PARTICIPANT INFORMATION SHEET – PARENT/GUARDIAN

Title:	TEXT message Behavioural Intervention for Teens on Eating, physical activity and Social Wellbeing
Short Title:	TEXTBITES Study
Protocol Number:	Version 4, 19th March 2020
Project Sponsor:	The University of Sydney
Coordinating Principal Investigator:	Dr Stephanie Partridge Westmead Applied Research Centre Westmead Hospital The University of Sydney +61 2 8890 8187
Westmead Hospital Principal Investigator:	Dr Clara Chow Westmead Applied Research Centre, Westmead Hospital +61 2 8890 3125
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Location	Westmead Hospital
Contact	Dr Stephanie Partridge Email: warc.textbites@sydney.edu.au Phone: 0412 961 432

PART 1: WHAT DOES MY CHILD'S PARTICIPATION INVOLVE?

1. INTRODUCTION

Thank you for taking the time to read this Information Sheet. This is an invitation for your child to take part in the TEXT message Behavioural Intervention for Teens on Eating, physical activity and Social Wellbeing (known as TEXTBITES study) because he/she is above a healthy weight.

Please read this sheet carefully. Ask questions about anything you do not understand or want to know more about. Before deciding whether to allow your child to take part, you may want to talk to them about it or with a relative, friend or local doctor.

Participation in this study is **voluntary**. If you do not want your child to take part, they do not have to. If you agree to have your child participate in this study, you will be asked to sign the Consent Form. By signing it you are telling us that you:

- Understand what you have read
- Consent for your child to take part in the study

- Consent for your child to have the assessments and interventions that are described
- Consent to the use of your child's personal and health information as described

You will be given a copy of this Information Sheet and Consent Form to keep.

2. WHAT IS THE PURPOSE OF THIS STUDY?

This study looks at whether a text message healthy lifestyle program with optional health counselling will help young people 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 aim to test whether the receiving 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 participants are expected to take part in the TEXBITES study. The study has been funded by the Westmead Applied Research Centre at The University of Sydney. As well as by the National Health and Medical Research Council via people support. It will take place at Westmead Hospital, The Children's Hospital at Westmead and YMCAs.

3. WHAT DOES PARTICIPATION IN THIS RESEARCH INVOLVE?

Who can participate in the study?
Young people aged 13-18 years who are well above a healthy weight and own an active mobile phone are eligible to participate.

How long will the study go for?
The study is 12 months long. There will be 3 visits with the study team, these may be conducted in-person or over the phone.

If your child takes part in the study and you and your child will provide written informed consent. Your child will then complete an enrolment visit. At this visit, we will record your child's preferred name, mobile number and whether or not they 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 your child. This computer system is password protected. It is only accessible to study researchers.

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 12-month visit (control group). Your child will have a 50% chance of being in the intervention group or the control group. Your child will be notified of their group via text message.

It is not possible for your child 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 your child is 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 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 your child is selected, your child will be notified at their enrolment and 6-month visit. Another one-fifth (30/150) of participants will be randomly selected wear an accelerometer. This is a small, discrete, matchbox-sized portable device that

measures your child's physical activity. If your child is selected, your child will be notified at their enrolment and 6-month visit. Your child 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.

There are no additional costs associated with participating in this study. Nor will you or your child be paid. All assessments and text messages as part of the study will be provided to your child free of charge.

It is desirable that your child's local GP be advised of your decision to allow your child to participate in this study. If you have a local GP, we strongly recommend that you inform them of your child's participation in this study.

4. WHAT DOES MY CHILD HAVE TO DO?

If your child is eleigilble and you agree for your child to participate in this 12-month study, your child will complete:

1. A short screening process with study researchers (15 minutes – in-person or over the phone);
2. Co-sign the Parent/Guardian Participant Information and Consent Form;
3. An enrolment visit which (about 60-70 minutes – in-person or over the phone), where your child 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 (if needed, our study reseacher will be available to help your child complete the questionnaires) (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
Demographics	10	3 min
Short diet questions	13	6 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	23	4 min
Self-esteem	10	2 min
Self-efficacy	6	2 min
Social support	18	4 min
Eating disorders	28	8 min
Depression	10	2 min
*Feedback on the program***	20	5 min
*Telephone interview about experience in the program***	7	30 min
TOTAL TIME ENROLMENT		65 – 75 min
TOTAL TIME 6-MONTHS (with interview)		95 – 105 min
TOTAL TIME 6-MONTHS (without interview)		65 – 75 min
TOTAL TIME 12-MONTHS		44 min

*The Diet quality, food choices and food patterns questionnaire are only completed at your child's enrolment and 6-month visit;
**Feedback on the program and telephone interview about your child's experience in the program are only asked at your child's 6-month visit

c. Some participants (30/150) will be asked to wear an accelerometer for 7-days. Then return it to the researchers in-person or by a pre-paid post bag provided by the research team.

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

   a. If your child is in the intervention group, your child will receive 4 text messages per week with positive and encouraging advice and information about keeping healthy habits.
   b. Topics include healthy eating, physical activity, mental wellbeing, and as well as messages about time management and sleep. The messages are meant to support your child. Your child can save, share or delete the messages, if they'd like.
   c. All text messages will be sent at appropriate times. If your child is 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 your child is driving, please remind them that they must not read the text messages or use any other mobile phone functions while driving.
   d. Intervention participants 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 them to call the health counsellor to ask questions or request additional information. The health counsellor will monitor and responds to participants' 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.
   e. If your child is in the control group, your child 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 will contact you and your child to organise their 6-month follow-up visit. Your child should not reply to this. If your child would like to withdraw from the study, your child can withdraw by texting 'STOP'. See the 'What if withdraw my child from this research study?' section below for more details.

5. Attend a 6-month follow-up visit (about 60-70 minutes – in-person or over the phone), where your child 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 enrolment visit, including a feedback survey about what your child liked and disliked during the study (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);
   c. Some participants (30/150) will be asked to wear an accelerometer for 7-days. Then return it to the researchers in-person or by a pre-paid post bag provided by the research team.

6. Telephone interview (Optional): If your child received the text message intervention, your child 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 they liked and disliked about the text messages, so we can improve them for future users. We would like to make you aware that this session will be audiotaped for research purposes and will last about30 minutes.

7. Attend a 12-month follow-up visit (about 40 minutes – in-person or over the phone), where your child will complete:
   a. 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);

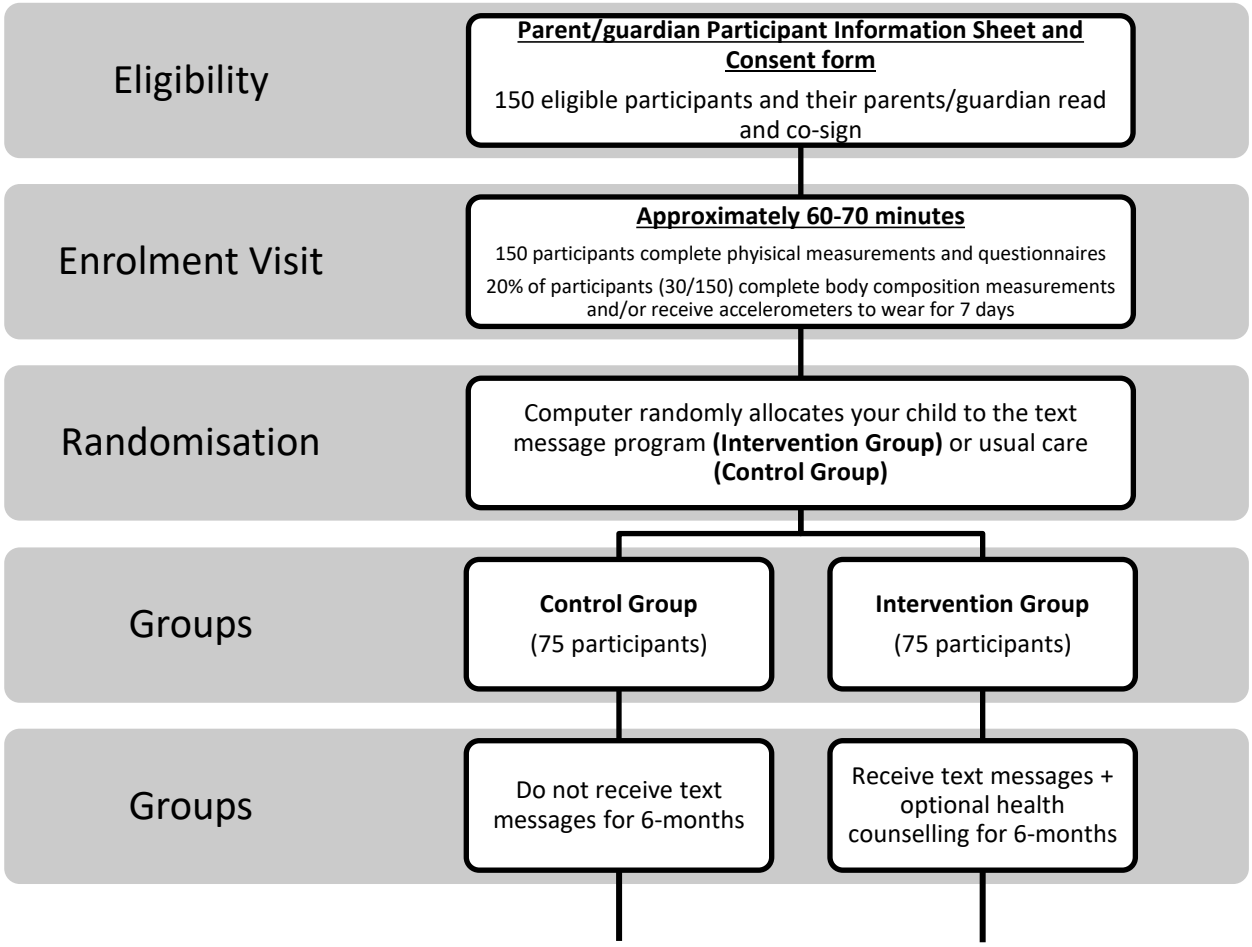
b. The same questionnaires as listed above in the enrolment and 6-month visits (if over the phone, you will be sent a secure online link to complete the surveys on your phone, laptop and tablet, while we stay on the phone with you to answer any questions or we can ask you the questions).

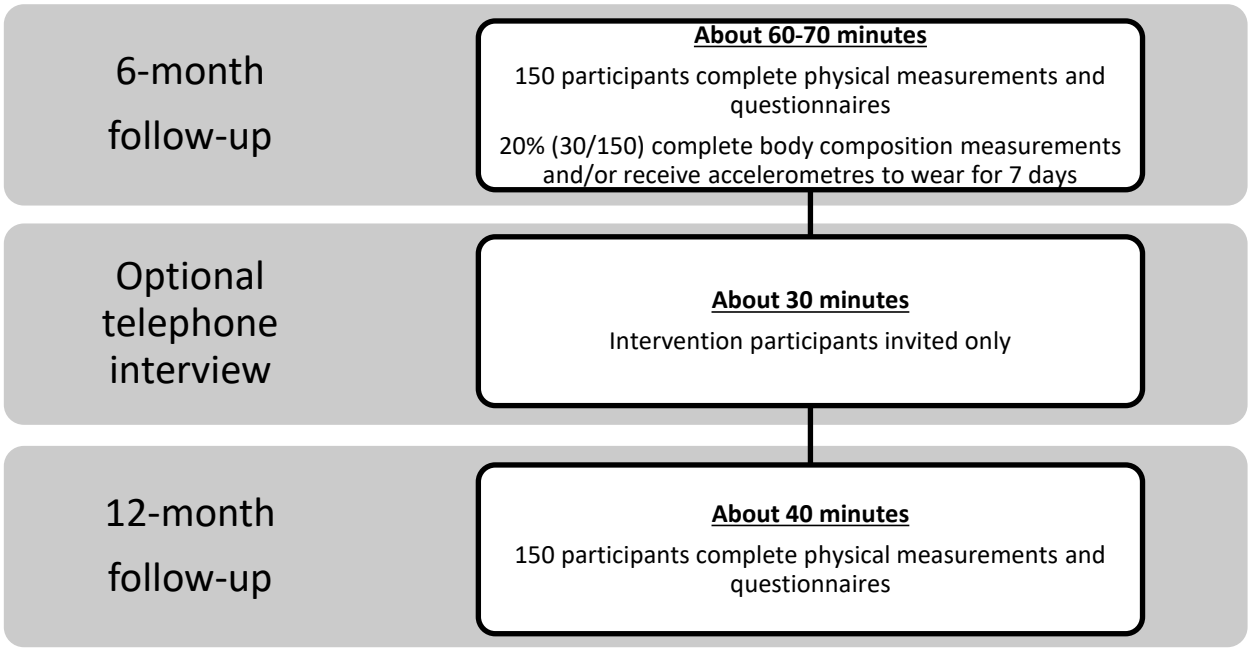
5. WHAT HAPPENS WHEN THE RESEARCH STUDY ENDS?

A text message service will be offered to participants in the control group at the end of the 12-month visit. This service is completely optional, voluntary and free of charge.

6. WHAT ARE THE ALTERNATIVES TO PARTICIPATION?

Your child does not have to participate in this study to receive help with their weight and lifestyle. If you do not want your child to take part in this study, or if they are not eligible, the study staff will talk with you and your child about other options or refer you to your child's local GP for care.





7. WHAT IF I WITHDRAW MY CHILD FROM THIS STUDY?

Your child can withdraw from the study at any time without giving a reason by replying 'STOP' to any of the messages. Or contacting a member of the research team via phone or email. Request for study withdrawal will be honoured and processed as soon as possible, usually within 72 hours.

If your child withdraws from the study, the study team will not collect additional personal information. However, information already collected will be kept ensuring the results of the study can be measured properly. You should be aware that data collected up to the time of withdrawal will form part of the study results.

8. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The support your child receives from the text messages and health counsellor may help him/her manage their weight and their lifestyle habits may improve.

9. WHAT ARE THE POSSIBLE RISKS AND DISADVANTAGES OF TAKING PART?

We do not expect side effects or risks by participating in our study. However, questionnaires relating to emotional health during the screening process or study may be distressing for some young people and may reveal undiagnosed eating disorder or depression. If this is the case, your child will be referred to their GP with a letter from the study PI. Your child may enrol in the study at a later date following clearance from their GP and after being re-screened. If the other screening processes or study makes your child feel distressed or upset, you or your child may stop the study at any time and we first recommend you contact your child's General Practitioner. Here are other contacts your child can talk to and websites your child can access if they feel distressed or upset, if that is what they want to do.

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

PART 2: HOW IS THE STUDY BEING CONDUCTED?

10. WHAT WILL HAPPEN TO INFORMATION ABOUT YOUR CHILD?

Information collected from your child during the screening process and study (including their name, date of birth, their nominated mobile number and your nominated email contact) 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.

Group results may be discussed at conferences or published in scientific journals. However, no child will be identifiable. The study team will send you a newsletter with the overall results of the study when it has finished. However, due to the length of the study, it may be some time before the team is able to do this.

All information collected during the screening process and study that can identify your child will be treated confidential in accordance with Australian privacy laws. Confidential data will be stored for a period of15 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. 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 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). Also, if we have reason to suspect that your child is at risk of being abused and/or neglected we must report this to the Child Protection Helpline run by the NSW Government Family and Community Services under the Australian Government's Mandatory Reporting of Child Abuse and Neglect Legislative Requirements.

11. WHO HAS REVIEWED THIS STUDY?

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.

If you have any questions, please do not hesitate to discuss them with the investigators listed below at:

Contact	**Phone Number**
Dr Stephanie Partridge	+61 2 8890 8187

This Information Sheet is for you to keep. We will also give you a copy of the signed consent form.

CONSENT FORM – PARENT / GUARDIAN

Title:	TEXT message Behavioural Intervention for Teens on Eating, physical activity and Social Wellbeing
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Declaration by Parent / Guardian

I have read and understand the Participant Information Sheet.

- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to my child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.
- I understand that I will be given a signed copy of this document to keep.

I consent for my child to receive text messages and health counselling telephone calls and for my child's name and nominated mobile number to be stored by the study team: ☐ Yes ☐ No

Name of Child (please print): _____

Signature of Child: _____ Date: _____

Name of Parent / Guardian (please print): _____

Signature of Parent / Guardian: _____ Date: _____