A 3-Arm randomised controlled trial of Communicating Healthy Beginnings Advice by Telephone (CHAT) to mothers with infants to prevent childhood obesity

Statistical Analysis Plan

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Contents

1. Introduction

This is a 3-arm randomised controlled trial (RCT) with a consecutive sample of 1056 mothers with their newborn children in New South Wales (NSW) Australia. Pregnant women who are between weeks 28 and 34 of their pregnancy and attend one of seven hospitals within four NSW Local Health Districts will be invited to participate in the CHAT trial. Informed consent will be obtained, and after baseline data collection, participants will be randomly allocated to the telephone intervention, text messaging intervention, or the control group. The randomisation is stratified by Local Health Districts. The intervention comprises telephone consultations or text messages, together with 6 intervention packages being mailed at specific times from the third trimester of pregnancy until 12 months post birth.

This study aims to determine the effectiveness of Communicating Healthy Beginnings Advice by Telephone (CHAT) to mothers with infants in improving infant feeding practices and preventing the early onset of childhood overweight and obesity. The following data analysis plan is for data analyses at 6, 12 and 24 months of child age.

2. Objectives

To examine the effectiveness of telephone and SMS intervention in:

- improving mothers' infant feeding and physical activity practices at 6, 12 and 24 months of child age
- reducing overweight and obesity at 12 and 24 months of child age

Hypotheses to be tested

Compared with usual care, the intervention using either telephone support or SMS will lead to:

(*primary outcomes*)

- an increased breastfeeding rate and duration at 6 and 12 months
- appropriate timing of the introduction of solids at 6 months;
- a reduction in child BMI & BMI z-score at 12 and 24 months; and

(secondary outcomes)

- an increased rate of practising "tummy time" at 6 months;
- an increased rate of cup use and drinking water at 6 and 12 months;
- a decreased rate of bottle use at bedtime at 12 and 24 months;
- an increased rate of healthy dietary behaviour (i.e. having a meal together, family meal and no food for reward) of the child at 12 months;
- an increase in child physical activity levels and a reduction in child TV viewing time at 12 and 24 months;
- an increase in dietary quality (i.e. an increased intake of fruits/vegetables) and improved dietary behaviour (i.e. decreased food for reward) of the child at 24 months;
- demonstrated cost-effectiveness; and
- demonstrated feasibility and acceptability of the interventions.

3. Methods

3.1 Study population/Subgroup

The analysis populations: pregnant women and their children.

The inclusion criteria for pregnant women are:

- aged 16 years and over,
- at 28–34 weeks of pregnancy,
- able to communicate in English,
- having a mobile phone and
- living in the recruitment areas.

3.2 Data sources

- Participants' Registration form
- Baseline telephone survey
- 6 months telephone survey
- 12 months telephone survey
- 24 months telephone survey
- 24 months anthropometric measurement via home visit

3.3 Endpoints & Study measures

Endpoints are 6, 12, and 24 months of age. Data will be collected by CATI at baseline (third trimester), 6, 12, and 24 months of child age.

3.3.1 Main exposure variables (definitions and derivations see Appendix I):

- intervention allocations
- recruitment sites
- women's age at registration
- children's age at data collection time points
- country of birth
- language spoken at home
- annual approximate household income
- women's current employment status
- marital status
- education level
- child's father's employment status
- child's father's education level
- first-time mother

3.3.2 Outcome variables

at 6 months (definitions and derivations see Appendix II)
- exclusive breastfeeding status
- current breastfeeding status
- introduction of solid food
- cup usage
- age of starting tummy time
- tummy time frequency

at 12 months(definitions and derivations see Appendix III)
- current breastfeeding status
- breastfeeding duration
- child BMI & BMI z-score
- cup usage
- bottle use at bedtime

- meal together
- family meal (same meal)
- food for reward
- child active time
- child screen time

at 24 months (definitions and derivations see Appendix IV)
- child BMI & BMI z-score
- breastfeeding duration
- bottle use at bedtime
- children's vegetable consumption
- children's fruit consumption
- meal together, have family meal, food for reward
- child outdoor play time
- child screen time

3.4 Data cleaning & Missing data

Outliers will be double checked and corrected. They will be treated as missing data if the values are not realistic and we cannot trace back to the original data source. Reponses like 'don't know' and 'refuse to answer' will be treated as missing values if the number of such response is limited, otherwise, the response will be categorised as one category.

To address potential bias due to missing data and loss to follow-up, missing data will be imputed using multiple imputations with chained equations.

3.5 Statistical methodology/Sequence of planned analyses

Statistical analysis will be conducted using statistical software Stata version 13 (StataCorp, 2013). Data analysis will be conducted after the data collection at 6, 12 and 24 months of child age respectively as the outcome measures are age specific.

The intention-to-treat principle will be applied for data analysis, i.e., we compared the outcomes based on participants' initial group allocations at baseline regardless of whether they received the interventions (i.e. telephone support or SMS) or not. Both intention-to-treat analysis with multiple imputations and complete-case analysis will be conducted to see whether results from multiple imputations are supported by those from complete-case analysis.

3.5.1 Descriptive analysis

Descriptive analysis will be conducted. Mean and standard deviation will be reported for continuous variables. Number and percentage will be reported for categorical variables. For intention-to-treat analysis with multiple imputations, Stata's '**mi estimate**' command will be used to estimate the means or proportions for continuous variables or categorical variables respectively.

3.5.2 Hypotheses testing

The hypotheses will be tested firstly by fitting multiple regression models (linear regression models for continuous outcomes, logistic regression models for binary outcomes). Recruitment sites will be included in the models. Other potential confounding factors will be assessed and addressed. A 10% change in coefficient or odds ratio will be used as the cutoff to determine confounding factors.

For multiple linear regressions models, adjusted coefficient (β) with 95% confidence interval (CI) will be reported. For multiple logistic regression models, adjusted odds ratios (AORs) with 95% CI will be reported. All P values are two sided and significance level is set at 5%.

Since there are multiple outcomes at 6, 12 and 24 months, multiple comparisons which may cause false positives will be inevitable. Therefore, Bonferroni correction will be used to account for multiple testing.

Analysis at 6 and 12 months of age

Cross-sectional comparison analysis will be conducted for outcomes at 6 and 12 months since most outcomes are age specific and not measured repeatedly.

Analysis at 24 months of age

Random-intercept mixed models or generalised estimating equations(GEE) will be built to take into account correlations between repeated measures such as child BMI or BMI z-score and dietary behaviour (measured at both 12 and 24 months of age) when analysing data at 24 months.

Survival analysis will be conducted for the outcome of breastfeeding duration at 24 months. Multiple Cox proportional hazards regression models adjusted for recruitment sites will be built to examine the intervention effect on breastfeeding duration. The

estimated adjusted hazard ratios (AHRs) for breastfeeding cessation with 95% CI will be calculated.

3.5.3 Sub-group analysis

Sub-group analysis for control group will be conducted to investigate the associations of demographics and mothers' health related behaviours and practices with primary and secondary outcomes.

Sub-group analysis will also be conducted by Local Health Districts, i.e.

- Sydney Local Health District
- South Eastern Sydney Local Health District
- South Western Sydney Local Health District
- Southern NSW Local Health District

4. Planned tables and figures

4.1 Analysis at 12 months

Table 1: Mothers' characteristics at baseline by group allocation

Variables	Total N= n (%)	Tel-support n= n (%)	SMS n= n (%)	Control n= n (%)
Mother's age				
16-24	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
25-29	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
30-34	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
35-39	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
40-49	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Country of birth				
Australia	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Other	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Language spoken at home				
English	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Other	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Annual household income				
< $ 40,000	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
$ 40,000 to $79,999	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
≥ $ 80,000	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Don't know/Refused	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Employment status				
Employed (employed/paid/unpaid maternity leave)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Other	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Unknown	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Marital status				
Married/de-facto partner	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Other	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Unknown	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Education level				
Up to HSC* to TAFE^/Diploma	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
University	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Unknown	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Father's employment status				
Employed	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Other	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Unknown	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Father's education level				
Up to HSC* to TAFE^/Diploma	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
University	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Unknown	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
First time mother				
No	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)

*HSC: Higher School Certificate (Year 12), ^TAFE: Technical and Further Education

Table 2 Mothers' baseline characteristics by survey completion at 6 and 12 months

Mother's baseline demographics	6 months survey completion		P	1 year survey completion		P
	Yes n (%)	No n (%)		Yes n (%)	No n (%)	
Age (years)			xxxxx			xxxxx
16-24	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
25-29	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
30-34	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
35-39	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
40-49	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Country of birth			xxxxx			xxxxx
Australia	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Overseas	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Language spoken at home			xxxxx			xxxxx
English	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Other	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Annual household income			xxxxx			xxxxx
<$ 40,000	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
$ 40,000 to $79,999	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
≥$ 80,000	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Don't know	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Employment status			xxxxx			xxxxx
Employed	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Other	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Unknown	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Marital status			xxxxx			xxxxx
Married/de-facto partner	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Other	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Unknown	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Education level			xxxxx			xxxxx
University &	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Up to HSC/TAFE	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Unknown	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Father's education level			xxxxx			xxxxx
University &	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Up to HSC/TAFE	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Unknown	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Father's employment status			xxxxx			xxxxx
Employed	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Other	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Unknown	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
First-time mother			xxxxx			xxxxx
Yes	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
No	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	

P: P values of Pearson's Chi-squared tests.

Table 3: Comparisons of outcomes between each of the intervention groups and control group at 6 and 12 months of age (intention-to-treat analysis with multiple imputations)

Outcomes	Tel-support Total=xxx n (%)	Control Total=xxx n (%)	SMS Total=xxx n (%)	Tel-support vs. Control AOR (95% CI)	SMS vs. Control AOR (95% CI)
Outcomes at 6 months					
Exclusive breastfeeding					
Yes	xx (xx)	xx (xx)	xx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Current breastfeeding					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Introduction of solid food					
6 months	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Age of starting tummy time					
<4 weeks	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Tummy time frequency					
Every day	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Drinking from cup					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Outcomes at 12 months					
Current breastfeeding					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Drinking from cup					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Having bottle at bedtime					
No	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Having meal together					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Having family meal					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Food for reward					
No	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Child active time					
>2 hours/day	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Ever having screen time					
No	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)

AOR: adjusted odds ratio, adjusted for recruitment sites.   [*]: P values with Bonferroni correction <0.05.

Table 4 Comparisons of outcomes between each of the intervention groups and control group at 6 and 12 months of age (complete case analysis)

Outcomes	Tel-support n (%)	Control n (%)	SMS n (%)	Tel-support vs. Control AOR (95% CI)	SMS vs. Control AOR (95% CI)
Outcomes at 6 months					
Exclusive breastfeeding					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
No	xxx (xx)	xxx (xx)	xxx (xx)		
Current breastfeeding					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
No	xxx (xx)	xxx (xx)	xxx (xx)		
Introduction of solid food					
6 months	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Before or after 6 months	xxx (xx)	xxx (xx)	xxx (xx)		
Age of starting tummy time					
<4 weeks	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
≥4 weeks	xxx (xx)	xxx (xx)	xxx (xx)		
Tummy time frequency					
Every day	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Not every day	xxx (xx)	xxx (xx)	xxx (xx)		
Drinking from cup					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
No	xxx (xx)	xxx (xx)	xxx (xx)		
Outcomes at 12 months					
Current breastfeeding					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
No	xxx (xx)	xxx (xx)	xxx (xx)		
Drinking from cup					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
No	xxx (xx)	xxx (xx)	xxx (xx)		
Having bottle at bedtime					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
No	xxx (xx)	xxx (xx)	xxx (xx)		
Having meal together					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
No	xxx (xx)	xxx (xx)	xxx (xx)		
Having family meal					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
No	xxx (xx)	xxx (xx)	xxx (xx)		
Food for reward					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
No	xxx (xx)	xxx (xx)	xxx (xx)		
Child outdoor play time					
>2 hours/day	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
≤2 hours/day	xxx (xx)	xxx (xx)	xxx (xx)		
Ever having screen time					
Yes	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
No	xxx (xx)	xxx (xx)	xxx (xx)		

AOR: adjusted odds ratio, adjusted for recruitment sites.
[*]: P values with Bonferroni correction <0.05.

4.2 Analysis at 24 months

Table 1 Mothers' baseline characteristics by survey completion at 1 and 2 years of age

Mother's baseline demographics	1 year survey completion		P	2 year survey completion		P
	Yes n (%)	No n (%)		Yes n (%)	No n (%)	
Age (years)			xxxxx			xxxxx
16-24	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
25-29	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
30-34	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
35-39	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
40-49	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Country of birth			xxxxx			xxxxx
Australia	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Overseas	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Language spoken at home			xxxxx			xxxxx
English	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Other	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Annual household income			xxxxx			xxxxx
<$ 40,000	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
$ 40,000 to $79,999	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
≥$ 80,000	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Don't know	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Employment status			xxxxx			xxxxx
Employed	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Other	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Unknown	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Marital status			xxxxx			xxxxx
Married/de-facto partner	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Other	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Unknown	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Education level			xxxxx			xxxxx
University &	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Up to HSC/TAFE	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Unknown	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Father's education level			xxxxx			xxxxx
University &	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Up to HSC/TAFE	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Unknown	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Father's employment status			xxxxx			xxxxx
Employed	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Other	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
Unknown	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
First time mother			xxxxx			xxxxx
Yes	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	
No	xxx (xx)	xxx (xx)		xxx (xx)	xxx (xx)	

P: P values of Pearson's Chi-squared tests.

Table 2 Risk of discontinuing breastfeeding by intervention groups

Variables	Risk of discontinuing breastfeeding	
	AHR (95% CI)	P
Intervention groups[*]		xxxx
Control	1	
Telephone support	xxx (xxx - xxx)	
SMS	xxx (xxx - xxx)	
Intervention groups[#]		xxxx
Control	1	
Telephone support	xxx (xxx - xxx)	
SMS	xxx (xxx - xxx)	

[*]: Intention to treat analysis with multiple imputations
[#]: Complete case analysis

Table 3: Comparisons of outcomes between each of the intervention groups and control group at 12 and 24 months of age (intention-to-treat analysis with multiple imputations)

Outcomes	Tel-support Total= mean (SD)	Control Total= mean (SD)	SMS Total= mean (SD)	Tel-support vs. control β (95% CI)	SMS vs. control β (95% CI)
BMI	xx (xx)	xx (xx)	xx (xx)	xx (xx to xx)	xx (xx to xx)
BMI z-score	xx (xx)	xx (xx)	xx (xx)	xx (xx to xx)	xx (xx to xx)
	n (%)	**n (%)**	**n (%)**	**AOR (95% CI)**	**AOR (95% CI)**
Having bottle at bedtime					
No	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Food for reward					
No	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Child outdoor play time					
>2 hours/day	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Ever having screen time					
No	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)

β: mean difference adjusted for recruitment sites, from linear random-intercept models.
AOR: adjusted odds ratio, adjusted for recruitment sites, from logistic random-intercept models.
[*]: P values with Bonferroni correction <0.05.

Table 4: Comparisons of outcomes between each of the intervention groups and control group at 12 and 24 months of age (complete case analysis)

Outcomes	Tel-support Total= mean (SD)	Control Total= mean (SD)	SMS Total= mean (SD)	Tel-support vs. control β (95% CI)	SMS vs. control β (95% CI)
BMI	xx (xx)	xx (xx)	xx (xx)	xx (xx to xx)	xx (xx to xx)
BMI z-score	xx (xx)	xx (xx)	xx (xx)	xx (xx to xx)	xx (xx to xx)
	n (%)	**n (%)**	**n (%)**	**AOR (95% CI)**	**AOR (95% CI)**
Having bottle at bedtime					
No	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Yes	xxx (xx)	xxx (xx)	xxx (xx)		
Food for reward					
No	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Yes	xxx (xx)	xxx (xx)	xxx (xx)		
Child outdoor play time					
>2 hours/day	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
≤2 hours/day	xxx (xx)	xxx (xx)	xxx (xx)		
Ever having screen time					
No	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xxx - xxx)	xxx (xxx - xxx)
Yes	xxx (xx)	xxx (xx)	xxx (xx)		

β: mean difference, from multiple linear regression models, adjusted for recruitment sites,.

AOR: adjusted odds ratio, from multiple logistic regression models, adjusted for recruitment sites.

[*]: P values with Bonferroni correction <0.05

5. Appendices

Appendix I

Main exposure variables

Labels	Variables	Responses	Type of data / coding
Intervention allocations	C_I_Group	Participants are randomly allocated to: Control Telephone support SMS	0 – Control 1 – Telephone support 2 - SMS
Recruitment sites	Site4g	SLHD SESLHD SWSLHD SNSWLHD	0 - SLHD 1 – SESLHD 2 – SWSLHD 3 - SNSWLHD
Women's age at registration	R_age	Years	Continuous data in years
	R-age5g		0- 16-24 1 - 25-29 2 - 30-34 3 - 35-39 4 - 40-49
Child age at 6 month survey	S6_Cage	Child date of birth 6 months survey date Calculation: Child date of birth – 6 months survey date	Continuous data in days
Child age at 1 year survey	Y1_Cage	Child date of birth 1 year survey date Calculation: Child date of birth – 1 year survey date	Continuous data in days
Child age at 2 year survey	Y2_Cage	Child date of birth 2 years survey date Calculation: Child date of birth – 2 years survey date	Continuous data in days
First-time mother	B_FirstTM	Have had babies before this pregnancy Haven't had baby before this pregnancy	0 - No 1 - Yes
Country of birth	B_41MCoungry	Australia Other	1 - Australia 0 - Other
Language spoken at home	B_42MH2g	English Other	1 - English 0 - Other

Appendix I Continuous

Labels	Variables	Responses/derivations	Type of data / coding
Annual household income	B_44Income4g	Less than $10 000	0 - <$40,000
		$10 000 – $19 999	
		$20 000 – $39 999	
		$40 000 – $59 999	1 - $40,000 to $79,999
		$60 000 – $79 999	
		$80 000 – $149 999	2 - ≥$80,000
		$150 000 or more	
		Don't know /Refused	3 – don't know (treat as missing data in complete case analysis)
Women's employment status	B_45MEmp3g	Employed full-time (include self-employed)	1 - Employed
		Employed part-time (include self-employed)	
		Paid maternity leave – employed	
		Unpaid maternity leave – employed	
		Unemployed	0 – Other
		Casually employed	
		Home duties	
		Student and working	
		Student and not working	
		Retired	
		Full-time carer	
		Unable to work due to health problems	
		Refused	2 – don't know (treat as missing data in complete case analysis)
Women's marital status	B_46MMarital3g	Married (refers to registered marriages)	1 - Married/living with partner
		De-facto partner	
		Divorced	0 - Never married/other
		Separated but not divorced	
		Widowed	
		Never married	
		Refused	2 – don't know (treat as missing data in complete case analysis)

Appendix I Continuous

Labels	Variables	Responses/derivations	Type of data / coding
Women's education	B_47MEdu3g	Completed primary school	0 - Up to HSC to TAFE certificate or Diploma
		Completed years 7 to 9	
		Completed School Certificate or Intermediate Certificate or Year 10 or 4th Form	
		Completed High School Certificate or Leaving Certificate or Year 12 or 6th Form	
		TAFE certificate or diploma	
		University or some other tertiary institute degree or higher	1 - University
		Other _____	Categorise into relevant group
		Don't know/ Refused	2 – don't know (treat as missing data in complete case analysis)
Father's employment status	B_53FEmp3g	Employed full-time (include self-employed)	1 - Employed
		Employed part-time (include self-employed)	
		Paid paternity leave – employed	
		Unpaid paternity leave – employed	
		Unemployed	0 – other
		Casually employed	
		Home duties	
		Student and working	
		Student and not working	
		Retired	
		Full-time carer	
		Unable to work due to health problems	
		Don't know /Refused	2 – don't know (treat as missing data in complete case analysis)
Father's education	B_54FEdu3g	Completed primary school	0 - Up to HSC to TAFE certificate or diploma
		Completed years 7 to 9	
		Completed School Certificate or Intermediate Certificate or Year 10 or 4th Form	
		Completed High School Certificate or Leaving Certificate or Year 12 or 6th Form	
		TAFE certificate or diploma	
		University or some other tertiary institute degree or higher	1 - University
		Don't know/Refused	2 – don't know (treat as missing data in complete case analysis)
		Other _____	Categorise to relevant group

Appendix II

Outcome variables at 6 months of age

Labels	Variables	Responses/derivations			Type of data / coding
Current breastfeeding status	S6_CBF2g	Since this time yesterday, has your child been breastfed?		Yes	1 - Yes
				No	0 - No
Exclusive breastfeeding status	S6_EBF2g	Since this time yesterday, has your child been breastfed?			
		Yes	Since this time yesterday, did your child receive any of the following?		
			No		
			i. Vitamins, mineral supplements, medicine		1 - Yes
			ii. Plain water		
			iii. Sweetened or flavoured water		
			iv. Fruit juice		
			v. Tea or infusion		
			vi. Infant formula		0 - No
			vii. Solid or semi-solid food		
			viii. Thickener in bottle		
			ix. Other (specify)_____		
			Refused (treat as missing data)		
		No			
Introduction of solid food	S6_AgeSolidFood2g	Has your child ever been given solid food?			
		Yes	At what age was your child first given solid food?		
			____weeks	Convert to weeks	6 months (≥26 & <30 weeks)
			____months		Before or after 6 months (< 26 or ≥30 weeks)
		No			1 - 6 months 0 - Before/after 6 months
Cup use	S6q24_cup2g	Yes			1 - Yes
		No			0 - No
		Don't know/refused (treat as missing data)			
Age of starting tummy time	S6q31_TTwk	days	Converted to days		Continuous data in days
		weeks			
		months			
		Don't know/refused (treat as missing data)			
	S6q31_TTwk2g	Categorised into 2 groups: <4 weeks (28 days) ≥4 weeks (28 days)			1 - <4 weeks 0 - ≥4 weeks

Appendix II Continuous

Labels	Variables	Responses/derivations	Type of data / coding
Tummy time frequency	S6q32_TTFrequency2g	How many days each week does your child spend time on their tummy when he/she is awake?	
		_____ days	1 - Every day (7 days) 0 – Not every day
		Not at all	
		Don't know/refused (treat as missing data)	

Appendix III

Outcome variables at 12 months of age

Labels	Variables	Responses/derivations	Type of data / coding
Current breastfeeding status	Y1_12_CBF2g	Yes	1 – Yes
		No	0 - No
		Don't know/refused (treat as missing data)	
Breastfeeding duration	Y1_13BFDurationWK	Including times of weaning, what is the total time your child was breastfed?	Continuous data in weeks
		_____ weeks	
		_____ months	
		Less than one week (code as 0.5 weeks)	
		Don't know/refused (treat as missing data)	
Child BMI	Y1_CBMI	Child weight _____ kg Child height _____cm Child age at 12 months telephone survey BMI will be calculated with	Continuous data
Child BMI z-score	Y1_CBMIZscore	Child weight _____ kg Child height _____cm Child age at 12 months telephone survey BMI z-score will be calculated with	Continuous data
Cup use	Y1_31cup2g	Is your child drinking from a cup?	
		Yes	1 – Yes
		No	0 - No
		Don't know/refused (treat as missing data)	
Bottle use at bedtime	Y1_33bottle2g	Yes	1 – Yes
		No	0 - No
		Don't know/refused (treat as missing data)	
Meal together	Y1_27mealtogether2g	How often do you sit down for family meals together?	
		Rarely	
		Never	0 - No
		Some of the time	
		Most of the time	1- Yes
		Always	
		Don't know/refused (treat as missing data)	

Appendix III Continuous

Labels	Variables	Responses/derivations	Type of data / coding
Family/same meal	Y1_28samefood2g	At meal times, how often do the adults in the house have the same food as the child?	
		Rarely	0 - No
		Never	
		Some of the time	
		Most of the time	1 - Yes
		Always	
		Don't know/refused (treat as missing data)	
Food for reward	Y1_29foodaward2g	Do you ever give your child food to encourage good behaviour?	1 – Yes 0 - No
		Yes	
		No	
		Don't know/refused (treat as missing data)	
Child outdoor play time	Y1_35Cactivity2g	Over the last seven days, how much time does your child usually spend being active and moving around per day?	
		None	≤2 hours/day
		0 – 15 mins	
		15 – 60 mins	
		1 – 2 hours	
		>2 hours	>2 hours/day
		Don't know/refused (treat as missing data)	
Child screen time	Y1_38ECST2g	Has your child ever had any screen-time? This includes watching TV, using a smart phone or watching an iPad.	1 – Yes 0 - No
		Yes	
		No	
		Don't know/refused (treat as missing data)	

Appendix IV

Outcome variables at 24 months of age

Labels	Variables	Responses/derivations		Type of data / coding
Child BMI	Y2_CBMI	Child weight _____ kg Child height _____cm Child age at 12 months telephone survey BMI=weight (kg)/height (m)^2		Continuous data
Child BMI z-score	Y2_CBMIZscore	Child weight _____ kg Child height _____cm Child age at 12 months telephone survey BMI z-score will be calculated with WHO Anthro (v3.2.2).		Continuous data
Child weight status at 2 years of age	Y2_CWeight4g	Child weight status (underweight, normal weight, overweight, and obesity) were identified using age- and gender-specific international cup-off points (Cole T et al. 2000; Cole T et al. 2007).		
		Boy	Girl	
		≤15.1	≤14.8	0 -Underweight
		>15.1 to <18.4	>14.8 ro <18.0	1 – Normal weight
		≥18.4 to <20.1	≥18.0 to <20.1	2 - Overweight
		≥20.1	≥20.1	3 - Obesity
	Y2_CWeight2g	Dichotomise child weight status by if they are overweight or obesity		0 – Normal/under weight 1 - Overweight/obesity
Bottle use	Y2_11bottle2g	Does your child still use a bottle?		1 – Yes 0 - No
		Yes		
		No		
		Don't know/refused (treat as missing data)		
Child fruit consumption	Y2_20CFruit	Over the last seven days, how many serves of fruit did your child usually eat in a day?		Continuous data in serves/day
		_____serves per day		
		Doesn't eat fruit		
		Don't know/refused (treat as missing data)		
	Y2_20CFruit2g	Dichotomise child fruit consumption by mean/mode		0 - <mean serves/day 1 - ≥mean serves/day
Child vegetable consumption	Y2_21CVeg	Over the last seven days, how many serves of vegetables did your child usually eat in a day?		Continuous data in serves/day
		_____serves per day		
		Doesn't eat fruit		
		Don't know/refused (treat as missing data)		
	Y2_20CVeg2g	Dichotomise child vegetable consumption by mean/mode		0 - <mean serves/day 1 - ≥mean serves/day

Appendix IV Continuous

Labels	Variables	Responses/derivations			Type of data / coding
Food for reward	Y2_29foodaward 2g	How often do you give your child food to encourage good behaviour?			1 – Yes 0 - No
		Yes			
		No			
		Don't know/refused (treat as missing data)			
Child outdoor play time	Y2_25COutdoorP WK	Think for a moment about a typical weekday for your child in the last month. How much time would you say your child spends playing outdoors on a typical weekday?			Continuous data in minutes/weekday
		_____ minutes			
		_____ hours			
		Don't know/refused (treat as missing data)			
	Y2_26COutdoorP WKN	Now think about a typical weekend day for your child in the last month. How much time would you say your child spends playing outdoors on a typical weekend day?			Continuous data in minutes/weekend day
		_____ minutes			
		_____ hours			
		Don't know/refused (treat as missing data)			
	Y2_AveOutdoorP	Calculated: (mins/weekday x 5 days + mins/weekend day x 2)/7days			Continuous data in minutes/day
	Y2_OutdoorP2g	Dichotomise child average outdoor play time by mean/mode			0 - <mean serves/day 1 - ≥mean serves/day
Child weekday screen time	Y2_27CSTWK	During a usual week, how much time does your child spend doing each of the following at home?			
		Monday - Friday	watching television programs (include watching Netflix, Foxtel, or YouTube)	____ hours	Continuous data in minutes/5 weekdays
				____minutes	
			watching smart phone, iPad, Tablet, etc.	____ hours	
				____minutes	
			using a computer or laptop	____ hours	
				____minutes	
			playing with an electronic game system (e.g. Playstation, Xbox, PSP etc.)	____ hours	
				____minutes	
		Refused (treat as missing data)			

Appendix IV Continuous

Labels	Variables	Responses/derivations			Type of data / coding
Child screen time at weekends	Y2_27CSTWKN	weekends	watching television programs (include watching Netflix, Foxtel, or YouTube)	____ hours	Continuous data in minutes/2 weekend days
				____minutes	
			watching smart phone, iPad, Tablet, etc.	____ hours	
				____minutes	
			using a computer or laptop	____ hours	
				____minutes	
			playing with an electronic game system (e.g. Playstation, Xbox, PSP etc.)	____ hours	
				____minutes	
Child average daily screen time	Y2_CST	Calculation: (child weekday screen time + screen time at weekends)/7days			Continuous data in minutes/day
	Y2_CST2g	Dichotomise child average screen time by mean/mode			0 - <mean serves/day 1 - ≥mean serves/day