**Linking two randomised controlled trials for optimising early obesity prevention programs for children under 4 years (Linked CHAT study)**

**INFORMATION FOR PARTICIPANTS**

**Introduction**

You are invited to take part in the Linked CHAT study that aims to test the effectiveness of telephone and SMS support in promoting healthy child feeding practices and active play for healthy child growth in their fourth year of life, compared to the usual care.

This study is based on the Communicating Healthy Beginnings Advice (CHAT) study that you have already been participating in. The CHAT study began in 2016 and was introduced to find out whether telephone support or text messaging with mail-outs could assist women in the third trimester of their pregnancy to adopt healthy infant feeding practices and active play in the first 24 months of their child’s life.

This study will invite all mothers/primary caregivers/guardians from the CHAT study to participate and to build on the success and learnings of the CHAT study. This Linked CHAT study will provide knowledge of how best to support mothers/primary caregivers/guardians to adopt healthy child feeding practices and active play during the child’s fourth year of life (from age two to four years).

The study is being conducted within the Sydney, South Eastern Sydney, South Western Sydney and Southern NSW Local Health Districts led by Chief Investigator Associate Professor Li Ming Wen. This study is funded by the NSW Ministry of Health and no conflict of interest issues are likely to arise in relation to the CHAT Trial and this study.

**What is involved?**

You would have received a letter in the mail inviting you to participate in this study, together with a copy of this document. Within approximately 14 days, you will receive a follow-up phone call from a research assistant inviting you to participate. You will be invited to participate in the data collection when your child is 2 (phone survey and child weight and height measurements), 3.5 (telephone survey only) and 4 years old (phone survey and child weight and height measurements).

If you choose to participate, this will include the following stages:

* When your child is aged 2 years:
	+ You will receive a phone call to provide verbal consent and a phone call to complete a survey about you, your child’s health, nutrition and active play.
	+ A trained research assistant will visit you at your home at a day/time that is convenient for you. The research assistant will measure yours and your child’s height and weight.
* During your child’s third year (between aged 2-3 years):
	+ If you are part of the control group, you will receive usual care and mailed information about child safety.
	+ If you are part of the intervention group, you will receive three telephone support sessions with a Child and Family Health Nurse, followed by SMS messages and mailed information.
* When your child is aged 3.5 years:
	+ You will receive a phone call to complete a survey about you, your child’s health, nutrition and active play.
* During your child’s fourth year (between aged 3-4 years):
	+ If you are part of the control group, you will receive usual care and mailed information about child safety.
	+ If you are part of the intervention group, you will receive two telephone support sessions with a Child and Family Health Nurse, followed by SMS messages and mailed information.
* When your child is aged 4 years:
	+ You will receive a phone call to complete a survey about you, your child’s health, nutrition and active play.
	+ A trained research assistant will visit you at your home at a day/time that is convenient for you. The research assistant will measure yours and your child’s height and weight.

The survey will take 20-30 minutes and will be about child feeding, child active play, and your dietary and physical activity behaviours. The home visit should take no more than 20 minutes. The research assistant will first answer any questions you may have about the study, and then ask you to sign the written Participant Consent Form. The trained research assistant will then measure your child’s height and weight with you present and in a private area.

After the survey and child measurements when your child is aged 2 years, and if you consent to participate in the two-year study, you will be randomly allocated to one of two groups. This will not be based on the group you were in during the previous study.

If you are allocated to the intervention (SMS + telephone support) group, you will receive three telephone support sessions with a Child and Family Health Nurse during your child’s third year (between age 2 and 3) and two telephone support sessions during your child’s fourth year (between age 3 to 4) to discuss your concerns and needs regarding healthy beginnings of life and childhood obesity and SMS and booklets during your child’s fourth year (between age 3 to 4). It is anticipated that the duration of each telephone session will be around 20 minutes. After each session, you will receive a set of SMS messages (2 messages per week for 8 weeks) to reinforce the support provided in the telephone session. You can decide which days of the week and times of day you would like to receive the SMS.

If you are allocated to the control group you will receive usual care, which all families with children aged under 5 years can access, provided by the New South Wales Local Health District, Child & Family Health nursing service. You will also receive home safety promotion materials and a newsletter on “Kids’ Safety” three times a year.

Due to the nature of this study, we would like to link your data from the CHAT study with this new Linked CHAT study. Furthermore, we would also like to use your data for future research purposes however; ethical approval will be sought prior to using your data in any further research. You can also choose not have your data used for future research purposes.

**Risks**

There are no potential risks associated with your participation in this study.

The weight and height measurements of your child will take place at your house with you present and will be conducted by a trained research assistant to ease any potential risk of discomfort for your child.

If you feel uncomfortable participating in the study, you are free to withdraw at any time without providing a reason. If you feel you need some support in relation to your mental health, your child’s health or other problems around looking after your child, our research team can support you with a referral to relevant clinical or other services.

**Benefits**

While we intend that this research study furthers knowledge of how to continue to support mothers/primary caregivers/guardians with their child’s feeding and active play practice in third year of life, this may not be of direct benefit to you. If the trial is successful, the further knowledge of how best to support mothers/primary caregivers/guardians with healthy child feeding and active play will be widely promoted and used by all Local Health Districts in NSW.

**Costs**

Participation in this study will not cost you anything, nor will you be paid. A $20 Woolworths or Coles gift voucher will be offered for your time to undertake the first survey (when your child is two years), then another two $20 Woolworths or Coles gift voucher will be offered for the second survey (when your child is three years), and the third survey (when your child is four years).

**Voluntary Participation**

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your relationship with Sydney, South Eastern Sydney, South Western Sydney and Southern New South Wales Local Health Districts. No staff from the Local Health Districts will be made aware of your participation or non-participation.

**Confidentiality**

All the information collected from you for the study will be treated confidentially, and only the chief researcher, A/Prof Li Ming Wen will have access to it. The hard copy data files will be stored securely in a locked cabinet and the electronic files will be stored securely on the server at the Health Promotion Unit at the Royal Prince Alfred Hospital. Seven years after the project is finished, all data files will be destroyed in accordance with NSW Government and NSW Health privacy policies. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable.

**Further Information**

When you have read this information, the researcherwill discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Associate Professor Li Ming Wen at the Sydney Local Health District Health Promotion Unit on:

Telephone: 02 9515 9078

Email: LiMing.Wen@health.nsw.gov.au.

This information sheet is for you to keep.

**Ethics Approval and Complaints**

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X18-0387.

The conduct of this study at the Royal Prince Alfred Hospital has been authorised by the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on 9515 7899 and quote protocol number LNR/16/RPAH/495 & LNRSSA/16/RPAH/646.

**Linking two randomised controlled trials for optimising early obesity prevention programs for children under 3 years (**Linked CHAT study)

**PARTICIPANT CONSENT FORM**

I, .......................................................................................................................... *[name]*

of ...................................................................................................................…. *[address]*

have read and understood the Information for Participants on the above-named research study and have discussed the study with..........................................................

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

I freely choose to participate in this study and understand that I can withdraw at any time.

I understand that the research study is strictly confidential.

I understand that my information from the previous CHAT study may be linked with this study and I agree to this.

I understand that the information may be used for future research purposes and I agree to this.  Yes  No

I hereby agree to participate in this research study

* I agree to the measurements and telephone survey at 2 and 4 years:  Yes  No
* I agree to the telephone survey at 3.5 years:  Yes  No
* I agree to be part of the full study (child aged 2 to 4 years):  Yes  No

**NAME: ..................................................................................................................**

**SIGNATURE: ..................................................................................................................**

**DATE: ..................................................................................................................**

**NAME OF WITNESS: ……..........................................................................................................**

**SIGNATURE OF WITNESS: ........................................................................................................**