

HAPPY

Project Evaluation Plan Summary

Better Start Bradford Innovation Hub

This is a summary document provided by the Better Start Bradford Innovation Hub for the Better Start Bradford and project teams. The document provides a brief overview of the project's current evidence base, a summary of the evaluation planned by the Innovation Hub, and the anticipated level of evidence following the planned evaluation. A more detailed account of the planned evaluation is provided in the Evaluation Protocol document, which can be requested from the Innovation Hub.

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To be updated by: Sara Ahern

Amendments to be agreed by the Nutrition and Obesity and Fidelity and Implementation workstreams

Plan approved by:

| Role | Name | Date |
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HAPPY Evaluation Plan

This document provides a summary of the evaluation planned for HAPPY in the Better Start Bradford area.

1. What we already know about HAPPY

- HAPPY is a theory based project and development was informed by Born in Bradford’s research funding by the NIHR PGfAR programme.
- The programme is offered to women who are identified as overweight or obese and targets key risk factors for developing childhood obesity.
- A feasibility RCT demonstrated that the programme was feasible and acceptable to participating women and programme facilitators and strategies to promote attendance were developed^[1].
- Although not sufficiently powered, results of the trial after 12 months indicated trends in a reduction of risk of infant obesity.
- The Early Intervention Foundation (EIF) has not rated the intervention, but the Innovation Hub suggests an EIF rating of 2 based on the EIF criteria. This means that there is preliminary evidence of improving child outcomes (see <http://www.eif.org.uk/eif-evidence-standards/>).

The Innovation Hub has identified this project as suitable for Implementation, ‘Before and after’, and Effectiveness evaluations (see BSBIH Framework for Monitoring and Evaluating BSB Projects for evaluation categories). It is anticipated that this evaluation has the potential to increase the evidence rating for HAPPY to the equivalent of EIF level 3 provided sufficient data are available.

Table 1: Summary of planned evaluation categories

| Evaluation Category | ✓/✗ | Rationale |
|---------------------|-----|---|
| Implementation | ✓ | Complete and agreed logic model and data requirements |
| Before and After | ✓ | Pre and post measures agreed, routinely collected and included in data requirements |
| Effectiveness | ✓ | Assessed as effectiveness evaluation ready by BSBIH using Evaluability Checklist (see BSBIH Framework for Monitoring and Evaluating BSB Projects for checklist) |
| Background studies | ✗ | No additional studies required |

2. Evaluation aim and objectives

The evaluation will assess the impact of HAPPY group programmes on outcomes for participating overweight or obese women and their children. This will include measures of parenting and infant feeding behaviours, and maternal and child diet and activity. The overall aim of the evaluation is to assess the impact of the programme on childhood obesity risk by comparing outcomes for participating families and non-participating families within the Born in Bradford's Better Start (BiBBS) birth cohort using a Trials within Cohorts (TwiCs) approach (see protocol document for more detail on this design). The evaluation will explore the programme's impact in relation to delivery, including implementation, fidelity, reach and engagement.

3. What we will know after the...

3.1. Implementation evaluation

- The recruitment, programme reach and level of attendance of HAPPY in the Better Start community
- How satisfied parents are with HAPPY programmes
- Whether the project inputs, activities, and outputs reflect the Logic Model and Service Design document
- Whether the project Logic Model, specifically the relationships between inputs, activities, and outputs, can be demonstrated in action
- Whether delivery of the project is feasible and acceptable, whether adoption of the programme has taken place as expected, and whether there is sufficient fidelity within the current context

3.2. 'Before and after' evaluation

- What change there has been in individual and family project specific outcomes. Specifically:
 - Whether participants on a HAPPY programme report increased parenting efficacy and healthier family lifestyles following completion of the programme.

3.3. Effectiveness evaluation

- Whether participation in a HAPPY programme impacts on children's BMI at age 2
- Whether participation in a HAPPY programme impacts on infant feeding practices

4. What we won't know after the evaluation

While attempts will be made to find out the reasons why some women choose not to enrol in the HAPPY programme, we will not know this for *all* of the women who refuse the offer.

5. What the evaluation will involve

5.1. Implementation

Data for the Implementation evaluation will be collected according to the project data requirements agreed within the Service Level Agreement (SLA) and as part of project monitoring (see Table 2). Where initial exploration of the monitoring data identifies potential issues, additional research questions will be considered (eg. *Why are high numbers of women refusing the offer of HAPPY? / Why are high numbers of women not completing the programme? / Why are women's satisfaction scores low?*) and will be incorporated into ongoing qualitative data collection.

What the Innovation Hub will need:

- a complete and agreed project Logic Model with measurable outcomes
- agreed data requirements, signed data sharing agreement and functioning data capture procedure (all data regularly sent and received as agreed)
- sufficient rates of consent to share project level data (ideally a target rate of 90% as greater rates of consent will mean a higher quality evaluation)
- good quality and complete monitoring data from the project in line with the Service Level Agreement (high levels of missing or incomplete data will hinder and may prevent evaluation)

5.2. 'Before and after'

Results from pre and post project questionnaires completed by participating women at the first and last programme sessions will be analysed. Data will be compared to establish changes in behaviour from before HAPPY programme attendance to after the programme completion (Table 3). The evaluation will use questionnaires collected routinely by HAPPY facilitators from all women who have provided consent to share their data.

Table 2: Implementation evaluation plan

| Areas to measure | Potential questions | Data source and collection method |
|---|---|---|
| 1) Content | <p>Was HAPPY implemented as planned?</p> <p>Were the same elements of HAPPY delivered across the different programmes in the same way?</p> | <p>Qualitative:</p> <p>Session observations</p> |
| 2) Coverage (reach) | <p>Were the women who were selected to be offered HAPPY, who enrolled onto the programme, and who completed the programme representative of the target population?</p> | <p>From routine data:</p> <p>Women's socio-demographics</p> <p>From monitoring data:</p> <p>No. of referrals</p> <p>Rates of recruitment and completion (by participant characteristics, e.g. socio-demographics, ethnicity, age etc.)</p> |
| 3) Frequency/Duration (Dosage, Dose delivery) | <p>Were the programmes delivered as expected (number/frequency)?</p> <p>Did women complete programmes (attend at least 8/12 sessions)?</p> <p>How many sessions did women attend?</p> | <p>From monitoring data:</p> <p>No. of programmes planned and delivered per venue</p> <p>No. of cancelled programmes/sessions and reasons</p> <p>No. of women who enrolled on and completed programmes (at least 8/12 sessions)</p> <p>Dates of attendance (per participant)</p> |
| 4) Recruitment | <p>Were anticipated numbers of women recruited to programmes?</p> <p>What constituted challenges to recruiting women?</p> <p>What constituted barriers to maintaining involvement of women?</p> | <p>From monitoring data:</p> <p>No. of referrals</p> <p>No. of women who enrolled on programme</p> <p>Qualitative:</p> <p>Analysis of contract review documents</p> <p>Interviews with Perinatal Project coordinator, HAPPY coordinator, programme facilitators</p> <p>Focus groups with participating women</p> <p>Short survey of women who refused offer</p> |
| 5) Strategies to facilitate implementation | <p>What strategies were used to support implementation of the programme?</p> <p>How were these strategies perceived by staff involved within project</p> | <p>Qualitative:</p> <p>Analysis of contract review documents</p> <p>Interviews with Perinatal Project coordinator, HAPPY coordinator and programme facilitators</p> |
| 6) Participant responsiveness | <p>How satisfied were parents with the programme?</p> | <p>From monitoring data:</p> <p>Satisfaction scores</p> <p>Qualitative:</p> <p>Focus groups with participating women</p> |

| Areas to measure | Potential questions | Data source and collection method |
|------------------------|--|--|
| 7) Quality of delivery | How was the quality of delivery of programme sessions? | <p>Qualitative:</p> <p>Interview with the HAPPY coordinator</p> <p>Session observations</p> <p>Quality of data</p> |
| 8) Context | What factors at political, economic, organisational and group levels affected the implementation of the programme? | <p>Qualitative:</p> <p>Analysis of contract review documents</p> <p>Interviews with Perinatal Project coordinator, HAPPY coordinator and programme facilitators and commissioners</p> |

What we will need:

- all requirements for Implementation evaluation also apply to ‘Before and after’
- sufficient rates of programme and questionnaire completion (90% of those completing the programme should have completed pre and post questionnaires)

3.1. Effectiveness

An effectiveness evaluation using a Trials Within Cohorts design will be conducted. Eligible pregnant women living in the Better Start Bradford area will be identified via Medway records (see protocol document for eligibility criteria). In line with the capacity of the project, a proportion of these eligible women will be selected at random to receive the HAPPY programme. The effectiveness evaluation will be powered to detect a difference in infant excess weight at age 2 years (BMI z-score) gathered routinely by health visitors between BiBBS women randomly selected for HAPPY, and a control group made up of the remaining eligible women and babies in the cohort (BiBBS women who were not offered HAPPY). Routine data for this outcome and other secondary outcomes (relating to long term outcomes, see Table 3) will be gathered for all eligible BiBBS families.

What we will need:

- Innovation Hub assessment that project is Effectiveness evaluation ready, based on the Evaluability Checklist (see BSBiH Framework for Monitoring and Evaluating BSB Projects for checklist).

- sufficient numbers of BiBBS families participating in HAPPY programmes to provide the required sample (an estimate of the required sample size is provided in the Evaluation Protocol document).

Table 3: Summary of HAPPY outcomes, data sources and collection methods

| Outcome | Potential questions | Data source & collection method |
|---|---|--|
| 'Before and after' - Project specific outcomes | | |
| Maternal diet | Do participating women report consuming a healthier diet post-intervention compared to at the beginning of the programme? | From monitoring data: HAPPY Pre and Post Questionnaire |
| Maternal activity | Do more women report meeting physical activity guidelines post-intervention compared to at the beginning of the programme? | As above |
| Infant feeding intention | How do participating women intend to feed their babies? | From monitoring data: HAPPY Pre Questionnaire |
| Infant feeding practices | Do participating women feed their baby as intended? How do participating women feed their babies? Do participating women report responsive feeding practices? | From monitoring data: HAPPY Post Questionnaire |
| Infant diet | Do participating women report that their children consume a healthy diet post-intervention? | As above |
| Infant activity | Do participating women report that their children meet physical activity guidelines post-intervention? | As above |
| Infant screen time | How much screen time do babies of participating women receive post-intervention? | As above |
| Parenting efficacy | Do participating women report high levels of parenting efficacy post-intervention? | From monitoring data: HAPPY Post Questionnaire* |
| Effectiveness - Long term outcomes | | |
| Primary | | |
| BMI at 24 months | Does HAPPY, compared with usual care/ advice provision, offer benefits in terms of lower BMI z scores at age 24 month? | From routine data: Health Visitor records |
| Secondary | | |
| Breastfeeding rates and duration | Does HAPPY, compared with usual care/ advice provision, offer benefits in terms of rates of breastfeeding initiation and duration? | From routine data: Maternity records Health Visitor records |
| Age of solid food introduction | Does HAPPY, compared with usual care/ advice provision, offer benefits in terms of fewer babies introduced to solid foods before 6 months of age? | From routine data: Health Visitor records |

| Outcome | Potential questions | Data source & collection method |
|--------------------------------------|---|---|
| BMI at age 4-5 years and 10-11 years | Does HAPPY, compared with usual care/ advice provision, offer benefits in terms of lower BMI z scores at age 4-5 years and 10-11 years? | From routine data: National Child Measurement Programme records** |

*A measure for this has not yet been identified and may be introduced later ** This is beyond the life of the project and will be a possibility provided additional funds are received.

6. Timing

6.1. Implementation

Provided implementation deadlines are maintained, it is anticipated that an initial Implementation evaluation of HAPPY will be completed within the first contract period, and a report on what is known to date will be prepared for BSB on or before September 2020. However, a more comprehensive Process evaluation will be completed as part of the planned trial to help inform findings around effectiveness.

6.2. 'Before and After'

Based on the estimated number of completed questionnaires required, it is anticipated that the 'Before and After' stage of the evaluation will take approximately 3 years from the start of outcome data collection. However, if a sufficient sample has not been achieved in this time, trends in outcome data will be reported as part of the Implementation Report made available to BSB by November 2020.

N.B. As data collection for both the Implementation and 'Before and after' evaluations is conducted as part of project monitoring, collection will commence at the start of programme delivery and be ongoing during the project contract period. However, before these stages of evaluation can be completed, it is important that an initial period of monitoring and review has taken place, which will provide both Better Start Bradford and the Innovation Hub with an understanding of programme delivery and establish the quality of collected data. Issues pertaining to low recruitment, incomplete or poor quality data, and/or low rates of consent may delay elements of the evaluation and/or impact significantly on findings.

6.3. Effectiveness

A sample of 714 women is needed for the trial (357 in the HAPPY group and 357 in the control group). Given the planned number of groups and group size, it is anticipated that the

Effectiveness evaluation will take a minimum of 5 and a half years. A shorter evaluation may be possible if data is made available from other HAPPY delivery sites (i.e. where HAPPY is being delivered outside of the BSB area). This will allow the sample size to be reached earlier. In this eventuality, a sensitivity analysis will be conducted in order to provide results and form conclusions specific to the BSB area.

7. Review

This evaluation plan will be reviewed as part of Innovation Hub Nutrition and Obesity work stream meetings and HAPPY project quarterly reviews.

It should be noted that timings of evaluations and the resulting reports may be subject to change as a result of issues relating to the availability and quality of data. However, these issues will be highlighted as part of the reviewing process and the evaluation team at Innovation Hub will ensure that the project team at Better Start Bradford are made aware of any issues as they arise.

8. References

- [1] R. R. C. McEachan, G. Santorelli, M. Bryant, P. Sahota, D. Farrar, N. Small, S. Akhtar, J. Sargent, S. E. Barber, N. Taylor, G. Richardson, A. J. Farrin, R. S. Bhopal, D. D. Bingham, S. M. Ahern, and J. Wright, "The HAPPY (Healthy and Active Parenting Programme for early Years) feasibility randomised control trial: Acceptability and feasibility of an intervention to reduce infant obesity," *BMC Public Health*, vol. 16, no. 1, 2016.

Appendix 1: Glossary of terms

All terms are defined in relation to their role in the Better Start Bradford evaluations.

| Term | Definition |
|---------------------------------|--|
| Before and after study | A study comparing outcomes for participants at the start and end of their participation in a project to estimate change in the outcome(s) |
| Case Study | An in-depth study of an individual unit (e.g. a person or a project) to describe, explain or explore it within a context. May use quantitative or qualitative approaches, or a combination. |
| Control group | A group of people who did not take part in the project, to compare with those who did take part. |
| Cost effectiveness study | A study that explores the relationship between the costs and effects of a project. |
| EIF rating | The Early Intervention Foundation's review and rating of the strength of evidence that a programme has an benefit on child outcomes for early life interventions. |
| EIF level NL2 | Not level 2 - No direct evidence about the scale of the impact of the programme at a "preliminary" level. |
| EIF level 2 | Preliminary evidence of improving a child outcome based on a study involving at least 20 participants, representing at least 60% of the sample and using validated instruments. |
| EIF level 3 | Evidence from at least one rigorously conducted evaluation demonstrating a statistically significant positive impact on at least one child outcome. |
| EIF level 4 | Evidence from at least two high quality evaluations (randomised controlled trials or quasi-experimental evaluations) demonstrating a consistently positive impact across populations and environments. This includes RCT/QED evidence of a long-term child outcome lasting a year or longer. |
| Effect | A change (positive or negative) due to a project, which may be intended or unintended. |
| Effectiveness evaluation | An assessment of the strength and direction of the effect(s) of a project on an outcome, and a judgement on the certainty of these findings. It always includes the use of a control group to compare findings between those who did and those who did not participate. |
| Engagement | Individuals' or groups' level of interest, involvement and participation in a project |
| Evaluability | The extent to which a project can be evaluated in a meaningful way. This includes assessment of whether there is a clear logic model, there are defined and measurable outcomes, and there is a comparison group. |
| Evaluation | An umbrella term for the systematic assessment of the value or significance of a project. |
| Evaluation plan | A short description of the evaluation(s) planned for a BSB project including aims, timeline and outputs. |
| Evaluation protocol | A detailed description of the planned evaluation including aims and context, timeline, outputs, methods of data collection and statistical analysis. |
| Evidence-based | The systematic use of scientific evidence to inform policy, services or other decisions. Many forms of evidence may be used, including evidence of effectiveness or implementation from scientific studies. |

| | |
|--|---|
| Fidelity | The extent which the key ingredients of a project have been delivered as intended (including as often and for as long as planned, by those trained to deliver, in the appropriate context) and received by participants. |
| Impact | Long term effects of a project (either positive or negative), which may be intended or unintended. |
| Implementation evaluation | An evaluation to explore the extent to which projects have been delivered as intended and according to the specifications in the service design document, logic model and manual. The evaluation will consider aspects of delivery, fidelity and participants' satisfaction. |
| Logic model | Logic models are visual ways of presenting the relationships between project activities and outcomes. There are different approaches to drawing logic models, but they often typically include project inputs, processes and activities, outputs, outcomes and impacts and the relationships between them. |
| Monitoring | Regular and systematic collection and review of data and data quality on specific indicators, including project inputs, activities and outputs. |
| Outcomes | The likely short or medium terms effects of a project. Outcomes should be specific and measurable for evaluation to take place. |
| Outputs | The immediate results of a project's activities, e.g. number of workshops run. |
| Pilot | A pilot study is a small scale preliminary study which may inform the feasibility and design of a future evaluation. |
| Process evaluation | The MRC defines process evaluation as "a study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors" (MRC, 2015). Explores why a project works or does not work, how and in what circumstances (in relation to outcomes). |
| Quasi-experimental evaluation | A study that estimates the effects of a project on outcomes using observational data on families who did and did not take part in combination with quasi-experimental methods (regression discontinuity, propensity score matching). |
| Reach | The extent to which people who participate in a project are representative of the target population. For a universal project this is the extent to which participating people are representative of the local BSB population. |
| Recruitment | Number of eligible participants who begin a project. Enrolment of people in BSB projects. |
| Standard project data | The data collected by the BSB project as specified in the data requirements during the service design process. |
| Randomised Controlled Trial (RCT) | A study in which people are randomly assigned to 2 (or more) groups to test a project or other intervention (e.g. a drug). One group (the experimental group) has the intervention, the other (the control group) has an alternative intervention or no intervention. Outcomes are compared between the two groups to assess the efficacy or effectiveness of the intervention. |
| Theory of change | An explanation of how the activities of a project are expected to lead to the outcomes and impacts. This is used to understand the sequence of changes that are expected to contribute to the outcome. |
| TwICs | Trial within Cohorts. To assess the effects of a project on outcomes using an experimental design. Eligible cohort members (BiBBS) are randomly allocated to a project so that participants and controls can be compared. |
| Validation study | A study that determines the validity, reliability and appropriateness of measures. |