



The HENRY Trial

Parent/carer information sheet

What is the HENRY trial?

We know that all parents face challenges when trying to provide a healthy lifestyle for their children. Programmes such as HENRY (Health, Exercise, Nutrition for the Really Young) are designed to help.

HENRY is a parenting programme delivered to groups of parents of 0-5 year olds in children's centres across the UK. Parents who enrol on to the HENRY programme will attend 8 x 2 hour sessions delivered over 8 weeks. Sessions are usually delivered by a member of staff from the children's centre or a health practitioner (e.g. health visitor). During the sessions parents will receive support for healthy diets, emotional well being, parenting skills, and leading a more active lifestyles. During the sessions parents are invited to think about what they are already doing well, and what they would like to change and decide on strategies to achieve their goals.

We would like to know whether HENRY is successful at supporting parents to provide a healthy lifestyle for their families by conducting a randomised controlled trial. In particular, we want to know if HENRY prevents children from becoming overweight. If HENRY is found to be effective, we hope that it can be rolled out to even more children's centres to support more parents.

The children's centre you attend is involved in the HENRY trial. Other children's centres across England and Northern Ireland are also involved. Half of the children's centres taking part in the trial will deliver the HENRY programme. Half will carry on as normal and not deliver HENRY. Parents who attend both types of centre are invited to take part in the trial. Half will attend a HENRY programme and half will not so we can compare whether HENRY makes a difference to family lifestyles. If your centre is selected to deliver HENRY programmes during trial you will attend the HENRY programme as well as taking part in the research. If your centre is not selected to deliver HENRY during the trial you will continue to attend your children's centre as normal whilst also taking part in the trial.

What will I have to do?

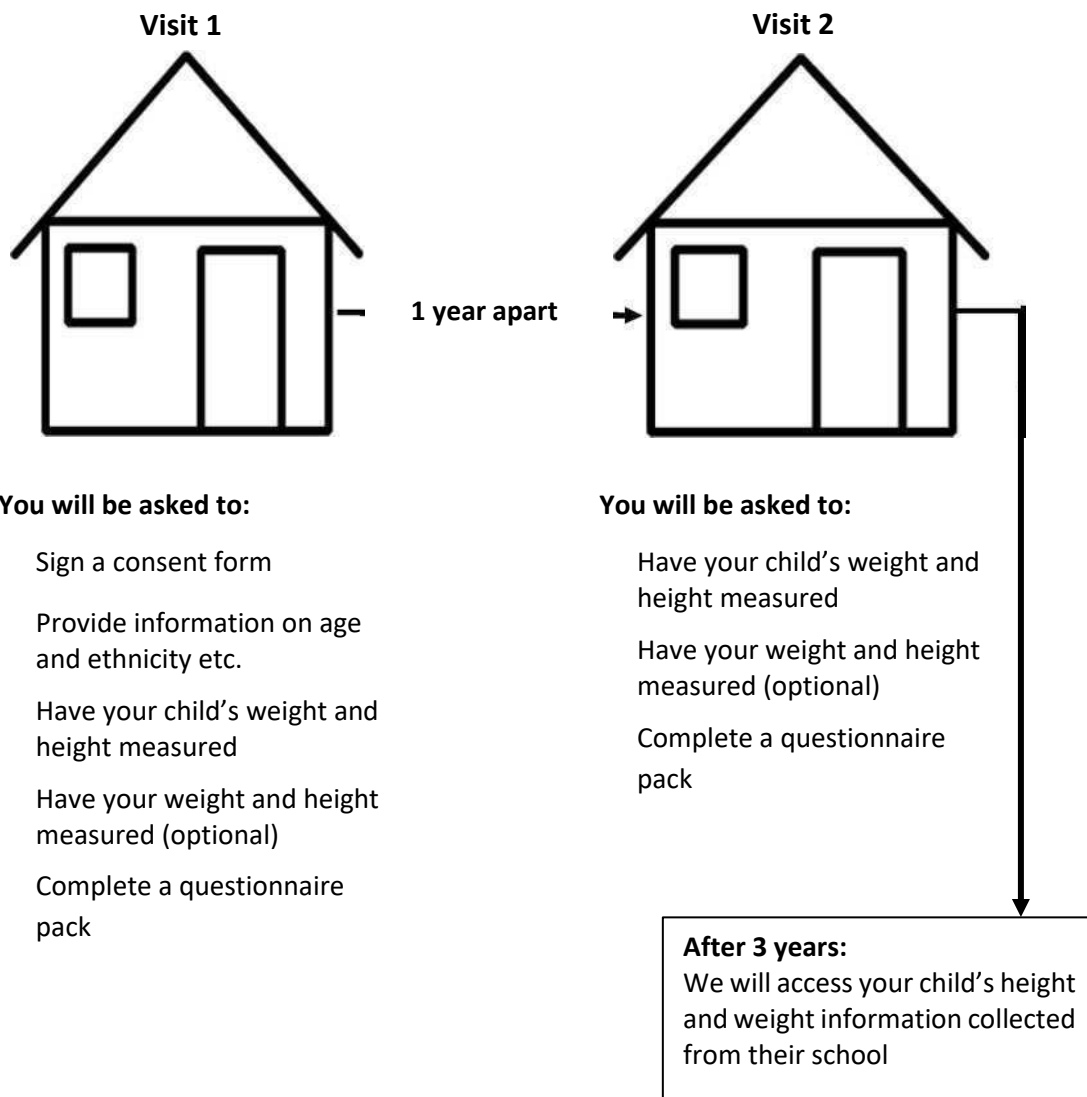
- If you decide to take part, you will be asked to sign a consent form at your children's centre and agree for your contact details to be passed on to a researcher. In England, the researcher will be from your local Regional Research Delivery Network (RRDN), which was previously known as the Clinical Research Network (CRN) so you will see both terms used in the trial documentation. In Northern Ireland, the researcher will be from Queen's University Belfast (QUB)
- A RRDN/QUB researcher will contact you to arrange to meet with you twice at your home, or at your children's centre if you prefer. Once at the start of the trial and then again after 12 months.
- The researcher visits will last approximately 1 hour. It is understandable if there are interruptions during the visit, therefore please do not be concerned if you need to take a break.
- At the first visit, you will be asked to answer some questions about you and your child (e.g. age and ethnicity).

- At both visits your child's height and weight will be measured. This data will be held securely at the University of Leeds and stored for at least five years after the end of the trial.
- We would also like to measure your height, weight and waist circumference, but this is not compulsory. By doing this we can find out if HENRY makes a difference to parents as well as their children.
- You will also be talked through a questionnaire pack relating to your family's eating habits, child's dental habits, and your confidence as a parent. At the follow up visit you will also be asked about your general health. If answering questions around these topics causes you to become upset or distressed the RRDN/QUB researcher may signpost you to local support services that will be able to help you. You can also contact your children's centre for advice on where you can access relevant support.
- If you have been invited to enrol onto a HENRY programme you will attend these sessions during the trial, just like you would attend any other programme which is delivered at your centre. We will also ask you to share data with us on how many sessions you attend but this is not compulsory. If you agree to share your attendance data, it will be anonymised and shared with researchers at University of Sheffield (if taking part in England), Queens University Belfast (if taking part in Northern Ireland) and University of Leeds to support the process evaluation part of the work.

What will happen next?

- After 3 years we will access routinely collected data from your child gathered as part of the National Child Measurement Programme or Child Health System data (collected by your child's school or health visitor).
- We would also like to access height and weight measurements collected for any other children you have, but this is not compulsory. For us to do this you will need to give us permission when you agree to take part in the trial.
- During the trial, we may ask you to take part in a research interview to talk about your experiences of taking part in the trial and (if applicable) your experience of the HENRY programme. Only some people will be asked to be interviewed, and if you are asked, you can say no. Further information and a separate consent form will be provided for the interviews. If you are taking part in England, these interviews will be undertaken by a researcher at University of Sheffield. If you are taking part in Northern Ireland, the interview will be undertaken by a researcher from Queens' University Belfast.
- If you provide an email address when you register for the trial, we will email you to remind you of your 2nd research visit and to keep you updated on the progress of the trial. We will also remind you that we will be accessing your child's height and weight information after 3 years.
- At the end of the trial, if you have provided an email address, we will send you a summary of the trial results so you can find out if HENRY does make a difference to improving family lifestyles. The trial summary will be emailed to you using the email address you provide at the start of the trial. The results of the trial will also be made available through the trial website and social media. You will be informed of how to access the trial website during the trial.

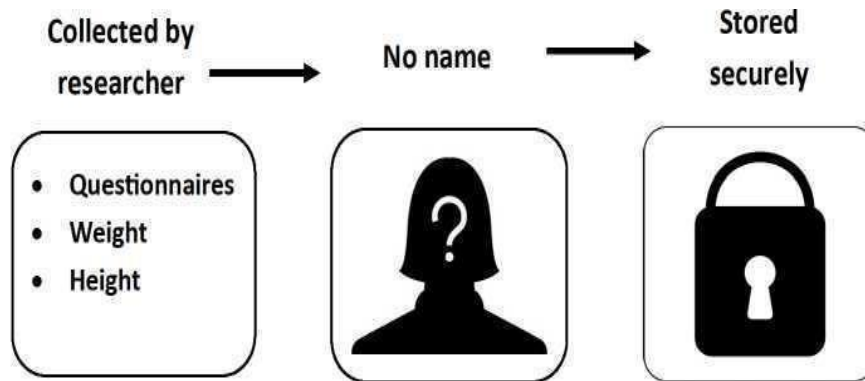
See the diagram on the next page



Will the information collected from me be kept confidential?

- Yes. If you decide to participate in this research project, the research data collected from you will be kept strictly confidential.
- However, if the RRDN/QUB research staff identify something of concern about you or your child(ren)'s health or you disclose anything that they feel puts you, or someone else at risk of harm, they may feel it necessary to report this to the appropriate persons. In these circumstances, the research teams will utilise their own policies and pathways in order to raise any safeguarding concerns.
- You will be allocated a trial number which will be used as a code to identify you on all the forms that we will use to collect the data as well as your data of birth and initials.
- Your signed consent form will also be stored securely and separately to the information you provide so they cannot be matched.
- Only the Clinical Trials Research Unit at the University of Leeds and the RRDN/QUB researchers will be able to identify you from this number.
- All of the information you provide will be securely stored at the Clinical Trials Research Unit at the University of Leeds.
- Your data will be held on paper and electronically under the provisions of the UK GDPR and 2018

Data Protection Act. It will be stored for at least 5 years after the end of the trial and then confidentially destroyed.



What will happen to my contact details?

- The RRDN/QUB researcher who visits your home will have secure access to your name, phone number and email address (if you have one) so you can be contacted during the trial if needed (for example to arrange the second visit).
- This information will be held separately to the research data you provide so that it cannot be matched.
- We may want to contact you about taking part in further research linked to the HENRY trial. If you would be happy for us to do so, your contact details may be shared with other members of the research team.
- Your contact details will not be shared with anyone outside of the research team and will be destroyed immediately after the trial.

What if I do not want to take part?

- You do not have to take part in this trial. If you decide not to, this will not affect your relationship with your children's centre in any way.
- If you decide that you would like to take part, it is important to remember that you will be asked to meet with the RRDN/QUB researcher twice; once at the start of the trial and again 12 months later.

What if I decide to take part and then change my mind?

- If you decide after your first RRDN/QUB researcher visit that you no longer want to take part, you are free to withdraw at any time without giving a reason.
- You will not be asked to provide any more data but the research data already collected from you will remain on file for a minimum of 5 years, and will be included in the final results.

What are the advantages and disadvantages of taking part?

Advantages

- The main advantage of taking part in the research is that you will be helping us to find out if HENRY is effective at supporting parents to provide a healthy lifestyle for their families. This will not help you directly, but it may help other families in the future.
- You will receive £30 in shopping vouchers as a token of gratitude for taking part in the trial, £15 at the first RRDN/QUB researcher visit after they have collected the trial information and measurement data, and £15 after the second data collection visit.

Disadvantages

- We do not expect that there will be any disadvantages in taking part in the trial. However, you will have to give up your time to meet with the RRDN/QUB researcher along with attending HENRY sessions if your centre is delivering the programme. If you attend a centre that is not delivering HENRY, you will be asked not to attend a HENRY programme at a different children's centre during the trial as this may affect our results.

What if there is a problem or something goes wrong?

If you have a concern about any aspect of this trial, you should ask to speak to the researcher who will do his/her best to answer your questions. If you are unhappy about talking to this person, you can contact the research team by emailing HENRY-Trial@leeds.ac.uk. If you wish to formally complain, you can contact someone at University of York (who are in charge of the whole study and independent of the trial: Stephen Holland, (01904) 323253/1 stephen.holland@york.ac.uk).

Who is organising and funding the research?

The Department of Health and Social Care has funded the project through the National Institute for Health Research as it is seen as an important area for research. In Northern Ireland, funding has also been provided by the Health and Social Care Research and Development (HSC R&D) Division of the Public Health Agency. Funding is held by the University of York who will be responsible for the organisation and running of the project.

Who has approved this trial?

This research has been approved by an NHS Research Ethics committee (ref 317992). The University of York is the trial sponsor who holds standard public liability insurance to meet the potential legal liability of the sponsor for harm to participants arising from the management of the research.

How will we use information about you?

We will need to use information from you and your child for this research project.

This information that we collect for the research will include:

- your name and contact details
- your child's sex, date of birth and NHS number
- your child's weight and height measurements collected at trial visits
- information about your child gathered as part of the National Child Measurement Programme or Child Health System data (collected by your child's school or health visitor)

- your height, weight and waist circumference measurements (if you agree)
- height and weight information from your other children collected as part of the national child measurement programme or Child Health System data (if you agree)
- your completed questionnaires

People will use this information only to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the trial, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the trial.

What are your choices about how your information is used?

The Universities of York and Leeds are publicly funded organisations that conduct research to improve health and healthcare services. In legal terms, we are using your information for this research as part of 'a task in the public interest'. The ability to change the data that we have collected, however, is limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at <https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/>
- at <https://ctru.leeds.ac.uk/privacy-cookies/ctru-comprehensive-privacy-guide/>
- by emailing either the University of York or the University of Leeds Data Protection Officer at dataprotection@york.ac.uk or DPO@leeds.ac.uk

What will happen to the results of the trial?

- When the trial is complete, the findings will be written in a report, and we will share with the public.
- Some of the trial data you have provided will be included in our report, but no individual participants will be identified in any of these.
- The trial data may be reused by the research team or researchers in other institutions but will not be used or released in such a way that you or your child could be identified.
- If you would like to obtain a copy of the published results, please let us know.

Data Protection

- The Universities of York and Leeds are the joint data controllers for the information collected for this research, which means that we are responsible for looking after your personal information and using it properly.
- If you are unhappy with the way your personal information has been handled, please contact either the University of York or the University of Leeds' Data Protection Officer who will investigate the matter. If you are not satisfied with our response, you have a right to complain to the Information Commissioner's Office.
- For information on reporting a concern to the Information Commissioner's Office, see www.ico.org.uk/concerns.
- The University of York Data Protection Officer can be contacted at dataprotection@york.ac.uk.
- The University of Leeds Data Protection Officer can be contacted at DPO@leeds.ac.uk.

How to contact us:

If you have a question about this trial, please contact:

HENRY-Trial@leeds.ac.uk