SingHealth

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

STUDY INFORMATION

Protocol Title:

Pilot evaluation of a mobile health intervention to identify early responders to treatment in adolescent obesity as a triage approach

Principal Investigator:

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Sponsor:

Paediatrics Academic Clinical Programme / Tan Cheng Lim Fund grant

If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child.

PURPOSE OF THE RESEARCH STUDY

You are being invited to participate in a research study. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

You are being invited to participate in a research study of using a mobile application and online coaching named Kurbo Program to help adolescents who are overweight. Kurbo Program is a commercial program that helps adolescents to eat healthier and exercise more through three ways. One is the use of the Kurbo mobile app to allow tracking of food and exercise and learn about a healthy lifestyle through videos and games. Secondly, based on the foods that you track, Kurbo app will suggest other healthy foods that you may enjoy. Thirdly, Kurbo provides one-to-one personal coaching with trained Kurbo coaches to help you stay on track. We hope to learn how Kurbo Program can help adolescents who are overweight manage their weight and lifestyle habits.

You were selected as a possible participant in this study because you are overweight.

This study will recruit 45 participants from KK Women’s and Children’s Hospital.

STUDY PROCEDURES AND VISIT SCHEDULE

If you agree to take part in this study, you will be asked to download Kurbo app and complete 12 sessions of Kurbo online coaching. Kurbo app teaches you on how to eat healthier and exercise more and allows you to track your weight, food and exercise. You will also receive personal coaching by Kurbo health coaches via phone, video chat or text to help you achieve your health goals. The 12 sessions of weekly only video coaching lasts for 15 minute only and is flexible and convenient. The Kurbo online coaching will commence before your doctor’s visit in the weight management clinic and will continue after your visit to the doctor.

Your participation in the study will last 6 months. You will use the Kurbo program for about 12

weeks and be followed up for 6 months. You will need to visit the doctor's office 3 times in the course of the study. Depending on your weight improvement after the first 4 sessions with Kurbo coaching, the doctor will recommend the necessary consultations with the medical team. If there is good weight improvement, you will be offered 2 monthly follow up with optional dietician and exercise physiologists counselling and exercise sessions. If there is poor weight improvement, there will be an assessment with a multidisciplinary team consisting of doctor, dieticians, exercise physiologist and medical social worker who will provide weekly follow up with the multidisciplinary team for 4 weeks followed by 2 weekly appointments for 2 months and monthly appointment thereafter based on clinical response.

Questionnaires administered include: Pediatric Quality of Life Inventory, Eating Pattern Inventory and Client Satisfaction questionnaire which will take approximately 20 minutes to complete. Your parent will also be required to complete parental report of Pediatric Quality of Life, baseline demographic questionnaire and Client satisfaction questionnaire which will take approximately 20 minutes to complete.

Physical activity will be assessed using an accelerometer which you will be required to wear for seven consecutive days on your hip during waking hours but not while bathing or swimming. During the measurement period, you will be required to complete an activity diary, providing information on activities / exercises engaged in during the measurement period. In the event the device is removed, you will be required to provide details (e,g, reason and duration) in the activity diary. As you will be required to wear the activity monitor throughout the day, including during school activities, a letter to the school / teacher will be provided to explain the reason for wearing the device during the study period.

Your blood test results will also be used in this study. Specifically the results from your fasting lipid profile, liver function test, insulin level and oral glucose tolerance test will be used if they are recommended by the physician as part of routine care. A small amount of blood sample (0.5 ml) which is less than a quarter of a teaspoon will be taken as part of this study for branched chain amino acid(BCAA), aromatic amino acid (AAA) and long chain acylcarnitines collected during collection of the fasting samples for metabolomics profiling as well as for point of care testing of HbA1C and lipid panel on visit 1 and visit 4. 2ml of blood will be taken for Vitamin D level, calcium, magnesium, phosphate and alkaline phosphatase may be performed to assess the bone health of the adolescents.

Food diary
You will be required to complete a 3-day food records at baseline, month 3 (Visit 3) and month 6 (Visit 5). Three day food diary consist of recording of actual intake of foods and beverages at the time of consumption. Food will be estimated using household measures (e.g. cups, tablespoons) and food pictures.

When your participation in the study ends, you will no longer have access to the online coaching component of Kurbo Program, unless special additional arrangements are made by the Principal Investigator.

	Baseline	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
Parental demographics and parental BMI	x					
Measurement (weight, height, waist circumference, blood pressure and body fat composition)	x		x	x		x
Peds QL questionnaire	x			x		x
Three day food diary	x			x		x
Eating Pattern Inventory	x			x		x
Evaluation questionnaire				x		
Accelerometry	x			x	x	
Fasting insulin, lipids, oral glucose tolerance test		x			x	
Plasma amino acid long chain acylcarnitine levels and vitamin D level, calcium, magnesium,phosphate and alkaline phosphatase		x			x	

Schedule of visits and procedures:

Visit 0: Recruitment, three day food diary, questionnaire and measurement and use of accelerometer

Visit 1(preferably before visit 2): Taking of fasting bloods

Week 1-12: 12 weekly sessions of Kurbo online coaching

Phone call 1 (Week 4): Nurse clinician call to follow up on Kurbo Program progress

Visit 2 (preferably between Weeks 4-11): Doctor's visit for weight management clinic and Measurements

Visit 3 (week 12-23): Measurements, three day food diary, questionnaires and Doctor's visit for weight management clinic and use of accelerometer

Visit 4 (week 24-36): Taking of fasting bloods and use of accelerometer

Visit 5 (week 24-36): Measurements, three day food diary, questionnaires, Doctor's visit for

weight management clinic and return of accelerometer

Any de-identified data obtained during the course of this study may be kept for future research beyond the completion of the study. For this purpose, consent for future research will be sought from you.

Any human biological material obtained during the course of this study will be stored and analysed only for the purposes of this study and will be destroyed after completion of the study.

The human biological material will be analysed and stored in Singapore only and the human biological material collected will not be used in restricted human biomedical research involving human-animal combinations in accordance to the Human Biomedical Research Act 2015 of Singapore (HBRA).

YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to participate in this study, you should :

- Download the Kurbo app and complete 12 sessions of Kurbo online coaching as instructed and follow the advice given to you by the study team.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Inform the Principal Investigator as soon as possible about any side effects that you may have encountered.
- Be prepared to visit the hospital for the visits and undergo all the procedures that are outlined above.
- You may receive phone call from study team members for food diary and administering of questionaire and for self-reported weight if you did not turn up for the visits.

WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

The study is being conducted because use of Kurbo Program as part of weight management clinic is not yet proven to be a standard treatment in participants with overweight issues. We hope that your participation will help us to determine whether use of Kurbo Program with weight management clinic is inferior, equal or superior to existing weight management clinic only.

Use of Kurbo Program, accelerometer and recording of food diary in this study is being performed for the purposes of the research.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

- Inconvenience and the discomfort of weighing for the Kurbo coaching sessions, as well as during the weight management clinic appointments, may be expected.
- Inconvenience of the coaching sessions by Kurbo coaches and attendance at the weight management clinic sessions may be expected.
- Temporary discomfort may arise as a result of sampling blood. Participants may experience temporary discomfort at the blood drawing site. There is also a remote possibility of inflammation or infection at the blood drawing site.

POTENTIAL BENEFITS

If you participate in this study you may reasonably expect to benefit from the study Kurbo Program in the following way:

Personal coaching from Kurbo coaches to eat healthier and exercise more.

Track your weight and diet using the Kurbo application to help you manage your weight more effectively.

ALTERNATIVES

If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution this would be standard weight management clinic.

COSTS OF PARTICIPATION

If you take part in this study, the following will be performed at no charge to you:

12 sessions of online Kurbo coaching

Allocation of accelerometer, food diary and questionnaire

If you take part in this study, you will have to pay for the following:

Blood tests as recommended by the doctors

Doctor's consultations

Dietician counselling

Physical activity counselling and sessions

You will be reimbursed for your time, inconvenience and transportation costs as follows:

- If you complete the study, you will be paid $50 for each visits you completed at the designated window period.
- In the event of deliberate misuse, loss or damage of the accelerometer during physical activity monitoring, participant may be required to replace the accelerometer at a cost of $200.

INCIDENTAL FINDINGS

This study do not anticipate any "incidental finding" (i.e. any abnormality that we did not expect to see in this study or unrelated to the purpose of this study) so we will not re-identify and give you any results from the research.

PARTICIPANT'S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your

willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

The human biological material collected for the study will be deemed to be given to KK Women's and Children's Hospital. You give up your rights to the human biological material and any intellectual property rights that may be derived from the use of the human biological material.

By signing and participating in the study, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study,

- You will still be offered follow up with weight management clinic

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

The human biological material collected for the study will be deemed to be given to KK Women's and Children's Hospital and will not be returned to you. However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if they have not been anonymised or it has been used for research but it is practicable to discontinue further use of the human biological sample(s) for the research.

Your doctor, the Principal Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons*:*

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the trial substance or research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment will not be provided by the KK Women's and Children's Hospital.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. Personal Data collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator(s) will have access to the confidential information being collected. However, the Regulatory Agencies, Institutional Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by KK Women's and Children's Hospital, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties."Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this "Personal Data", will be subject to review by the relevant institutional review board.

Data collected and entered into the Data Collection Form(s) are the property of KK Women's and Children's Hospital. In the event of any publication regarding this study, your identity will remain confidential.

In accordance with Kurbo Health Privacy Policy, you consent and acknowledge that the transfer of your personal data to, and/or the processing of your personal data in, the United States is necessary for the performance of Kurbo service.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact the Principal Investigator

Dr Chew Chu Shan Elaine

Department of Paediatrics Medicine
100 Bukit Timah Road, Singapore 229899
Tel: 63926042

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 6323 7515 during office hours (8:30 am to 5:30pm). If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM

Details of Research Study

Protocol Title:

Pilot evaluation of a mobile health intervention to identify early responders to treatment in adolescent obesity as a triage approach

Principal Investigator: Dr Chew Chu Shan Elaine

Department of Paediatrics Medicine
100 Bukit Timah Road, Singapore 229899
Tel: 63926042

I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Please also check one of these boxes:
□ Yes, I agree for a small amount of blood sample (0.5 ml) which is less than a quarter of a teaspoon to be taken for branched chain amino acid(BCAA), aromatic amino acid (AAA), long chain acylcarnitines and 2ml of blood for vitamin D level, calcium, magnesium,phosphate and alkaline phosphatase during collection of the fasting samples for metabolomics profiling as well as for point of care testing of HbA1C and lipid panel.
□ No, I do not agree for a small amount of blood sample (0.5 ml) which is less than a quarter of a teaspoon to be taken for branched chain amino acid(BCAA), aromatic amino acid (AAA),long chain acylcarnitines and 2ml of blood for vitamin D level, calcium, magnesium,phosphate and alkaline phosphatase during collection of the fasting samples for metabolomics profiling as well as for point of care testing of HbA1C and lipid panel.
□ Not applicable. I will not be going for blood test.

Please also check one of these boxes:

□ Yes, I agree for accelerometers to be fitted to assess physical activity.
□ No, I do not agree for accelerometers to be fitted to assess physical activity.

Consent for the Use of Data for Future Research

Please indicate your options by indicating a tick (√) on the checkboxes:	**Yes**	**No**
Do you consent for your data to be used for future research?	☐	☐

Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for the above participant to participate in the proposed research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Name of participant's parent/ legal guardian/ legal representative	Signature/ Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____

Name of witness | Date of signing

_____

Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant or legal representative thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained and clearly understands the nature, risks and benefits of his/ her/ his ward's/ her ward's participation in the study.

_____ _____ _____

Name of Investigator/ Person obtaining consent | Signature | Date