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A parenting course to reduce behavioural difficulties and improve the quality of life for families of those diagnosed with fetal alcohol spectrum disorders

Submission date
30/07/2022

Registration date
27/09/2022

Last Edited
19/02/2025

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Fetal alcohol spectrum disorder (FASD) is caused by drinking alcohol during pregnancy. Children with FASD have damage to the brain for the rest of their life. It makes it difficult to communicate, keep friendships, and stay calm and still, among other difficulties. They are more likely to be excluded from school. As grownups, they might suffer from mental ill-health, or get in trouble with the law. New research shows FASD is very common, affecting 2- 4% of children. This makes it more common than autism, but it is underdiagnosed. When a child gets diagnosed with FASD, the parents need help. A parenting course might help, but there is no course specifically for FASD. This makes it difficult for doctors to know what to recommend. Recently, the Department of Health and Social Care said we need “innovative approaches” to support those with FASD. The new National Institute for Health and Clinical Excellence (NICE) Quality Standard on FASD says each child should have a plan that “signposts to resources and services”. Our project fills these needs.

This research aims to test a new parenting course, called SPECIFIC. Experts including parents of people with FASD, charities and clinicians and academics helped us to develop SPECIFIC. We also trained nine families using SPECIFIC. These families helped us to make it better. Families will continue to be involved by helping us to run the project and analyse the data. The hope is that eventually the NHS and charities will be able to deliver the course to thousands of families. Firstly, a smaller test study needs to run called a feasibility test. This will tell us whether it is worth doing a bigger test, called a randomised control trial. This small-scale test will show whether it is easy to get parents to join and complete the programme and if it appears to improve the lives of families.

Who can participate?
Parents of children with FASD

What does the study involve?
SPECIFIC is a seven-week course where families meet online each week. There are two facilitators, one is a trainer and the other is an FASD-experienced parent. We will test SPECIFIC on ten groups of six families and compare findings with families that have not had the course. The families that have not had the course are called a 'control group'. After the course, we will measure the parents' stress levels and their parenting confidence. As soon as we have done the comparison, the control group will also get the training course.

What are the possible benefits and risks of participating?
There are possible benefits to participating because the programme is designed to improve the lives of children with FASD and their families, both in the short and long term. It is possible that by taking part in the programme a parent can learn more about the most effective ways to care for children with FASD. The possible risks relate to the fact that some of the issues discussed are potentially upsetting; however, the programme is designed to have a positive focus.

Where is the study run from?
University of Salford (United Kingdom)

When is the study starting and how long is it expected to run for?
July 2021 to October 2024

Who is funding the study?
1. National Institute for Health and Care Research Research for Patient Benefit (NIHR RfPB) programme (United Kingdom)
2. The Oglesby Charitable Trust (United Kingdom)

Who is the main contact?
1. Prof Penny Cook (Co-principal investigator) (United Kingdom)
p.a.cook@salford.ac.uk
2. Prof Raja Mukherjee (Co-principal investigator) (United Kingdom)

Study website
https://hub.salford.ac.uk/fasd/specific/

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319297

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR203536, IRAS 319297, CPMS 53960

Study information

Scientific Title
Parenting course for parents of children with fetal alcohol spectrum disorders (FASD) versus waitlist: a randomised controlled feasibility study of the SPECIFiC (Salford Parents and carers' Education Course for Improvements in Fasd outcomes In Children) Programme

Acronym
SPECIFiC

Study objectives
Parenting interventions reduce behavioural difficulties and improve the quality of life for families of those diagnosed with FASD

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 14/07/2022, University of Salford School of Health and Society Ethical Approval Panel (Salford Crescent, Salford, M5 4WT, United Kingdom; +44(0)161 295 4109; ethics@salford.ac.uk), ref: 6895
2. Approved 07/11/2022, North West – Greater Manchester (GM) East, (Research Ethics Committee, 3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)2071048009, +44 (0)2071048206, +44 (0)2071048199; gmeast.rec@hra.nhs.uk), ref: 22/NW/0287

Study design
Multicentre interventional double-blind randomized controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Stress reduction in families diagnosed with fetal alcohol spectrum disorder

Interventions
Families will be randomised 1:1 into the intervention or control arm. The intervention arm is SPECIFIC, a seven-week course where families meet online each week for 2.5 hours per week. Families will be trained in groups of 6 families. There are two facilitators, one is a trainer and the other is an FASD-experienced parent. All materials and information in the intervention are contained in a manual. The primary outcome measure for efficacy (Parenting Stress Index, PSI) will be used to compare the SPECIFIC arm against treatment as usual at 16 weeks, after which the control arm will receive the intervention.

Intervention Type
Behavioural

Primary outcome measure

Primary outcomes for this feasibility study:
1. Percentage of eligible parents invited who agree to participate measured using Clinic Registers at -4 and 0 weeks
2. Percentage of those participating who complete the study measured using intervention register at 0, 8 and 16 weeks

Primary efficacy outcome (proof-of-concept):
1. Parent stress measured using the Parenting Stress Index 4th edition Short Form (PSI-4-SF) at 0, 8 and 16 weeks

Secondary outcome measures
1. Children's behavioural difficulties measured using SDQ Strengths and Difficulties Questionnaire at 0, 8 and 16 weeks
2. Children's behavioural difficulties measured using ECBI Eyberg Child Behaviour Inventor at 0, 8 and 16 weeks
3. Parents' psychological wellbeing measured using CORE-OM The Clinical Outcomes in Routine Evaluation–Outcome Measure at 0, 8 and 16 weeks
4. Parenting self-efficacy measured using TOPSE Tool to measure Parenting Self-Efficacy at 0, 8 and 16 weeks
5. Parent's health-related quality of life measured using EQ-5D-5L Tool at 0, 8 and 16 weeks
6. Parent and Child health and social care service use measured using CSRI Client Service Receipt Inventory at 0, 8 and 16 weeks
7. Parent satisfaction ratings measured using the Session Evaluation Form at each session, i.e. at 1, 2, 3, 4, 5, 6 and 7 weeks
8. Parent knowledge measured using FASD Knowledge Questionnaire at 0, 8 and 16 weeks
8. Acceptability (qualitative) measured using qualitative interviews at 16 weeks (subsample)

Overall study start date
11/07/2021

Completion date
01/10/2024

Eligibility

Key inclusion criteria
For the index child:
1. Aged 5 to 12 years old (school years 1 to 7)
2. Diagnosis in line with internationally agreed criteria for FASD
3. Diagnosed within the previous 3 years

For parents:
1. Able to commit to the whole seven sessions
2. Willing to wait for intervention if required

Participant type(s)
Patient, Carer

Age group
Adult

Lower age limit
5 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
120

Total final enrolment
129

Key exclusion criteria
For parents:
1. Ever previously undergone specialist parenting training for FASD
2. Presence of acute safeguarding issues or concerns

Date of first enrolment
01/10/2022

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
FASD National Clinic
Gatton Place
St Matthews Road
Redhill
United Kingdom
RH1 1TA

Study participating centre
University of Salford Frederick Road Campus
University of Salford
Allerton Building
Frederick Road Campus
Salford

United Kingdom
M6 6PU

Study participating centre
FASD Hub Scotland
Adoption UK
Units 11 and 12
Vantage Business Park
Bloxham Road
Banbury
Banbury
United Kingdom
OX16 9UX

Sponsor information

Organisation
Surrey and Borders Partnership NHS Foundation Trust

Sponsor details
Two Bridges
Guildford Street
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United Kingdom
KT16 9AU
+44 (0)1372216584
olga.balazikova@sabp.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.sabp.nhs.uk/research

ROR
https://ror.org/00f83h470

Funder(s)

Funder type
Government

Funder Name
The Oglesby Charitable Trust

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We intend to produce the following outputs:
1. Short film about SPECIFIC and a project website (month 13)
2. Final project report/ papers (within a year of the end of the Trial)
3. Grant application for definitive trial (month 24)

If found to be effective, SPECIFIC will have a substantial impact on families affected by FASD, and our priority is, therefore, to maximise dissemination and ensure that stakeholders are in place to deliver the intervention. We will:
1. Present findings at national and international conferences
2. Planned publication in high-impact peer-reviewed journals
3. Develop a protocol for full trial (target: NIHR HTA scheme to test effectiveness and cost-effectiveness)
4. Disseminate through the team's and stakeholders' networks and social media
5. Create a dedicated project website, including the creation of a short film to bring SPECIFIC to life
6. Make use of our links to groups such as national and local charities, governmental bodies such as the FASD All-Party Parliamentary Group, and the Scottish Fetal Alcohol Advisory and Support Team
7. Develop local and regional training packages, supported by FASD charities
8. Work with our Lived Experience Advisory Panel to further develop engagement activities

Intention to publish date
31/08/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon reasonable request from the Chief Investigator Professor Penny A. Cook (p.a.cook@salford.ac.uk). Data will be quantitative (demographic and outcome variables, process measures) and qualitative (transcripts from interviews). Data will become available one year after the trial end date. Consent from participants was obtained using the statement "I understand that my anonymised data will be kept indefinitely and archived at the University of Salford in order to make them available to other researchers".

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 4	01/04/2024	14/08/2024	No	No
Statistical Analysis Plan	version 2.0	20/11/2024	19/02/2025	No	No