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MRC Epidemiology Unit

Establishing a healthy growth trajectory from birth: The *Baby Milk* Trial

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UK Clinical Research Collaboration — igniting our potential

University of Cambridge Institute of Public Health

University of East Anglia

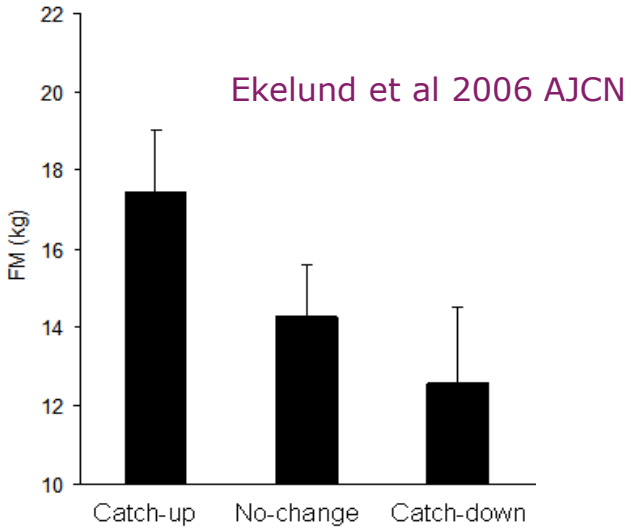
MRC Medical Research Council

Outline

- Infant feeding in obesity prevention
- The *Baby Milk* trial (669 Formula-fed babies, 93% FU at 6 months)
- The *Baby Milk* intervention (MRC Framework for complex interventions, social cognitive theory)
- Results (significant changes in maternal attitudes, baby's milk intake, weight gain to 6 months)
- Conclusions & next steps

Why infancy?

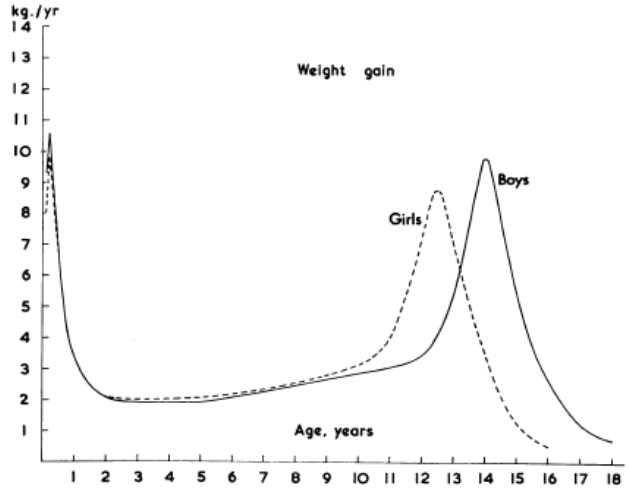
- In UK over 1 in 5 children overweight (13%) or obese (10%) by 6yrs National Child Measurement Programme 2011
- Rapid weight gain during infancy is associated with later obesity
- Infancy is a period of rapid growth and habit formation
- Evidence of programming
  - Appetite
  - Flavour
  - Metabolic

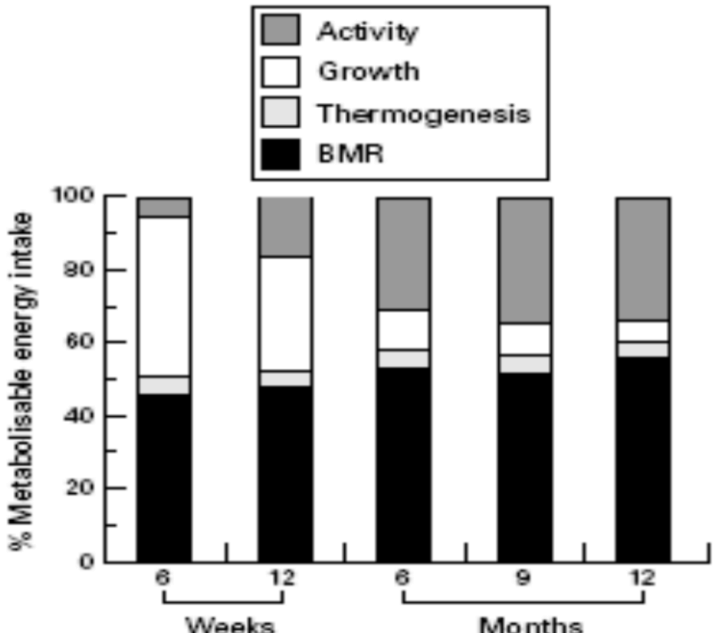


Why infancy and energy intake?

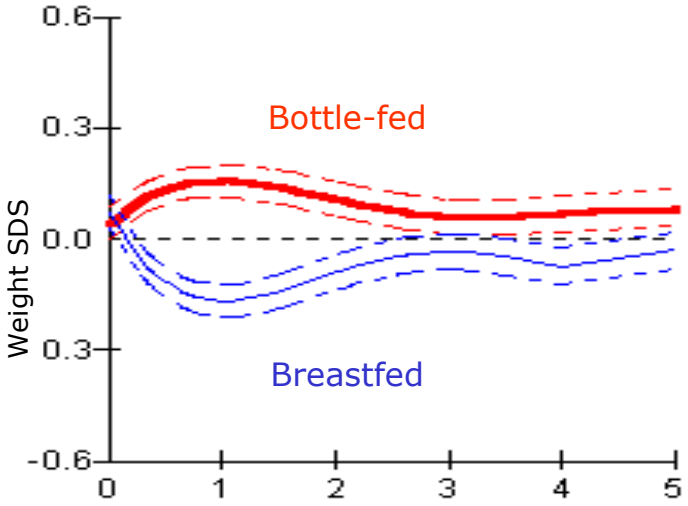
FAO/WHO/UNU 2004

- Maximum growth velocity during infancy
- First year weight triples: 3kg to 9kg
- Energy used for growth
  - 40% 1st month
  - 3% at 12months
  - 1-2% till adolescence
- Energy intake predicts growth

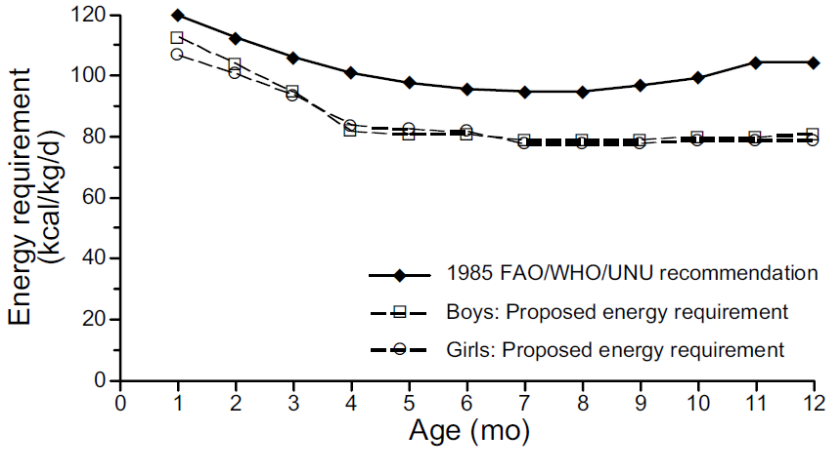




Why formula-milk?



Ong et al 2002 Paed Research



FAO/WHO/UNU 2004

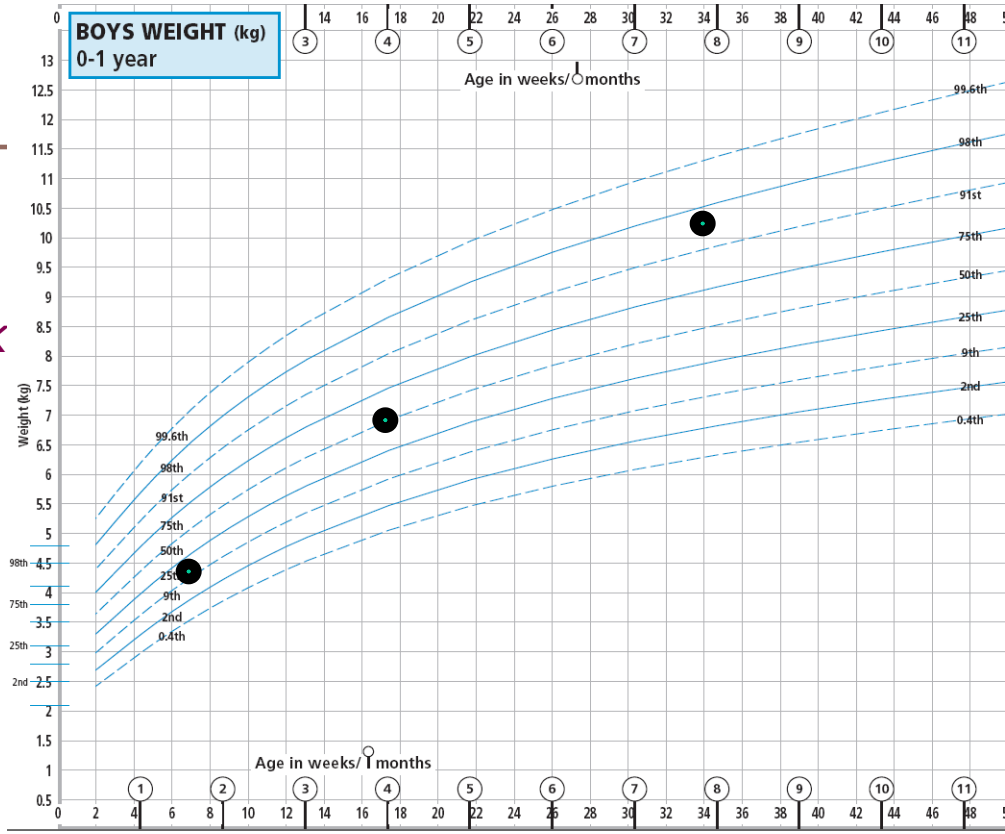
- Formula-fed babies grow faster
- In UK 78% of babies are formula-fed at 6 weeks Infant Feeding Survey 2010
- 2004 FAO/WHO/UNU recommendations 15-20% lower than 1985
- Formula-fed babies likely to be overfed
- Larger portion sizes, overriding satiety cues

What is the Baby Milk Trial?

- Explanatory RCT to examine the **safety, acceptability and effectiveness** of the *Baby Milk* intervention

  - Prevent excess weight gain during infancy

  - Reduce formula milk intake



- Understand the underlying psychological mediators

Parents often blind to obesity

Article | Comments (16)

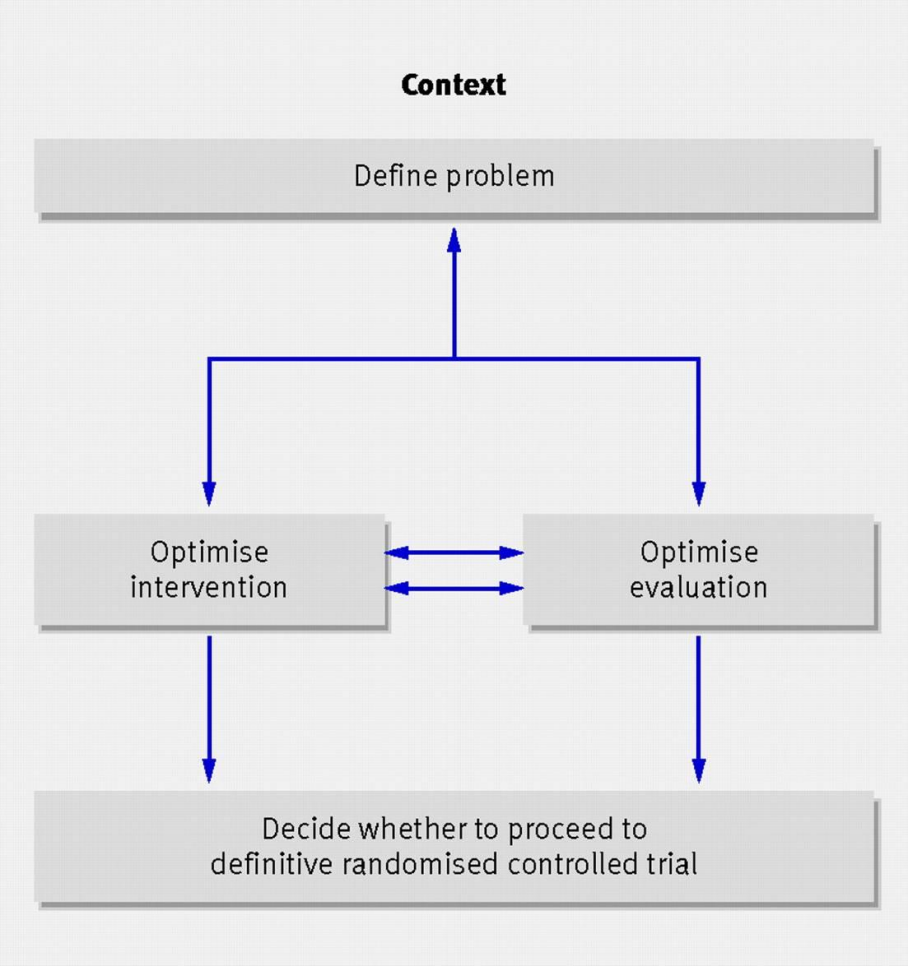
PATRICK WHITE
From Tuesday's Globe and Mail
October 21, 2008 at 9:13 AM EDT

The battle against the childhood bulge has a new culprit: clueless parents.

While public awareness campaigns have been carping on the issue of childhood

How we designed the intervention & evaluation

- Systematic Reviews
- Qualitative studies
- Questionnaire development
- Iterative process
- Multi-disciplinary team



Campbell; 2007; BMJ Framework for complex interventions

Mothers' experiences of bottle feeding: a systematic review of qualitative and quantitative studies

Rajalakshmi Lakshman, David Ogilvie and Ken Ong

Arch. Dis. Child. published online 14 Jul 2009;
doi:10.1136/adc.2008.151910

- Aim: how parents decide on how much and how often to feed their babies?
- 23 studies
- No literature on this

- **Inadequate information and support**
- Negative emotions- guilt, worry, sense of failure
- Mistakes in feed preparation
- Frequent formula-feed changes

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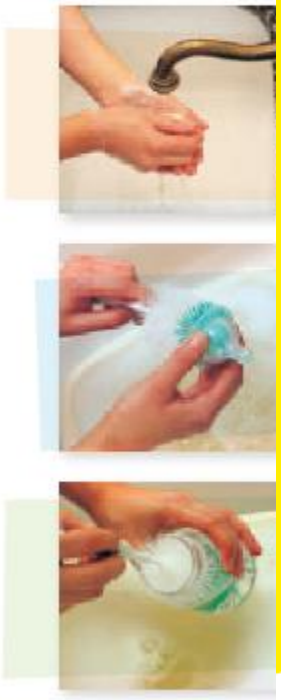
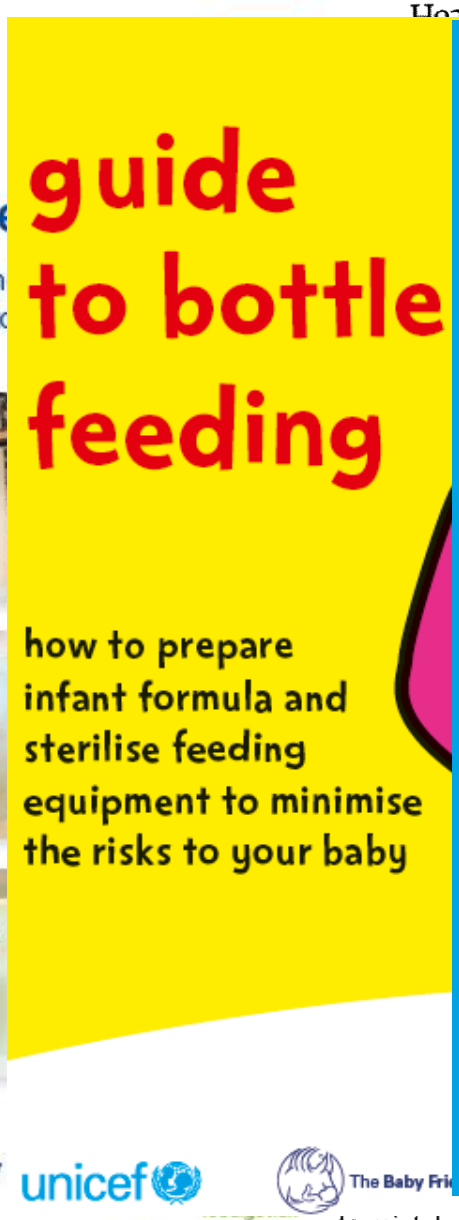
Bottle-feeding 'could risk health'
Updated on 14 July 2009





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Child: care, health and development
Original Article
doi:10.1111/j.1365-2214.2011.01283.x

Developing a programme for healthy growth and nutrition during infancy: understanding user perspectives

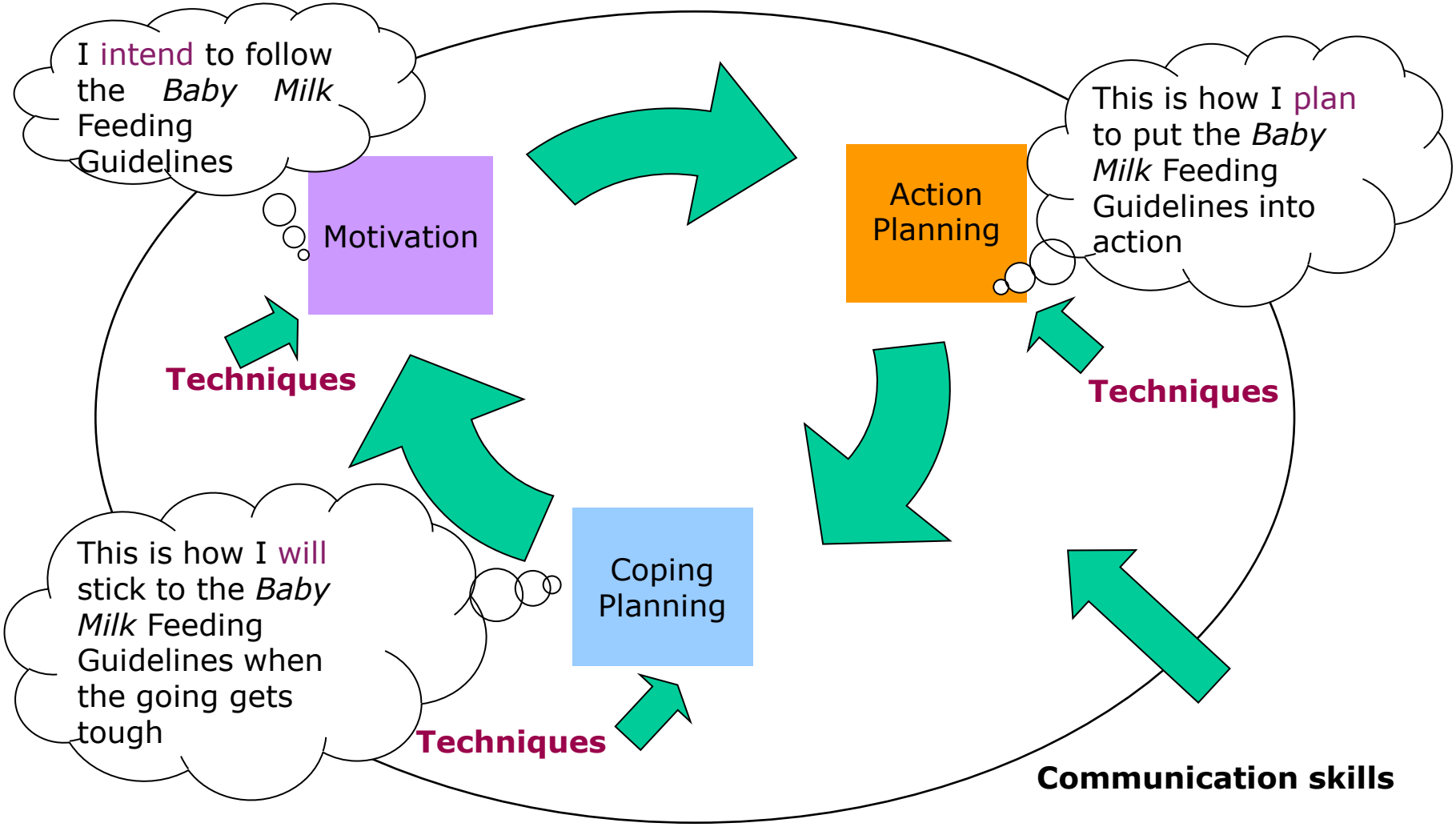
R. Lakshman,*† J. R. Landsbaugh,*† A. Schiff,*† S. Cohn,‡ S. Griffin*† and K. K. Ong*†§

- Interviews, Focus groups
- Mothers, Healthcare providers

- *'I had no advice on bottle feeding and he was crying so much that I was feeding him every ten minutes…..'*

- *'He drank for six and a half hours and he was swallowing for six and a half hours. He would drink about two and a half bottles. …..sometimes he'd have nine bottles a day.'*

The Baby Milk intervention



The Baby Milk intervention

What if the baby cries between feeds?

Trying to figure out why your baby is crying can be tricky at first until a schedule is established. It is easy to make the mistake of assuming that crying always means your baby must be hungry and needs feeding. However, babies cry for different reasons. They may be thirsty, tired, cold, hot, have a dirty nappy or want some attention. When following the new recommendations it is important to give your baby some cooled, boiled water between feeds so that your baby gets sufficient fluids.

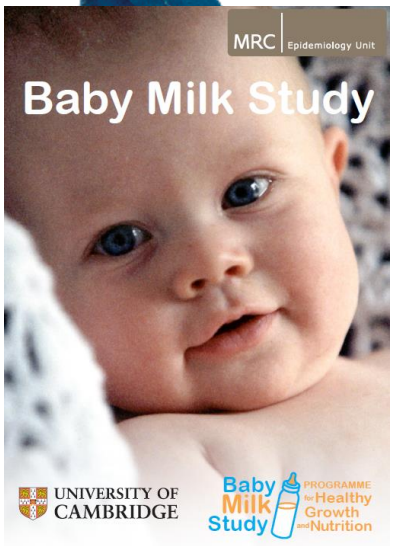
It will be very helpful if you can keep a record of how closely you follow the recommendations each day. List any difficulties that you have in following the recommendations so that we can discuss these at each of your visits.

How do I know if my baby is getting sufficient milk?

The most accurate way to know if your baby is getting sufficient milk is to monitor their growth. In the days immediately after birth it is normal for a baby to lose some weight. However, babies usually regain their birth weight within the first two weeks. Babies also go through periods when they grow fast and other times when they do not grow as fast. It is therefore recommended that babies do not need to be measured more often than:

- once a month for the first six months
- once every two months from six months to one year
- once every three months after one year.

On a day-to-day basis, a baby who is getting sufficient milk will be settled between feeds, have awake and alert periods, and have at least six wet nappies over 24 hours. Babies will also give signals that they have had enough milk such as spitting out the feed, playing with the teat, falling asleep during the feed or not drinking. It is important to pay attention to these signals and not to force your baby to finish all the milk in the bottle.



Age	Feeds per day	Scoops per feed	ml	Total scoops/ml per day
Birth – 1 month	6	3	6x90	18 scoops/540ml
1-2 months	6	3 feeds of 3 scoops 3 feeds of 4 scoops	3x90 3x120	21 scoops/630ml
2-4 months	5	3 feeds of 4 scoops 2 feeds of 5 scoops	3x120 2x150	22 scoops/660ml
4-6 months	5	6	5x180	30 scoops/900ml
6-7 months	4	7	4x210	28 scoops/840ml
7 months onward	3	7	3x210	21 scoops/630ml

Babies introduced to formula feeds within 14 weeks of birth

Baseline visit (n=669, mean age 2.3 months)

Intervention (n= 340)

Behavioural intervention

Control (n= 329)

Standard advice

Baby's age 6 months: End of intervention

93% 6 months (n= 310)

6 months (n= 314)

88% 12 months (n= 293)

12 months (n= 293)

Results: Baseline characteristics, babies

	Control n=329	**Intervention** n=340
Age, months	2.3 (1.0)	2.3 (1.0)
Gestational age, weeks	39.6 (2.7)	39.7 (1.4)
Female (%)	150 (45.6%)	158 (46.5%)
Fully formula-fed (%)	277 (93.3%)	277 (95.5%)
First born (%)	167 (53.0%)	174 (51.9%)
Birth weight, kg	3.41 (0.5)	3.47 (0.5)

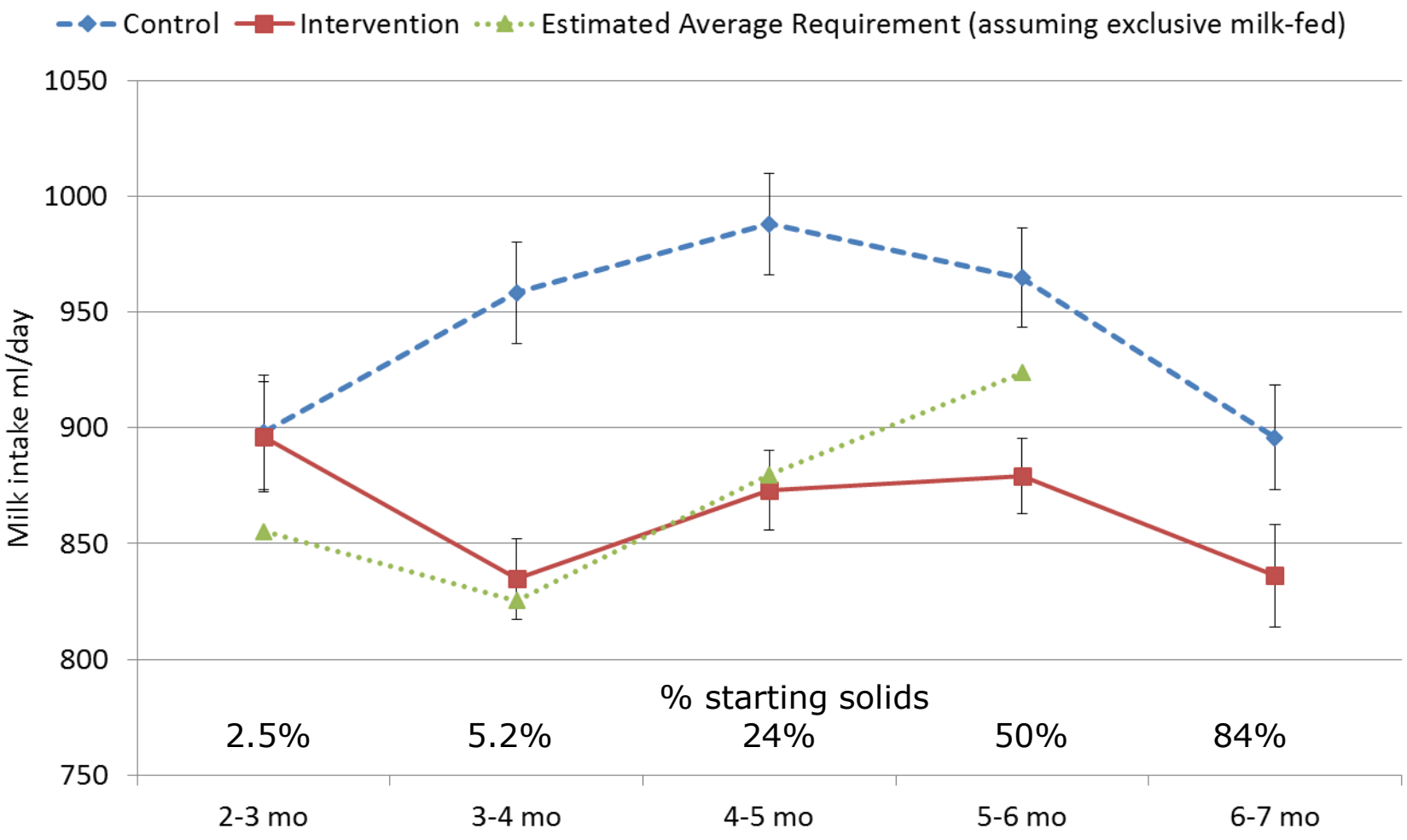
Means (SD) for continuous variables, Numbers (%) for categorical variables; SDS using WHO 2006 growth charts

Results: Baseline characteristics, mothers

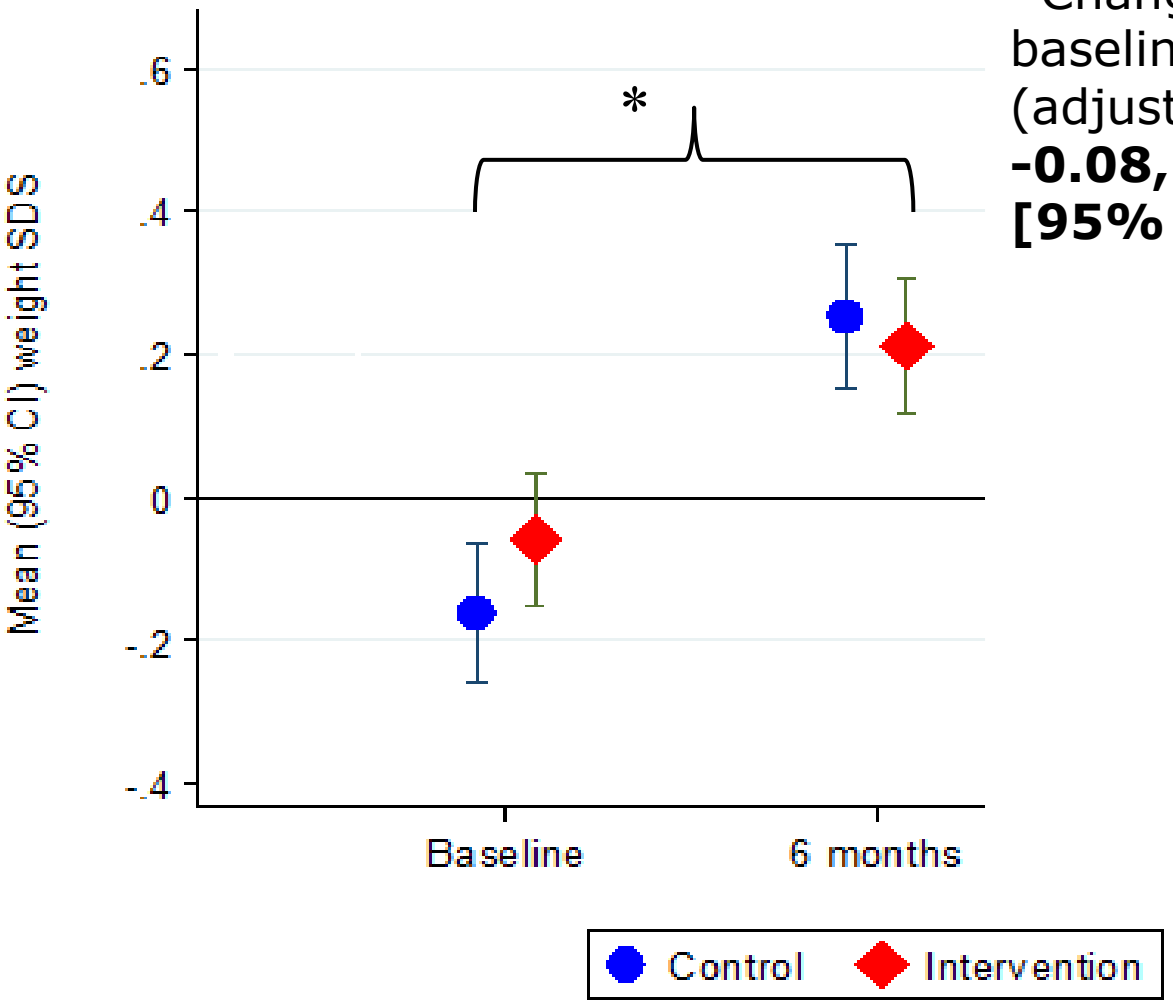
	Control n=329	**Intervention** n=340
Age, years	31.3 (5.8)	31.9 (5.9)
BMI, kg/m^2	27.8 (5.4))	28.1(5.5)
Pregnancy weight gain, kg	12.7 (6.9)	13.0 (6.8)
Age completed education, years	19.5 (3.6)	19.6 (3.5)
Degree or higher	38.3%	37.4%
Professional, higher managerial, administrative occupation	52.3%	43.3%
White ethnicity	93.1%	95.8%
Married	58.2%	56.9%
Smoked during pregnancy	12.0%	11.3%
Consumed alcohol during pregnancy	20.2%	17.2%

Means (SD) for continuous variables
Numbers (%) for categorical variables

Results: Differences in milk intake ml/d

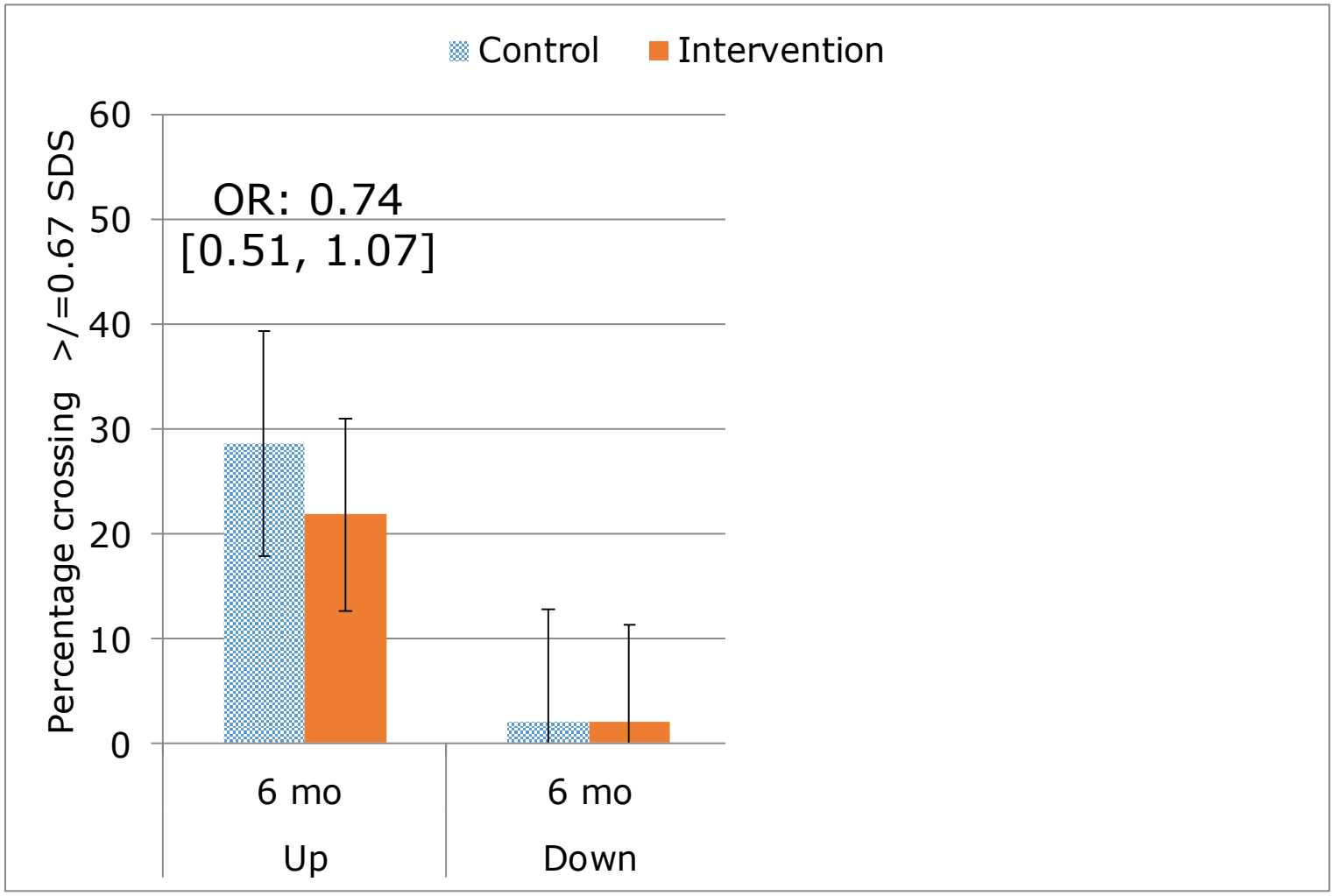


Results: Differences in weight SDS to 6mo

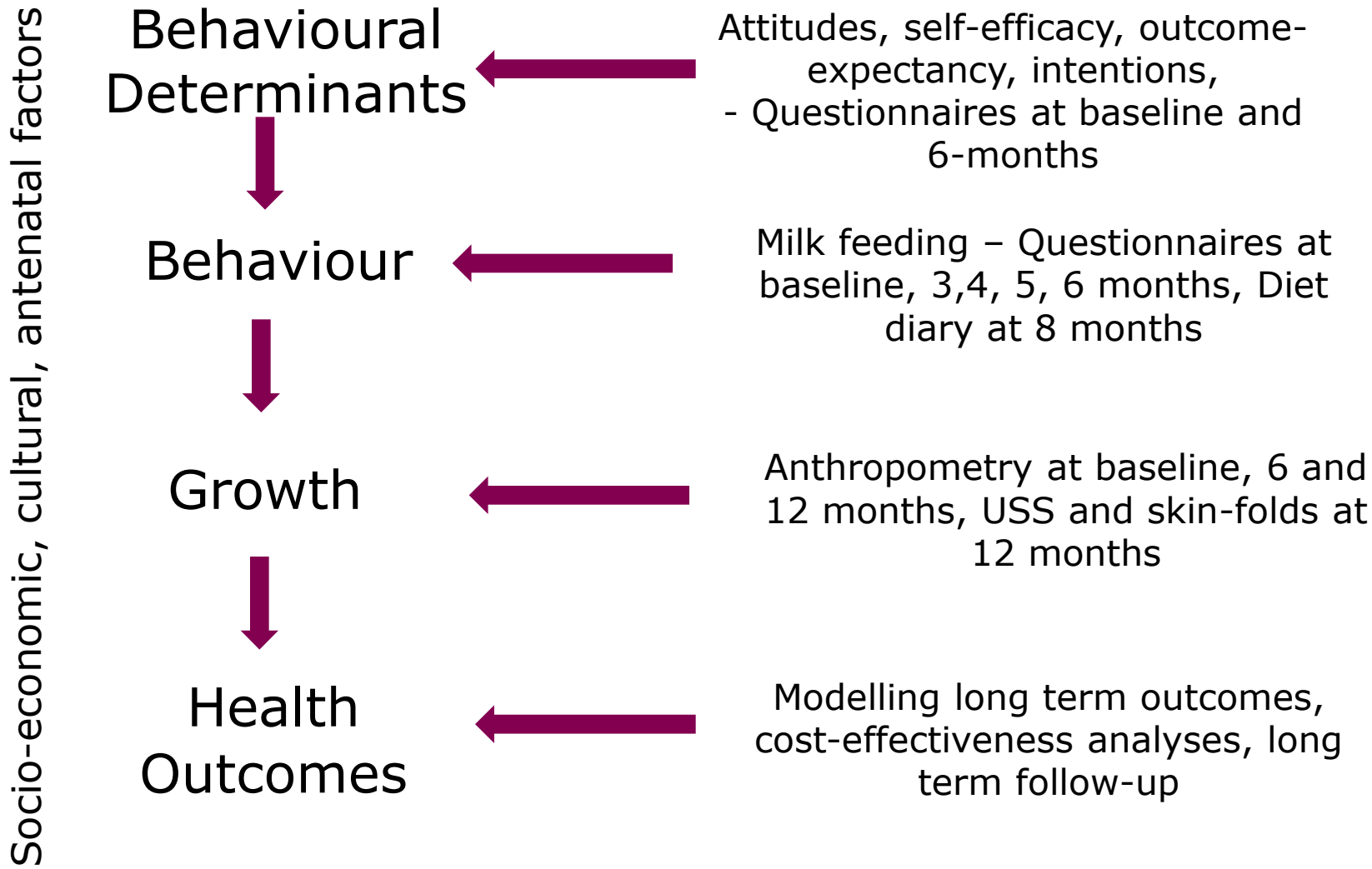


*Change in weight SDS from baseline to 6 months (adjusted for baseline)
-0.08,
[95% CI; -0.17, -0.004]

Results: % crossing 1 centile (0.67 SDS) to 6mo



Explanatory RCT: Causal modelling



Study Measures

	Baseline	6 mo	8 mo	12 mo
Questionnaire measures				
Pregnancy, Demography, Lifestyle etc	I,C			
Milk feeds (also at 3,4,5 mo)	I,C	I,C		
Feeding and psychological mediators	I,C	I,C		
Temperament, sleep, eating behaviour	I,C	I,C		
4-day diet diary			I,C	
Health service utilisation		I,C		I,C
Maternal QoL	I,C	I,C		I,C
Intervention evaluation		I		I
Anthropometry				
Parents' anthropometry	I,C	I,C		I,C
Baby's anthropometry	I,C	I,C		I,C

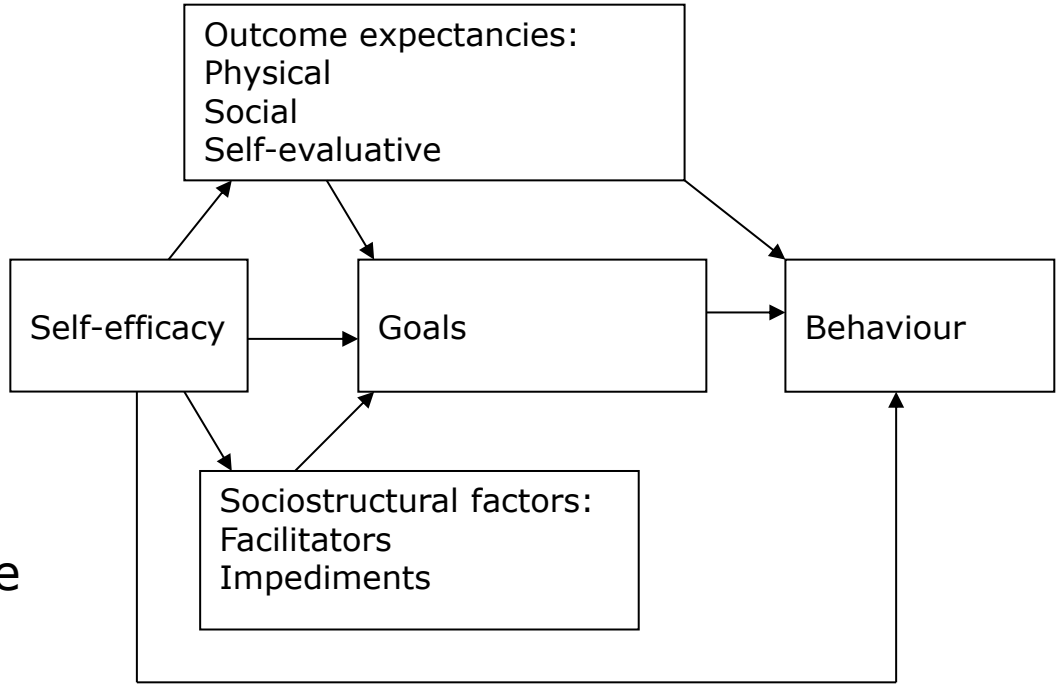
I- Intervention, C- Control group

Social Cognitive Theory Bandura

- Self- Efficacy
- Confidence in performing a particular behaviour and in overcoming barriers to that behaviour
- Baby cries, friends, partner/family, general

- Outcome Expectancy
- Thoughts or beliefs about the results or consequences of a behaviour
- Baby will be healthy, hungry, wake-up, best for baby, feel good

Luszczynska A el al , 2005, Predicting Health Behaviours



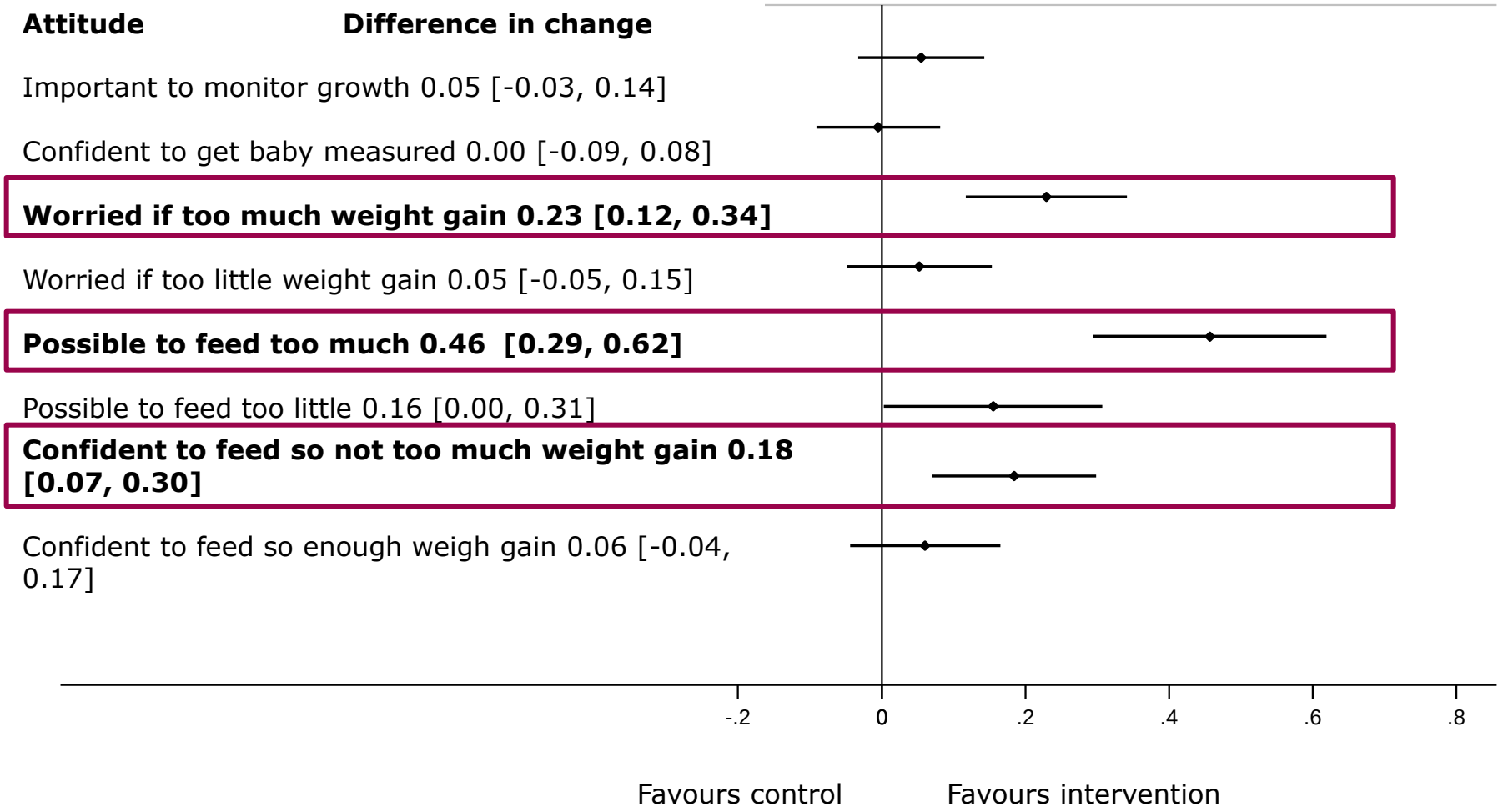
RESEARCH Open Access

Development of a questionnaire to assess maternal attitudes towards infant growth and milk feeding practices

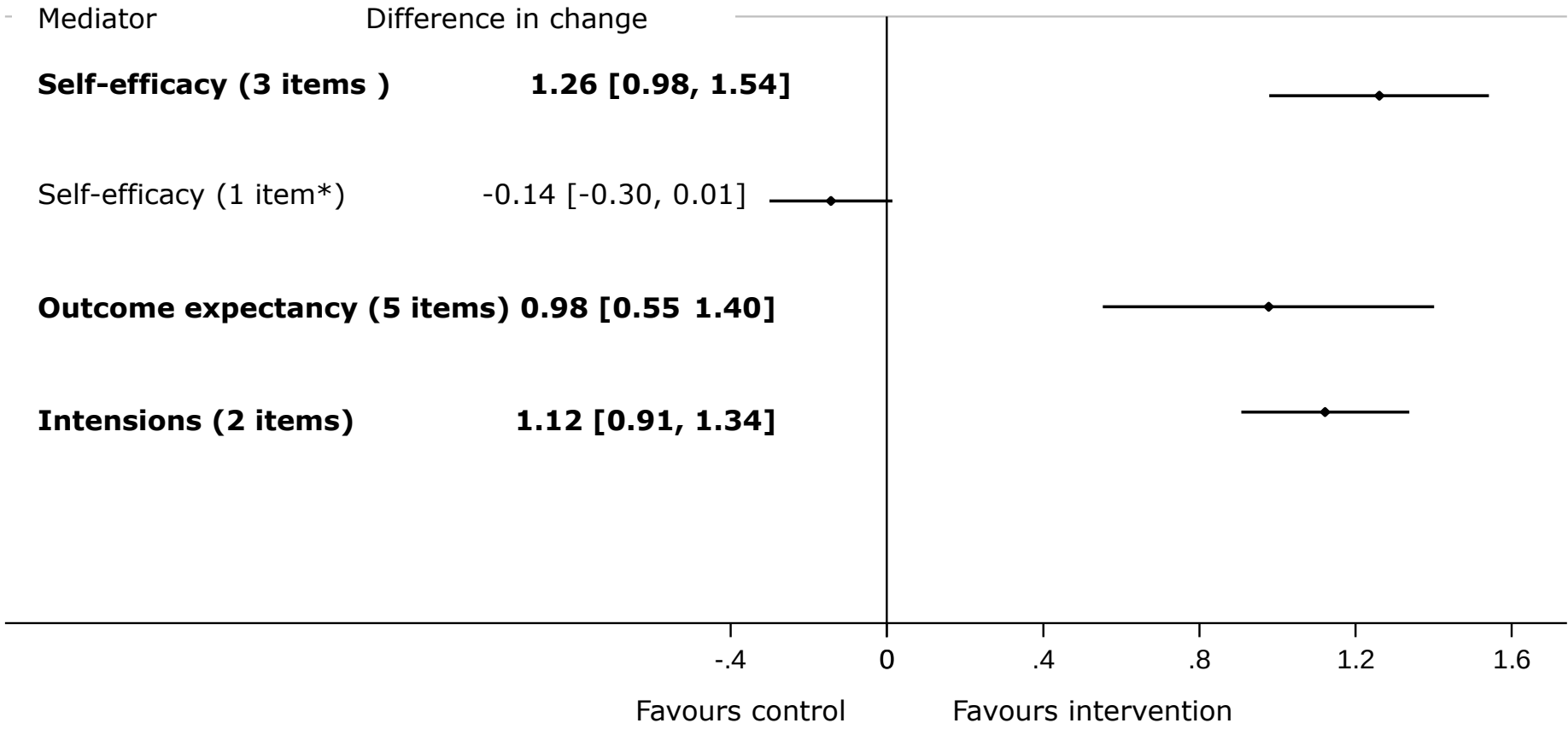
Rajalakshmi R Lakshman[1,4*], Jill R Landsbaugh[1,4], Annie Schiff[1,4], Wendy Hardeman[2], Ken K Ong[1,3,4] and Simon J Griffin[1,4]

Results: changes in maternal attitudes

assessed on a 5-point Likert scale

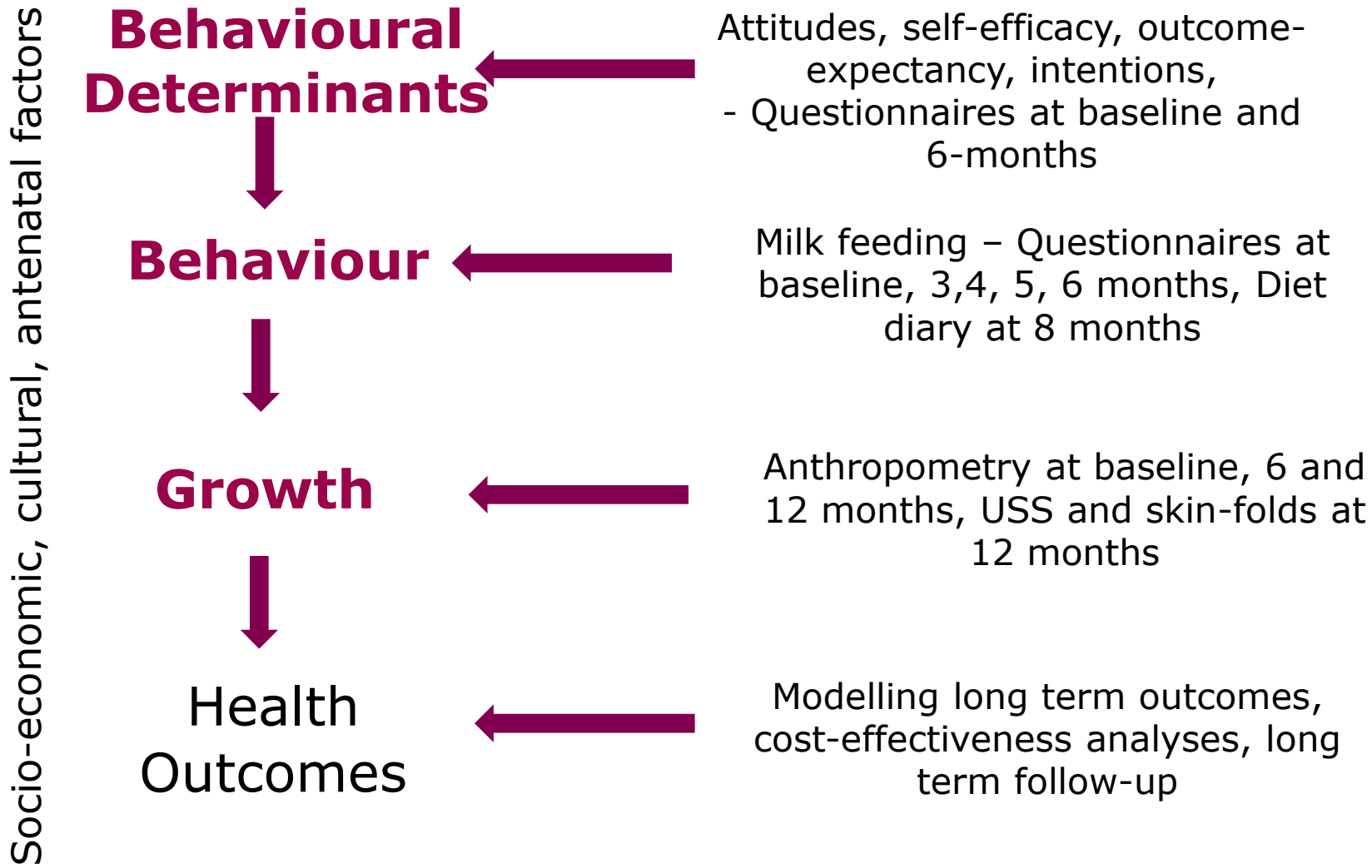


Results: changes in theory-based psychological mediators

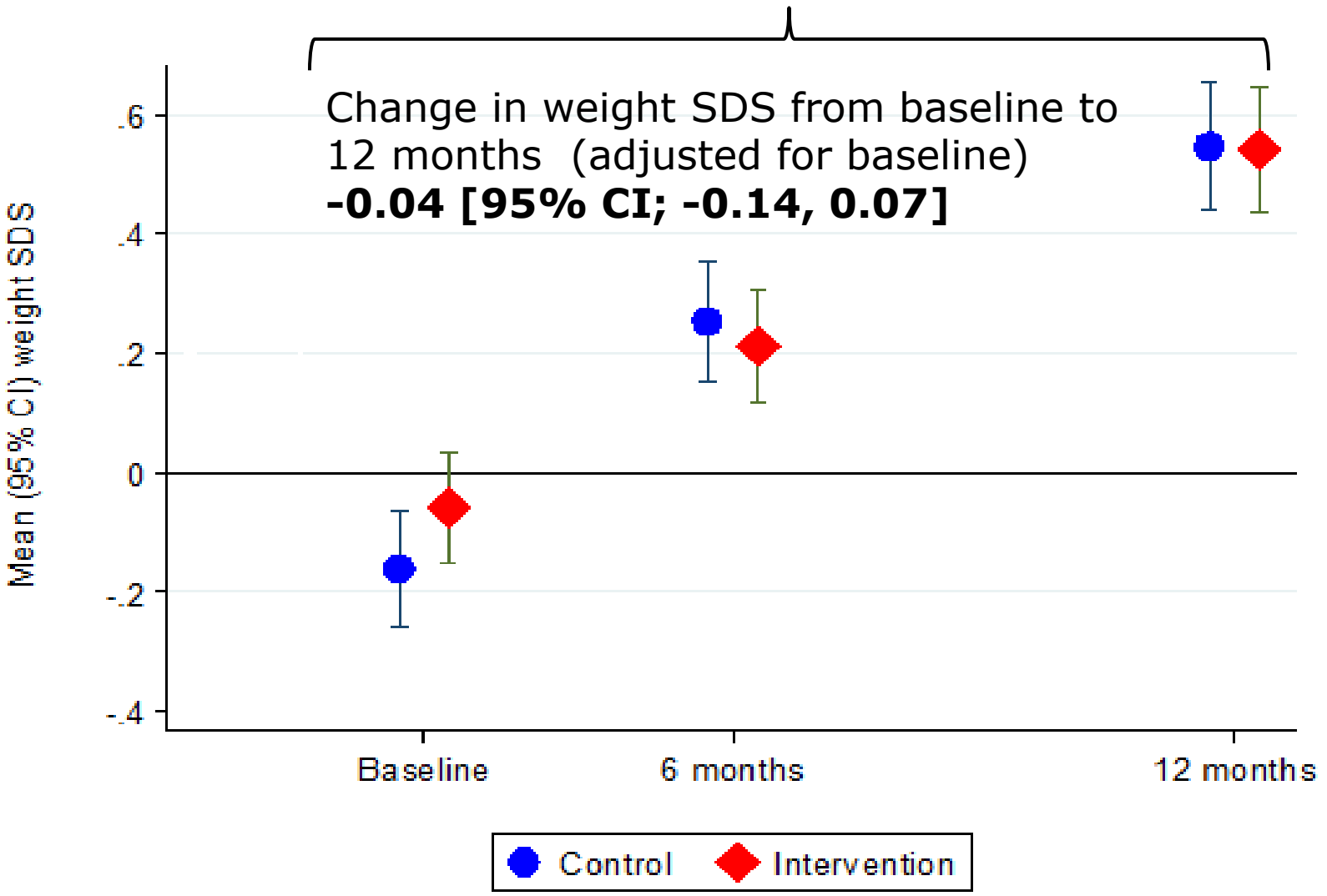


* Items for self-efficacy were combined if Cronbach alpha $\geq$ 0.6. One self-efficacy item ("difficult to follow feeding recommendations without partner/family support") was analysed separately as its inclusion in the combined self-efficacy score gave a Cronbach alpha of 0.4

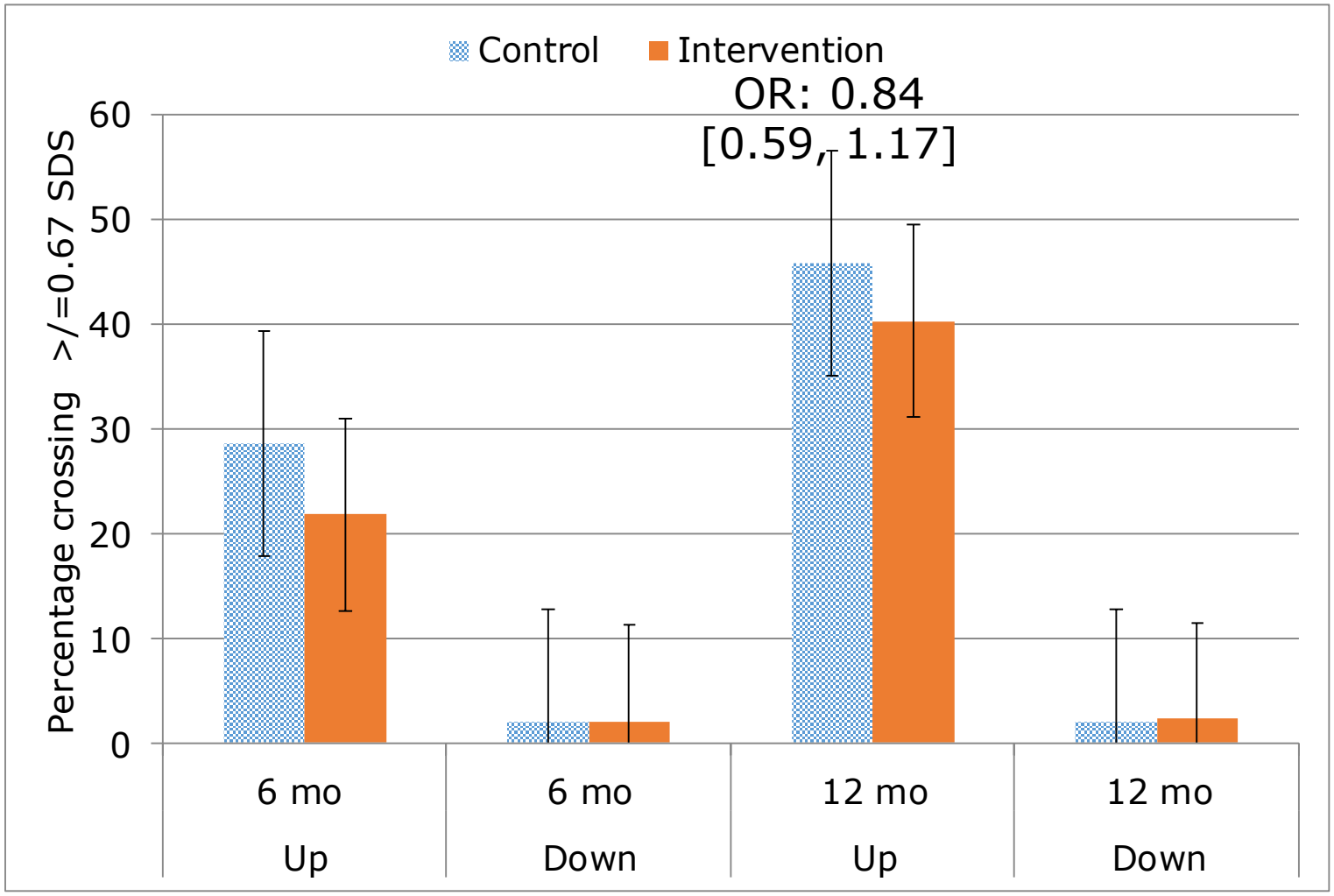
Explanatory RCT: Causal modelling



Results: Differences in weight SDS to 12 months



Results: % crossing 1 centile (0.67 SDS) to 12mo



Summary & next steps

- A theory-based behavioural intervention to reduce formula-milk intake was **acceptable**, **safe** and **effective** in reducing milk intake, and slowed weight gain **to 6 months**

- But effects on calorie intake and weight were **not sustained**. Energy intakes at 8 months in both groups exceeded WHO recommendations (773kcal/day versus the WHO recommendations of 666kcal/day)

Summary & next steps

- A theory-based behavioural intervention to reduce formula-milk intake was **acceptable**, **safe** and **effective** in reducing milk intake, and slowed weight gain to 6 months
- But effects on calorie intake and weight were **not sustained**. Energy intakes at 8 months in both groups exceeded WHO recommendations (773kcal/day versus the WHO recommendations of 666kcal/day)
- **Research in this area is recent and limited**

Results in context

Interventions for Childhood Obesity in the First 1,000 Days

A Systematic Review

Tiffany L. Blake-Lamb, MD, MSc,[1,2] Lindsey M. Locks, MPH,[3] Meghan E. Perkins, MPH,[4]

- The most recent systematic review identified 26 interventions (none targeted formula-milk intake) Blake-Lamb et al 2016
- 2 effective interventions altered the **composition** of formula-milk (hydrolysed/lower protein formula-milk)
- 7 effective interventions were **behavioural** (breastfeeding, sleep, weaning, maternal - child diet and physical activity)
  - Effective behavioural interventions were delivered for ~1 to 10 years
  - No interventions have shown long-term persisting effectiveness (i.e. months to years after the intervention ended)

Summary of effective behavioural interventions

Trial	Reference	Intervention target	Intervention duration
STRIP	Hakenen 2006	Family diet & PA	Birth to 10yrs
Healthy Beginnings	Wen 2012	Family-child diet & PA, breastfeeding	Pregnancy to 2 yrs
Lifestyle Counselling	Mustilla 2012	Mother diet & PA	2mo to 4 yrs
Prevention of overweight	Verbesteel 2013	Family diet & PA	9mo to 3 yrs
Maternal-child Pastoral	Navarro 2013	Mother-child diet, parenting	Pregnancy to 2 yrs
NOURISH	Daniels 2013	Diet- anticipatory guidance	4 to 15 mo
SLIMTIME	Paul 2011	Sleep & diet	2wks to 6 mo
INSIGHT	*Savage 2016*	*Sleep, diet & PA- responsive parenting*	*2wks to 9 mo*

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- A theory-based behavioural intervention to reduce formula-milk intake was **acceptable**, **safe** and **effective** in reducing milk intake, and slowed weight gain to 6 months
- But effects on calorie intake and weight were **not sustained**. Energy intakes at 8 months in both groups exceeded WHO recommendations (773kcal/day versus the WHO recommendations of 666kcal/day)
- Research in this area is recent and limited
- Baby Milk would complement other interventions that target sleep, activity, the **weaning period and beyond…**
- **Population-level** change is required in addition to **individual-level** intervention

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ACKNOWLEDGEMENT

This work was undertaken by the Centre for Diet and Activity Research (CEDAR), a UKCRC Public Health Research Centre of Excellence. Funding from the British Heart Foundation, Economic and Social Research Council, Medical Research Council, the National Institute for Health Research, and the Wellcome Trust, under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged.

The trial is funded by the National Prevention Research Initiative (http://www.npri.org.uk). The Funding Partners relevant to this award are (in alphabetical order): Alzheimer's Research Trust; Alzheimer's Society; Biotechnology and Biological Sciences Research Council; British Heart Foundation; Cancer Research UK; Chief Scientist Office, Scottish Government Health Directorate; Department of Health; Diabetes UK; Economic and Social Research Council; Health and Social Care Research and Development Division of the Public Health Agency (HSC R&D Division); Medical Research Council; The Stroke Association; Wellcome Trust; Welsh Assembly Government; and World Cancer Research Fund.

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

MRC Medical Research Council

NHS National Institute for Health Research

British Heart Foundation

wellcome trust

The Baby Milk Team

http://www.mrc-epid.cam.ac.uk/research/studies/babymilk/

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MRC Epidemiology Unit

School for Public Health Research

Public Health Evidence Briefing

Building the evidence for cost-effective public health practice

NHS National Institute for Health Research

What determines obesity-related behaviours in young children?

- Obesity is common even in young children and habits formed in early life persist.
- A literature review on factors influencing behaviour has helped identify which ones to target with interventions to change behaviour.
- Parenting practices, such as role modelling, monitoring and feeding practices, are important influences across all behaviours
- Provider training and nutrition policies are also positive influences in the early years setting.

Socio-ecological model of determinants

Behavioural Determinant → Behaviour → Obesity/overweight

Our reviews provide understanding of these factors to identify which are modifiable and can be targeted in a future intervention

The link between behaviour and obesity already established

1 in 5 children are overweight or obese when they start school and obesity tracks into later life, hence early prevention is important

Key issues

- Obesity is common even in young children and habits formed in early life persist.
- In order to change behaviour we need to understand the factors that influence the behaviour.
- Factors influencing children's behaviours act at multiple levels (child, parents/family, childcare/preschool, community, policy).
- The study found that parental practices and early years settings (childcare/preschool) influenced young children's behaviour.
- It found unhealthy behaviours cluster (e.g. sugar-sweetened beverage intake & TV viewing) and may be targeted together.

What we did

A literature review was conducted on the factors influencing:

1. Sugar sweetened beverage intake
2. Fruit & vegetable intake and
3. Physical activity & sedentary behaviours

in children under seven with the aim of informing interventions/ policies to change these behaviours.

What next?

Knowledge gained from these reviews will inform early life obesity prevention interventions and guide future research.

Findings and implications

- Multi-level interventions (child, parents, early years settings) show promise in changing obesity-related behaviours in young children.
- Parental practices and factors in the early years settings are important modifiable determinants of these behaviours and should be targeted in future interventions.
- Research in this age-group is recent (mainly since 2007) and very few community or policy-level interventions have been evaluated.
- Sustainability, scalability and impact on inequalities need to be considered in future interventions.

References:

Lakshman R, et al. Protocol for systematic reviews of determinants/ correlates of obesity related dietary and physical activity behaviours in young children (preschool 0-6yrs): evidence mapping and syntheses. Systematic Reviews, 2013, http://www.systematicreviewsjournal.com/content/2/1/28

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Prospero registration CRD42012002881

SPHR Contact/Find out more about this study at:

http://www.iph.cam.ac.uk/nihr-sphr/research/obesity/