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The HENRY trial: testing whether the HENRY parenting programme prevents children from becoming overweight

Submission date
19/10/2022

Recruitment status
Recruiting

Registration date
01/11/2022

Overall study status
Ongoing

Last Edited
07/10/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
One in five children in the UK start school overweight or with obesity. This is more common in children living in deprived areas. 'HENRY' is an intervention to help families be more healthy to prevent children from becoming overweight. Around 24,500 families have attended HENRY since 2008. HENRY is delivered in children's centres across the UK. In centres where HENRY is delivered, staff are trained on the HENRY approach and encouraged to provide a healthy environment. Some staff are then trained to deliver HENRY. Research that has already been done suggests that obesity levels are lower in areas that deliver HENRY. This has not yet been proven because it is difficult to find out exactly what makes obesity rates go up and down. Obesity can be influenced by things such as the environment, culture and the way our bodies are made. Other interventions besides HENRY might also help us to be healthy, so it can be hard to understand exactly what role HENRY might play.
The aim of this study is to find out whether children whose parents attend HENRY are less likely to become overweight or develop obesity than those that do not. The researchers also want to find out whether HENRY gives value for money, improves the health of parents and carers that attend, benefits the staff that work in children's centres, and benefits the wider community. They have already carried out some research to test whether these questions can be answered by our study (e.g., if our methods will work), and the results showed that they can.

Who can participate?
Parents of preschool children; mothers, fathers and other carers (e.g. with children living in stable/long-term foster care).

What does the study involve?
Children's centres that do not deliver HENRY will be randomly selected to either be trained to deliver HENRY alongside standard sessions (like 'stay and play'), or to continue to offer standard sessions only. The researchers will recruit 14 local authorities and ask each to choose around sixof their centres to take part (82 centres total). They will then collect information from 984 families and children's centre staff from both types of centre, including height, weight, waist circumference, food intake, physical activity and quality of life. The researchers will then collect

the same information 12 months later to see if there are any differences between participants from centres delivering HENRY and those that did not.
To find out whether HENRY has any long-term influence on childhood obesity, the researchers will collect data that is already routinely collected from children by health visitors and schools after 3 years. They will then compare obesity rates in those who took part in the trial to the rest of the local population.
The researchers will explore the wider influence of HENRY on obesity within local government areas and across the country. To do this, they will speak to around 60 people (including parents, health visitors, local council representatives), hold a workshop, and review documents (e.g. council strategies, planning rules).

What are the possible benefits and risks of participating?
Participants will not receive any direct benefit from participation; however, they may feel a sense of satisfaction from participating in a research study, particularly in the field of preventing obesity in children. Parents will receive £30 worth of shopping vouchers for taking part in the trial (£15 baseline and £15 at follow-up). No direct harms are anticipated, however, the researchers are aware that collecting height and weight data may be sensitive for some participants.

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
September 2022 to August 2026

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
1. Prof. Maria Bryant, maria.bryant@york.ac.uk
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
317992

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 317992, CPMS 53381

Study information

Scientific Title
Evaluation of a sustainable obesity prevention programme delivered at scale 'HENRY' (Health, Exercise, Nutrition for the Really Young): effectiveness, cost-effectiveness and its role in obesity prevention within the wider complex system

Acronym
HENRY

Study objectives
1. What is the effectiveness and cost-effectiveness of HENRY in terms of reducing the risk of obesity in children?
2. Does HENRY reduce the risk of obesity in parents, siblings and health practitioners who have attended training?
3. What does the obesity system in which HENRY is positioned look like?
4. What role does HENRY play in childhood obesity prevention within the wider system?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 30/09/2022, University of York Health Sciences' Research Governance Committee (Department of Philosophy, Heslington, York, YO10 5DD, UK; +44 (0)1904 323253/1; stephen.holland@york.ac.uk), ref: HSRGC/2022/258/C
2. 2. Approved 28/04/2023, North West - Preston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8079; preston.rec@hra.nhs.uk), ref: 23/NW/0089

Study design
Multi-centre open-labelled two-group prospective, cluster randomized controlled trial, with cost-effectiveness analysis, and embedded mixed methods complex systems evaluation and internal pilot

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of obesity in children

Interventions
Local authorities across the UK will be approached to take part. Each local authority will nominate six children's centres. Participating centres within each local authority will be randomised to HENRY or control in a 1:1 allocation ratio by the Leeds CTRU. Minimisation, incorporating a random element, will be used to ensure the treatment groups are well-balanced for the following characteristics:
1. Size of centre (≤8 / >8 permanent centre members of staff, not including staff using the centre such as Health Visitors, nursery workers etc., gathered from centre baseline environmental questionnaire).
2. Area level ethnicity (<80% / ≥80% White British using Census data based on centre postcode, gathered from local authority centre nomination form)
3. Area level deprivation (≤10% / >10% ranking within Index of Multiple Deprivation at the Lower Layer Super Output Area, gathered from local authority centre nomination form)

The following information for each centre will also be required at randomisation:
1. Centre name and postcode
2. Manager contact details (gathered from local authority centre nomination form)
3. Confirmation of local authority and centre eligibility (gathered from local authority eligibility checklist)

Each children's centre will recruit parents and their children to take part in the trial.

Intervention:
The HENRY 'Right from the Start' Programme is aimed at providing parents with practical skills in authoritative parenting skills, increasing self-esteem, adopting healthy family lifestyles, goal setting, oral health, active play, portion sizes, and learning about food labels. HENRY is widely

commissioned by local authorities in the UK and is delivered in children's centres by health practitioners including health visitors, dietitians and children's centre staff. During the trial, each children's centre in the intervention arm delivers 2-3 ‘Right from the Start’ group programmes per year, each consisting of 8 x 2-hour sessions.

Control:
Children's centres continue to deliver usual programmes or 'standard practice'.

Parents and children in the trial are followed up at 12 months and 3 years. Members of staff working within children's centres will also be recruited to assess the wider impact of HENRY.

Intervention Type
Behavioural

Primary outcome(s)
Child age and gender-adjusted BMI measured using height and weight measurement at 12 months

Key secondary outcome(s))
1. Parent self-efficacy measured using Dumka Parenting Self-Agency Measure (PSAM) at 12 months
2. Family eating behaviours measured using the Golan Family Eating and Activity Questionnaire at 12 months
3. Feeding behaviours measured using the Baughcum pre-school feeding questionnaire at 12 months
4. Dental health measured via a bespoke questionnaire at 12 months
5. Obesity in parents and staff measured using BMI and waist circumference at 12 months
6. Children's centre environment measured using a bespoke environmental questionnaire at 12 months
7. Safety (related unexpected serious adverse event [RUSAE]) measured via case report form (CRF) safety form measured throughout the trial
8. Parent quality of life measured via EQ-5D-5L at 12 months
9. Long-term effects on obesity (including siblings) measured using routine National Child Measurement Programme (NCMP) data at 3 years
10. Attendance at HENRY measured using attendance register completed for each session /programme
11. Contamination measured via staff movement between centres during the trial

Completion date
30/08/2026

Eligibility

Key inclusion criteria
1. The target population for the intervention are parents of preschool children; mothers, fathers and other carers (e.g. with children living in stable/long-term foster care). Parents may not be registered more than once but they may be screened on more than one occasion if not registered following the first screening, as both eligibility and willingness to participate may change.
2. Parents must have at least one child aged 6 months to 5 years (18 months to 6 years at 12-month follow-up). If more than one child in the family fulfils eligibility criteria, the youngest child

(by birth timing if twins) will be considered as the reference child (from which data will be collected).
3. Parents must be willing to attend the programme sessions (intervention centres) and willing to provide data in accordance with the data collection protocol. Parents will be provided with full details of the data collection requirements in advance so that they can make informed decisions as to whether to participate.
4. Parents must speak English unless they wish to bring their own interpreter with them (e.g. family member) (the intervention and data collection forms are currently only available in English).

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Parents with severe learning difficulties that preclude them from taking part in group sessions in which they need to be able to read and write, judged on a case-by-case basis with consultation with the HENRY team where appropriate.
2. Parents whose reference child is tube fed (PEG or nasogastric) or with other known clinical conditions likely to affect growth over the period of the trial (e.g. cancer, coeliac disease, or renal or cardiac problems). A detailed list of excluded conditions will be provided at screening, with any uncertainties resolved via clinical input from the HENRY team.
3. Parents who have attended a HENRY group for a previous child

Date of first enrolment
01/09/2023

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre

To be determined
United Kingdom
-

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact CTRU-DataAccess@leeds.ac.uk in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security), and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing and believes it is best practice for researchers who generate datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree on suitable requirements for release.

Individual participant data from routine sources, including data from the National Child Measurement Program or equivalent in Northern Ireland will not be shared unless permitted by the data provider.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/03/2024	27/03/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes