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Testing the feasibility of applying a 'trial within a cohort study' (TWiCS) to evaluate a programme for parents of toddlers

Submission date
27/04/2023

Recruitment status
No longer recruiting

Registration date
12/05/2023

Overall study status
Completed

Last Edited
30/12/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Born in Bradford's Better Start (BiBBS) is an interventional birth cohort study that runs in parallel to Better Start Bradford (https://www.betterstartbradford.org.uk/), and is designed to support the evaluation of the effectiveness of early life interventions. The Incredible Years programme (IY) is offered via Better Start Bradford to parents of 1–3-year-olds. BiBBS provides an opportunity to test a Trial Within a Cohort Study (TwiCS) evaluation of IY, where a randomised trial is nested within an observational cohort. Individuals are randomly selected to be offered an intervention and their outcomes are compared to those not selected. The staged information and consent process is person-centred and aims to replicate real-world practice where only those who have access to the intervention being trialled are given information about the intervention. The TwiCS design has shown enormous potential for the conduct of pragmatic trials in other settings but has not yet been applied to an birth cohort to test the effectiveness of a parenting intervention.
A feasibility study is necessary due to key uncertainties about the evaluation design. First, the BiBBS cohort is managed by the BiBBS team within the Bradford Institute for Health Research, and they need to obtain consent from parents for a referral to IY-T because IY-T is delivered by an external organisation. This introduces an 'extra step' which has not yet been tested in this cohort nor with this intervention, as the BiBBS team does not usually offer intervention referrals, and IY-T usually receive their referrals from their work with the local community. Second, due to the timing of recruitment and the timing of the intervention (where participants are eligible when they have a child aged 12-36 months old), participants will be contacted between 12-36 months after they have enrolled in the BiBBS cohort. This introduces uncertainty about the rate of intervention take-up since most participants will only have heard from the BiBBS project via annual birthday cards/newsletters. Third, contamination (where participants who are allocated to the control group receive the intervention) may occur in this study since IY-T will still receive their usual referrals during the implementation of the TWiCS, however, the level at which this may occur has not yet been measured and remains unknown. Finally, previous studies of parenting programmes have suffered from poor take up and attendance of the intervention, particularly for parents in disadvantaged areas and parents with a higher level of need. This study therefore needs to test the rates of participation and completion of the

intervention to inform the feasibility of a larger evaluation, particularly in a disadvantaged setting.
This is a feasibility study testing the application of a TWiCS design for offering the IY intervention through the BiBBS cohort. The specific objectives of this feasibility study are:
1. To establish whether TWiCS methodology can be implemented to create a control and intervention group, while documenting any incidences of contamination
2. To establish whether satisfactory rates of conversion of randomised participants into intervention participants can be achieved
3. To establish whether satisfactory rates of retention of randomised participants in the intervention can be achieved

Who can participate?
Parents of children aged between 12 and 36 months, who are enrolled in the BiBBS cohort.

What does the study involve?
The researchers will conduct a small-scale feasibility TwiCS to pilot study procedures. This involves identifying an eligible population within BiBBS, randomly selecting and contacting participants to be offered IY, seeking consent to pass contact details onto IY, and monitoring the take-up and engagement of IY. A control population will also be randomly allocated within BiBBS, but no data will be collected from this group of participants.

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. BiBBS participants consented to be randomly allocated to interventions when they enrolled in the cohort. All study staff are trained in Good Clinical Practice and provide opportunities for signposting to relevant services. The IY team will not alter their delivery in any way.

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?
October 2022 to December 2023

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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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
01

Study information

Scientific Title
A feasibility ‘trial within a cohort study’ (TWiCS) of the 'Incredible Years Toddler' parenting programme: a Born in Bradford’s Better Start cohort sub-study

Study objectives
This study aims to establish whether it is feasible to conduct a TWiCs evaluation of a parenting programme for parents of toddlers initially recruited during pregnancy into the Born in Bradford’ s Better Start (BiBBS) birth cohort.
The specific objectives address key uncertainties and are as follows:
1. To establish whether TWiCS methodology can be implemented to create a control and intervention group, while documenting any incidences of contamination
2. To establish whether satisfactory rates of conversion of randomised participants into intervention participants can be achieved
3. To establish whether satisfactory rates of retention of randomised participants in the intervention can be achieved

Ethics approval required
Old ethics approval format

Ethics approval(s)
The protocol for BiBBS recruitment and collection of routine outcome data was approved by Bradford Leeds NHS Research Ethics Committee (15/YH/0455). The protocol for the current sub-study has been submitted to Bradford Leeds NHS Research Ethics Committee as an amendment to the existing BiBBS protocol.

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

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

Interventions
This study will assess the feasibility of a Trial Within a Cohort Study (TWiCS) evaluation of the Incredible Years Toddler (IY-T) programme using BiBBS cohort participants.

Eligible participants in the BiBBS cohort will be individually randomised 1:1 to the intervention (n = 120) or control group (n = 120), using blocked randomisation with stratification by child age (1 year or 2 years at the time of randomisation) and ethnicity (White British, South Asian, or other). The six allocation sequences (one for each stratum) will be generated using Stata/SE v17.0 (for Windows 64-bit x86-64) or later, using the user-written Stata command ralloc.

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). The total duration of the intervention is 13 weeks. The duration of follow-up in this study is until the end of the intervention period, so is 13 weeks post intervention enrolment.

Intervention Type
Behavioural

Primary outcome(s)
The primary outcomes are feasibility outcome targets which will all be measured after recruitment and the intervention have completed. Please note that an 'enrollee' is referred and seen face to face in at least one pre-course contact, a 'participant' is someone who attends at least 1 week of the groups, and a 'completer' is someone that attends at least 8 of the 13 group-based sessions. A RAG rating/traffic light system has been applied to support the feasibility assessment of each objective: to be rated as green (achieved), amber (partly achieved) and red (not achieved). For an objective to be achieved and rated green, it must reach the percentage level specified above (e.g. 70% for contactable women, 50% for converting randomised participants into referrals). The levels at which we reach amber are equal to the green target, minus 20%. This is with the exception of the rate for contamination (outcome 2), where the rates are set on achieving less than 1% contamination. The outcomes are:

1. Feasibility of randomisation pathways (intervention): Successfully contact 70% of participants who were randomised to the intervention
2. Describe any incidences of contamination: Describe any incidences of contamination between

the control and intervention allocations, and successfully create intervention and control participants with minimal contamination (<1% crossover across both groups)
3. Retention to intervention (referral consent): Convert 50% of contactable parents into referrals into Incredible Years
4. Retention to intervention (enrolees): Convert at least 50% of the participants who accept the randomised referral into enrollees in Incredible Years
5. Retention to intervention (participants): Convert at least 90% of the participants who enrol in Incredible Years into participants
6. Retention to intervention (completers): Convert at least 60% of the participants who enrol in Incredible Years into completers in Incredible Years

All outcomes will be recorded up until the end of December 2023

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Pregnant mothers are eligible for recruitment to BiBBS if they are living in the BSB area and are registered to give birth at Bradford Teaching Hospital NHS Foundation Trust (BTHFT) (see Dickerson et al., 2016 for further details).
For this feasibility TWiCs of IY-T, caregivers will be eligible if they:
1. Provided consent to BiBBS cohort study and agreed to be contacted for future research
2. Have not withdrawn consent to the BiBBS cohort at the time of randomisation
3. Are still living in the BSB area at the time of randomisation
4. Have one or more BIBBS child(ren) aged between 12 and 36 months at the time of randomisation
5. NHS tracing confirms that their child is still living with them, and is alive
6. Have not already received IY-T in the BSB area for any of their children

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
37

Key exclusion criteria

Not currently enrolled in the BiBBS cohort study

Date of first enrolment
01/06/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Better Start Bradford
Bradford
United Kingdom
BD5 9NP

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Charity

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		30/01/2024	31/01/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (preprint)		05/09/2023	26/09/2023	No	No