ISRCTN16523503 https://doi.org/10.1186/ISRCTN16523503

OPTIMA: A randomised controlled trial to evaluate a digital intervention (STEPS) designed to provide parenting support during the wait for child and adolescent mental health service assessment

Submission date
12/11/2021

Recruitment status
No longer recruiting

Registration date
18/11/2021

Overall study status
Completed

Last Edited
20/02/2025

Condition category
Mental and Behavioural Disorders

[X] 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
Around 4% of UK children have high levels of hyperactivity/impulsivity and inattention - 90% of whom also display difficult-to-manage behaviour known as conduct problems. This can stress parents, lower their self-esteem, and negatively impact family life.
The National Institute for Health and Care Excellence recommends that parents of children with these kinds of problems get support as soon as possible after they seek professional help. However, clinical services are overstretched, and traditional in-person parent training is expensive, families often wait very long to receive this vital input.
To address this, we have created a digital parent training course - Structured E-Parenting Support (STEPS). It is delivered as a mobile app and provides low-cost support that can be easily accessed at parents' convenience. This study aims to test if STEPS helps parents reduce children's conduct problems during the difficult waiting period for clinical assessment.

Who can participate?
Parents of children, who have recently been accepted onto a waitlist by children's health services (from both NHS and non-NHS organisations), and who have high levels of hyperactivity /impulsivity, inattention, and conduct problems.

What does the study involve?
Participants will be randomly allocated to receive will receive STEPS for three months or continue waiting for a clinical assessment. Parents will also complete questionnaires about their child's behaviour and attention and about parenting – this will be done five times over 12 months; parents and children will also complete a joint online drawing task. We will test whether STEPS helps parents manage and reduce their children's conduct problems and whether the app is good value for money. We will also look at the effects of STEPS on parenting, including parenting-related strain, and parent-child relationship and check for any unexpected negative

effects of STEPS. Finally, we will interview clinicians to better understand whether using STEPS during waitlist period is helpful and of use to the services.

What are the possible benefits and risks of participating?
We hope that STEPS will help parents to become more confident and effective in managing their children's difficult behaviour. The app is designed to be particularly helpful for the parents of children who are temperamentally more difficult to manage, such as those with attentional and impulse control problems. There is a small possibility that completing online questionnaires or using the STEPS app may result in parents having new concerns about their children's behaviour, their relationship with their children or even how they manage as a parent.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
March 2020 to September 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Prof Edmund Sonuga-Barke, Edmund.sonuga-barke@kcl.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
303121

Protocol serial number
CPMS 50901, RP-PG-0618-20003, IRAS 303121

Study information

Scientific Title
Online Parent Training for the Initial Management of ADHD Referrals: A two-arm parallel randomised controlled trial of a digital parenting intervention implemented on a treatment waitlist

Acronym
OPTIMA RCT

Study objectives
STEPS will lead to improvements in children's behaviour as reported by parents in the short term (3 months post-randomisation) and these effects will persist over a 12-month follow-up period. These improvements will be accompanied by improved parenting, an increase in child-parent closeness, and reductions in parenting-related strain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/11/2021, North West - Liverpool Central Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8118; liverpoolcentral.rec@hra.nhs.uk), ref: 21/NW/0319

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Children's behaviour problems

Interventions
Participants (n=352) will be randomised to either the intervention or the wait-as-usual group using online randomisation system provided by Sealed Envelope. Measure will be taken at baseline (T1), scheduled within one month before randomisation and then at three months (T2), six months (T3), nine months (T4) and 12 months (T5) post-randomisation.

Intervention:
Structured E-Parenting Support (STEPS) is a parenting intervention delivered as a digital

application. It can be accessed through a smartphone at any time and place. STEPS is inspired by the New Forest Parenting Programme, a face-to-face parent training intervention. Its content has been shaped by the latest research about parenting and child behaviour as well as many years of clinical experience. Users can move through the content, organised as eight modules (steps), at their own pace – it usually takes about 20 minutes to complete a module in one go. STEPS is an unguided intervention, which means there is no personal clinical support for parents using the app. The content is delivered mainly using short videos and audio clips supplemented with downloadable text resources. Participants in the treatment arm will have access to the STEPS app for 3 months.

Comparator (Wait As Usual; WAU):
Those randomised to WAU will receive STEPS (for 3 months) after they have completed the 12-month follow-up. In the sites across our trial centres, we do not expect any patients to receive their clinical assessment and initiate treatment within the first three months of randomisation (T2) or few - if any - patients to engage in self-initiated treatment during this period. Parents will not be stopped from initiating their own access to services over the 12 months of the trial.

Intervention Type
Behavioural

Primary outcome(s)
Parent-reported mean child behaviour problems measured with the eight-item ODD subscale of the Swanson Nolan and Pelham Rating Scale at 3 months post randomisation

Key secondary outcome(s))
Current secondary outcome measures as of 12/09/2022:
1. Mean parent-rated child hyperactivity/impulsivity and inattention measured using the respective subscale of the Swanson, Nolan, and Pelham Rating Scale – the MTA version measured at baseline, 3 months and 12 months post-randomisation
2. Parenting style measured with the laxness and overactivity subscales of The O'Leary Parenting Scale measured at baseline, 3 months and 12 months post-randomisation
3. Parenting satisfaction and efficacy measured using the Parental Sense of Competence scale measured at baseline, 3 months and 12 months post-randomisation
4. Parenting-related strain measured using the Caregiver Strain Questionnaire measured at baseline, 3 months and 12 months post-randomisation
5. Child-parent closeness measured with a subscale from the Child-Parent Relationship Scale measured at baseline, 3 months and 12 months post-randomisation
6. Children's and parents' health-related quality of life. The former will be measured with the Child Health Utility measure (CHU9D) and the latter with the EQ-5D-5L. Measures will be taken at baseline, 3, 6, 9 and 12 months post-randomisation

Exploratory outcomes:
1. Mean rating of child oppositional and defiant speech during an online parent-child drawing task, Etch-a-Sketch Online, measured with independent observer ratings on Childhood Oppositional and Defiance Speech Sample Scale at baseline, 3 months and 12 months post-randomisation
2. Mean parent-rated child emotional problems measured with the respective subscale of the Strengths and Difficulties Questionnaire at baseline, 3 months and 12 months post-randomisation
3. 3. Whether children had received a diagnosis/been prescribed medication extracted from medical records at 12 months follow-up

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Previous secondary outcome measures:
1. Mean parent-rated child hyperactivity/impulsivity and inattention measured using the respective subscale of the Swanson, Nolan, and Pelham Rating Scale – the MTA version measured at baseline, 3 months and 12 months post-randomisation.
2. Mean child behaviour problems during an online drawing task measured using a rating provided by an independent observer using the Child Oppositional and Defiance Speech Sample Scale measured at baseline, 3 months and 12 months post-randomisation.
3. Parenting style measured with the laxness and overactivity subscales of The O'Leary Parenting Scale measured at baseline, 3 months and 12 months post-randomisation.
4. Parenting satisfaction and efficacy measured using the Parental Sense of Competence scale measured at baseline, 3 months and 12 months post-randomisation.
5. Parenting-related strain measured using the Caregiver Strain Questionnaire measured at baseline, 3 months and 12 months post-randomisation.
6. Child-parent closeness measured with a subscale from the Child-Parent Relationship Scale measured at baseline, 3 months and 12 months post-randomisation.
7. Children's and parents' health-related quality of life. The former will be measured with the Child Health Utility measure (CHU9D) and the latter with the EQ-5D-5L. Measures will be taken at baseline, 3, 6, 9 and 12 months post-randomisation.
8. Whether children had received a diagnosis/been prescribed medication by 12 months follow up. Information will be extracted from medical records 12 months post-randomisation.

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Parents of all new referrals of children aged 5 years 0 months to 11 years and 11 months that have been accepted onto the assessment waiting list and the referred child (optional). A 'new referral' is defined as a child who has been on a waiting list for assessment for no longer than nine calendar months.
2. Parents aged 18 years or older: confirmed through screening.
3. Child scored > = 8/10 on the hyperactivity/inattention and >= 4/10 on the conduct problems subscale of the SDQ, established through screening medical records. These cut-offs identify the top 10% of the population.
4. English language competence: parent confirms through screening.
5. Access to a STEPS compatible mobile device (iOS 9.0 or later; Android 4.1 or later) with access to the internet (i.e., mobile internet or wi-fi).; parent confirms through screening.

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Total final enrolment
352

Key exclusion criteria
1. Child living under local authority care; confirmed through screening medical records.
2. Child completed clinical assessment; confirmed through screening medical records and discussion with parents (e.g., in case of privately obtained diagnosis/treatment).
3. Child started a pharmacological or non-pharmacological treatment for ADHD; confirmed through screening medical records.

If two children from the same family are referred during the trial at the same time and both meet inclusion criteria, then only the older of the two will be included. If they are referred at different times the first child will be included.

Date of first enrolment
09/05/2022

Date of final enrolment
26/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bethlem Royal Hospital
South London and Maudsley NHS Foundation Trust
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

Study participating centre
Solent NHS Trust
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Study participating centre
Black Country Partnership NHS Foundation Trust
Delta Point
Greets Green Road
West Bromwich
United Kingdom
B70 9PL

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
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RM13 8GQ

Study participating centre
Nottingham City Council
Southchurch Drive
Nottingham
United Kingdom
NG11 8AB

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
National Institute for Health Research (NIHR) (UK)

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 current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/12/2022	13/12/2022	Yes	No
HRA research summary			28/06/2023	No	No
Protocol (other)	Process evaluation protocol	17/05/2024	20/05/2024	No	No
Protocol file	version 2.2	01/07/2022	12/09/2022	No	No
Protocol file	version 2.7	01/07/2023	28/11/2023	No	No
Protocol file	version 2.10	02/12/2024	20/02/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes