

# Enhancing Social and Emotional Health in the Early Years

<b>Submission date</b> 02/04/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/05/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/06/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Behavioural and mental illness has become a public health crisis. There is a strong link between parent and child wellbeing. Incredible Years (IY) group-based parent programmes aim to promote social and emotional wellbeing in children aged 0 to 12 years. Reliable evidence for IY children aged over 3 years demonstrates increased child social and emotional wellbeing, fewer behavioural difficulties and, importantly, a positive impact on parent wellbeing – a major risk factor for healthy child development. However, few programmes and little evidence exist for the 0 to 2 year age range. So, in this study we aim to investigate whether the IY-Infant and IY-Toddler (0 to 2 years) programmes are effective (and cost-effective) in enhancing child social and emotional wellbeing at 20 months of age compared to usual care.

### Who can participate?

Parents and co-parents of children aged 0 to 2 months.

### What does the study involve?

Before the main study we will conduct an 18-month pilot study across two areas in the UK. The main study will follow this, lasting 30 months and involving four areas of the UK. Participants will be allocated at random either to receive usual care, or to receive access to some part of the Incredible Years programme. All families on the study will be asked to complete surveys and be videoed with their child during visits to their home by researchers. Those allocated to receive a level of the Incredible Years programme will receive different levels/types of the programme depending on their level of need, which will be assessed by completion of a mental health questionnaire. Those allocated to receive Incredible Years will all get an Incredible Years (IY) book, and may be offered either or both of the IY-Infant (8 to 10 weeks; 2 hours per week) and IY-Toddler (12 weeks; 2 hours per week) programmes, depending on the results of the questionnaire. Involvement of families in the study will last 18 months (until the child is 20 months old) and at the last home visit parents and co-parents will be asked to complete the final surveys, including in relation to the child's social and emotional well-being. Linked projects will take place during the pilot study and the main study to consider how best Incredible Years could be offered in the future, and to compare the results of our research with other similar research in the UK and abroad.

What are the possible benefits and risks of participating?

Through taking part in the study the parents and co-parents may benefit from learning new parenting skills, which could in turn improve the future health and wellbeing of their child. This research may also help to improve family and children's services for other similar families both in their area and across the country. This is because the Incredible Years programmes will be available more widely if shown to be effective. We do not believe that there are any risks to families taking part in this study.

Where is the study run from?

University of York (UK)

When is the study starting and how long is it expected to run for?

February 2015 to June 2020

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Sarah Blower (sarah.blower@york.ac.uk)

Dr Tracey Bywater (tracey.bywater@york.ac.uk)

## Contact information

### Type(s)

Public

### Contact name

Dr Sarah Blower

### ORCID ID

<https://orcid.org/0000-0002-9168-9995>

### Contact details

Department of Health Sciences

Seebohm Rowntree Building

University of York

York

United Kingdom

YO10 5DD

+44 (0)1904 328107

sarah.blower@york.ac.uk

### Type(s)

Scientific

### Contact name

Prof Tracey Bywater

### Contact details

Department of Health Sciences

Seebohm Rowntree Building

University of York  
York  
United Kingdom  
YO10 5DD

## **Additional identifiers**

### **Protocol serial number**

N/A

## **Study information**

### **Scientific Title**

Enhancing Social-Emotional health and wellbeing in the Early Years: a community-based randomised controlled trial and economic evaluation of the Incredible Years infant and toddler (0-2) parenting programmes

### **Acronym**

E-SEE (Enhancing Social-Emotional health and wellbeing in the Early years)

### **Study objectives**

The key research question is: are the Incredible Years Book and Infant (IY-I) and Toddler (IY-T) programmes, when delivered in dose proportionate to need and when compared to services as usual (SAU), effective and cost-effective in enhancing child social and emotional wellbeing at 20 months of age?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. University of York Education Ethics Committee, 10/08/2015, ref: FC15/03
2. UK NHS Research Ethics Committee Wales REC 5, 22/05/2015, ref: 15/WA/0178

### **Study design**

Two-phase randomized controlled trial (RCT) comprising an 18-month internal pilot conducted in two research sites and a 30-month pragmatic two-arm RCT conducted in four sites (the original two pilot sites plus two additional sites)

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **Health condition(s) or problem(s) studied**

Children's mental health

### **Interventions**

We plan an 18-month internal pilot randomised controlled trial (RCT) leading to a definitive 30-month RCT. Participants will be randomly allocated to Incredible Years (IY) or service as usual

(SAU) according to level of need based on primary carer depression scores and gender of child and primary carer. Intervention parents will receive an IY-Infant (IY-I) book (universal level) followed by an IY-I programme (8 to 10 weeks; 2 hours/ week) and/or IY-Toddler (12 weeks; 2 hours/ week) dependent on level of need at data collection points 2 and 3. Control parents will receive services as usual.

## **Intervention Type**

Behavioural

### **Primary outcome(s)**

Child Primary Outcome (primary outcome for the study):

Social and emotional wellbeing – to establish effectiveness at each and all Incredible Years dose levels, using parent report Ages & Stages Questionnaire – Social Emotional (ASQ:SE-2) (measured at baseline and 2, 9 and 18 months post-baseline)

Parent Primary Outcome (key secondary outcome for the study):

Depression – to establish effectiveness at each and all Incredible Years dose levels, using the parent report Patient Health Questionnaire (PHQ-9) (measured at baseline and 2, 9, and 18 months post-baseline)

### **Key secondary outcome(s)**

Current secondary outcome measures as of 06/02/2020:

Child Secondary Outcomes:

1. Behaviour – measured at 18-month follow-up using the Strengths and Difficulties Questionnaire (SDQ)
2. Attachment – using the CARE Index (measured at baseline and 2, 9, and 18 months post-baseline)
3. Cognitive development – measured at 18-month follow-up using parent report PedsQL Infant Scale
4. Health (quality of life) – measured at 18-month follow-up using parent report PedsQL Infant Scale
5. Service use – using parent report: Client Service Receipt Inventory (CSRI) (measured at baseline and 2, 9, and 18 months post-baseline)

Parent Secondary Outcomes:

1. Carer-child attachment/interaction – measured at 18-month follow-up using parent report Maternal Postnatal Attachment Scale (MPAS) and/or Paternal Postnatal Attachment Scale (PPAS)
2. Parenting skill – using parent report Parent Sense of Competence (PSOC) (measured at baseline and 2, 9 and 18 months post-baseline)
3. Health Related Quality of Life (HRQoL) – using parent report EQ5D5L (measured at baseline and 2, 9 and 18 months post-baseline)
4. Service use – using parent report CSRI (measured at baseline and 2, 9, and 18 months post-baseline)
5. Demographics – using bespoke parent report demographics form capturing key information on age, ethnicity, religion, income, marital status, parent/co-parent education (measured at baseline and 2, 9 and 18 months post-baseline, with a shorter version used for all appointments except baseline).

Measures for the economic evaluation:

1. Service use – using parent report CSRI (measured at baseline and 2, 9 and 18 months post-baseline)

Measures for the process evaluation:

1. Facilitators' adherence to core components – standard, weekly-completed, self-rated Incredible Years checklists
2. Implementation fidelity – researcher-rated Parent Programme Implementation Checklist (PPIC), which comprises indices for adherence, dose/exposure, quality of delivery and participant responsiveness, observations conducted at a random subset of meetings.
3. Parent/co-parent satisfaction – standard Incredible Years parent satisfaction questionnaires are also completed after each session, and at the end of each programme.
4. Acceptability and feasibility of the intervention - focus groups and semi-structured interviews with key stakeholders including parents and professionals, using developed topic guides, after the programmes have been delivered.

---

Previous secondary outcome measures:

Child Secondary Outcomes:

1. Behaviour – measured at 18-month follow-up using parent report Eyberg Child Behaviour Inventory (ECBI)
2. Attachment – using the CARE Index (measured at baseline and 2, 9, and 18 months post-baseline)
3. Cognitive development – measured at 18-month follow-up using parent report PedsQL Infant Scale
4. Health (quality of life) – measured at 18-month follow-up using parent report PedsQL Infant Scale
5. Service use –using parent report: Client Service Receipt Inventory (CSRI) (measured at baseline and 2, 9, and 18 months post-baseline)

Parent Secondary Outcomes:

1. Carer-child attachment/interaction – measured at 18-month follow-up using parent report Maternal Postnatal Attachment Scale (MPAS) and/or Paternal Postnatal Attachment Scale (PPAS)
2. Parenting skill – using parent report Parent Sense of Competence (PSOC) (measured at baseline and 2, 9 and 18 months post-baseline)
3. Health Related Quality of Life (HRQoL) –using parent report EQ5D5L (measured at baseline and 2, 9 and 18 months post-baseline)
4. Service use – using parent report CSRI (measured at baseline and 2, 9, and 18 months post-baseline)
5. Demographics – using bespoke parent report demographics form capturing key information on age, ethnicity, religion, income, marital status, parent/co-parent education (measured at baseline and 2, 9 and 18 months post-baseline, with a shorter version used for all appointments except baseline).

Measures for the economic evaluation:

1. Service use – using parent report CSRI (measured at baseline and 2, 9 and 18 months post-baseline)

Measures for the process evaluation:

1. Facilitators' adherence to core components – standard, weekly-completed, self-rated Incredible Years checklists
2. Implementation fidelity – researcher-rated Parent Programme Implementation Checklist (PPIC), which comprises indices for adherence, dose/exposure, quality of delivery and participant responsiveness, observations conducted at a random subset of meetings.
3. Parent/co-parent satisfaction – standard Incredible Years parent satisfaction questionnaires are also completed after each session, and at the end of each programme.
4. Acceptability and feasibility of the intervention - focus groups and semi-structured interviews

with key stakeholders including parents and professionals, using developed topic guides, after the programmes have been delivered.

**Completion date**

30/06/2020

## Eligibility

**Key inclusion criteria**

1. Have the main parental responsibility for a child <8 weeks at initial engagement
2. Be willing to participate in the research
3. Be willing to be randomised and, if allocated to intervention, be able to receive Incredible Years services offered
4. Not be enrolled on another group parent programme at sign-up

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

341

**Key exclusion criteria**

1. The child has obvious or diagnosed organic or child developmental difficulties
2. Do not have the main parental responsibility for a child <8 weeks at initial engagement
3. Are not willing to participate in the research
4. Are not willing to be randomised and, if allocated to intervention, to receive Incredible Years services offered
5. Are enrolled on another group parent programme at sign-up

**Date of first enrolment**

05/11/2015

**Date of final enrolment**

05/09/2018

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Lancashire Care NHS Foundation Trust**  
Ingol Health Centre  
Village Green Lane  
Preston  
United Kingdom  
PR2 7DS

**Study participating centre**  
**Blackburn with Darwen Borough Council**  
Children's Services Department  
10 Duke Street  
Blackburn  
United Kingdom  
BB2 1DH

**Study participating centre**  
**Action for Children**  
Care of Whipton Children's Centre  
Hill Lane  
Whipton  
Exeter  
United Kingdom  
EX1 3JP

**Study participating centre**  
**Virgin Care Ltd.**  
Capital Court  
Bittern Road  
Sowton  
Exeter  
United Kingdom  
EX2 7FW

**Study participating centre**  
**Harrogate District Hospital**  
Lancaster Park Road  
Harrogate  
United Kingdom  
HG2 7SX

**Study participating centre**  
**Western Community Hospital**  
William Macleod Way  
Southampton  
United Kingdom  
SO16 4XE

**Study participating centre**  
**Suffolk County Council**  
Endeavour House  
8 Russell Road  
Ipswich  
United Kingdom  
IP1 2BX

**Study participating centre**  
**North Yorkshire County Council Children and Young People's Service**  
County Hall  
Northallerton  
United Kingdom  
DL7 8AD

## **Sponsor information**

**Organisation**  
University of York

**ROR**  
<https://ror.org/04m01e293>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
National Institute for Health Research

## Alternative Name(s)

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

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		04/04/2022	05/04/2022	Yes	No
<a href="#">Results article</a>		01/06/2022	05/06/2024	Yes	No
<a href="#">Protocol article</a>		19/12/2018		Yes	No
<a href="#">Dataset</a>		04/04/2022	05/06/2024	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Interim results article</a>	pilot trial results	12/06/2021	11/05/2022	Yes	No
<a href="#">Other publications</a>	economic evaluation	23/06/2022	24/06/2022	Yes	No
<a href="#">Other publications</a>		30/12/2024	09/06/2025	Yes	No
<a href="#">Plain English results</a>	Video summary of findings		11/05/2022	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes