Feasibility RCT of HAPPY
Healthy and Active Parenting Programme for early Years

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Childhood obesity prevention intervention targeting overweight/obese pregnant women

Development: NIHR PGfAR within BiB

Evaluation:
- Feasibility RCT
- Phase III RCT - effectiveness
Born in Bradford (BiB)

Examine genetic, nutritional, environmental, behavioural and social factors impact on health and development 2007-2010

12453 women

13776 pregnancies

THE BACKGROUND

BRADFORD CITY

6TH LARGEST CITY IN THE UK

A MULTI-ETHNIC POPULATION OF >500,000

HIGH LEVELS OF DEPRIVATION

20% OF POPULATION IS SOUTH ASIAN

60% OF CHILDREN ARE BORN INTO THE POOREST 20% OF POPULATION

70% HIGHER RATE OF INFANT ILLNESS
Describe health and ill-health and their causes;

Develop, design and evaluate interventions to promote health;

Provide a model for integrating research into practice

Build and strengthen local research capacity in Bradford
12435 Mothers
13776 pregnancies
176 sets of twins
3 sets of triplets
ROUTINE DATA
- Ultrasound data - 12, 20 & 34 wks
- Maternity IT data
- Biochemistry antenatal blood results
- Yorkshire Water chlorination
- Local Authority air pollution

BIRTH
- Secondary care records
- SystmOne primary care records
- Child health data
- Summary care records
- Education data

MOTHER
- Antenatal blood, urine
- Father saliva sample

NEONATE
- Cord blood

INFANT
- ALL IN Blood sample
- ALL IN 12 mths

CHILD
- ALL IN Blood sample
- ALL IN 24 mths
- ALL IN 3 years
- ALL IN 4 years

**RESEARCH - EXAMINATION & QUESTIONNAIRE DATA**
- Baseline questionnaire 26-28 weeks gestation
- Partner completed questionnaire

**BIB 1000**
- 6 mths
- 12 mths
- 18 mths
- 24 mths

**BIB 1000**
- 3 years
- 4 years

*ALL IN = Allergy and Infection sub cohort  **BIB 1000 = Obesity sub cohort
HAPPY Development

Understand predictors and influences of health related behaviours

<table>
<thead>
<tr>
<th>Cohort analysis</th>
<th>Social, cultural and environmental determinants of childhood obesity</th>
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<tbody>
<tr>
<td>Risk factors</td>
<td>Observations, focus groups, interviews</td>
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<tr>
<td>N=1,700</td>
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Systematic Review
Obesity prevention programmes for South Asians

Intervention mapping

HAPPY

BRADFORD INSTITUTE FOR HEALTH RESEARCH
MAKING RESEARCH REAL
**Intervention mapping**

1. **Step 1**
   - Needs assessment: What do we know? What do we need to change?

2. **Step 2**
   - Specifying objectives: What are the key aims of our intervention?

3. **Step 3**
   - Specifying HOW we are going to achieve change: What methods and strategies will we use?

4. **Step 4**
   - Creating an organised programme: Pulling it all together

5. **Step 5**
   - Piloting: How can we ensure adoption and implementation

- Generation of an evaluation plan
Expectant mothers BMI ≥ 25 kg/m²
6 weekly ante natal sessions
6 post natal sessions
Integrated in Family Links Nurturing Programme
Culturally ‘appropriate’
Healthy food choices during & after pregnancy

PA during pregnancy

Weaning at 6 months

Development of healthy food preferences

Encourage infant activity

Discourage sedentary behaviour
Feasibility trial

- Inform a full RCT trial
- Recruitment and attrition
- Acceptability
- Inform sample size calculation
- Explore outcomes and measures
Feasibility trial

Recruitment at routine antenatal
N=120

- Intervention (N=59)
  - 6 month (N=42)
  - 12 month (N=39)

- Control (N=61)
  - 6 month (N=41)
  - 12 month (N=46)
Overweight/obese women identified via maternity notes

Screened at 20 week anomaly scan
341 women invited

Initial agreement
First contact

Baseline visit and randomisation n=120

Recruitment rate = 30% (screening / baseline)

- Couldn’t contact: 54 women
- Changed mind: 44 women
- Didn’t contact: 23 women
- Insufficient English: 11 women
- Miscarriage: 7 women
- Ineligible: 6 women
Sample characteristics

**Intervention**
- Mean BMI: 29.4
- 49% Pakistani
- 32% White British
- 47% <= GSCE
- First child: 34%

**Control**
- Mean BMI: 29.8
- 43% Pakistani
- 26% White British
- 44% <= GSCE
- First child: 26%
Intervention attendance

**Antenatal sessions**
- 26 attended at least one session
- 21 attended at least 4 sessions
- Average 4.8 sessions per person

**Postnatal sessions**
- 18 returned for postnatal groups
- All 18 attended at least 3 sessions
- Average 4.6 sessions per person
Acceptability

How was today’s session for you?

1. Awful
2. 3
3. Great

Content
- “to learn about babies. How to bond with your child and everything” (Antenatal session [AN]1)
- “Finding out that exercise is ok in pregnancy” (AN2)
- “Breast feeding advantages and disadvantages” (AN3)

Peer support
- “Getting out of the house and meeting new people” (AN1)
- “coming to the group” (AN6)
- “Sharing different thinking of others”, (AN2)
## Babies weight at 12 months

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<tr>
<th></th>
<th>Intervention (N=38)</th>
<th>Control (N=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age and sex adjusted SDS score Mean (95% CI)</td>
<td>0.33 (0.02 – 0.64)</td>
<td>0.53 (0.24 – 0.81)</td>
</tr>
<tr>
<td>&gt;1 centile band Birth – 12 months Percent (95% CI)</td>
<td>18.4 (8.7 – 34.8)</td>
<td>25.0 (13.6 – 41.3)</td>
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Lessons for the phase III RCT

**Recruitment**
- Research midwives CRN
- Targets established

**Logistical considerations**
- Cluster groups
- Central location
- Geographical recruitment?

**Encourage attendance at first session**
- Manage expectations
- Meet with facilitator
- Points of contact

**Primary endpoint**
- 24 months
- BMI z-score
Objectives

1. To establish research-calibre routine data collection on growth through strengthening routine surveillance and monitoring growth trajectories

2. To identify modifiable risk factors for childhood obesity that can be targeted in future interventions

The scientific team

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- Neil Small (Bradford)
- Amanda Farrin (Leeds)
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- Helen Ball (Bradford)
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