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Enhancing Social and Emotional Health in the Early Years

Submission date
02/04/2015

Recruitment status
No longer recruiting

Registration date
11/05/2015

Overall study status
Completed

Last Edited
09/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] 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)

Study website
https://www.york.ac.uk/healthsciences/research/public-health/projects/e-see-trial/

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Location-dependant participant information sheets available, please use the contact details to request copies

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 measure
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)

Secondary outcome measures
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.

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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)

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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.

Overall study start date
01/02/2015

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

Age group
Mixed

Sex
Both

Target number of participants
869 parent-child dyads

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
England

United Kingdom

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

Sponsor details
Research Innovation Office
Innovation Centre
York Science Park
Heslington
York
England
United Kingdom
YO10 5DG

Sponsor type
University/education

Website
http://www.york.ac.uk/

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

Publication and dissemination plan
The E-SEE study has developed a publication policy and a core publication group. The publication policy contains guidelines on how to approach authorship and a publication plan.

Intention to publish date
31/12/2021

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?
Protocol article		19/12/2018		Yes	No
Results article		04/04/2022	05/04/2022	Yes	No
Interim results article	pilot trial results	12/06/2021	11/05/2022	Yes	No
Plain English results	Video summary of findings		11/05/2022	No	Yes
Other publications	economic evaluation	23/06/2022	24/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Dataset		04/04/2022	05/06/2024	No	No
Results article		01/06/2022	05/06/2024	Yes	No
Other publications		30/12/2024	09/06/2025	Yes	No