questions about you and your health;
2. Sign the Parent/Guardian Participant Information and Consent Form with your parent or carer;

Visit 1 (Enrolment Visit)

Visit 1 is an enrolment visit (about 65-75 minutes – in-person or over the phone), where you will complete:

- a. Clinical measurements such as weight, height, waist circumference and/or body composition (if this is done over the phone we will provide you with instructions to complete correctly);
- b. The following questionnaires (our study researcher will be available to help you complete the questionnaires, if you need it) (if over the phone, you will be sent a secure online link to complete the surveys on your phone, laptop and tablet, while we stay on the phone with you to answer any questions or we can ask you the questions):

Questionnaire topic	# Questions	Minutes to complete
<i>Demographics</i>	10	3 min
<i>Short diet questions</i>	13	6 min
<i>Diet quality, food choices and food patterns*</i>	134	15 min
<i>Physical activity levels</i>	5	3 min
<i>Sedentary activity</i>	4	2 min
<i>Sleep quality</i>	7	3 min
<i>Quality of life</i>	23	4 min
<i>Self-esteem</i>	10	2 min
<i>Self-efficacy</i>	6	2 min
<i>Social support</i>	18	4 min
<i>Eating disorders</i>	28	8 min
<i>Depression</i>	10	2 min
TOTAL TIME ENROLMENT		65-75 min

*The Diet quality, food choices and food patterns questionnaire are only completed at your enrolment and 6-month visit;

**Feedback on the program and telephone interview about your experience in the program are only asked at your child's 6-month visit

Approximately 1-3 days after the enrolment visit, you will receive a "welcome to the study" text message. This will tell you which group you are in. Either the intervention group or the control group.

- a. If you are in the intervention group, you will receive 4 text messages per week with positive and encouraging advice and information about keeping healthy habits. The messages are meant to support you. You can 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 text messages will only be sent before school between 7:30 am to 8:30 am or after school hours, 3:30 pm to 7:30 pm. If you are driving, please remember that you must not read the text messages or use any other mobile phone functions while driving.
- c. If you are in the intervention you will also have the option to talk to a university qualified health counsellor once per month (6 calls in total). Once a month, intervention participants will be sent a text message encouraging you to call the health counsellor to ask questions or ask for more information. The health counsellor will monitor and respond to your request for a call by text message or phone call 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.

Everyone will receive a text message after 6-monthsaying that someone will contact you to organise your 6-month follow-up visit. You should not reply to this. If you would like to withdraw from the study, you can by texting 'STOP'.

Visit 2 (6-month Visit)

Visit 2 is a 6-month follow-up visit (about 65-75 minutes – in-person or over the phone), where you will:

- a. Complete clinical measurements such as weight, height, waist circumference and/or body composition (if this is done over the phone we will provide you with instructions to complete correctly);
- b. Complete the same questionnaires as the first visit, including a feedback survey about what you liked and didn't like during the study (if over the phone, you will be sent a secure online link to



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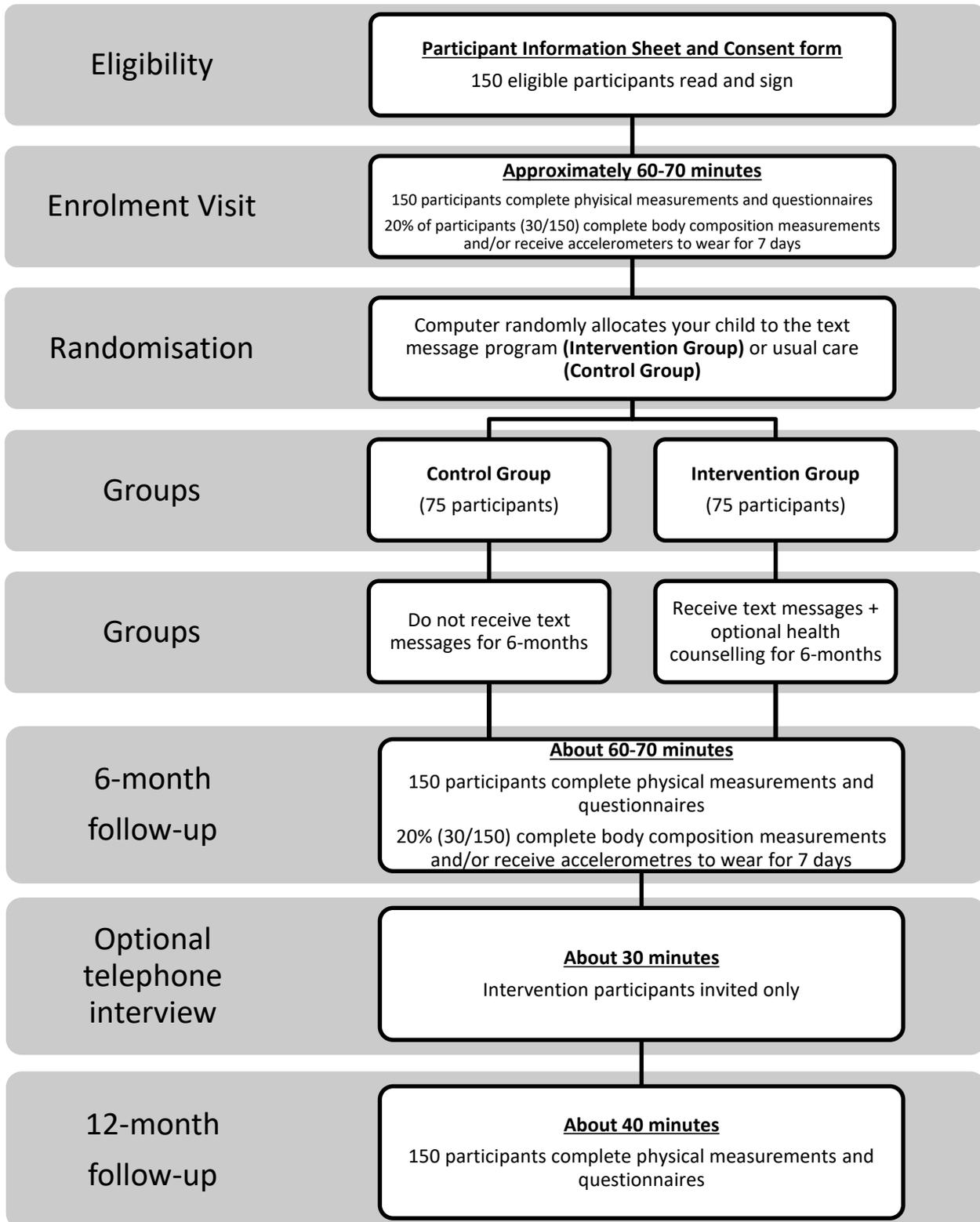
complete the surveys on your phone, laptop and tablet, while we stay on the phone with you to answer any questions or we can ask you the questions);

Telephone interview (Optional): If you received the text message intervention, you will be invited to a telephone interview with a study researcher. This will be at the end of the intervention period (6-months) to discuss what you liked and disliked about the text messages, so we can make them better in the future. We would like to make you aware that this session will be recorded for research purposes and will last about 30 minutes.

Visit 3 (12-month Visit)

Visit 3 is a 12-month follow-up visit (about 44 minutes – in-person or over the phone), where you will complete:

- c. Clinical measurements such as weight, height and waist circumference (if this is done over the phone we will provide you with instructions to complete correctly);
- d. The same questionnaires that you did at visit 1 and visit 2 (if over the phone, you will be sent a secure online link to complete the surveys on your phone, laptop and tablet, while we stay on the phone with you to answer any questions or we can ask you the questions).



3. DO I HAVE TO TAKE PART IN THE RESEARCH?

No you don't. If you say no, that is ok. It is up to you.



Even if you take part at the beginning and change your mind later on and don't want to be a part of the study, that is okay as well. All you need to do is reply 'STOP' to any of the messages, or you can contact a member of the research team via phone or email. If you choose to no longer take part, it will be processed as soon as possible, usually within 72 hours. You also don't need to answer any question that you don't want to as well, that is okay too.

4. WILL ANYONE KNOW THAT I AM TAKING PART OR HEAR ABOUT WHAT I TELL YOU?

No, no-one will know what information you gave to the researchers. You can tell them whatever you want and no-one will know that it came from you.

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.

5. IS THERE ANYTHING THAT MIGHT MAKE ME UPSET IF I TAKE PART IN THE RESEARCH?

We do not expect side effects or risks by taking part in our study. However, questionnaires relating to your emotional health may be distressing and may reveal undiagnosed eating disorder or depression. If this happens, you will be referred to your GP with a letter from us. You may enrol in the study at a later date following the ok from your GP and after being re-screened. 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 is what you want to do. The researcher can help you do that. Here are other contacts 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

The Butterfly Foundation:

T: 1800 334 673

W: thebutterflyfoundation.org.au

ReachOut:

W: au.reachout.com

HeadSpace:

W: headspace.org.au and

6. WHAT WILL HAPPEN TO INFORMATION I TELL YOU?

Information collected from you during the screening process and study will be stored in a secure web application called REDCap. This system is managed by the University of Sydney. It will be used by researchers to send out the text messages and analyse the information we collect during the study. The information could be used with information from other young people in reports or papers about the research. You will not be able to be identified in these reports or papers.

The information you tell us will be treated confidentially in accordance with Australian privacy laws. Confidential information will be stored for a period of 15 years from the time of the study is completed. This information will only be accessible to study investigators. After 15 years, computer files will be deleted, and paper files will be shredded.

If you have any questions about the research study or you want to talk about it, please do not hesitate to contact us at:

Phone Number

Contact

Dr Stephanie Partridge

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This project has been approved by Sydney Children's Hospitals Network Human Research Ethics Committee. If you have any concerns about the conduct of this study, please do not hesitate to contact the Executive Officer at the Ethics Committee (02 9845 3066) and quote approval number HREC/18/SCHN/374.



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