

Reducing obesity in pre-school children: Implementation and Effectiveness of the HENRY Programme, Luton, UK

Submission date 23/02/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/03/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/06/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

There is increasing concern about rates of childhood obesity in the UK. The HENRY Programme helps parents to adopt healthier family lifestyles and habits such as family mealtimes and building activities into weekly routines. It is designed for parents or carers of pre-school children who are obese or at risk of obesity. The aim of this study is to find out whether the HENRY Programme is effective for families.

Who can participate?

Parents/carers with children aged under 5 years, HENRY-trained practitioners/Family Support Workers, HENRY operational and project leads, and Local Authority commissioners

What does the study involve?

Parents/carers attend the HENRY Programme which consists of eight sessions of 2.5 hours duration. Parents are asked to evaluate their own progress in the following areas: parenting skills, emotional well-being, healthy lifestyle, healthy eating and increased activity. Interviews are also conducted with parents after the Programme has finished to find out whether they have been able to maintain the changes they have made. HENRY group facilitators, HENRY managers and local authority commissioners are interviewed regarding the implementation of the Programme.

What are the possible benefits and risks of participating?

Previous research suggests that HENRY helps people to make positive changes for themselves and their families. The interviews allow participants to give their views on the HENRY Programme. There are no anticipated risks.

Where is the study run from?

1. University of Bedfordshire (UK)
2. Flying Start Luton (UK)

When is the study starting and how long is it expected to run for?
February 2016 to November 2018

Who is funding the study?
1. University of Bedfordshire (UK)
2. Flying Start Luton (UK)

Who is the main contact?
Dr Rosemary Davidson
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

FS_HENRY

Study information

Scientific Title

Reducing levels of obesity in pre-school children: A Process and Outcome Evaluation of the HENRY Programme, Luton, UK

Acronym

HENRY

Study objectives

The HENRY Programme uses behaviour change and self management approaches to support parents to adopt healthier family lifestyles thus reducing levels of childhood obesity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University Research Ethics Committee, University of Bedfordshire, 10/04/2017, ref: UREC103

Study design

Process and outcome evaluation of a single-centre targeted intervention versus national database of matched behavioural outcomes

Primary study design

Interventional

Secondary study design

Process study

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Childhood obesity

Interventions

The HENRY Programme trains Early Years Practitioners (suitable for Health Visitors, Midwives, Children's Centre workers, Nutritionists, Dieticians and Childminders) usually based in Children's Centres to facilitate groups with families and carers of 0 to 5 year olds. The eight week programme (2.5 hours per week) builds upon mutual support and praise, with families and facilitators working together to focus on factors known to be associated with later obesity. The approach is based on behaviour change and self management techniques.

The study design is a process and outcome evaluation using a mixed method approach. The process evaluation aims to understand how and why the intervention was adopted, drivers and barriers to implementation and the role of context. With respect to HENRY this will involve semi-structured interviews with families, staff and stakeholders at agreed time points throughout the delivery of the HENRY Programme, and observations of staff training and HENRY sessions and settings.

The outcome evaluation will measure the progress of families who attend the HENRY Programme. The study will monitor specific HENRY outcomes: parenting skills, emotional well-being, healthy lifestyle, healthy eating, and increased physical activity.

Intervention Type

Behavioural

Primary outcome measure

Self-reported measures pre and post HENRY (8 weeks) and 12 weeks post Programme:

1. Parenting skills (self rated confidence; cooperation and setting limits)
2. Emotional well-being (stress levels)
3. Healthy lifestyle (types of activity, screen time)
4. Healthy eating (eating patterns, cooking)
5. Increased activity (duration)
6. Parent attendance, documented over the 8 week duration of the course and reasons for absence (family issues, illness, change of job, uncomfortable with course or facilitator etc.) coded where possible

Secondary outcome measures

1. What went well, less well, what they would do differently, group dynamics, any parents appearing uncomfortable, reviewed by Group Facilitators each session
2. Overall impressions of HENRY including changes observed in parents and any challenges identified, reviewed by facilitators at the end of the Programme
3. Parents' level of enjoyment rated on a likert scale and further comments, collected using an anonymous appraisal at the end of the Programme

Overall study start date

01/02/2016

Completion date

01/11/2018

Eligibility

Key inclusion criteria

1. Parents/carers with children under 5 years
2. HENRY trained practitioners/Family Support Workers
3. HENRY operational and project leads
4. Local Authority commissioners

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

200

Key exclusion criteria

1. Persons with no experience of HENRY
2. Persons with no experience of working in the early years sector

Date of first enrolment

01/05/2017

Date of final enrolment

01/06/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Institute for Health Research

University of Bedfordshire

University Square

Luton

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LU1 3JU

Study participating centre
Flying Start Luton
The TOKKO Building
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Sponsor information

Organisation
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Organisation
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LU1 2QP

Sponsor type
Government

Website
<https://www.flyingstartluton.com>

Organisation

National Institute for Health Research

Sponsor details**Sponsor type**

Government

Website

<http://www.nihr.ac.uk/>

ROR

<https://ror.org/0187kwz08>

Funder(s)**Funder type**

University/education

Funder Name

University of Bedfordshire

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

Flying Start Luton

Results and Publications**Publication and dissemination plan**

Study protocol is available on request. One outcome and one process evaluation article are planned. The outcome article will report on the pre- and post behavioural measures collected from participants. The process evaluation article will report on implementation and progress of the HENRY Programme.

Intention to publish date

01/06/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Rosemary Davidson (rosemary.davidson@beds.ac.uk). Process and outcome data will be available from November 2018 for three years post evaluation. Any data requests will be subject to HENRY approval for post hoc analyses. All data is anonymised. Consent has been obtained from participants for their anonymised data to be used.

IPD sharing plan summary

Available on request