

Summary of key information:

- You are being invited to take part in the E-SEE study, if you would like to take part you will be asked to complete a consent form.
- The study has been set up to look at whether a new programme for parents of very young children has benefits for children's social and emotional development over and above existing services.
- If you take part you will end up in one of two groups. One group will receive an Incredible Years parenting book and possibly a place on an Incredible Years parenting programme. The other group will carry on as normal receiving existing services.
- You cannot choose which group you are in.
- Regardless of which group you are in you will be visited four times over 18-months by a researcher to complete questionnaires.
- As a thank-you for your time at these visits we will give you high-street vouchers to spend on you or your baby.
- We would like your permission to contact you again in the future, after the study has ended, but you can say no to this and still take part.
- You can withdraw from the study at any time without giving a reason.
- If you have any questions or need further information you can call us on the contact details provided.



Enhancing Social Emotional Health and Wellbeing in the Early Years (The E-SEE Project)

Information Sheet for Co-Parents



**Are you a co-parent of a baby less than two months old?
Would you like to take part in a study to shed light on the
best ways to help support families and to give babies the
best possible start in life?**

**If so, you could take part in the Enhancing
Wellbeing (E-SEE) study.**

Please read this information leaflet.

NHS

**National Institute for
Health Research**

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Public Health Research (NIHR PHR) Programme (project number 13/93/10)

Invitation to take part in The E-SEE Project

You are being invited to take part in a research study funded by The Department of Health. The research is being led by The University of York in collaboration with The University of Sheffield and The University of Exeter. This sheet tells you about the research and how you can be involved. Please read it and feel free to discuss it with your family or friends before deciding whether to take part. Please ask us if there is anything that is not clear or if you need more information.

Why are we doing the research?

The E-SEE study aims to find out if a new form of support for parents called the Incredible Years programme has benefits for the wellbeing of parents and their babies. We are interested in finding out whether this new programme is more helpful than services that are already available to families in your area.

The study will look at whether there are benefits for both parents and their babies but we are especially interested in whether the new programme influences the social and emotional aspects of child development - that's why we called it the 'E-SEE' study (Enhancing Social and Emotional health and wellbeing in the Early years).

We hope that findings from the E-SEE study will ensure parents will receive the most appropriate support to give children the best start in life.

Why have I been invited to take part in this research?

We are inviting as many parents as we can who live in your area who have very young children (less than two months old) to take part in the study. You have received this information because you share a parenting role with someone who may be participating in this research.

What would I have to do if I take part in the E-SEE study?

The E-SEE study aims to find out if a new support programme for parents is more helpful to families than existing local services. This is the first time a version of the Incredible Years programme for parents of infants and toddlers has been evaluated in England. To find out if it makes a difference we compare outcomes of those who receive Incredible Years to those who do not.

Who can I contact if I want to discuss the project or have a question?

Please feel free to contact any of the people listed below if you would like to find out more or discuss the E-SEE study:

Nicole Gridley (Trial Co-ordinator): Tel (01904) 328152

Sarah Blower (Trial Manager): Tel (01904) 328107

You can also email Nicole or Sarah at e-see@york.ac.uk

Or, visit our website <http://e-see-trial.org/>

If you have a concern about any part of this study you should ask to speak to the researchers who will do their best to answer your questions.

If they are unable to help you or you wish to make a formal complaint please contact Stephen Holland (Chair of the University of York Department of Health Sciences Ethics Committee): Email: stephen.holland@york.ac.uk

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION AND FOR CONSIDERING TAKING PART IN THE E-SEE STUDY

Anonymised information we have collected about you may be used in the future to support other research studies so that we can learn more about family health and wellbeing and how best to support parents and babies to have a happy and full life. We may also combine anonymous results from this research study with information from other research projects.

What will happen at the end of the study?

You will be involved in the E-SEE study for approximately 18 months. The overall study will take four and a half years to complete. We will not be able to give information on individual results for you and your baby but at the end of the study, a summary report on the findings will be available to all families who have taken part.

We would like to be able to hold your contact details on record so that we can get in touch with you again in the future about this research. We will only do this if you give us your permission.

How do I take part?

If you wish to take part in the study please keep this sheet for future reference. We will ask you to sign a consent form, and will give you a copy as a record of your agreement to be part of our study.

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

You can withdraw from some or all of the study at any time, without giving a reason. Withdrawing from the study will not affect your use of other local services or the Incredible Years programme if you have been offered it. Also, if you are offered a place on the Incredible Years programme but choose not to attend for any reason we would still like to visit you to complete questionnaires. If at any point you do decide to withdraw from the study please contact Nicole Gridley or Sarah Blower using the contact details in the next section. The researcher will ask whether you would like to withdraw from the whole study or just part of it (i.e. just from the Incredible Years programme or the home visits), and whether you are happy for us to retain the information about you we have already collected. We may not be able to destroy information that has already been included in the analysis, or is stored in archived database back-ups.

If you would like to hear more a researcher will meet with you at your home (or somewhere else if you prefer, such as a local children's centre) to give you more information and answer any questions you may have. Once you have had a chance to talk things through with the researcher, and if you are still happy to take part, they will ask you to sign a consent form. You will then be asked to complete a small number of questionnaires. This first visit will take about 40 minutes.

We will get in touch with you 1-2 weeks later to let you know whether you are in the group of families that will be offered Incredible Years or in the group that will carry on as normal with access to existing local services (which at this time does not include Incredible Years). It is important that you understand that you will not be able to choose which group you will be in.

Regardless of which group you are in, we would like to visit you again another three times.

1. We will contact you when your baby is around 4 months old to fill out questionnaires. This visit will last around 30 minutes.
2. We would like visit you again when your baby is nearing their first birthday (11 months old).
3. At the final visit, when your baby is nearly two years old (20 months) we will ask you to fill out some more questionnaires. This visit will take about 45 minutes.

You will be part of the study for around 18 months. All of the families who take part in our study are hugely important to us and we are very grateful for their help. As a thank-you for completing questionnaires regardless if you received the Incredible Years services or regular services, each family will be offered vouchers to spend in high-street shops:

- £10 voucher when you complete the first set of questionnaires
- £15 at the second visit
- £20 at the third visit and
- £25 at the fourth and final visit

What will happen if I am in the group of families that are the offered Incredible Years parenting programme?

If you are in the group that is offered Incredible Years you will receive a copy of the *Incredible Babies Book: A Guide and Journal of your Baby's First Year*. This book was written to help parents understand a baby's physical, social, emotional and language development.

emotional and language development.

Depending on your circumstances and the number of interested families in your area you may also be offered a place in one or both of the following parenting support groups:

The Incredible Parents and Babies programme: this is run by two trained facilitators in a local venue for two hours a week for 10 weeks with small groups of parents and their babies. It includes training in how to make babies feel secure, and understand their physical and language development.

The Incredible Parents and Toddlers programme: this follows a similar format, but is for parents of children aged approximately 1-2 years, and is for two hours a week over 12 weeks. It includes training on encouraging toddlers' language, social, and emotional development. A crèche may be provided for this programme.

If you attend one or more of these group programmes you may also be invited to attend an additional session at the end of the study, when your child is about 20 months old, to help us with our evaluation of the Incredible Years programme. This will last no more than two hours and will involve talking with other parents in a small group, or individually with a researcher. In particular, we would like you to discuss if the programme was useful, the methods used to involve fathers and other co-parents, and your experience of being part of the Incredible Years parenting sessions. This additional session is voluntary and your involvement in the programme will not be affected in any way if you decide not to accept the invitation. If you do take part, the discussion will be audio recorded but anything that you say will be made anonymous so you will not be identified and the recordings will be destroyed at the end of the study period. For your participation you will receive travel, refreshments and a small gift.

What will happen if I am in the group of families that are not offered Incredible Years?

Some families will not be offered Incredible Years and will instead carry on as normal using services available to them locally. The reason for this is because we do not know whether or not this new version of the Incredible Years programme is any more beneficial for parents and babies than these existing services. If you are in the group that does not receive Incredible Years you will still play a very important role in the study and we will be able to compare the benefits of both types of support. We will still visit

you four times to complete questionnaires. Your family will still receive the vouchers as detailed above.

What are the advantages and risks of taking part?

Through taking part in the E-SEE study you may learn new skills and information, which could improve the future health and wellbeing of your child. This research may also help to improve family and children's services for other families like yours both in your area and across the country e.g. the Incredible Years programmes will be available more widely if shown to be effective. You will also have access to the study's findings. We do not believe that there are any risks to you or your family by taking part in this research.

What kind of information will you be collecting about me and my baby?

The questionnaires you complete at each visit will tell us about your child's health and development, your relationship with your baby and your own well-being.

What will happen to the information I provide?

All of the researchers involved in this study have a duty of confidentiality to you and we are not allowed to tell people who are not involved in the research about you and your family. We would only break confidentiality if we believe you and/or your child/ren are at risk of harm.

Data will be managed according to Medical Research Council best research practice guidelines. Your personal contact details (i.e. your name, address, telephone numbers) will be kept separately from the information we collect. Your family will be assigned a code number so that we can do this. All the data we collect will be stored securely with strict access controls (such as locked cabinets or password-protected computers in locked offices). The information/data collected by researchers from the Universities of York and Exeter will be entered onto a central secure database that is managed by the University of Sheffield. Your data can only be accessed by members of the research team who are working on this study at the three Universities involved. You and your baby will not be identified in any reports or publications that we write about this study.

Data from the study will be stored for at least 10 years following completion of the study.