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Effectiveness evaluation of the Incredible Years Toddler programme

Submission date
18/01/2023

Recruitment status
No longer recruiting

Registration date
03/04/2023

Overall study status
Ongoing

Last Edited
28/09/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims

There is evidence to suggest that a poor parent-infant relationship is associated with the ability of a child to regulate their own behaviour. In addition, parent-child attachment and parental sensitivity are important for the development of children's social and emotional competence, cognitive functioning, physical health, and mental health. Children with insecure attachments or experiences of low parental sensitivity are more at risk for negative outcomes in these domains. The Incredible Years (IY) parent programmes (https://incredibleyears.com/) are parent education and training interventions which are informed by social learning theory and designed to enhance the social and emotional wellbeing of children aged 0-12 years. The more recently developed Toddler (IY-T) version, for 1-3-year-olds, is an adapted version of the preschool BASIC programme. Parents learn more effective strategies for dealing with unwanted child behaviour when they have opportunities to practise and perceive themselves as effective in using them. Effective parenting strategies help the child learn how to better manage his or her emotions and behaviour.

IY Toddler has an evidence rating of 2+ by the Early Intervention Foundation (EIF), which means it has evidence of improving a child outcome from a study involving at least 20 participants, representing 60% of the sample, using validated instruments. Previous research suggests that IY Toddler may have positive benefits for children and families. There have been two studies demonstrating immediate positive results. These studies looked at outcomes up to 12 months later. IY-T has relatively little evidence in comparison to the other IY programmes. Further, evaluation is required to understand the longitudinal effects of IY Toddler on child outcomes in England with an ethnically diverse, disadvantaged, population.

IY-T is currently being delivered by Barnardo's in the Better Start Bradford (BSB) programme (https://www.betterstartbradford.org.uk/). Born in Bradford's Better Start (BiBBS) is an interventional birth cohort study that runs in parallel to BSB, and is designed to support the evaluation of the effectiveness of early life interventions. All mothers and children in the BiBBS cohort have in-depth baseline data captured during pregnancy and consent to routine linkage to their health and education records. As a part of the consent to BiBBS, mothers agree to the information about them being used to evaluate interventions.

This study aims to:

1. Establish if IY-T is effective in improving child social and emotional development at age 5 (primary outcome) when compared to services as usual

2. Establish if IY-T is effective in improving children's early years school skills at age 5 (secondary outcome) when compared to services as usual
3. Establish whether the impact of IY-T on the above outcomes is moderated by (a) child age, (b) programme delivery mode (online versus face to face), (c) socioeconomic status, and (d) ethnicity
4. Estimate the cost of the intervention (including delivery and training to deliver Incredible Years)
5. Provide a description of the costs and outcomes in the IY group and where possible a no-intervention comparator

Who can participate?
Parents of children aged between 12 and 36 months who have either enrolled or not enrolled in IY-T. To be eligible for this evaluation, participants must be in the BiBBS cohort. Whilst not all participants that enrol in the intervention will be BiBBS participants, all participants in the analysed intervention and matched comparison group will be BiBBS participants.

What does the study involve?
This study will compare outcomes for BiBBS children whose parents have taken part in IY-T to BiBBS children whose parents have not taken part in IY-T. It will explore the effects of IY-T on children's Early Years Foundation Stage Profiles (EYFSP), and conduct an economic evaluation.

What are the possible benefits and risks of participating?
There are no anticipated additional risks or benefits as all processes are a part of standard midwifery care and all data collection has been undertaken as a part of the existing BiB/BiBBS studies. All study staff are trained in Good Clinical Practice and provide opportunities for signposting to relevant services.

Where is the study run from?
Better Start Bradford, Better Start Bradford Innovation Hub (UK)

When is the study starting and how long is it expected to run for?
September 2018 to August 2028

Who is funding the study?
1. The National Lottery Community Fund (UK)
2. National Institute for Health and Care Research (UK)

Who is the main contact?
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Contact information

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Additional identifiers

Protocol serial number
01

Study information

Scientific Title
Quasi-experimental evaluation of the Incredible Years Toddler programme for improving children's socioemotional development at age 5: a Born in Bradford's Better Start (BiBBS) cohort study

Study objectives
1. Establish if the Incredible Years Toddler programme (IY-T) is effective at improving child social and emotional development at age 5 (primary outcome) when compared to services as usual
2. Establish if IY-T is effective in improving children's early years school skills at age 5 (secondary outcome) when compared to services as usual
3. Establish whether the impact of IY-T on the above outcomes is moderated by (a) child age, (b) programme delivery mode (online versus face to face), (c) socioeconomic status, and (d) ethnicity
4. Estimate the cost of the intervention (including delivery and training to deliver Incredible Years)
5. A description of the costs and outcomes in the IY group and where possible a no-intervention comparator

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/11/2015, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (Room 001, Jarrow Business Centre, Viking Industrial Park Rolling Mill Road, Jarrow, NE32 3DT, UK; +44 (0)207 104 8083, +44 (0)207 104 8210; bradfordleeds.rec@hra.nhs.uk), ref: 15/YH/0455

Primary study design
Interventional

Study design
Quasi-experimental longitudinal study design using an intervention and matched control group in a single centre

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of parental distress resulting in child conduct and behavioural disorder

Interventions
This study will compare outcomes for BiBBS children whose parents have taken part in IY-T to BiBBS children whose parents have not taken part in IY-T. It will explore the effects of IY-T on children's Early Years Foundation Stage Profiles (EYFSP), and conduct an economic evaluation.

Within Incredible Years Toddler (IY-T), parents learn how to help their toddlers feel loved and secure, encourage social and emotional development, and establish strategies for developing routines, handling separation, and managing misbehaviour (The Incredible Years, 2013). Parents /carers receive three promotional contacts prior to the beginning of the group via assertive outreach, consisting of telephone contact and at least one home visit. The initial telephone contact introduces the parents to the project and Group Facilitators and aims to build the participants' confidence in attending. The home visits are intended to create a sense of rapport

between the family and Group Facilitators and alleviate any barriers that families might have in accessing the group such as crèche, language difficulties or concerns about what the group might involve.

For more detail on the content and delivery of the IY-T intervention, please see the online information and materials here: https://incredibleyears.com/programs/.

The IY-T theory of change and logic model developed by Barnardo's states that IY-T will result in improvements in child social and emotional development over the medium and long term. This is thought to translate into children entering school with improved language and communication skills. Following this, children would have better literacy and language throughout school, and better achievement on leaving primary school. This logic model was developed the reflex the local BSB implementation.

The intervention will be delivered in a combination of face-to-face and virtual formats (dependent on lockdown rules in place at the time of the study and participant needs).

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome is the child's Early Years Foundation Stage (EYFS) profile which will be linked to individual BiBBS children through their routine education records. The EYFS profile is completed by teachers for children when they reach age 5 years of age, at the end of their term in reception. It contains 17 Early Learning Goals (ELGs) relating to different areas of learning (Department for Education, 2021). Children are assigned a score of either "Emerging" (not reaching expected levels) or "Expected" (reaching expected levels) for each ELG.

For the primary outcome (child social and emotional development), the researchers will examine only the most relevant ELGs to IY-T. These are the 'communication and language' and 'personal, social, and emotional' development areas, with a total of five goals. The binary responses for each of these six goals will be summed to generate a summary score between 0 and 5.

Key secondary outcome(s)
Child early years development: the binary responses for each of the 17 ELGs will be used to generate a summary score, where a total score between 0 and 17 will indicate how many of all the ELGs were assigned a score of 'expected'. Measured when children reach age 5 years of age.

Completion date
31/08/2028

Eligibility

Key inclusion criteria
Eligibility criteria for the intervention group:
1. Consented to be a part of BiBBS
2. Parent consented to a referral and enrolled in IY-T

Eligibility for the matched comparison group:
1. Consented to be a part of BiBBS
2. Parent of a child aged between 12 and 36 months at any time in the duration of service

delivery (to ensure that matched cases are comparable)
3. Parent has not been referred or enrolled in IY-T at any timepoint

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Participant is not currently enrolled in BiBBS cohort study

Date of first enrolment
01/08/2018

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Better Start Bradford
Bradford
United Kingdom
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Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
National Lottery Community Fund (previously the Big Lottery Fund; Ref 10094849)

Alternative Name(s)
Big Lottery Fund, TNLcommunityfund, TNLComFund, The National Lottery Community Fund

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
National Institute for Health and Care Research (NIHR): Applied Research Collaboration (YHARC)

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
Researchers are encouraged to make use of the BiB data, which are available through a system of managed open access. Before contacting the researchers, please read the Guidance for Collaborators (https://borninbradford.nhs.uk/research/guidance-for-collaborators/). The BiB executive review proposals on a monthly basis and will endeavour to respond to requests as soon as possible. Find out about the different datasets in the Data Dictionary

(https://borninbradford.github.io/datadict/) or contact a member of the BiB team (borninbradford@bthft.nhs.uk). Once you have formulated your request please complete the 'Expression of Interest' form available here (https://borninbradford.nhs.uk/wp-content/uploads/BiB_EoI_v3.1_10.05.21.doc) and send it to borninbradford@bthft.nhs.uk. If the request is approved you will be asked to sign a Data Sharing Contract (https://borninbradford.nhs.uk/wp-content/uploads/BIHR-Data-Sharing-Contract.docx) and a Data Sharing Agreement (https://borninbradford.nhs.uk/wp-content/uploads/BIHR-Data-Sharing-Agreement.docx), and if the request involves biological samples you will need to complete a material transfer agreement (https://borninbradford.nhs.uk/wp-content/uploads/BiB-Material-Transfer-Agreement-v4-0.docx).

Born in Bradford (BiB) is a longitudinal research project. The aim of BiB is to work out why some people have good health or well-being, while others have difficulties. To do this, BiB collects information from participants about all aspects of their lives at different ages using surveys, research clinics and other assessments. BiB also gathers information about families from other sources, such as health records, or environmental records. BiB processes the data to make sure it is accurate, well organised, and to make it so that no person can be identified from the data. BiB then shares this processed data with scientists conducting research with potential public benefit. These scientists can be based anywhere in the world. The data that is available to be shared can be seen here: https://borninbradford.github.io/datadict/bibbs/

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/09/2023	28/09/2023	Yes	No
HRA research summary			28/06/2023	No	No