NIHR PHR

Protocol for Cluster Randomised Controlled Trial of HENRY

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

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CONTENTS PAGE

1 TRIAL SUMMARY

Trial 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.	
Trial short title	HENRY III Trial	
Trial design	A multi-centre, open-labelled, two group, prospective, cluster randomised controlled trial, with cost-effectiveness analysis, and embedded mixed methods complex systems evaluation and internal pilot.	
Key inclusion criteria	Local authorities (or other associations that commission HENRY in centres) will nominate any type of children's centre (or other early years setting) that is considered to be HENRY naive. Centres will recruit parents of pre-school aged children (aged 6 months - 5 years) to take part in the trial.	
Planned sample size	82 eligible children's centres (hereon called 'centres') within ~ 14 local authorities (depending on the number of centres per local authority) over 18 months. From these, 984 eligible parents will be recruited.	
Experimental intervention duration	8 weeks	
Follow up schedule	Participants in the trial are followed up at 12 months (short term) and 3 years (medium term). (Longer term BMI trajectories are estimated using matched cohorts of Millennium Cohort Study [MCS] participants)	
Planned trial period	September 2022 - September 2028	
	Objective	Outcome measures
Primary (12 months)	Child BMI z-score (age and sex adjusted BMI) at 12 months	Child height and weight
Secondary	Self-efficacy	Dumka PSAM
	Eating behaviours	Golan Family Eating and Activity Questionnaire
	Feeding behaviours	Baughcum pre-school feeding questionnaire
	Dental health	Bespoke dental questionnaire
	Obesity in parents and staff	BMI, waist circumference
	Children's centre outcomes	Bespoke environmental questionnaire
	Safety (RUSAEs) Unintended consequences	CRF safety form

	Parent quality of life Costs and resource use and 12-month cost-effectiveness Medium-term effects on obesity (including siblings) and cost-effectiveness Long-term cost-effectiveness Attendance at HENRY Contamination	EQ-5D-5L and ICECAP-A Bespoke resource use questionnaires Routine NCMP or Health visitor data on BMI HENRY participant data linked to participants in the Millennium Cohort Study (MCS) HENRY attendance data Staff movement between centres
Active intervention	HENRY (Health, Exercise and Nutrition for the Really Young); a community-based programme, designed to alter early years settings, upskill the early years workforce and improve lifestyle behaviours of parents/carers (hereon called 'parents') and their pre-school aged children.	
Standard care	Children's centres continue delivering existing programmes, such as 'stay and play' without the addition of HENRY.	
Internal pilot	To assess centre recruitment, parent recruitment and HENRY programme delivery. Progression within the trial will be based on the success of meeting pre-defined progression criteria: recruiting at least 54 centres within 12 months; recruiting an average of 4 parents per programme / equivalent; ensuring at least 80% of intervention centres have started delivery of at least one programme within 18 months. Trial continuation will be conditional on these targets being met.	
Economic evaluation	To reduce decision uncertainty about whether HENRY should be commissioned. Analysis will be conducted in three stages with three different time horizons: short term (one year within-trial cost-effectiveness analysis of the incremental cost per unit change in BMI z-score); medium term (3 year) cost-effectiveness analysis of the incremental cost per unit change in BMI z-score and analysis of linked NCMP or health visiting BMI z-score data collected on individual trial participants ~3 years post-recruitment; and longer-term analyses (whereby estimates of longer-term BMI z-score trajectories using the matched cohorts of MCS participants will be used to predict longer term changes in healthcare utilisation beyond three years post follow-up).	
Process evaluation	Qualitative systems based process evaluation to (1) produce a map of the system within which HENRY operates and identify hypotheses about how this may be disrupted in response to HENRY, (2) analysis of the system in which HENRY is embedded to understand how the system and its elements change over time in response to HENRY and (3) traditional process evaluation to understand context, mechanism and implementation of HENRY.	

FIGURE 1: TRIAL SUMMARY

HENRY study: Evaluation of a sustainable obesity prevention programme delivered at scale 'HENRY': Effectiveness, cost -effectiveness and its role in obesity prevention within the wider complex system

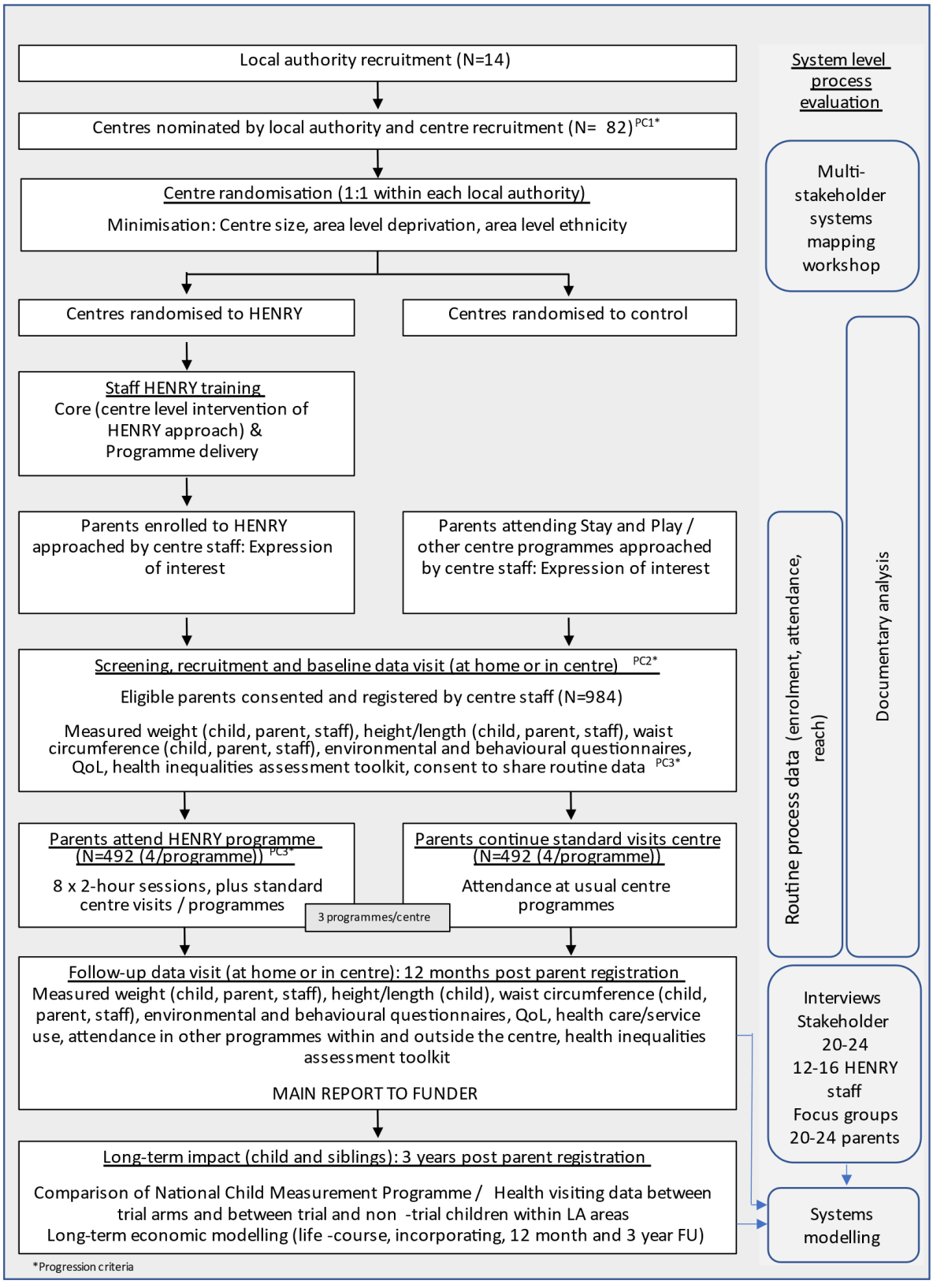
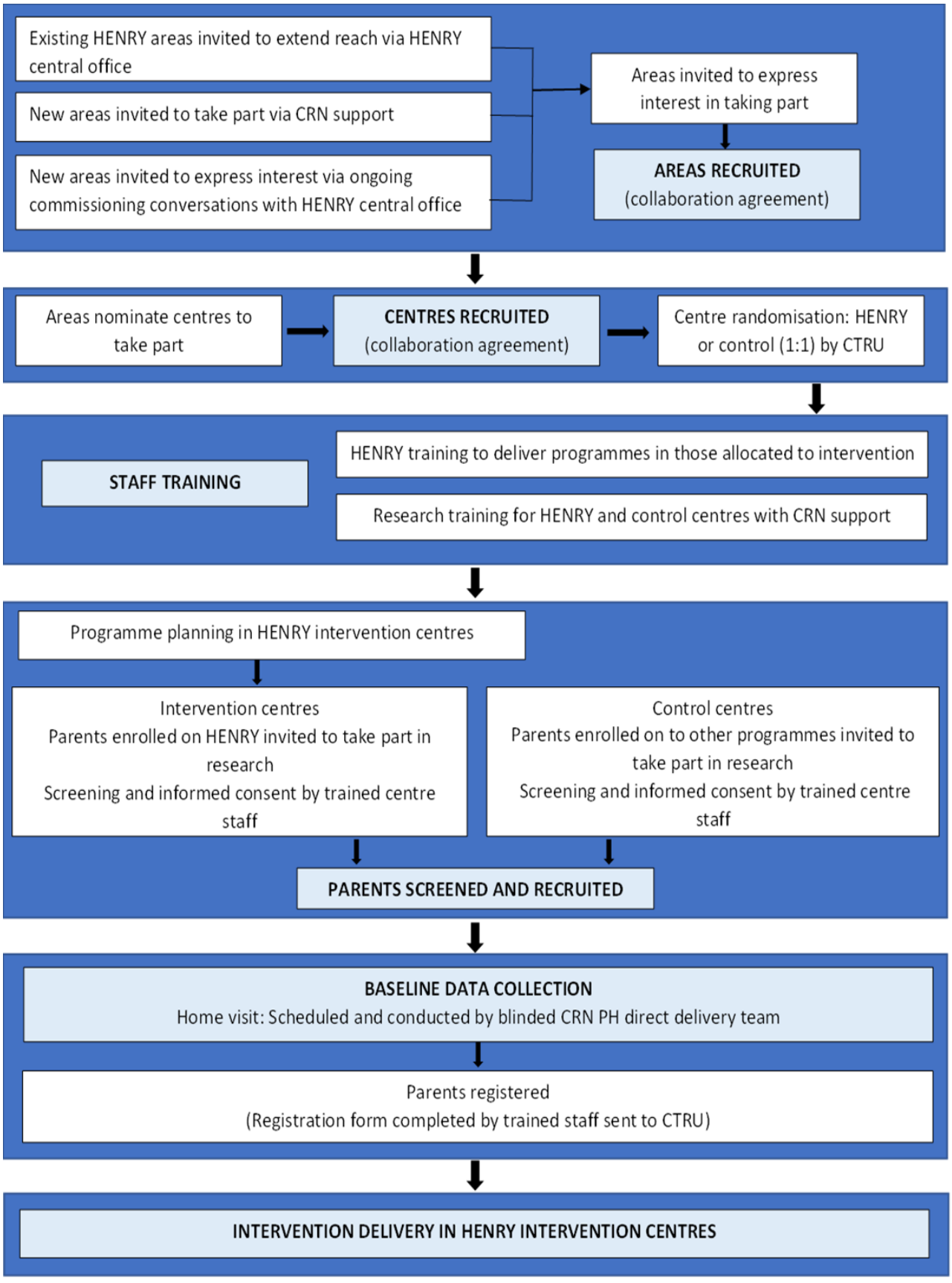


FIGURE 2. RECRUITMENT PATHWAY: IDENTIFICATION AND CONSENT



3 GLOSSARY OF TERMS

AE	Adverse Event
BMI	Body Mass Index
CEAC	Cost-effectiveness acceptability curve
CHEERS	Consolidated Health Economic Evaluation Reporting Standards
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case report form
LCRN/CRN	(Local) Clinical Research Network
CTRU	Clinical Trials Research Unit
DMEC	Data Monitoring and Ethics Committee
DOB	Date of birth
GCP	Good Clinical Practice
GP	General Practitioner
HENRY	Health, Exercise, Nutrition for the Really Young
HES	Hospital Episode Statistics
ICC	Intracluster Correlation Coefficient
ICECAP-A	ICEpop CAPability measure for Adults
ITT	Intention to Treat
LA	Local Authority
LICTR	Leeds Institute of Clinical Trials Research
LIHS	Leeds Institute of Health Sciences
LTHT	Leeds Teaching Hospitals Trust
MAR	Missing at random
MCS	Millennium Cohort Study
MNAR	Missing not at random
NAPSACC	Nutrition and Physical Activity Self-Assessment for Child Care
NCMP	National Child Measurement Programme
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NRES	National Research Ethics Service
PAG	Parent Advisory Group
PPI	Patient and Public Involvement
PSSRU	Personal Social Services Research Unit
QA	Quality Assurance
QALY	Quality adjusted life year
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RM	Research Manager
RUSAE	Related Unexpected Serious Adverse Event
SAE	Serious Adverse Event
SOEP-IS	Socio-Economic Panel - Innovation Sample
SOP	Standard Operating Procedure
TMG	Trial Management Group
TOR	Terms of Reference
TSC	Trial Steering Committee

4 BACKGROUND

Addressing the rising prevalence of childhood obesity, particularly among people living in deprived areas, is a public policy priority. This is even more urgent since the COVID-19 pandemic, with around one third (27.7% on average and up to 34.5% in higher deprivation areas) of children defined as overweight (13.3%) or having obesity (14.4%) when they start school (and up to 34.5% in areas of highest deprivation) compared to 23.2% pre-COVID (1). This is the largest annual increase since National Child Measurement Programme (NCMP) recording began. Health inequalities have also broadened, from a 6.3% difference in rates of overweight and obesity between the most and least deprived areas in 2019/20 to 10.7% (1, 2).

Preventing excess weight in childhood is beneficial for health and wellbeing, with potential to simultaneously reduce utilisation of health services among children living with obesity, including mental health services and those used to treat and manage respiratory diseases such as asthma (3). Obesity prevention during childhood can also reduce excess weight gain and obesity in later life (4, 5) which is difficult to reverse once established (6-8) and is a cause of numerous long-term, chronic health conditions. However, prevention interventions have resulted in modest but inconsistent benefits (6-9). Given that obesity is caused by a wide range of factors, this is unsurprising and means that the role and cost-effectiveness of locally delivered programmes within a large and complex system is uncertain. Public Health England (PHE) advocates systems approaches; encouraging local areas to adopt a range of interventions and policies inside and outside the healthcare sector to collectively tackle obesity and related health inequalities. While guidance supports the implementation of this approach, it remains unknown what role individual interventions play in disrupting the system (10), and which of these interventions are most effective and cost-effective. It is possible, for example, that interventions are unable to make a discernible impact due to system loopholes (such as targeting easier to reach populations rather than a focus on those in greatest need or loss of resources due to diversion of funds). Conversely, interventions that may only have a small impact on large numbers of people can be effective and cost-effective at the population-level if they are able to positively influence the system. There are also methodological challenges in investigating the impact and cost-effectiveness of childhood interventions, including the need to capture health and other benefits that may not fully materialise until many years in the future. Overall, this might mean there is a tendency for policy makers to favour interventions that only have short-term impacts on relatively small numbers of people, because these are more amenable to evaluation, even if in reality they are less (cost-)effective long-term.

One obesity prevention programme which has been delivered at scale for many years in the UK is HENRY (Health, Exercise and Nutrition for the Really Young); a community-based programme, designed to alter early years settings, upskill the early years workforce and improve lifestyle behaviours of parents/carers (hereon called ‘parents’) and their pre-school aged children. Although HENRY was designed to be a universal programme, it has been predominantly delivered in children’s centres/community venues located in areas of high deprivation. Evidence suggests it has potential to impact on population obesity (11) but (cost) effectiveness is not yet established. Given the need to consider programmes within obesity systems, this research not only evaluates the effectiveness and cost-effectiveness, but also considers the potential role that HENRY plays to disrupt the system.

There is an expressed need to improve all aspects of the system which contribute to the disproportionate effects of obesity on children living in deprived areas. Not only does childhood obesity increase the risk of negative adult outcomes, our work demonstrates an impact during childhood; including increased risk of type II diabetes and non-alcoholic fatty liver disease (12). Work by PHE provides insights from local authorities who have seen downward trends in childhood obesity which indicates that having a strong

focus on early years is a key approach (13, 14). HENRY is a well-established programme with demonstrable sustainability through its continued implementation at scale. It is externally recognised (Royal Society of Public Health accredited; CANparent Quality Mark) and is the 'go to' programme for many areas.

Evidence highlights that locally delivered public health prevention programmes can be cost-effective (15, 16); however, there is limited evidence specifically looking at obesity prevention delivered at scale. Our evaluation will consider children and sibling obesity outcomes in the short-term, (using data collected in the trial), medium-term (using routine data collected on trial participants at 3 years) and longer-term (using economic modelling and secondary datasets). Our novel approach will also place emphasis on the ability of HENRY to influence the system (and the system balancers which may reduce its potential for population impact).

Existing research has explored the potential impact of HENRY (17, 18), but there has been no independent effectiveness or cost-effectiveness evaluation. We successfully completed a NIHR funded feasibility study; randomising 12 centres across two local authorities to HENRY or usual practice (19). This was the first time that weight and height were measured from children whose parents' attended HENRY. Results indicated feasibility, providing clear lessons for the phase III trial design and the impact on excess weight gain showed promise. Through our work (18, 20-23), we have a good understanding of the influence that context plays on the ability of programmes like HENRY to influence population health. However, there remains a need to explore the role it could play to support long-term positive improvement of childhood obesity rates within the wider system to justify future spending.

5 AIMS AND OBJECTIVES

5.1 Aim:

To establish the effectiveness and cost-effectiveness of an obesity prevention programme delivered at scale, including its potential role from a wider systems perspective.

5.2 Research Questions:

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?

5.3 Primary objective

1. The primary objective of the trial is to determine whether HENRY reduces child BMI z-score (child age- and sex-adjusted BMI) in 12 months.

5.4 Secondary objectives

1. To determine whether HENRY improves parent self-efficacy, eating behaviours, feeding behaviours, dental health, and quality of life
2. To explore whether HENRY influences rates of obesity in parents, siblings and staff (health practitioners)

3. To examine the social and physical environment in the children's centres
4. To explore the long-term effects on child BMI
5. To monitor any safety issues from the intervention, including adverse events or unintended consequences
6. To determine whether HENRY provides an overall cost saving (e.g. to the NHS)

5.5 Internal pilot objectives

To assess centre recruitment, parent recruitment and HENRY programme delivery against pre-defined progression criteria.

5.6 Process evaluation objectives

1. To produce a map of the system within which HENRY operates and identify hypotheses about how this may be disrupted in response to HENRY
2. To analyse the system in which HENRY is embedded to understand how the system and its elements change over time in response to HENRY
3. To undertake a traditional process evaluation nested within the trial to understand reach of HENRY within target population, potential contamination and how it has been implemented.

6 DESIGN

A multi-centre, open-labelled, two group, prospective, cluster randomised controlled trial, with cost-effectiveness analysis, and embedded mixed methods complex systems evaluation and internal pilot (See Trial Summary and Figure 1). 82 eligible children's centres from within ~ 14 local authorities (depending on the number of centres per/ local authority) will be randomly allocated (1:1) to HENRY or control. From these, 984 eligible parents will be recruited.

Outcomes will be collected from parents at 12-months and from routinely collected data at 3 years post parent registration. Outcomes from staff will be collected 12 months post baseline data collection. A mixture of quantitative and qualitative methods will be used throughout the trial.

7 ELIGIBILITY

7.1 Inclusion Criteria

Local authorities (or other associations that commission HENRY in centres), centres, parents and staff meeting all of the relevant inclusion criteria, and none of the relevant exclusion criteria, will be considered for participation in the trial.

Local authorities (or other associations that commission HENRY in centres):

- Local Authorities can be new to HENRY or already commissioning HENRY, provided they have at least 2 centres (ideally 6) meeting centre eligibility criteria (below). At the point of recruitment, they will be asked to provide assurance that each centre randomised to HENRY will be able to deliver 3 programmes during the course of the research.
- Local authorities using external teams outside of the centre to deliver HENRY programmes (e.g. health visitors) will be eligible, in addition to those wishing to train internal centre staff to deliver programmes (the most common model currently used).
- Any delivery model (i.e. online or face-to-face) will be considered eligible.

Centres:

- Any type of centre or other early years setting such as a nursery or community venue.
- Centres must aim to run HENRY programmes starting within 12 weeks of training completion and aim to run 3 programmes during the trial.
- Centres should be in geographically separate areas to protect against contamination (judged on a case by case basis).
- Centre managers must agree to support participant recruitment within their centres.

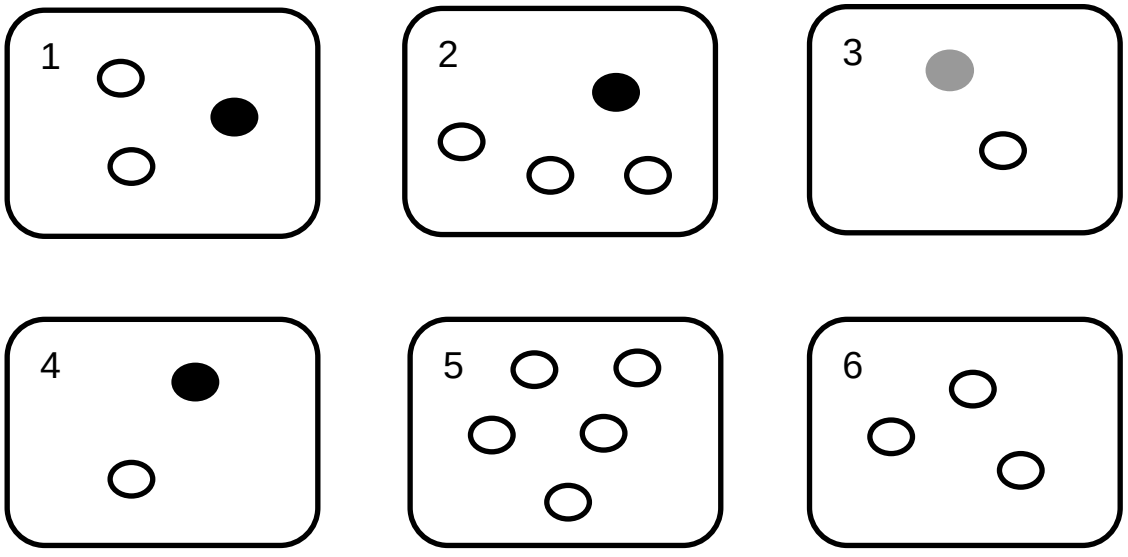
All centres will be nominated to take part in the trial by their local authority (or similar organisation). Children's centre managers will be required to sign a children's centre agreement agreeing to adhere to their delegated duties. Staff from participating centres will be required to undertake appropriate training in intervention and trial procedures prior to the start of participant recruitment into the trial.

If the children's centre operates as part of a cluster, that cluster must be deemed to be HENRY naive. HENRY naive clusters are defined as:

> A group of centres within a cluster that do not include any centres that are (a) currently delivering HENRY or (b) have been trained to, or delivered HENRY within the past 2 years.

An example is provided in the diagram below:

There are only three naïve clusters in this example. Centres in these two naïve clusters containing **only** ○ would be eligible (e.g. clusters 5 and 6). Centres in other clusters that are either currently delivering HENRY or have previously delivered HENRY in the last two years are not eligible – even if they have never delivered HENRY in those centres.



Parents:
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 first screening, as both eligibility and willingness to participate may change.

- Parents must have at least 1 child aged 6 months - 5 years (18 months-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).
- 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.
- 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).

Staff:
All centre staff will be invited to participate in the research including those directly and indirectly involved in HENRY.

Eligibility waivers to **inclusion** criteria are not permitted.

7.2 Exclusion Criteria

Local authorities (or other associations that commission HENRY in centres):

- Local authorities without coverage of a NIHR local clinical research network (the teams responsible for collecting trial data from parents and staff).

Children's Centres:

- Centres that currently deliver HENRY, or have done within the past two years.
- Centres where staff have received training to deliver HENRY within the past two years.
- Centres that share staff between nominated centres.

Parents:

- Parents with severe learning difficulties that preclude them 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.
- 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.
- Parents who have attended a HENRY group for a previous child.

8 RECRUITMENT AND RANDOMISATION

8.1 Recruitment overview

Recruitment of local authorities will be done in three ways. Firstly, authorities that make enquiries to the HENRY central office will be invited to take part during standard commissioning conversations. Second,

local authorities that (a) have previously enquired, but not yet commissioned HENRY, over the previous 12 months or (b) currently commission HENRY, will be invited to take part via postage invitation mailed from HENRY. In this approach, only authorities with centres within HENRY naive clusters (i.e. not running HENRY programmes) will be eligible (Section 7). Third, areas will be invited to express an interest following promotion by local CRN teams (after notification from the Yorkshire CRN).

Centres will be nominated by the commissioning leads, again, following standard procedures. Parents will be screened and consented by centre staff who will receive relevant training in research procedures with the support of the CRN. Contact details of those registered will be sent to researchers at local CRN public health teams (e.g. direct delivery teams) via secure data transfer, who will store details locally in order to schedule home visits for baseline and follow up data collection via phone and/or email.

8.2 Recruitment process and eligibility screening

Local authorities

We plan to recruit approximately 10-14 local authorities or other associations that commission HENRY in children's centres from any area across England or Wales (extended to the UK depending on availability of data collection research teams), from which children's centres and parents will be recruited. During local authority recruitment (Section 8.1), a designated member of staff at the HENRY central office and/or CRN will be responsible for liaising with commissioners (new and existing). This will include providing them with information about the trial, and an eligibility checklist. Commissioners will be asked to complete and return the eligibility checklist to the CI, which will also confirm their expression of interest. Once received, the checklist will be reviewed by the CI and CTRU who will check eligibility. All eligibility checklists / expressions of interest will be recorded on an expression of interest recruitment log.

All commissioners that express an interest in taking part will be contacted by researchers at the UoY to confirm eligibility, reiterate trial expectations and answer any questions. Commissioners will then be given up to 12 weeks to decide on whether or not to participate (allowing time for necessary meetings/discussions to occur). Areas invited to take part will be asked to 1) nominate at least 2 (ideally 6 or more) centres which meet trial eligibility criteria and 2) sign an agreement before entering the trial. In areas where centres are tendered to service providers, trial details and agreements will be sent to these service providers in addition to the commissioning lead. Both the commissioner and the service provider need to agree to participate in order to take part. Areas declining participation or not responding will continue with their standard practice and/or HENRY commissioning processes if applicable. Basic demographic information and reasons for declining participation (where appropriate) will be recorded on a local authority recruitment log.

Centres

Centres within each local authority will be nominated to take part in the trial by the local authority / service provider commissioning lead. The choice of centres to deliver HENRY programmes will be based on a number of factors, including perceived level of need and / or deprivation. This process will continue, although local authorities will have to agree to have half of the centres randomised to a no intervention control group. Local Authorities / service providers will be asked to nominate approximately twice the number of Centres that they wish to commission HENRY for, so that approximately half can be randomised to receive HENRY and half can be randomised to control. Although there are no exclusions based on the demographics of centres, location will be monitored and commissioners encouraged to nominate centres to include a range of diverse social and environmental characteristics. Centres will be incentivised by receiving the service support costs for every participant who is registered to the trial. Basic demographic information and reasons for declining participation (where appropriate) will be recorded on a local authority recruitment log.

Parents

All parents who are booked to attend a HENRY programme will be invited to take part in the research during HENRY programme enrolment by centre staff (not necessarily HENRY facilitators). If interested, they will be screened for eligibility (by the member of staff completing a parent screening form) and consented to take part (either at the same time as enrolment on to HENRY, or a later time prior to commencing the programme, depending on the needs of the parent). All completed screening forms (containing basic demographic information) will be returned to CTRU regardless of whether the parent is recruited to the trial. If a parent does consent to take part in the trial, they will also consent for their contact details to be passed on to a local CRN researcher in order to set up the data collection visits (at home or at the children's centre). Screening and recruitment will begin as soon as HENRY programmes begin enrolment and we will work with centres to ensure that this is done at least 6 weeks prior to the start of each programme. Programmes typically enrol an average of 8 parents, of whom our design aims to recruit an average of 4 parents. Once consented (including providing consent to pass on contact details), centre staff will securely transfer contact details to the Local Clinical Research Network (LCRN). LCRN will then contact the participant to arrange the baseline visit and complete trial registration.

A similar process will be conducted to recruit parents from the control centres. Here, parents who attend other programmes (e.g. stay and play) in the centres will be invited to take part in the research. Given that centres do not all offer the same programmes, we will work with the local teams to ensure that parents are screened from appropriate programmes (i.e., not those designed to support obesity prevention). In all circumstances, no contact information will be shared externally by the centre unless consent to the trial has been obtained.

Upon receipt of the parent contact details a local CRN researcher will call parents to arrange a home visit or a meeting at the centre where they will have an opportunity to ask any additional questions prior to the collection of baseline data and registration. Parents who are ineligible or decline will continue to attend HENRY or equivalent sessions. Anonymised details of those not recruited will be collected and stored at CTRU as a way of tracking recruitment rates.

The CRN researcher will be blinded to whether the participant was recruited via a centre receiving the intervention or acting as a control. Parents will also be asked not to divulge this information. Where the CRN researcher does become aware of participant allocation, an un-blinding form will be completed.

In active and control centres, parents will also have the opportunity to self-refer into the trial via recruitment posters displayed in the centres. Where a parent has learnt about the trial via recruitment poster and wishes to self-refer, they will contact a member of the centre staff directly using the contact information provided within the poster.

Parents will be incentivised to participate by advertising that they will learn more about their child's growth and habits at the end of the trial and will receive a £15 shopping voucher at baseline and follow up (£30 total).

Staff

Children's Centre staff can be recruited (to provide outcome data) once they have completed site training. They will be sent a participant information sheet prior to completing the training (ideally at least two-weeks before) so that they are already aware of this component of the research and can consider whether or not they would like to take part. It will be highlighted to staff when they are sent the information sheet and during the training that participation is entirely voluntary, and that they do not need to agree to take part immediately (this is also included in the staff participant information sheet). We will request that all staff complete an anonymous screening form even if they do not want to be enrolled to

provide outcome data, but this is also voluntary. Staff who would like to take part will be asked to give consent and provide their baseline data (height, weight and waist circumference), which they can self-measure.

Local authorities, centres, parents and staff who do not proceed into the trial due to ineligibility or because they decline participation will have the reason for ineligibility / non-entry to the trial recorded. Documented reasons for ineligibility or declining participation will be monitored by CTRU as part of a regular review of recruitment progress. This information will also allow for reporting of trial results in accordance with CONSORT reporting guidelines.

8.3 Informed Consent

Informed consent to participate will be sought from local authorities, centres, parents and staff.

Local authorities

A verbal explanation of the trial will be provided to commissioning leads via attendance at an online event or remotely by the CI and/or authorised members of the HENRY central office team during the early stages of the commissioning process. In addition, local authorities that currently commission HENRY or have expressed an interest in commissioning HENRY over the last 12 months will be informed about the trial. Contact details for the trial team at the University of York will be provided to allow the local authorities to seek more information about the research. Once local authorities have expressed an interest and had their eligibility confirmed, each will be given up to 12 weeks to consider participation in the trial. If after 12 weeks, no response has been provided, a member of the research team or HENRY will follow-up with the local authority via phone, email and / or letter. If after a further 2 weeks there is no response, it will be assumed that the local authorities do not wish to take part in the trial.

If a local authority agrees to take part, a letter of agreement will be sent to the commissioning lead where they will provide details of their nominated centres. Consent to participate in the trial will be assumed via signing of the agreement. In areas where HENRY is delivered by an external service provider (such as Barnardo's), a separate agreement will be completed by these service providers. These agreements will be identical, with the option to delete names (Commissioner/service provider) as appropriate.

Centres

Local authorities who have consented to participate in the trial will provide details of centres in their areas that they wish to take part in the research and provide the name and contact details of the centre manager. In all local authorities, half of the nominated centres will be randomised to receive training to deliver the HENRY programme. The remaining centres will not receive any form of HENRY training. The commissioning leads will be encouraged to discuss this with centre managers in advance so that they are already familiar with the details. If the manager is happy to proceed, researchers at CTRU will send a centre agreement confirming their participation. Information will be provided within this agreement of the manager's delegation of duties. It will also be reiterated that they will be randomised to either receive HENRY or be in the control arm; both of which will require support to recruit parents. Consent at this level will be implied by the centre manager signature of the agreement.

Parents

All parents approached to take part in the trial will be given a participant information leaflet designed with the support of the PPI group. The leaflet will also contain details of a point of contact that participants can use during the trial (a dedicated member of the research team (Burton) and/or a children's centre contact) should they have any queries or are considering withdrawing from the trial. The parent will have

an opportunity to fully consider participation alongside other family members. The parent consent will include four options, consent to take part in the trial only (including passing contact details to CRN team), consent to provide HENRY programme attendance data (if attending a HENRY programme), consent to be contacted about taking part in a process evaluation interview, and consent to share routinely collected NCMP data after 3 years for the purposes of the economic evaluation. If parents are and continue to be interested in participating in the trial, the member of staff at the children's centre will witness their signature and countersign. Confirmation of consent and contact details will be passed on to the CTRU and LCRN researchers via secure data transfer so that the LCRN can schedule the baseline visit at home. A copy of the consent form will be mailed to CTRU separate from any study data with the participant keeping the original copy. All parents have the right to refuse consent without giving reasons and they remain free to withdraw from the trial at any time without giving reasons. Data provided up to that point will be kept on file and used in the analysis (as detailed in participant information sheet).

It is possible that the siblings of index children could be aged over 16 years before the end of the whole trial period. In the (unlikely) event of any such instances, existing parental consent will be retained as it will not be feasible to obtain new consent from these individuals.

Staff

Following receipt of a participant information sheet and completion of site training (as described above) staff can have as much time as they need to decide whether or not to take part. Staff will also have the opportunity to consent to being contacted about taking part in a process evaluation interview. Staff members will be made aware (as detailed in the information sheet) that they can withdraw from data collection at any time but that any data collected up to that point will be kept on file and used in the analysis.

Staff who would like to take part will be provided with a link to a HENRY III Online Survey where they will read a data collection statement, confirm they have completed site training, provide online consent for providing data and then enter their self-measured baseline data (height, weight and waist circumference). The survey will be pseudonymised (unique identifiers and initials only). The University of Leeds has a subscription to Online Surveys and recommends using this tool for collecting online research data.

8.4 Centre staff training to screen and consent parents

Centre staff will be trained to screen participants and capture informed consent. This training will be delivered to as many staff within each centre as possible and will be written by the central research team and CTRU in collaboration with the LCRN teams. Training will be developed so that it can be delivered remotely. In addition (following on from feedback from our feasibility study), the online training portal / video (with submission of an online Form to confirm training) will enable new staff to be trained later. This can also be used to provide 'refresher training'.

If considerable imbalance between arms occurs, we will undertake further staff education to ensure consistency across centres and ask staff to focus (or avoid) recruitment of participants from specific sessions where it is more/less likely that people with known characteristics attend (e.g. avoid baby massage if predominantly attended by financially secure families). In addition, we will set up (and adapt) a real-time sampling framework (using demographics of parents registered at each centre) which will allow staff to target recruitment of parents within control centres to match those recruited in the HENRY intervention centres.

8.5 Randomisation

Following fully signed local authority (and service provider if applicable) and centre agreements, 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:

- 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).
- Area level ethnicity (<80% / ≥80% White British using Census data based on centre postcode, gathered from local authority centre nomination form).
- 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:

- Centre name and postcode
- Manager contact details (gathered from local authority centre nomination form)
- Confirmation of local authority and centre eligibility (gathered from local authority eligibility checklist)

After randomisation, CTRU will notify HENRY central office, the local authority lead and the centres of the outcome in order to instigate necessary training arrangements. Notification will be sent by email. CRN researchers will not be notified to maintain blinding of the researchers performing data collection.

8.6 Registration

Once parents have consented for their contact details to be shared, LCRN teams will arrange a baseline assessment. The LCRN team will complete a pre-registration step to create a link for the baseline questionnaires to be sent.

Registration will be completed by LCRN teams following confirmation of eligibility and collection of baseline data using the CTRU automated 24-hour web-based registration system. Usernames and passwords, provided by the CTRU, will be required to access the registration system. Each parent will be allocated a unique trial identification number following registration.

The following details will be required at pre-registration:

- Personal username and 4 digit password of person performing pre-registration
- Name of centre and centre code
- Screening log number
- Confirmation of informed consent
- Confirmation parent/carer agree to the researcher visit at baseline
- Email address of researcher who will perform baseline visit

The following details will be required at registration:

- Personal username and 4 digit password of person performing registration
- Name of centre and centre code

- Screening log number
- Trial number
- Participant (parent/carer) initials
- Participant (parent/carer) date of birth
- Confirmation that baseline measurements and eligibility have been fully completed

CTRU 24 hour automated service
Web: https://lictr.leeds.ac.uk/webrand/

9 INTERVENTION DETAILS

9.1 HENRY

WHAT: Set up with DH funding in 2008, HENRY has been widely commissioned by >50 areas (training >15,000 practitioners and providing programmes to ~24,500 parents).
HENRY includes core practitioner training and group facilitation training (www.henry.org.uk).

Core practitioner training supports staff to deliver the HENRY approach, which incorporates evidence-based behaviour change models, including the Family Partnership model, motivational interviewing and solution focused support, with information about a healthy start that is consistent with national guidance.

Facilitation training enables the delivery of an 8-week universal 'Right from the Start' programme to parents to provide 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.

WHO: Core practitioner training is provided to health visitors, dieticians and staff (e.g. at children's centres, community centres/hubs - hereon called 'centres') allowing parental support to be an intrinsic part of their role, whilst influencing culture and policy within early years settings. Facilitator training is delivered to a (usually) smaller selection of staff who have attended core training to certify them to deliver small group sessions 'Right from the Start'. Parents with a child aged up to 5 years are eligible to attend HENRY. Language needs are addressed locally depending on the population needs, with some areas providing dedicated support. Without this, the other approach is to invite parents to attend with a friend or family member to support translation and other activities. Although considered to be a Universal programme, practitioners often refer families 'at risk' to HENRY and the delivery model within children's centres allows parents from the most deprived neighbourhoods to attend.

HOW: Core practitioner training is designed to allow staff to integrate evidence based models to develop motivation and support lifestyle change for families. This can then be embedded into all interactions with families, in addition to supporting positive changes to the centre environment (space to play, freely available water, food policies etc.). The 'Right from the Start' programme is delivered to groups of approximately 8-10 parents over 8 sessions. Each interactive session focuses on a separate theme and includes resources for families to take home.

WHERE: Traditionally, HENRY was delivered solely within Sure Start centres and other children's centres; however, like many other community based interventions, it is now often provided within other community settings, including schools, mosques and churches. In order to meet the needs of local areas, more flexible delivery models are now implemented, including different delivery approaches in addition to different settings. For example, local authority areas can choose to have HENRY programmes delivered directly by HENRY central teams (less common approach), pay to commission

training, licensing and support from HENRY (most common approach), offer a blended approach, or provide training to deliver local trainers (most common in larger local authority areas).

WHEN AND HOW MUCH: Core training is designed to consistently influence the environment and practice immediately following training. Each centre delivers 2-3 ‘Right from the Start’ group programmes per year, each consisting of 8 x 2-hour sessions.

MODIFICATIONS: In response to the COVID pandemic, HENRY has developed training and programme sessions which allow for remote training and delivery. These continues to be used in some areas, although feedback from the HENRY central office indicates that commissioners, parents and facilitators prefer in-person participation. In addition to allow a richer level of communication, the in-person training can be completed in a shorter time frame (2-day in-person training is delivered over 6 weeks remotely). We will include both delivery modes in the proposed research. This will allow us to be flexible depending on external issues, in addition to supporting an evaluation of a pragmatic intervention. Our analysis plan includes consideration of different delivery approaches.

9.2 Control group

Staff within control centres will not receive HENRY training and will continue to deliver usual programmes or ‘standard practice’ (e.g., ‘stay and play’, ‘cook and eat’). In short, this means that families registered to take part in the research will receive the standard level of support provided within their community / centres. Services are aimed at supporting families with a focus on the most disadvantaged families. These vary between and within local areas but usually include access to health visiting teams, breastfeeding support, parenting advice and access to specialist services including speech and language therapy.

10 CONTAMINATION

The key ‘high chance, high impact’ contamination activity identified in our previous research was HENRY-trained staff at intervention centres also working at control centres and sharing their knowledge with staff and families in those control centres. Mitigation of the impact of this potential form of contamination will be via:

- Adding eligibility criteria for local authorities: requesting the nomination of at least 2 centres (preferably 6) that are ‘distinct’ (not sharing staff)
- Requesting geographically dispersed centres
- Including contamination as a key part of research training: asking staff not to share intervention content with control sites, and informing staff why this is important
- A monitoring plan will ensure transparent reporting of staff movement by sites.

We will monitor whether this preventative action is successful within our process evaluation, where we will collect data on the movement of HENRY-trained staff between centres at two time periods: to coincide with the second phase of the internal pilot (including data up to end of May 2024) and at the end of the intervention delivery period. If we identify contamination during the internal pilot we will further emphasise the need to cease knowledge-sharing during online ‘top-up’ training for staff. If we find it exists at the end of the intervention delivery period we will identify control centres where this occurred and undertake a sensitivity analysis that excludes these centres. Contamination between centres will also be explored qualitatively within the process evaluation during staff interviews. We will ask HENRY participants not to share intervention content and materials until the end of the evaluation. We will also

ask ‘contamination questions’ on the final outcome measurement questionnaire and during interviews, including disclosing HENRY information (for intervention arm), knowledge of HENRY content (control arm) or attending other centres (both arms).

11 WITHDRAWALOF CONSENT

Centres and/or local authorities can withdraw at any point during the trial. They will be able to withdraw from the trial, including withdrawing consent for further data collection. Data collected up to the time of withdrawal will be retained for analysis and data from parents and staff will still be collected provided they have not withdrawn consent themselves. Centres may stop delivering the HENRY programme during the trial period independently from the trial (e.g. centre closures, restructuring). Trial procedures will continue in this eventuality and all recruited parents and staff will remain in the trial (and data will continue to be collected from them) unless they actively withdraw.

Where parents or staff wish to withdraw, there will be clarification whether this is withdrawal from short term trial data collection, or from medium term trial data collection (using routine data) or a combination of these. Non-attendance at HENRY intervention sessions are not classed as a withdrawal from the trial. All parents who withdraw from HENRY intervention or who do not attend the intervention will still be followed–up for data collection unless they specifically express a wish to withdraw from trial processes.

Local authorities, centres, parents and staff can withdraw by making contact with the central team (email HENRY-Trial@leeds.ac.uk). They will be asked to give a reason for their decision but are not required to do so if they prefer not to. Any data collected up to the point of withdrawal will be used in the final trial analysis. This will be made clear at the time of consent and when they withdraw from the trial.

12 DATA COLLECTION AND TRANSFER

A summary of required data, assessment tools, collection time points and processes are provided below in Table 1.

Table 1 Data collection summary

Data/outcomes	**Measures**	Collected by	LA / CC Screening and consent	Centre baseline	Participant screening	Participant informed consent and registration	Participant / staff Baseline	Short term follow-up (12 months post registration)	Medium-term follow-up (3 years)
Local authority									
Eligibility	LA Eligibility checklist	LA self complete	x						
Basic demographics / reasons for declining	LA / CC Recruitment log	UoY / HENRY	x						
Centre contact details	Centre nomination form	LA self complete	x						
Local authority agreement / consent	Local authority agreement	LA self complete	x						
Centre									
Eligibility	LA Eligibility checklist	LA self complete	x						
Reasons for declining / ineligibility	LA / CC recruitment log	UoY	x						
Centre agreement / consent	Children's Centre agreement	Centre self complete	x						
Stratification factors	Children's centre nomination form	LA self complete		x					
Centre randomisation allocation	Randomisation form	CTRU		x					
Demographics	Centre nomination form / Environmental Questionnaire	LA / Centre self complete		x					

Data/outcomes	**Measures**	Collected by	LA / CC Screening and consent	Centre baseline	Participant screening	Participant informed consent and registration	Participant / staff Baseline	Short term follow-up (12 months post registration)	Medium-term follow-up (3 years)
Details of other courses	Environmental Questionnaire	Centre self complete		x				x	
Parent									
Initial eligibility check	Screening form	Centre staff			x				
Confirmation of eligibility	Eligibility checklist	LCRN				x			
Reasons for declining / ineligibility	Screening form	Parent self complete			x				
Demographics (parent, child and family)	Screening form Baseline form	Parent self complete CTRU (recruitment log)			x		x		
Consent to trial participation and data collection (including NCMP)	Consent form	Parent self complete				x			
Use of Centres	Baseline form Follow up form	LCRN					x	x	x
Outcomes									
Child and parent:									
Child height & weight	Measured	LCRN					x	x	
Parent behaviours:							x	x	
Parent self-efficacy	Dumka (27)	LCRN					x	x	

Data/outcomes	**Measures**	Collected by	LA / CC Screening and consent	Centre baseline	Participant screening	Participant informed consent and registration	Participant / staff Baseline	Short term follow-up (12 months post registration)	Medium-term follow-up (3 years)
Family eating / activities	Golan (28)	LCRN					x	x	
Feeding questionnaire	Baughcum (29)	LCRN					x	x	
Dental health (child)	Dental questionnaire	LCRN					x	x	
Parent height & weight:	Measured	LCRN					x	x	
Parent waist circumference	Measured	LCRN					x	x	
Staff:									
Staff screening	Staff screening form	Staff complete at centre		x					
Staff height & weight	Measured	Self-measure					x	x	
Staff waist circumference	Measured	Self-measure					X	x	
Children's Centre:									
Centre social, physical and political environment (e.g. policies around food)	Environmental questionnaire	Centre self complete		x				x	
Safety:									
Adverse events / unintended consequences	SAE / RUSAE forms	LCRN / centre self complete						x	
Health economics:									
Health care resource	Resource use	LCRN						x	

Data/outcomes	**Measures**	Collected by	LA / CC Screening and consent	Centre baseline	Participant screening	Participant informed consent and registration	Participant / staff Baseline	Short term follow-up (12 months post registration)	Medium-term follow-up (3 years)
use for child	questionnaire								
Health care resource use for parents	Resource use questionnaire	LCRN						x	
Private costs (e.g. travel costs, additional food expenses, lost productivity)	Resource use questionnaire	LCRN						x	
Parent's Health-related Quality of Life	EQ-5D-5L (30) and ICECAP-A [31]	LCRN					x	x	
Routine data:									
NCMP Child and sibling data (trial participants)									x
NCMP regional child data (not trial participants)									x
Process evaluation/delivery of HENRY programmes:									
Attendance * *Data collection not timed to trial time points	HENRY attendance records	Centre staff / HENRY facilitator							
Contamination checks* *Data collection not timed to trial time points	Staff movement form	Staff self complete							
HENRY training								x	x

Data/outcomes	**Measures**	Collected by	LA / CC Screening and consent	Centre baseline	Participant screening	Participant informed consent and registration	Participant / staff Baseline	Short term follow-up (12 months post registration)	Medium-term follow-up (3 years)
attendance and knowledge									
Qualitative data									
System map and sub maps* *Data collection not timed to trial time points	n/a	University of Sheffield							
Systems mapping interviews with local authority stakeholders* *Data collection not timed to trial time points	n/a	University of Sheffield							
Interviews with centre staff* *Data collection not timed to trial time points	n/a	University of Sheffield							
Interviews with parents* **Data collection not timed to trial time points	n/a	University of Sheffield							

12.1 Expression of Interest / Screening

Local authorities
Local authorities will be emailed an eligibility checklist to complete within the expression of interest MS Word document to determine eligibility in regards to the number of HENRY naïve centres in their area that would be permitted to participate (Section 7).

Eligible local authorities that wish to proceed into the trial will then be sent a centre nomination form along with their local authority agreement, where contact details of the centre managers will be collected along with centre addresses (to determine their Index of Multiple Deprivation score). Centre nomination forms will be returned to University of York in the first instance so that agreements can be sent out and managed. The forms will then be transferred to CTRU via secure data transfer, with the originals being stirred at University of York until the end of the trial.

Centres
Eligibility of centres will be gathered during the recruitment of local authorities. Once a local authority has been deemed eligible, signed an agreement and nominated all of its centres, a centre agreement will be sent to each centre manager.

Parents
When introduced to the trial during attendance at their centre, either within a 'Stay and Play' session (controls) or when enrolling to attend the HENRY programme (active intervention), all parents will be asked to complete a screening form to provide basic demographic information, indicate eligibility and express interest in learning more about the trial. This will collect the following information:

- Sex
- Ethnic group
- Age range
- Attendance at previous HENRY programme
- Primary caregiver of a child aged 6 months to 5 years
- Type of caregiver
- If they would like to learn more about the trial and reasons for non-interest

Those that are interested in learning more will receive a participant information sheet given by centre staff. If they are happy to take part, they will be consented by a member of the children's centre staff (including providing consent to share contact details with LCRN Section 8.3). Visits to collect baseline data will be arranged by the LCRN. All screening forms will be sent to CTRU. If a parent requires additional time to think about their participation in the trial, they will inform the member of staff once they have made their decision at a subsequent visit to the centre.

Staff
Site training will be provided to train staff in screening and consent procedures, as well as to provide information regarding the trial processes. All staff completing the training will be eligible to take part (and provide outcome data) and will be asked to complete an anonymous screening form.
The screening form will capture:

- Sex
- Ethnic group

- Age
- Reasons for non-consent to participation

All screening forms will be sent to the CTRU regardless of whether the staff member subsequently participates in the trial. Informed consent must be obtained prior to undertaking any trial-specific procedures (e.g. submitting height, weight and waist circumference measurements).

12.2 Baseline and follow up data

The trial team will provide training to LCRN teams for participant registration and collection of baseline and follow up data. An online training module will be made available for both children's centre staff and LCRN researchers as a refresher and for use with staff who are appointed after training. The LCRN researcher will destroy any data collected for participants that do not go on to be registered (with the exception of data collected on the screening form).

A standardised protocol will be used for the measurement of weight, length, height and waist circumference. Parent questionnaires will be completed by LCRN researchers using an interview administration process either electronically or via paper CRF.

Children's Centre

A 12-item environmental questionnaire will be sent to managers at baseline and follow up by CTRU. At baseline, we will ask that managers do this as part of the agreement procedure (i.e. both the agreement and the questionnaire will be shared at the same time, so that once they have signed, they are able to complete the questionnaire). This questionnaire is a trial-specific shortened version of the NAPSACC self-assessment instrument (32) a validated tool designed to assess preschool environments. Items have been chosen based on their relevance to the HENRY core training (Environmental Questionnaire).

A bespoke questionnaire will be used to collect information on staff movement for centres in the HENRY arm.

Parent

Data will be collected from parents in their homes unless they prefer to meet in another location as feedback from our parent advisory group suggests that some parents/carers may prefer a visit at their centre rather than in their home. Data collection at their centre will be possible if requested however, as HENRY programmes will be advertised within centres, it may lead to un-blinding of the CRN researcher. Thus, location of all visits and assessments will be recorded so any un-blinding can be assessed. Case Report Forms will be completed using an interview administration process by trained, blinded researchers from the CRN workforce.

After 12 months post registration, the participant will be contacted again by the CRN researcher to arrange a second visit where 12 month follow up data will be collected. Attempts will be made to use different researchers at follow-up if the researcher who conducted the baseline assessment is aware of participant allocation.

The following data will be collected:

Demographics and attendance at Children's Centre (Baseline form)

- Parent age range, sex and ethnicity
- Relationship of primary caregiver to child
- Place where baseline visit takes place (postcode to derive deprivation index)

- How participant learned about the trial
- Date of birth, sex and ethnicity of child
- NHS number of the child (for linking with NCMP routine dataset)
- Number of other children in household
- Date of birth and sex of other children in household
- NHS number of other children in household (if consented, for linking with NCMP routine dataset)
- How many adults live in the household (including the parent)
- Primary caregiver pregnant or not pregnant at baseline
- Programmes attended at centres in last 12 months
- Friends or relatives that have attended HENRY
- Friends or relatives that attend different centres in the local authority
- Details of other centres attended by parent
- Selected questions from the Socio-Economic Panel Innovation Sample (SOEP-IS) survey instrument [33]
- Socioeconomic status of the parents and household

Reference child height and weight

- Length/cm or Height/cm
- Weight/kg

Primary caregiver height and weight (optional)

- Height/cm
- Weight/kg
- Waist circumference/cm

Parenting self-efficacy

The HENRY approach aims to empower parents through promotion of parenting efficacy. Assessment of this will be gathered via the Dumka Parenting Self Agency Measure (5-items) (27).

Family eating/ activities

Data will be collected via the validated Golan Family Eating and Activity Habits Questionnaire (32-items) (28). This questionnaire collects data that are specific to the objectives of HENRY including:

- Leisure time activities
- Eating habits and style
- Hunger and satiety cues
- Exposure to and availability of problematic foods and stimulus control
- Frequency of parent and child eating meals and snacks together

Feeding questionnaire

Data will be collected via the Baughcum pre-schooler feeding questionnaire (37 items) (29). This questionnaire measures the feeding practices of young children between the ages of 2 to 5 years relating to the following areas of importance to HENRY:

- Maternal feeding practices
- Child eating behaviours
- Maternal beliefs

Dental questionnaire

A questionnaire has been developed based on the Dental Health Survey of Children and Young People by the University of Leeds, School of Dentistry to measure the potential wider impact of HENRY and a child's dental health (Dental Questionnaire). This contains 5 questions related to tooth brushing, dental attendance and whether the child has received general anaesthetic treatment.

Health-related Quality of Life and resource use

Health-related Quality of life will be measured among parents using the EQ-5D-5L and ICECAP-A. Resource use and cost data will be collected using a trial-specific questionnaire.

Safety

Adverse events and unintended consequences will be measured using trial-specific questionnaires.

Attendance data

All participants that are registered for the trial will be issued with a participant ID. The consent form has an optional statement whereby the parent agrees to share their attendance data if attending a HENRY programme. Following each HENRY programme, an attendance data specification form will be completed by the Children's Centre/HENRY group facilitator. The forms will be pseudonymised and the participant ID and initials will be used to ensure that attendance data is only collected for trial participants that provided written informed consent for this.

Contamination

Contamination will be assessed using trial-specific questionnaires. We will ask centres from both arms to complete a brief online survey to indicate whether they have delivered HENRY since the end of their 18 month data collection period (also seeking details of delivery of other relevant programmes). As discussed below, parents will be contacted in this period about their HENRY participation (if they provide consent).

Training

We will summarise information on the number of staff trained to deliver HENRY.

Medium-term follow up (3 years)

Parents will be contacted at the medium-term follow-up period and asked to share information about whether they have attended a HENRY programme since the end of the main trial period. This will include both those who have already attended HENRY (i.e to explore repeat attendance for other children) and those who attended control centres. In addition to this, we will seek information about the name of the centre at which they attended the programme to support the documentation of HENRY implementation post the main trial period (post 12 month follow-up). To capture this, a brief online form (Parent medium-term follow-up form) will be shared with participants.

Parents will be asked to provide consent for access to routine data that will be collected from their child as part of the National Child Measurement Programme (NCMP) when their child starts school or via Health visiting data (aged 2 years). These data will be linked by gathering child NHS number at baseline. As part of the economic evaluation, we will also ask that parents provide consent to obtain NCMP from siblings to the reference child (though this will not be compulsory). Given the wide age range of child eligibility at recruitment, the exact length of follow-up for each child will differ depending on the age of the child when their parent was recruited to the trial (though the maximum follow-up period will be set at 3 years follow-up).

12.3 Parent engagement

During the trial, participants will receive a newsletter which will be written with the support of the PPI group updating them on trial progress. The PPI group will also help to produce result summaries to share trial findings.

Participants will be sent a text and/or email reminder by CTRU around the time of their follow up visit to remind them that they will soon be contacted by a LCRN researcher to schedule the visit. Participants will be reminded they will receive a £15 voucher following the visit to encourage their continued participation. Participants will be encouraged to inform the trial of any change of address, email or mobile number to ensure correct details are used at follow-up.

12.4 Data transfer

All data provided will be stored, handled and processed in accordance with UK General Data Protection Regulation and the Trial Publication Policy. The rights for this data belong to the Trial Sponsor and no processing, including further data transfer in whole or in part to a 3rd party, is permitted other than as stated in the data transfer agreements.

Local authority and centre level data

Each local authority will return an Eligibility Checklist and children's centre nomination form directly to the CI or programme manager (MB / WB) at the University of York or HENRY central office to facilitate local authority and children's centre agreements to be drawn up. Once centre agreements have been signed, a copy of the children's centre nomination form will be sent to CTRU via secure data transfer for randomisation purposes and to enable centre managers to be contacted by the trial team to arrange training etc. which will be stored in a secure location on the CTRU network. The source data will be held securely at University of York and archived at the end of the trial.

Centre level data (i.e. centre characteristics and environmental data) will be transferred from centres to CTRU via secure file transfer and stored on a secure electronic database.

Parent data

Completed parent screening forms and consent forms (within centres by Centre staff) will be posted separately to the CTRU or scanned and emailed to the CTRU via secure file transfer. Contact details will be shared with the LCRN team to enable them to arrange home visits and data collection. This will be done using the secure electronic CTRU database.

Case Report Forms will be completed by LCRN researchers. Data will either be captured directly on to a secure electronic CTRU database or via paper CRF which will be posted or scanned and emailed to the CTRU via secure data transfer prior to being entered onto a secure electronic database. Case report forms will be pseudonymised (unique identifiers, DOB and initials only).

A unique identifier will be provided to participants who attend the HENRY programme by the CTRU following registration. These will be linked to the HENRY identifier but no other information will be provided. This will enable us to link routine attendance data collated by HENRY to participants that have agreed to take part (and will be consented). Attendance data will be sent upon completion of the programme by HENRY to CTRU (using the unique identifier) via secure data transfer and stored on a secure electronic database. These data will be shared anonymously with researchers at the University of York and University of Sheffield as required (via secure data transfer) to support the systems based process evaluation.

13 PARTICIPANT SAFETY

The interests of all participants, including families, the centre staff and representatives from the local authority will be guarded by the normal duties of care, following appropriate information and clinical research governance approval procedures. It is not expected that that serious adverse events (SAE) will occur as a result of taking part in the trial, but we will look for and report any RUSAEs: Related Unexpected Serious Adverse Event', an SAE occurring to a research participant in the opinion of the Chief Investigator the event was:

Related' that is, it resulted from the administration of any of the research procedures, and Unexpected' that is, the type of event is not listed in the protocol as an expected occurrence.

All LCRN researchers will follow the organisation's safeguarding pathway for secondary care as per their standard practice. If a parent becomes upset or distressed during a visit, the CRN researcher will follow the University of York HENRY trial distress protocol for trial participants.

14 STATISTICAL, HEALTH ECONOMIC AND PROCESS EVALUATION ENDPOINTS

14.1 Primary endpoint

Child age and sex adjusted Body Mass Index (BMI z-score) at 12 months post parent registration

14.2 Secondary endpoints

Short-term, using data collected at 12 months post parent registration:

Parent behaviours

- Parenting self-efficacy via the Dumka PSAM (5-items)
- Eating behaviours via the Golan Family Eating and Activity Habits Questionnaire (32-items)
- Feeding behaviours via the Baughcum pre-schooler feeding questionnaire (37-items)
- Dental health via bespoke questionnaire

Parent / child Physical

- Child height, weight (kg), unadjusted BMI and weight/BMI percentiles
- Parent height (m), weight (kg) and BMI
- Parent waist circumference (cm)

Staff Physical

- Staff height (m), weight (kg) and BMI
- Staff waist circumference (cm)

Children's Centre

- Centre environmental characteristics via bespoke questionnaire

Safety

- Number and proportion of RUSAEs
- Number of RUSAEs per participant
- Details of RUSAEs including severity
- Unintended consequences

Health Economics

- Incremental cost per unit change in BMI z-score
- EQ-5D-5L and ICECAP-A measures among parents (spillover benefits)

Medium-term, using routinely collected NCMP or Health visitor data at 3 years post parent registration:

- Child (and sibling) height (m), weight (kg), unadjusted BMI and weight/BMI percentiles
- Incremental cost per unit change in BMI z-score

Longer-term:

- Estimates of long-term BMI z-score trajectories using the matched cohorts of Millennium Cohort Study (MCS) participants

Process evaluation:

- Systems map describing the system in which HENRY operates
- Understanding of how the system in which HENRY operates changes over time in response to HENRY (qualitative report/refined map)
- Participant characteristics in relation to target population
- Acceptability of HENRY programme, perceptions of how HENRY is implemented during trial mechanism of impact and perceptions of how HENRY facilitators health improvement or not
- Participant attendance at HENRY programmes
- Staff movement between centres during the trial and identification of potential sources of contamination as perceived by stakeholders

15 STATISTICAL CONSIDERATIONS

15.1 Sample size

41 centres per arm (from 10-14 Local Authorities), each recruiting 12 parents on average (4 parents from 3 programmes, 984 parents in total) will provide 90% power to detect a small standardised effect size of 0.27 as per previous trials [25-28] for BMI z-score at a 5% significance level, assuming an ICC of 0.03 [16, 25, 29, 30, 32] to account for clustering by centre, a coefficient of variation of 0.48 to account for variation in centre recruitment and 20% loss to follow-up [18].

15.2 General considerations

Statistical analysis of the quantitative endpoints is the responsibility of the CTRU Statistician under the supervision of the Lead Methodologist/Supervising Statistician with the exception of the health economic endpoints which will be analysed by the Health Economics team in LIHS. The qualitative systems and process evaluation endpoints will be analysed by the team at the University of Sheffield. The analysis

plan outlined in this section will be reviewed and a final more detailed statistical analysis plan will be written before any analysis is undertaken. The analysis plan will be written in accordance with current CTRU standard operating procedures and guidelines and will be finalised and agreed by the appropriate members of the research team and reviewed by the Trial Steering Committee. Any changes to the finalised analysis plan, together with reasons for changes will be fully documented. All analyses for which CTRU has responsibility will be conducted using SAS version 9.4 unless stated otherwise.

15.3 Frequency of analyses

Progression to the main trial will be assessed at the corresponding time point for each progression criteria (see Section 15.10). Following this, no formal interim analyses of primary or secondary endpoints will be undertaken.

Analysis of the short-term data will be conducted after the trial is closed to recruitment and the final 12-month parent follow-up data has been received. These analyses will be carried out when all available outcome data has been received and when the database for the 12-month follow-up data has been cleaned and locked.

Analysis of the medium-term data and the MCS data (for the longer-term analysis) will be conducted after the National Child Measurement Programme (NCMP) data has been received. The medium- and longer-term analyses are planned to be carried out approximately 2.5 years after the end of recruitment.

Blinded interim reports will be presented to the TSC and DMEC containing descriptive information annually (or more frequently as requested by the committees). Reports will include data on recruitment, follow-up, safety and data quality.

15.4 Analysis populations

Summaries relating to data collected prior to centre randomisation will be based on data from all local authorities / centres screened for entry to the trial.

Summaries relating to data collected prior to parent registration will be based on data from all parents screened for entry to the trial.

Analysis will be carried out on the intention-to-treat (ITT) population defined as all local authorities / centres randomised and all parents registered to the trial, regardless of adherence to the protocol, withdrawal of consent or losses to follow-up. Local authorities / centres will be included within the treatment arm to which they were randomised and parents will be included within the treatment arm to which they were registered. A two-sided 5% significance level will be used for statistical endpoint comparisons, unless otherwise specified.

Missing data is expected, the mechanisms for missing data will be explored and the proportion of missing data compared between intervention and control groups. If it can be assumed that data is missing at random (MAR), the primary ITT analysis will use multiple imputation, enabling us to include all randomised participants in the ITT analysis. If the data cannot be assumed MAR, we will explore the use of other more complex methods for the primary analysis taking account of data missing not at random (MNAR), such as pattern mixture modelling.

15.5 Summary of Screening, Flow of Patients and Baseline Characteristics

The flow of local authorities, centres and participants through the trial will be presented in a Consolidated Standards of Reporting Trials (CONSORT) diagram, which will include number of local authorities approached / agreeing to participate / not agreeing to participate, number of centres randomised / not randomised together with reasons for non participation / randomisation. Centre withdrawals including timing of and reasons for withdrawal will be summarised. The numbers of parents screened, eligible, consented and registered, and numbers of parents not eligible, not consented and not registered, together with reasons for ineligibility / non-consent / non-registration will be presented. The flow of parents post-registration, including the number of parents followed-up and analysed, will be presented, including the number of and timing of withdrawals.

Summary statistics will be presented for baseline data by arm using means, standard deviations, medians, minimum, maximum, and quartiles for continuous variables, and counts and percentages for categorical variables. Summaries will be calculated at the parent level and/or the centre level as appropriate.

As appropriate for cluster trials recruiting participants after randomisation (34), statistical testing of baseline participant data will be undertaken periodically to assess for evidence of selection bias, including at the end of the internal pilot and at the end of the trial. Throughout the recruitment period we will regularly monitor for selection bias by i) reviewing numbers and proportion of eligible families screened, consented and recruited by arm and by centre, checking for imbalance; and ii) monitoring recruited participant characteristics (e.g. socio-economic status and ethnicity) by arm.

15.6 Primary Endpoint Analysis

The primary outcome, child age and sex adjusted BMI (BMI z-score), will be analysed using a multi-level linear regression with children nested within centres, and centres treated as a random effect. The model will be adjusted for the following fixed effects: centre-level stratification factors, important parent-level and child-level covariates (e.g. baseline child BMI z-score and sex, parent BMI), and other relevant known predictors of outcome. Missing data will be imputed at the individual participant level where appropriate. Estimated mean differences will be reported with 95% confidence intervals, p-values and ICCs. Model diagnostics will be used to check the underlying assumptions of the model and alternative methodology will be used if required. Sensitivity analyses of the primary endpoint will be conducted to assess the impact of missing data, the choice of imputation model and the missing at random assumption, as appropriate. If contamination between intervention and control centres is identified, a sensitivity analysis excluding the relevant control centres will be conducted.

Summary statistics for the primary outcome will be presented at baseline and 12 months post-parent registration overall, by arm (means, standard deviations, medians, minimum, maximum, and quartiles for continuous variables, and counts and percentages for categorical variables).

15.7 Secondary Endpoint Analysis

For secondary outcomes, summary statistics will be presented at baseline and 12 months post-parent registration overall and by arm (means, standard deviations, medians, minimum, maximum, and quartiles for continuous variables, and counts and percentages for categorical variables). Analysis will use the same approach as the primary outcome for different outcome types, using multi-level linear or logistic regression as appropriate, with multiple imputation for missing data.

Analysis of the health economic endpoints will be conducted by the Health Economics team in LIHS and

is detailed in Section 15. Analysis of the qualitative process evaluation endpoints will be conducted by the team from the University of Sheffield and is detailed in Section 17.

Child outcomes:

In addition to the primary outcome, child height (m), weight (kg), unadjusted BMI and weight/BMI percentiles will be summarised.

Parent outcomes:

Full details on scoring methods for questionnaires will be included in the Statistical Analysis Plan, together with interpretation of scores.

Parenting self-efficacy via the Dumka PSAM (5-items): A 5-point Likert scale will be used and the outcome will be defined as the total score.

Eating behaviours via the Golan Family Eating and Activity Habits Questionnaire (32-items): The outcome will be defined as the sum of the scores for each individual item.

Feeding behaviours via the Baughcum pre-schooler feeding questionnaire (37-items):

Dental health of participants will be summarised overall and by trial arm.

Parent height (m), weight (kg), and waist circumference (cm) will be summarised. Parent BMI will be generated from height and weight (Weight(kg)/Height(m)2).

Staff outcomes:

Staff height (m) and weight (kg), and waist circumference (cm) (self-measured) will be summarised overall and by arm. BMI for the staff will be generated from self-measured height and weight (BMI, Weight(kg)/Height(m)2).

Children's centre outcomes:

Environmental characteristics of centres will be summarised overall and by centre.

Safety:

RUSAEs will be summarised. including the number of RUSAEs, proportion of participants experiencing a RUSAE and details of the RUSAEs. Safety endpoints will be analysed descriptively between arms and no formal statistical comparisons will be made.

Process evaluation:

Quantitative process evaluation data (attendance and staff movement) will be summarised by CTRU. In the intervention arm, parent attendance data will be summarised overall and per programme, including number of sessions attended and reasons for absence. Staff movement will be summarised overall and by centre.

15.8 Sub group analyses

If numbers allow, exploratory analysis will examine differences in intervention effect between different socio-economic and ethnic groups, and also between online and face-to-face delivery of HENRY.

15.9 Interim analyses

No interim analyses are planned, except for safety data that are required for review by the Data Monitoring and Ethics Committee (Section 25.3).

15.10 Medium-term analysis

Medium-term analysis (3-years post parent recruitment) will compare regional population level BMI z-score (trial local authority areas) with that of trial participants and siblings (HENRY and control) to investigate differences in BMI z-score.

15.11 Internal Pilot and Progression Criteria

This trial includes an internal pilot with assessment taking place at three separate time points, with a single progression criteria analysed at each time point. The internal pilot will assess recruitment of both children's centres and parents and delivery of the intervention against pre-defined progression criteria and trial continuation will be conditional on these targets being met.

Progression criteria are outlined below, based on a traffic-light system of green (go), amber (review) and red (stop), and will be agreed by the independent TSC and funder. The TSC will be provided with descriptive data, presented overall, by arm and by centre to assess whether internal pilot progression criteria have been met and will use this data to inform a decision on the modification or continuation of the trial. If the progression criteria are met (green) then the trial will continue. If any criteria are graded as amber, a rescue plan will be developed outlining steps to be taken to improve recruitment of centres and parents and intervention delivery (as appropriate) and will be approved by the TSC before submission to the NIHR. If any of the progression criteria are not met (red), this would be discussed with the TSC and the funder and the trial may be stopped.
The design of the internal pilot and full trial, including intervention delivery and data collection, are identical, in order that data from the internal pilot can be used as part of the final trial analysis data set.

Criteria	Green (go)	Amber (review)	Red (stop)
Centre Recruitment Centres open within 12 months of starting centre recruitment (including data up to the end of month 19). A centre will be defined as open if it has been randomised and is open to recruitment.	≥54	42-53	<42
Parent Recruitment Average number of parents recruited per programme / equivalent (including data up to the end of month 23, allowing for 6 months of parent recruitment):	≥4	3 to <4	<3

Criteria	Green (go)	Amber (review)	Red (stop)
HENRY Programme delivery Percentage of intervention centres having started delivery of at least 1 programme (including data up to the end of month 27, allowing for 18 months from starting centre recruitment). The denominator will include all centres allocated to the intervention arm. The numerator will be all of those intervention centres who have started to deliver at least one programme, defined as delivering at least one session to parents.	≥80%	50% to 80%	<50%

At the time of review of the internal pilot relating to parent recruitment, the Trial Steering Committee (TSC) will also be provided with a comparison of the baseline characteristics (including baseline child BMI z-score, parent socio-economic status and ethnicity) to allow assessment of the level of selection bias which can be used to inform the decision to continue with the trial.

16 HEALTH ECONOMIC EVALUATION

Our proposed trial design seeks to address a number of challenges that are well recognised in literature on conducting economic evaluations of public health interventions which mean that standard approaches to health economic evaluation (in clinical settings) are often not feasible. For example, it is not possible to collect quality of life data (e.g. EQ-5D) in young infants and, secondly, many of the health benefits (and NHS cost savings) of healthy weight during childhood won't be realised until later on in childhood or adulthood.

The overarching aim of the health economic analysis is to reduce decision uncertainty about whether HENRY should be commissioned. The analysis will be conducted in three stages with three different time horizons: one year (stage i.), three years (stage ii.), and longer-term (stage iii.) analyses. The one year analysis will only use data collected in this trial whereas the three year and longer-term analyses will additionally use secondary data on trial participants from the National Child Measurement Programme (NCMP) and data from matched individuals in the Millennium Cohort Study (MCS).

As the time horizon increases, it is highly likely that we will observe a reduction in decision uncertainty in the sense that it will become much clearer whether or not HENRY should be commissioned. This is because the three year and longer-term analyses will incorporate additional health gains and healthcare cost savings that only materialise later on in childhood or early adulthood, making it increasingly likely that the benefits of HENRY will outweigh the costs of delivering HENRY, all of which are incurred upfront during the first year. For example, we might anticipate that the longer term analyses would shift the cost-effectiveness point-estimate from the NE to the SE quadrant of the cost-effectiveness plane. Similarly, we may find that the cost-effectiveness acceptability curve (CEAC) shifts in an upwards direction, even

in cases where the cost-effectiveness point estimate remains in the SE quadrant. In each of these examples, this would provide stronger evidence that HENRY should be commissioned.

16.1. Short term: This will consist of a one-year within-trial cost-effectiveness analysis of the incremental cost per unit change in BMI z-score. Supplementary analyses will calculate the cost per unit change in weight after controlling for height, and the cost per change in obesity cases. Resource use data at the child- and household-levels will be collected in the parent 12 month follow-up questionnaires. These questionnaires will incorporate the child's primary care (e.g. GP and nurse contacts) and secondary care (e.g. outpatient visits and hospital stays) visits, medication use, selected household expenditure (out of pocket expenses, including food shopping) and the time that parents taken off work for attending HENRY sessions. The recall period will be three months for healthcare use and one month for household expenditure. The household expenditure questions will be designed for this trial in consultation with our parent advisory group and based on questionnaires we have used in other studies, in similar settings.

Unit costs for each healthcare resource use item will be obtained from the Personal Social Services Research Unit (PSSRU) Unit Costs of Health and Social Care, the Department of Health's National Schedule of Reference Costs and the British National Formulary (BNF). The time off work data will be used to measure productivity loss, costed using the human capital approach. Intervention costs will include intervention delivery, measured using a bottom-up, micro-costing approach which will incorporate both fixed and variable costs. Calculation of the core practitioner and facilitator training costs will account for staff turnover rates in the centres which will be assessed in the staff interviews and documentary review described in the systems level process evaluation.

Primary analyses will adopt an NHS and local authority perspective. Supplementary analyses will adopt a wider societal perspective by assessing household costs and productivity losses. Spill over benefits to parents will also be captured by calculating differences between the two treatment groups in terms of quality adjusted life years (QALYs) over 12 months. Utility scores will be measured using both the EQ-5D-5L (as per feasibility study) and the ICECAP-A measures, which will be collected using data from parent completed validated questionnaires described in Section 12.2 Baseline and Follow up. These supplementary analyses will be presented as secondary outcomes in a disaggregated format so that commissioners can factor in these effects when considering whether HENRY provides value for money.

All analyses will be conducted using the ITT population. Seemingly unrelated regression will be used to account for the correlation between costs and outcome measures. Multilevel models will be used to account for children nested within centres. Decisions about which child-level, parent-level and centre-level covariates to include in the models will be made after assessing differences in baseline characteristics, and through discussion with the trial statisticians. Patterns (and reasons) of missing data will be investigated in collaboration with the trial statisticians and appropriate imputation techniques will be used. Supplementary analyses will assess whether there are differences in costs and effectiveness by the intervention delivery method by including an interaction term between method (i.e., online vs. face-to-face) and the treatment variable. In order to address whether or not the intervention is equally cost-effective among children living in the most deprived areas and households, analyses will also use interaction terms for household-level socioeconomic status (which will be measured in the patient-completed questionnaires) and for area level deprivation (≤ 10%/> 10% ranking within Index of Multiple Deprivation at the Lower Super Output Area). To assess whether a parent/carer's propensity to commit to engage with HENRY was affected by their attitude to risk or perceptions about their long-term health prospects, analyses will also use interaction terms for self-reported measures of these factors based on questions used in the English Longitudinal Study of Ageing (ELSA) and German Socioeconomic Panel (SOEP). Uncertainty in our cost-effectiveness estimates will be characterised by presenting bootstrapped estimates on CEACs using a wide range of different cost-effectiveness thresholds (£/BMI

change).

16.2. Medium term: This will consist of a three-year cost-effectiveness analysis of the incremental cost per unit change in BMI z-score. In addition to the BMI data recorded in Stage 1, this analysis will incorporate linked NCMP or health visiting BMI z-score data collected on individual trial participants ~3 years post-recruitment. Healthcare utilisation will be estimated by matching trial participants to children in the MCS [35] on a >5:1 ratio using a rich set of characteristics (including BMI z-score). The MCS includes >18,000 children, with height and weight measures every 2-3 years from age 3-22 and is linked to Hospital Episode Statistics (HES) data. Cost measurement and data analysis will be conducted using methods described above in Stage 1. Appropriate discount rates will be applied to costs and benefits arising after 12 months in this analysis. A supplementary analysis will include spill-over benefits to other children in the household, captured using their NCMP BMI data collected during the same trial period.

16.3. Longer term: Estimates of longer-term BMI z-score trajectories using the matched cohorts of MCS participants will be used to predict longer term changes in healthcare utilisation beyond three years post follow-up. This will enable us to make a more comprehensive assessment of the likelihood that HENRY is cost saving and more effective (i.e. in the SE quadrant of the cost-effectiveness plane) under a variety of different long term weight gain assumptions. Value of information analyses will also be conducted, including an assessment of uncertainty in parameters (stochastic uncertainty) that contribute to the remaining decision uncertainty. Literature searches, supported by Information specialists, will seek to reduce parameter uncertainty. We will also make recommendations about the value of collecting more data in order to address remaining parameter uncertainty. Since it is not possible to collect health-related quality of life data in the young infants included in this trial this could include, for example, a recommendation that funding is sought to collect data in trial participants when they are a little older (using e.g. the EQ-5D-Y instrument which can be used with children of junior school age).

Results for all economic analyses will be reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines.

17 SYSTEMS BASED PROCESS EVALUATION

HENRY is a complex intervention that can be viewed as an event within a system [36]. Therefore, we will adopt a complex systems perspective, using a framework for qualitative systems process evaluations [37] and quantitative systems evaluation, embedded within a mixed methods process evaluation [38]. The evaluation will consist of the two-stage qualitative systems approach: (1) initial systems mapping, and (2) analysis of the system within which HENRY is embedded. It will also include a traditional process evaluation to understand context, mechanisms and implementation of HENRY [38] and quantitative systems modelling.

17.1. Systems approach Stage 1- mapping: The first stage of qualitative systems process evaluation involves producing a map of the system within which HENRY operates and identifying hypotheses about how this may be disrupted in response to HENRY. The map will be constructed at the start of the RCT in which we will identify: structure (e.g. levels of national, regional and local); elements (e.g. national public health priorities around childhood health, obesity and parenting; local authority priorities and funding situation; health visitor responsibilities; organisations providing HENRY; welfare benefits systems; historical events affecting childhood obesity); relationships and interactions between elements; and boundaries (what is inside and outside the system).

The overall map may ultimately consist of a number of sub-maps which will highlight causal inter-relationships between each of the elements of these areas. It may also present HENRY at different levels (the local authority, centre, parent/child and other) identified via this research. These maps will

comprise fundamental systems thinking ‘building blocks’ in the form of causal-loop diagrams and/or stock-and-flow structures as appropriate. Each set of diagrams (or system maps) will seek to relate parameter/variable components of the local system through positive/negative causality and ordinalities such that a dynamic representation of inter-relationships can be viewed graphically. This conceptualisation is crucial to presenting possible links between obesity rates and local, national or global influencing variables. Discussion and interaction with stakeholders will support interpretation of causes and effects, *in vitro* of the actual system (yet pertaining to it).

While we foresee that our system boundary will sit at the local authority level (albeit highlighting external influences) the boundary will be defined in the early stages of the map development. The map development will adopt an iterative, co-created approach involving stakeholders such that the system boundary will seek to include and identify endogenous and exogenous elements of the entire system which HENRY encapsulates (or is encapsulated by).

We will begin the process of system mapping with a stakeholder workshop (n=30-40) including early years teams in local authorities, voluntary organisations, schools and nurseries, local authority commissioning and delivery representatives, parents, community leads and other community delivery organisations delivering HENRY such as Barnardos. We will ask them to map the system in a set of sub-maps and interactions between elements in the system, focusing on issues that might impact on childhood obesity and/or be impacted by HENRY. We will also ask them to identify hypotheses for ways in which HENRY could change the system. Iteration of this map and sub maps will occur throughout the day-long workshop. If our stakeholders identify the need to involve new relevant stakeholders, we will contact them by telephone/zoom to seek their views on the evolving system map. During this process, we will also identify relevant documents for documentary analysis to facilitate the construction of the final baseline system map. The resulting system map and sub-maps will be the foundation for the sampling and data collection in Stage 2.

17.2. Systems approach Stage 2 - Analysis of the system stimulated by behavioural and health responses to the HENRY intervention: The second stage of qualitative systems process evaluation involves understanding how the system and its elements change over time in response to HENRY. Six months prior to the end of the RCT, we will undertake qualitative telephone interviews/virtual interviews with 20-24 national, regional and local key stakeholders representing elements of the Stage 1 map. We will undertake purposive sampling by type of stakeholder, including many of the participants from Stage 1. We may use snowball sampling if early interviewees identify other stakeholders for inclusion. We will send the Stage 1 system map and a relevant sub-map to interviewees prior to the interview. Interviews will discuss the system structure and elements, how they have changed over time, the way the system responded to HENRY, and how responses amplified or dampened HENRY’s impacts. Different elements in the system will have strategies for addressing health inequalities and we will explore how HENRY affected or was affected by these strategies. Interviews will last approximately one hour, be audio recorded and transcribed verbatim. For the analysis we will draw on concepts from complex adaptive systems thinking e.g., adaptation, feedback, unintended consequences, system trajectories.

17.3 Context, mechanisms and implementation of HENRY: To complement McGill’s qualitative systems process evaluation we will focus on understanding the reach of HENRY within the target population, how HENRY works, potential contamination, and how it has been implemented within the RCT [34]. We will undertake semi-structured interviews with staff providing HENRY to explore their views of the feasibility of HENRY, how it has been delivered in different centres over time (variation in implementation), access to HENRY for different socio-economic and ethnic minority groups (reach), perceptions of differential health outcomes for different socio-economic and ethnic minority groups (that is, how it addresses health inequalities or not), and views of potential contamination in the RCT. We will undertake semi-structured interviews with parents attending HENRY to explore acceptability of the intervention and perceptions of

how it facilitated health improvement or not. In both sets of interviews, we will explore mechanisms of impact (how HENRY has affected parenting, nutrition and weight of children), facilitators and barriers to delivering or attending HENRY, reach in terms of accessing those most in need, and implementation in practice. We will also include a systems lens by putting context at the centre of the interviews and explore the impact of system elements on HENRY, specifically asking about how elements of the system documented in Stage 1 interacted with HENRY.

We will identify a diverse set of 4-8 local authorities from which to target recruitment for this part of the evaluation. This will include purposively sampling areas with different delivery models. We will select a centre in each local authority (sampled by level of social deprivation and ethnicity). Across these centres, we will interview 12-16 staff managing or providing HENRY and 20-24 parents who have attended HENRY. We will aim for maximum diversity of staff in terms of length of experience of delivering HENRY and experience of delivering face-to-face or online. We will also aim for maximum diversity of parents from different backgrounds (ethnic minority groups, socio-economic background) and who have received HENRY in different ways (face-to-face, online or hybrid). We will also include parents who have completed HENRY or who have not completed their programme. Where parents prefer to be interviewed in their first language, we will make use of any interpretation facilities on offer at each centre so that parents are familiar with the interpretation process. Through ongoing conversations with the CRN, we have also established a model of working that supports inclusivity through the use of dedicated CRN research teams for local communities (set up in response to the INCLUDE agenda) to support recruitment and data collection with families with additional language needs. Interviews will be face-to-face unless staff or parents prefer online or telephone interviews (or due to restrictions). They will last around one hour and be audio recorded and transcribed verbatim. These interviews may affect our understanding of why HENRY was implemented in different ways in different localities or at different times, and the extent to which health inequalities have been addressed by HENRY. For analysis, we will use the Framework approach, developing an initial thematic framework based on familiarisation of a range of transcripts, analysis of qualitative interviews from the feasibility study [39], and the process evaluation framework (mechanisms, context and implementation) [38].

We will also collect quantitative process data. First, we will analyse attendance to summarise attendance and drop out by centre and overall. Quantitative data will also be used to support the monitoring and evaluation of contamination (detailed in 4.3). Thus, in addition to exploring contamination through qualitative interviews, data on staff movement and sharing of HENRY related messages will be captured. Key to this will be an online HENRY-trained staff survey at two time periods (towards the end of the internal pilot and at the end of the RCT intervention period) asking whether, how and when staff shared HENRY practice outside their centre.

17.4 Quantitative systems modelling: Our planned systems modelling will inform how HENRY can influence population obesity [40, 41]. Using existing evidence, and our trial and process data, we will apply a causality-based model of obesity prevention to develop a systems archetype [42]. Analysis will incorporate Morphological Analysis and Fuzzy Cognitive Mapping techniques [30] to evaluate and assign inter-relationships between components through causal weights and network directionality. We will examine the range of operating conditions of the HENRY system model to classify its overall dynamic behaviour (identifying which Systems Archetype HENRY most closely resembles [42]; providing a basis for comparison to other obesity models (e.g., Foresight) to explain how HENRY may disrupt obesity prevalence in childhood).

17.5. Sample size for our qualitative research: Estimating and justifying sample size for qualitative research is challenging. Researchers can aim for large numbers to mirror quantitative research and then not have the capacity to undertake an in-depth analysis on the collected data. Researchers use the

concepts of data saturation [44] and information power [45] to determine sample size. Sample sizes of 9-17 interviews have been found to reach data saturation in homogeneous populations [44]. Information power is about the amount of information the sample holds relevant to the research aim. The amount of information power can be achieved with different sample sizes depending on the aim of the trial and the quality of the dialogue (amongst other things). We will undertake interviews that last an hour, focused on experiences of HENRY and the systems it operates within, undertaken with a diverse sample. All interviewees are likely to offer large amounts of relevant insights and we believe that information power will be high using the intended sample sizes. If data saturation is not reached we will need to continue interviewing beyond the proposed sample sizes but we believe our estimates are likely to be adequate.

18 INTEGRATION OF COMPONENTS OF THE PROCESS EVALUATION AND RCT

We will bring together different components of the process evaluation using adapted triangulation protocol where we place findings from each component side by side and consider where they converge, explain, or disagree. Process evaluations aim to explain RCT results. We will take a similar approach by placing findings of the process evaluation and the RCT side by side and considering the relationship between them.

19 DATA MONITORING

19.1 Data monitoring

Missing local authority and centre demographic and screening data will be chased until it is received, confirmed as not available or the trial is at analysis, by CTRU. Parent data will be monitored for quality and completeness by the CTRU using established verification, validation and checking processes. Data monitoring reports will be generated by CTRU ahead of Trial Management and Project Delivery Meetings.

All original records and certified copies necessary for the reconstruction and evaluation of the trial are classified as source data. Source data are contained in source documents; these include data entered on to case report forms (CRFs) and information sent to UoY via word document (e.g. LA eligibility checklist and CC nomination form). CRFs sent to CTRU should only include trial identification number, initials and date of birth to identify the participant. The exception to this is the participant consent form, where the participant name and signature must not be obliterated. If signed consent forms are posted to the CTRU, they must be sent in a separate envelope, and not accompanied by any case report forms or other documents containing participant data.

Source data from all visits with the participant, including children's centre screening and baseline visit, will be entered onto CRFs by the children's centre or research staff. This can be a paper record, or in the case of direct online completion, an electronic record.

Information sent via email attachment to the University of York from local authorities (children's centre nomination form) will be saved in a secure network location. Following this, the original email attachment will be deleted.

Source data collected from children's centres for staff movement and environmental data will be entered directly onto CRF (paper or electronic) by children's centre managers and staff. CRFs will be mailed to

CTRU upon completion.

Attendance records will only be collated and transferred to CTRU for participants that have provided written informed consent. A data spec will be used to specify which participants have provided data using only participant ID. Attendance data will be pseudonymised.

A source data location plan will be produced by CTRU. The sponsor has the right to conduct source verification although this is not anticipated given safety and efficacy are not endpoints of this trial.

19.2 Clinical governance issues

To ensure responsibility and accountability for the overall quality of care received by participants during the trial period, clinical governance issues pertaining to all aspects of routine management will be brought to the attention of the TSC and, where applicable, to individual local authorities and/or centres.

20 QUALITY ASSURANCE AND ETHICAL CONSIDERATIONS

20.1 Quality assurance

The trial will be conducted in accordance with the principles of the current MRC Good Clinical Practice (GCP) guidelines, and ESRC Research Framework, through adherence to CTRU standard operating procedures (SOPs) and trial-specific SOPs where appropriate. Appropriate storage, restricted access and disposal arrangements of personal and clinical details will be put in place.

20.2 Ethical considerations

The trial will adhere to ethical principles, approach, aims and methods of the ESRC research framework. The right of local authorities, centres and parents to refuse participation without giving reasons will be respected. Local authorities, centres and parents will remain free to withdraw from the trial at any time without giving reasons and without prejudicing their relationships. Trial documentation will be submitted by the CI, with support from the CTRU to the University of York Research Ethics Committee. Approval will be received prior to any sites entering the trial.

21 CONFIDENTIALITY

All data collected by LCRN during the course of the trial will be collected, transferred and stored in line with the Data Protection Act and ISO 27001, and specific strategies will be used to maintain anonymity and confidentiality.

Research data received from LCRN will be held securely on paper and electronically at the Clinical Trials Research Unit (CTRU). The CTRU will comply with all aspects of the 2018 Data Protection Act and operationally this will include:

- Local authority and parent level screening data (containing data on local authorities/centres/individuals that decline).
- Where documentation is required that includes identifiable information from sites e.g. postcode, the source data will be held at University of York and data required for randomisation etc. will be securely transferred to the CTRU.
- Consent from participants to record participant contact details (including name, address, email

address and telephone number) will be collected by centres during screening and shared with LCRNs via secure database to facilitate trial registration.
- Consent from participants for access to their NCMP data by responsible individuals from the research staff, where it is relevant to trial participation.
- Consent from participants to share contact details with University of York or University of Sheffield if required, to send trial newsletters and invite participants to take part in process evaluation interviews etc. If so, data will be transferred and stored securely.
- All trial data collected from participants will be mailed or sent to the CTRU via secure file transfer (if using paper CRFs) or entered directly onto electronic case report forms. All completed CRFs will be coded with a unique trial ID and two identifiers (the participant's initials and date of birth).
- Where anonymisation of documentation is required, children's centres, LCRN and HENRY are responsible for ensuring only the instructed identifiers are present before sending.

If a local authorities/Centres or parents withdraw consent from further collection of data, the existing data that they have provided up to the date of withdrawal, will remain on file and will be included in the final trial analysis.

22 END OF TRIAL AND ARCHIVING

22.1 Definition of end of trial

The end of trial is defined as when the last data query is returned from sites during data cleaning and before database lock (i.e. following completion of longer term follow-up (3 years post parent registration)).

22.2 Archiving

At the end of the trial, data will be securely archived at the CTRU for a minimum of 5 years. Arrangements for confidential destruction will then be made. No records may be destroyed without first obtaining written permission from the Sponsor.

23 STATEMENT OF INDEMNITY

This trial is sponsored by the University of York and the University of York will be liable for negligent harm caused to participants arising from the management of the research.

24 TRIAL ORGANISATIONAL STRUCTURE

Responsibilities

Sponsor
As defined by the NHS Research Governance Framework, the Sponsor is the organisation that takes responsibility for confirming there are proper arrangements to initiate, manage, monitor and finance the trial. The Chief Investigator is employed by the University of York.

Chief Investigator (University of York)
The Chief Investigator is responsible for the design, management and reporting of this trial, the whole research programme and its constituent parts. Specifically the CI is responsible for oversight of:

- Overall supervision of the trial, in particular, maintenance of confidentiality and trial progress
- Scientific and clinical input to the trial documentation
- Oversight of documentation submitted to external bodies (including the original and any subsequent submissions to ethics and centres)
- Review and reporting of research misconduct
- Ensuring that the trial is conducted in accordance with the principles of Good Clinical Practice
- Maintenance and archiving of trial documentation
- Ensuring all appropriate permissions are in place prior to randomisation of centres and recruitment of parents
- Trial reporting to the appropriate authority / body – including misconduct, end of trial, early termination, adverse events, serious breaches of GCP.

Oversight will be supported by the trial steering committee, the trial management team and parent advisory group.

Research Manager (RM) (University of York)

- Project management duties, including integration of main trial and systems process evaluation
- Lead PPI activities
- Preparation of trial protocol, subsequent protocol amendments and dissemination of approved amendments as appropriate
- Preparation of applications for Ethical review (in consultation with Sponsor)
- Developing and providing information sheets
- Liaising with sites during recruitment (with support from HENRY)
- Undertaking qualitative and quantitative data collection for process evaluation

Clinical Trials Research Unit (CTRU)

The CTRU will have responsibility for the conduct of the trial in accordance with the Research Governance Framework, MRC GCP standards and the principles of CTRU SOPs.

- Trial management/coordination including protocol sign/off, processing approvals, circulating documents, monitoring recruitment and QA
- TSC/DMEC management
- Randomisation duties including cluster randomisation and informing local authorities/centres of allocation
- Database development and testing
- CRF development and preparation
- Monitoring of participant consent
- Maintenance of a Trial Master File, including all essential documentation
- Management of data collection including supporting researcher training, monitoring of data quality and adherence to timelines
- Development and Maintenance and archiving of trial documentation
- Development of statistical analysis plan and data analysis (quantitative endpoints listed in Section 14 with the exception of those relating to Health Economics and qualitative endpoints relating to the Process Evaluation)

Health Economists

The Health Economics collaborators (Martin) will assist the CTRU in protocol development and will be responsible for the selection and / or design of the economic questionnaires, collation of unit costs, facilitation during the commissioners stakeholder event and the conduct, interpretation and writing up of the economic evaluation.

HENRY Central Office

HENRY will be responsible for supporting recruitment of Local Authorities as part of their usual commissioning process. They will also be responsible for implementing training and standard QA to staff within centres allocated to the active treatment arm. HENRY Central Office will continue to collect attendance data as per standard practice and will be responsible for transferring relevant data to CTRU for trial analysis and process evaluation if requested.

University of Sheffield

Professor Alicia O'Cathain and Dr Alexis Foster will:

- Work with all team members to identify workshop participants
- Lead the workshop in conjunction with the Chief Investigator
- Work with the University of Bradford to develop maps and sub maps of the system
- Write up the workshop
- Lead, deliver, analysis and report three sets of qualitative interviews: workshop attendee interviews, centre staff, and parents
- Integrate findings from different components of the process evaluation
- Contribute to integrating findings from the RCT and the process evaluation

25 Trial Oversight

25.1 Trial Steering Committee (TSC)

The TSC provides overall supervision of the trial including completion of the internal pilot to pre-defined progression criteria. In particular, they are responsible for monitoring: trial progress, adherence to protocol and consideration of new information. The committee will meet once during set up and then annually for the duration of the trial. It includes an Independent Chair and three other independent members, including an experienced Trial Statistician. The Chief Investigator and other members of the internal project team will attend all TSC meetings and present and report progress. The TSC operates in line with the CTRU's Committee ToR (or equivalent charter) as amended and agreed by TSC members at their first meeting.

25.2 Trial Management Group (TMG)

A TMG (Chair: Michelle Collinson), comprising the Chief Investigator, Research Manager, CTRU team (Collinson, Groves-Williams, Copsey and health economist (Martin) will be assigned responsibility for the set-up, on-going management and promotion of the trial. The TMG will operate in line with the agreed Terms of Reference (ToR).

25.3 Data Monitoring and Ethics Committee (DMEC)

A DMEC will be convened to monitor safety events, risk of selection bias and data collected during the study, and make recommendations to the TSC on whether there are any ethical or safety reasons as to why the trial should not continue. It will consist of an independent chair, an independent statistician, and an independent clinician. The DMEC will meet annually as a minimum. The DMEC will not review any primary or secondary outcome data prior to the final results of the study.

26 PUBLICATION POLICY

Authorship and acknowledgement

The success of the research depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated in the research, through authorship and by contribution. Uniform requirements for authorship for manuscripts submitted to journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

- conception and design, or acquisition of data, or analysis and interpretation of data
- drafting the article or revising it critically for important intellectual content
- final approval of the version to be published
- and that all these conditions must be met (www.icmje.org).

In light of this, the Chief Investigator, co-applicants and relevant CTRU staff will be named as authors in any publication, and an appropriate first author agreed through discussion amongst the Trial Management Group members. In addition, all collaborators will be listed as contributors for, giving details of their roles in planning, conducting and reporting the research. The HENRY team should be acknowledged in all publications, as should the NIHR PHR programme (as detailed below). Other key individuals will be included as authors or contributors as appropriate and at the discretion of the TMG and mentoring team. Any disputes relating to authorship will be resolved by the TSC.

The Chair and Independent members of the TSC will be acknowledged, but will not qualify for full authorship, in order to maintain their independence.

The TSC will agree a publication plan and must be consulted prior to release or publication of any trial data.

Individual collaborators must not publish data concerning their participants which is directly relevant to the questions posed in the research until the main results have been published. Local collaborators may not have access to data until after publication of the main results.

Processes for the drafting, review and submission of abstracts and manuscripts:
The agreed first author of abstracts is responsible for circulating these to the other members of the TMG and mentoring team for review at least 15 days prior to the deadline for submission.

The agreed first author of manuscripts is responsible for ensuring:

- timely circulation of all drafts to all co-authors during manuscript development and prior to submission
- timely (and appropriate) circulation of reviewers' comments to all co-authors
- incorporation of comments into subsequent drafts
- communication with the TSC (i.e. ensuring submission is in line with TSC publication plan, and ensuring TSC receive the final draft prior to submission)

The first author is responsible for submission of the publication and must keep the HENRY central office team and all authors informed of the abstract's or manuscript's status. The TSC will be kept informed of rejections and publications as these occur. On publication, the first author should send copies of the abstract and manuscript to the TSC, the TMG, all co-applicants, the Sponsor and to all other co-authors, and ensure communication with the NIHR PHR programme as outlined below.

NIHR PHR requirements will be adhered as per the contractual agreement.

Other outputs

During the trial, participants will receive a newsletter which will be written with the support of the PPI group updating them on trial progress. The PPI group will also help to produce result summaries to share trial findings.

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