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A protocol for the process evaluation of a Structured E-parenting Support (STEPS) in the OPTIMA randomised controlled trial.

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A protocol for the process evaluation of a Structured E-parenting Support (STEPS) in the OPTIMA randomised controlled trial.

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A protocol for the process evaluation of a Structured E-parenting Support (STEPS) in the OPTIMA randomised controlled trial.

Abstract

Introduction: *Structured E-parenting Support* (STEPS) is a digital application (app) designed to help parents manage behaviour of their children who are referred to mental health services and are waiting for an assessment or treatment. STEPS is currently being evaluated in The Online Parent Training for the Initial Management of ADHD (OPTIMA) randomized controlled trial. Alongside the examination of STEPS' clinical and cost-effectiveness, we are conducting a process evaluation to better understand the contextual factors that may influence study outcomes. The purpose of this protocol is to describe the aims, objectives and methodology of the process evaluation prior to it taking place to add to the fidelity and rigour of the trial process and outcomes. Our goal is to adapt STEPS to optimise its benefits in future applications. **Methods:** In line with the Medical Research Council guidelines for evaluating complex interventions, the process evaluation will adopt a mixed method design using qualitative data collected from clinicians and parent interviews and app usage data from participants assigned to the intervention arm. **Analysis:** Qualitative data from semi-structured interviews and free text box responses included in trial questionnaires will be analysed thematically using framework analysis to better understand how parents use STEPS, how it works and key factors that could aid or hinder its effective implementation in routine clinical practice. **Ethics:** The application for ethical approval for the study was submitted to the North West - Liverpool Central Research Ethics Committee and received a favourable opinion on further information on 26 November 2021, reference number 21/NW/0319. **Dissemination:** The process evaluation aims to explore how a digital app might support parents in managing their child's behaviour. Implications for policy and research will be explored and the clinical implications of offering the app to a wider audience to address the lack of support to parents as highlighted in this paper. We plan to publish findings in international, peer-reviewed journals as well as present at conferences.

Trial registration: The trial has been prospectively registered on 18 November 2021; ISRCTN 8 16523503. https://www.isrctn.com/ISRCTN16523503.

Keywords: Process evaluation, ADHD, Conduct problems, Randomized Controlled Trial, Digital health, Parenting intervention

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Strengths and Limitations of this study

- Framework analysis allows for in-depth data analysis using a rigorous and transparent methodology.
- Outcomes for quantitative data such as app usage metrics will be integrated with qualitative findings.
- Inclusion of members from the OPTIMA patient and public involvement panel to advise on best practice in working with participants as well as assisting in data analysis and interpretation of the study results.
- All eligible participants were invited to partake in interviews, including those who did not complete all timepoints and those who did not download or use the app, to further understand barriers to uptake and usage of the STEPS app.
- A potential limitation of this study is the crossover of team members working on both the RCT and the process evaluation which may influence the interpretation of the qualitative data.

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INTRODUCTION

Attention-deficit/hyperactivity disorder (ADHD) is a common neuro-developmental condition characterised by symptoms of inattention and/or impulsivity-hyperactivity (1). Children referred for ADHD assessment may also present with co-morbidities such as symptoms of conduct problems (2), which can negatively impact the family (3). The National Institute for Health and Care Excellence (NICE) recommends families should receive support as soon as possible after their referral, however, despite these recommendations, parents frequently endure long waiting times for diagnostic assessment and treatment. The average time between seeking help and receiving an ADHD diagnosis has been estimated as 18.3 months in the UK: the longest average interval compared to other European countries (4). Lengthy waiting times and scarcity of services are the most common barriers to accessing mental health services for children and adolescents as reported by parents (5). Furthermore, these waiting times are likely to get even longer, given consistent rises in the number of referrals to Child and Adolescent Mental Health Services (CAMHS) (6).

A robust body of research has established the efficacy of parent training as a psychosocial intervention for children and young people (7). Research has found that parent training may reduce conduct problems in children with ADHD (8). Moreover, Daley et al. (9) conducted a meta-analysis on behavioural interventions that established improvements in parenting quality as well as a reduction in child ADHD symptoms and conduct problems. However, despite evidence of its efficacy, parent training may not be made available until a diagnosis has been established, leaving parents without support during the lengthy waiting period which can have a detrimental effect on children and their families (10).

Considering evidence that parent training can have a positive outcome for both parent and child, and to provide families with much-needed timely and accessible support, we have developed a digital parenting application called Structured E-Parenting Support (STEPS). Research suggests that digital health interventions (DHIs), such as mobile apps, may have great potential to deliver large-scale, cost-effective support (11). However, there is a real need to understand how health and digital research can work together for effective implementation (12).

The STEPS app and OPTIMA trial

Inspired by the New Forest Parenting Programme (13), STEPS has been designed to support parents of children with ADHD-type symptoms that are accompanied by challenging behaviour and who are awaiting clinical diagnostic assessment.

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STEPS is a standalone training delivered via a mobile app that aims to improve parents' understanding of their child's challenging behaviour and increase their perceived self-efficacy to manage such behaviours, as well as facilitate effective parent-child communication. STEPS has one preparatory module, "Introduction", followed by eight separate intervention modules (steps) to be followed in order. Each of the eight steps is designed to take about 20 minutes if completed in one go.

The content is delivered via short videos, audio clips and text, and parents can download resources as well as make notes on their own reflections within each of the modules (steps) (Table 1).

Table 1.

The STEPS app modules' titles and aims.

MODULE Title	Module Aim
1. Make a fresh start	To encourage parents to see their child and themselves in a new, more positive way.
2. Look after yourself	To emphasize the importance for parents to find time for themselves and to make links with other parents.
3. Get their cooperation	To explain ways parents can communicate more effectively with their children
4. Build their confidence	To highlight the importance for parents to create situations in which they can praise their child
5. Lead by example	To help parents think of ways they can avoid losing their temper with their children when they are being difficult.
6. Guide & support them	To show how parents can help their children navigate difficult situations where they may find themselves getting upset.
7. Give them structure	To demonstrate how vital it is that everyone signs up to and follows the house rules
8. Reducing conflict	To explain how using rewards and sanctions can promote better behaviour in children.

The efficacy and cost-effectiveness of STEPS is currently being evaluated in the Online Parent Training for The Initial Management of ADHD referrals (OPTIMA) randomized controlled trial (14). Optima is a two-arm, superiority parallel randomised controlled trial

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with an internal pilot. Parents (n=352) are randomly assigned to either the intervention group (access to the STEPS app for 3 months) or the Wait as Usual comparison group (WAU) on completion of baseline measures. Questionnaires are administered via a secure platform, Sealed Envelope, every three months at five timepoints. Participants are recruited from mental health services across London, Nottingham, Portsmouth, Southampton and Gloucester, after initial eligibility has been established via a positive screen for high levels of hyperactivity (≥8) and conduct problems (≥4) as measured by the Strengths and Difficulties Questionnaire (15).

The primary outcome of the OPTIMA trial is the severity of behaviour problems at 3 months post-randomisation compared to WAU care using parent-reported child behaviour problems measured with the eight-item ODD subscale of the Swanson Nolan and Pelham Rating Scale (SNAP-IV) (16).

Process Evaluation Aims and Objectives

Establishing a methodology by which the process evaluation will adhere to a priori is useful to ensure rigour and improve trial quality. Using Medical Research Council (MRC) guidelines (17) this protocol describes the method for the process evaluation of STEPS within the OPTIMA trial. Furthermore, the Standard Protocol Items: recommendations for interventional trials (SPIRIT) checklist has been utilised to provide evidence-based guidance in producing this protocol and is a widely accepted standard for trial protocols (18). Specific objectives are to:

1. To assess the i) reach ii) dose iii) fidelity iv) impact and v) context of the intervention. Table 2 defines the components of process evaluation and shows the methods by which the required information is gathered.
2. To describe how parents implement STEPS.

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Table 2.

The STEPS Process evaluation components and methodology.

	Description	Data collected	Method of evaluation
Reach	The extent to which the intervention reached the intended participants as outlined above in criteria	Data capture via a secure web platform (SE) including age, ethnic origin, education and income of parents and age, gender and ethnicity of child collected at baseline.	Basic statistics including means, ranges and standard deviations. Attrition rates to be calculated at each timepoint.
Dose	Level of intervention delivered and received	STEPS app data downloaded via the application developers Bitjam.	STEPS usage data including time spent per STEP before moving on to the next one, time spent within each STEP and number of STEPS completed. Mean times, ranges and standard deviations will be calculated.
Fidelity	Was the intervention delivered as intended including exploring adaptations or changes made during the study	Data from captured via a secure web platform (SE) on trial expectations. Recordings and minutes from regular PPI panel meetings.	Trial expectations collected at baseline as multiple choice and free text boxes. PPI panel feedback on suggestions for change/adaptations.
Impact	Did the intervention produce change? If so, how?	Parent and clinician interviews. Quantitative data exploring changes in outcome measures (ADHD and ODD).	30-45 minute interviews on the experiences of using the STEPS app including technology, engagement with the STEPS, effect on child behaviour and suggestions of adaptions to the app (see appendix A). Interviews with clinicians on noticed effects on patients, barriers to use within the service and other relevant feedback. SNAP-IV O and A subscales measured at baseline and 3 months
Context	External factors influencing change in parent and/or child behaviour and intervention uptake.	Parent interviews exploring changes in child behaviour, clinician interviews, experience of parenting and MAPED feedback.	Interviews as above. Data capture via a secure web platform (SE) capturing EoP and MAPED.

Note. ADHD=Attention Deficit Hyperactive Disorder; EoP=Experience of Parenting; MAPED= Medical and psychological events and difficulties; ODD=Oppositional Defiance Disorder; PPI=Patient and Public involvement; SE=Sealed Envelope; SNAP IV O (oppositional problems) and A (hyperactive symptoms) (20,21)

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3. To explore parents' and clinicians' views concerning the value of STEPS and to describe this in the context of their respective needs.
4. To explore external factors that may have acted as barriers to, or facilitators of, STEPS uptake and engagement.
5. To consider the sustainability of the STEPS app beyond the trial and, if shown to be effective, the possible ways it could be incorporated into the clinical pathways.
6. Evaluation of mechanisms of impact (mediating factors contributing to the outcome) and context (intrapersonal and environmental factors influencing app usage).

Following MRC guidelines for process evaluations (17), a logic model has been developed (Table 3) to elucidate the mechanisms by which the STEPS intervention will produce an outcome and inform the framework of the qualitative analysis. A logic model can be useful in representing the theory of the intervention and its outcomes and helps to clarify the main aspects of the intervention as well as aid in data collection and analysis (19). The STEPS logic model clarifies the current issues in parent support for those waiting on a diagnosis for their child as well as expands on the implications for STEPS use beyond the study. Moreover, by providing a step-by-step process from developing the research question to understanding how outcomes were achieved, it ensures that researchers adhere to the pre-determined process of delivery and analysis.

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Table 3.

STEPS Logic Model

Problem	Proposed Solution	Input and intervention	Mechanisms of impact	Intended outcomes	Intended impact
ADHD is accompanied by Oppositional Defiant Disorder in up to 90% of referred cases. This is associated with child and parent distress and impairment which often drives referrals. Lengthy waiting times to receive assessment and diagnosis which can add to parent and child stress.	To provide low-intensity, unguided support for parents to help them better manage their children's challenging behaviour while they are awaiting formal clinical assessment.	Parents are screened via a secure hosting platform (MHE) or through local health services utilising the SDQ (≥4 conduct problems and ≥8 attention and hyperactive problems). Access to STEPS is given post randomization to the intervention group (n=172) via research administrators and supported via text/email to download and utilise the app. The self-guided, parent training intervention, STEPS, is delivered via a mobile phone application. Parents work through 8 modules (steps) with content delivered via short videos and audio clips. Parents can download additional resources	STEPS draws heavily on the evidence based NFPP. It includes education about ADHD and uses behavioural techniques, including an emphasis on praise. The delivery of the intervention is underpinned by social learning theory. Modelling techniques are used to develop parenting skills (mastery) and to increase confidence (self-efficacy).	Increased parental understanding of ADHD and its impact on child behaviour. Increased knowledge of strategies to manage challenging child behaviour. Development of a positive parenting style. Improved parent-child communication Improved parental well-being and confidence in managing their child's oppositional behaviour. Reduced levels of oppositionality and defiance in children.	Improved support for parents while waiting on an assessment and diagnosis for their child. Cost-effective and time efficient delivery of parent training, potentially reducing load on stretched child mental health services. Implementation of STEPS into the care pathway for children with symptoms of ADHD. Extension of parent training to more difficult to reach families and those too busy to attend training sessions. Engagement of a broader range of family members and key adults (e.g., fathers/grandparents/child minders)

Problem	Proposed Solution	Input and intervention	Mechanisms of impact	Intended outcomes	Intended impact
Lack of parenting support during waiting times can further add to parent stress and unwanted child behaviour.		and are prompted to reflect on progress via written or audio notes. Engagement is encouraged through use of digital buddies and pre-programmed prompts.			

ADHD=Attention Deficit Hyperactive Disorder; MHE=myHealthe; NFPP=New Forest Parenting Program; SDQ=Strength and Difficulties Questionnaire; STEPS= Structured E-parenting support

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METHOD

Design

This mixed-method process evaluation integrates qualitative and quantitative data. Qualitative data will be gathered from semi-structured interviews with parents and clinicians to explore the implementation of the intervention and the perceived impact of the intervention on parenting and child behaviour as well as expectations about the trial as reported by participants via free text responses on the trial questionnaires. Parallel to this, we will use quantitative data such as demographic data and app usage metrics. Table 2 describes the methods and evaluation of data collection.

Qualitative data collection

Qualitative data collection will include semi-structured interviews with parents and clinicians and trial expectations. Participants will be approached to take part in interviews if they meet the following criteria i) have consented to be contacted for interviews via the study consent form (optional consent statement), have been randomised to the STEPS arm. Both parents who have completed the three months follow up and those that have not are invited as all parents remain in the study unless they explicitly withdraw. Participants will be invited to take part in interviews irrespective of whether they engaged with the STEPS app or not. Views of participants who have not completed any of the steps are very important in the context of understanding barriers to usage. We aim to recruit n=50 parents for interviews. Participants who have consented to be contacted about interviews will be approached by a researcher other than the one who has enrolled them on the trial to avoid unblinding. Selection and allocation of eligible participants is completed by the trial manager and trial administrators. Researchers will email potential participants an invitation explaining the interview process. The default method for conducting interviews will be a video/phone call (about 45 minutes duration). Participants who wish to complete the interview via email will be sent an adapted interview schedule. The interview will be recorded and stored securely within King's College London cloud storage infrastructure (OneDrive for Business or Microsoft SharePoint) with the transcript.

The interview schedule has been developed by a team of experienced qualitative researchers in collaboration with the OPTIMA Patient and Public Involvement group. Questions explore the technical experience of downloading and using the app, views on content and features of the app, such as the STEPS buddies, feedback on if/how the app influenced aspects of

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parenting and child behaviour management. They will also ask participants about their thoughts on the effectiveness of STEPS in reducing their child's behavioural challenges and, if applicable, the perceived mechanisms by which STEPS is effective (see appendix A for full interview schedule).

Managers in the clinical services that have supported OPTIMA RCT recruitment will be approached with a request to circulate the clinician information sheet to members of the team. Those interested in taking part are asked to contact the team directly. Clinicians will have been made aware of patient participation via patient notes added to the clinical records system. Clinicians will be asked whether they have received feedback from parents about the app and their thoughts on parents' engagement with STEPS. There are also questions on institutional factors such as implementation feasibility, benefits and obstacles. Clinician interviews can help add depth to the qualitative data in terms of understanding the clinical context in relation to any outcomes shared by parents in terms of contact with services or receiving an assessment and/or diagnosis. Our aim is to include n=10 interviews from clinicians. Clinicians will all be interviewed via phone/video call and data stored as per the participants' data above.

The trial expectations questionnaire completed online using the Sealed Envelope platform contains a free text box on parents' hopes and worries about using the STEPS app.

Quantitative data collection

To determine the intervention's reach, the process evaluation will use data collected from parents at baseline (pre-randomisation) via an online secure platform, Sealed Envelope including demographic data about the parent, such as parent's gender, parent ethnicity, parental education, parent employment status, parent relationship status and family socioeconomic status based on total household income as well as child's age, sex and ethnicity. To describe the severity of oppositional and defiant disorder symptoms and hyperactivity/impulsivity and inattention symptoms in the sample, the respective subscales from the parent-completed SNAP questionnaire will be used (20,21). Furthermore, given that ADHD and ASD often co-occur, mean scores and standard deviations from the Social Communication Questionnaire (SCQ) will be included (22). At baseline, parents are asked about their trial expectations. Parents are also asked about previous engagement in parent training (yes/no answer), expectations of receiving parent training (strongly disagree to strongly agree), and expectations of the STEPS app (strongly disagree to strongly agree).

DATA ANALYSIS

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Our objectives are to explore the reach, dose, fidelity, impact and context of the intervention. Qualitative analysis will use a framework approach (23), utilising NVivo version 12, complemented by quantitative analysis. Framework analysis sits within the broader qualitative methodology of thematic analysis and allows researchers to compare data across cases as well as within cases, ensuring the individual's view is retained (23). Researchers will start by identifying a coding framework that aligns with the objectives of the study. Creating a data set, researchers will map out the codes and start looking for themes and relationships in the data set. As data moves from codes to themes, the original research questions as well as existing literature will be referred to and discussed and reviewed within the multidisciplinary team to ensure transparency and avoid bias. The method is appropriate for incorporating data from semi-structured interviews, PPI panel discussions and free text box data from questionnaires.

Descriptive data on the study sample will be presented to include means, SD, medians, ranges, n values and percentages. Reach and dose will be assessed using app data to look at the app usage in terms of how many people downloaded it, the number of steps (modules) completed and timings. In addition, feedback from participants on preferred times (and places) to use the app and reasons why individual steps were or were not completed will help provide an overall picture of reach and dose. Attrition rates from the intervention group at each timepoint will also be explored. Fidelity will be assessed through interviews in terms of parent feedback on ease of understanding instructions given both via the app as well as the research team. Any changes made to instructions part way through the study will also be considered in terms of how changes may have impacted usage, for example, further instructions given to participants on how to download and engage with the app sent throughout the study to encourage uptake.

The impact will be evaluated through analysis of the transcripts. Parents will be asked for specific examples of when and how they used learnings from the app and any perceived effect on child behaviour. Parents will also be asked more generally about any impact the app has had on their lives. Quantitative data measuring changes in oppositional behaviour (SNAP (O)) between baseline and 3 months and making within-group comparisons will also help to assess impact of the app. Context will be measured using data from the interviews. Parents are asked specifically about where and when they used the app, external factors influencing app usage at the time (e.g., changes in normal routines at home) and any noticeable changes in child behaviour during this time. Interviews with parents will also allow us to understand

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barriers or facilitators of STEPS usage and uptake. Furthermore, family and socioeconomic data will be included such as family composition and work status.

Data integration

The qualitative data extracted from interviews with parents and clinicians as well as text box data exploring parents' expectations from the study will provide the main source of data to explore the aims and objectives of the process evaluation. Alongside this descriptive data from the online questionnaires will be used, both to provide context to the qualitative data in terms of demographics, but also to help refine the themes emerging from the qualitative data analysis. Mixed methods afford multiple perspectives and seek to converge the findings (24). Researchers will analyse the data synchronously and integrate the outcomes from the different datasets to provide a holistic overview of the results.

Patient and Public Involvement (PPI)

The OPTIMA RCT and STEPS app were developed in conjunction with an advisory board made up of parents of children with neurodevelopmental disorders including ADHD. In addition to regular PPI panel meetings throughout the study period, panel members advised on subjects such as how to most effectively communicate with parents, suggestions of how best to reward parents for their time in the study and other study questions. Further, members will be involved in the data analysis process, reading transcripts and taking part in meetings to discuss codes and meanings with OPTIMA researchers.

Ethics and Dissemination

All participants in the study consented to take part via e-consent on Sealed Envelope after having received written and oral information about the study including a brief participant information sheet (PIS) with condensed information in an easy-to-understand format and as well as a full PIS for their reference. All parents received a counter signed, by the researcher, copy of their consent form. The study received ethical approval from the North West - Liverpool Central Research Ethics Committee on 26 November 2021, reference number 21/NW/0319. Findings will be published in open access, peer-reviewed scientific journals as well as be presented at conferences.

DISCUSSION

STEPS is a digital, self-guided app that is currently being evaluated in the OPTIMA RCT (14). To better understand the study outcomes and contextual factors influencing these, we are conducting a process evaluation using qualitative and quantitative data gathered from parents, clinicians, app usage and demographic data. We expect the results to allow us to understand how the app has worked, such as if it worked as intended, with the aim of

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understanding the implications of the potential wider use of STEPS, especially within a clinical setting. In understanding the strengths and weaknesses of the intervention, how the intervention was delivered and whether the intended audience received the intervention and how the app can be further developed and improved to attain its intended purpose, we aim to provide support to parents awaiting clinical assessment and/or diagnosis for their child and make the app available to those parents who may need it.

Research suggests that DHIs may have great potential to deliver large-scale, cost-effective support (11). The STEPS app may be able to bridge the gap between lengthy waiting times for a diagnosis of ADHD and the strains of managing difficult child behaviour. Furthermore, the study will contribute to a body of research that aims to understand how digital interventions work and the factors that contribute to their efficacy, with the aim of improving and understanding the practical implication of using STEPS as a viable DHI to be accessed by a wider population.

Strength and limitations

Integrating qualitative and quantitative data provides a comprehensive evaluation of the way in which the intervention has worked. Capturing the lived experience of parents through interviews will give valuable insight into both the mechanics of how the app works as well as the impact on parenting and child behaviour. The data from the app provide detailed measures of how the app was used by participants and will help to better understand how the app was utilised (e.g., the number of times app was used or the length of time per each app use).

Limitations in terms of breadth of participant involvement may occur, for example, participants who do not engage with the study may be less likely to respond to invites to take part in interviews. Participants' interview invites clearly state that the researchers are interested in all views, including those who did not engage with the STEPS app to ensure as wide reach as possible is attained.

Interviews with clinicians may provide limited data as many parents in the study will not yet have been assessed, even after completing the final 12-month timepoint, meaning clinicians may have limited feedback/views from the parents regarding the app.

Conclusion

Process evaluations are an essential part of evaluating complex interventions to understand the potential causal mechanisms within the study. Within research, transparency of implementation and rigour and validity throughout the trial is essential. A process evaluation can further the understanding of the mechanisms by which an intervention is successful and

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for whom it is successful and in what circumstances. Preparing a protocol prior to the process evaluation taking place will further ensure that the planned methodology is adhered to, adding to the validity of the process evaluation. Furthermore, a process evaluation may establish fidelity and quality of the implementation and mechanisms of change and help to understand the context in which the intervention is effective (25).

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PARENT INTERVIEW SCHEDULE

Preamble

- Check that the interviewee has received the information sheet, has initialled the box stating they are happy to be contacted for an interview on consent form, understands the OPTIMA trial project and his/her role in it.

- Explain that:
    - The aim of the OPTIMA study is to investigate whether a digital parent education programme, STEPS, can help parents to become more confident and effective in managing their children's difficult behaviour.
    - The research team is talking to some of the parents who are taking part in the study to see how they feel about participating in the trial and using the STEPS app.
    - We are interested in individual experiences and thoughts about STEPS, so please give honest responses, as both positive and negative feedback will help us improve the intervention.
    - We will ask questions relating to your expectations of STEPS, its impact on your parenting and on your child.
    - We will combine all our interview responses so that we can provide an overall picture of parents' views about STEPS. Any comments in the study report are attributed very generally, for example, "A parent commented that…" All comments/opinions will be strictly confidential.

Ask: Do you have any initial questions about the project?

Ethics

- The interview will take about 30-45 minutes
- You do not have to answer any questions that you are not comfortable with and there are no 'right' or 'wrong' answers.
- You can turn your camera off, if you prefer.
- You can stop at any time, no explanation needed
- If you need a comfort break, please just say, that's absolutely fine
- If any question doesn't make sense, ask for an explanation.
- You will receive a £20 shopping voucher as a thank you for taking part. A voucher will be emailed to you within the next 5-7 days.

With your permission we are going to audio/video (if you keep your camera on) record the interview so that we can focus on what you are saying. The interviews will be transcribed by a member of our research team. We remove any reference to any places, clinicians/therapists/family members that may give away your (or others) identity during transcription.

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The original transcription will be stored in a restricted-access folder restricted-access folder on the King's College London (KCL) cloud server, and no one other than immediate members of the research team can access this.

Anonymised quotes from transcripts will be used in written reports, published journal articles and presentations including online. Again, any reference to places/family members/clinicians and so on will be removed.

Ask: Do you have any questions about how we use your comments? Please feel free to ask anything however minor it may seem at this stage or at any time later.

Ask: Is it okay to record the interview?

- If participant not satisfied: answer any questions they have. If they do not want to participate, thank them for their time and finish the interview at this point.

Explain procedure

I will begin the interview with my name, the date, time and the identifying code we have assigned to you and your child - this is just to keep the recordings organised. All your identifying details will be removed when the data is transcribed. The first part will be a little about yourself and your family, followed by general questions about the project such as how you were recruited and your expectations, then moving on to the STEPS programme more specifically and then ending with any recommendations and your overall experience of being involved in OPTIMA.

Ask: Do you have any questions before we start?

Ask: Is it okay for me to start recording now?

State researcher's name, date, time, and identifying code (for data management)

Warm up

Please tell me a bit about your family. Where do you live? How many children do you have?

Can you tell me why you went for an assessment for your child (name).Did you go via school? Did you self-refer? GP?

Thinking about the last three months you have taken part in the trial, have you noticed any changes in your child's behaviour? Types of behaviour? Severity of behaviour? Frequency and so on.

I am now going to ask you some questions about being part of the OPTIMA trial and using the STEPS app.

1) Tell me a bit more about your technical experience of using the app
   - How did you feel about the downloading/logging on process?
   - Was it technically easy to use/easy to understand?
   - How did you feel about the way the material was presented? Was it easy to navigate each STEP
   - Did you receive reminders to use the app? If so, how did you feel about these (eg length, regularity)

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2) Tell me a bit more about what you thought about the content of STEPS
   - What did you think about what was included? (thinking about the videos/text)
   - How did you decide which buddy to choose? Did you change buddies at all while using the app? What did you think about the buddies? (If they did not like the buddies, probe asking what would have made them like them better/what type of buddy would they like to see).
   - If you used the STEPS that included examples with children, what did you think about these examples? (Probe would they have like to see more of the children? If they did not like these examples, why?)
   - Was there any content that you felt worked particularly well? Anything that could have done better?

3) Using the app
   - At the time of using the app, what did your life look like? Would you say it was as normal, busier, quieter?
   - Did you go through all the STEPS? If not, which/how many STEPS did you do?
   - If you did not complete all STEPS was there a reason for this? What, if anything, would have made you complete all 8 STEPS?
   - How did you find fitting the recommendations/strategies into everday life?
   - Were there any times of day in particular that you used the app?
   - Were there any particular places that you used the app? Prompt: At home, car, on school run etc
   - Did you use the STEP in the order it was set out or did you move around within each STEP (eg download resources before watching the film clip).
   - Did you complete a STEP all in one go or did you dip in and out?
   - Did you show the app or talk about it to anyone in your family such as partner or grandparents? Did anyone else interact with the app? If so, how often?

4) Implementing the app
   - Did STEPS influence the way you approached your child´s behaviour? If yes, in what way. If no, why do you think this was?
   - Did you use any of the strategies in the app? If so which ones? If you did not make any changes to parenting or your thinking, why?

5) Expectations and reality of using the app
   - Thinking about your **expectations** of STEPS prior to usage. How effective did you **expect** it to be? Prompt for expected effects
   - Did you expect benefits in any other aspects of life?
   - Thinking about the **reality** of using the STEPS once you had started using it. How effective did you find it to be? Prompt for impact on child's behaviour.
   - Did you find benefits in any other aspects of life?
   - Which aspects of the STEPS programme were particularly helpful/unhelpful?

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Follow up question depending on answer: You have mentioned that the programme impacted on X (Follow-up from previous questions). How do you think STEPS influenced that? Was there anything that influenced the impact that STEPS had? If no impacts prompt why?

6) Would you change anything about the STEPS intervention?
   - What additional information, if any, should be included?
   - Was anything included that was unnecessary?

7) How did you feel about receiving STEPS as a digital intervention?
- Would you have preferred another format? If so what?

8)Had you received any parent training prior to (or during) being offered STEPS? If no move on to next question. If yes, ask

- What type of parenting training did you receive? When did you receive it?
- Did the other PT change the way you viewed STEPS? Probe: Was it helpful? Different?

Thank you for answering these questions. We only have a few questions left now and these will focus on the future of STEPS:

Future Direction

8) If the STEPS programme is found to be effective, are there any changes you can think of that we should make before it is routinely offered to parents seeking help for their child's behavioural difficulties?

9) At what point in seeking support from a service do you think it would be most helpful for parents to be given access to STEPS?
- How should this access be given (e.g. through the school, GP, CAMHS)
- Would you recommend the STEPS programme to other parents whose children need support?
- Can you give me a few words that you would use to describe the STEPS app to someone else?

For the final questions I wanted to ask about your experiences of the recruitment process into the OPTIMA trial. The OPTIMA trial is a study where we are testing whether providing support to parents on a service waitlist via a mobile phone app is an effective way of helping them to deal with some parenting challenges.

10) How did you feel about the way you were approached to take part? If you remember how long you had been on the waiting list when we contacted you, would you have preferred to be contacted earlier or later on?

11) What made you decide to take part in the study? What were your initial thoughts about the OPTIMA study?

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12) How did you feel when you were told you would be testing the STEPS app?
    - What did you hope to get out of testing the app from both you and your child's point of view?

13) Finally, what did you think of the online questionnaires such as how long they took, the ease of understanding the questions and getting a voucher as an incentive.

End of questions

That reaches the end of the interview and questions I wanted to ask you.

Thank you so much for giving me your time.

- Do you have anything else you wish to speak about that hasn't been mentioned?
    - Let interviewee talk if they have anything else to add
    - If nothing else – then close interview

If you are okay to end the interview there, I will stop recording now.

Stop recording

Mood Repair

Ask the participant if they have anything nice planned for the rest of the day. If they have any family plans for the weekend (or similar ensuring the participants mood is lifted before you close the interview).

Debriefing

- Ask how they are feeling – whether anything in the interview has troubled them or distressed them or if anything requires clarification
- They can email me if they have any follow up questions
- Thank them again, and ask if they are feeling okay to end interview here.
- Remind about the voucher.

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A protocol for the process evaluation of a Structured E-parenting Support (STEPS) in the OPTIMA randomised controlled trial.

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Manuscripts

A protocol for the process evaluation of a Structured E-parenting Support (STEPS) in the OPTIMA randomised controlled trial.

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A protocol for the process evaluation of a Structured E-parenting Support (STEPS) in the OPTIMA randomised controlled trial.

Abstract

Introduction: *Structured E-parenting Support* (STEPS) is a digital application (app) designed to help parents manage behaviour of their children who are referred to mental health services and are waiting for an assessment or treatment. STEPS is currently being evaluated in The Online Parent Training for the Initial Management of ADHD (OPTIMA) randomized controlled trial. Alongside the examination of STEPS' clinical and cost-effectiveness, we are conducting a process evaluation to better understand the contextual factors that may influence study outcomes. The purpose of this protocol is to describe the aims, objectives and methodology of the process evaluation prior to it taking place to add to the fidelity and rigour of the trial process and outcomes. Our goal is to adapt STEPS to optimise its benefits in future applications. **Methods:** In line with the Medical Research Council guidelines for evaluating complex interventions, the process evaluation will adopt a mixed method design using qualitative data collected from clinicians and parent interviews and app usage data from participants assigned to the intervention arm. **Analysis:** Qualitative data from semi-structured interviews and free text box responses included in trial questionnaires will be analysed thematically using framework analysis to better understand how parents use STEPS, how it works and key factors that could aid or hinder its effective implementation in routine clinical practice. **Ethics:** The application for ethical approval for the study was submitted to the North West - Liverpool Central Research Ethics Committee and received a favourable opinion on further information on 26 November 2021, reference number 21/NW/0319. **Dissemination:** The process evaluation aims to explore how a digital app might support parents in managing their child's behaviour. Implications for policy and research will be explored and the clinical implications of offering the app to a wider audience to address the lack of support to parents as highlighted in this paper. We plan to publish findings in international, peer-reviewed journals as well as present at conferences.

Trial registration: The trial has been prospectively registered on 18 November 2021; ISRCTN 8 16523503. https://www.isrctn.com/ISRCTN16523503.

Keywords: Process evaluation, ADHD, Conduct problems, Randomized Controlled Trial, Digital health, Parenting intervention

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Strengths and Limitations of this study

- Framework analysis allows for in-depth data analysis using a rigorous and transparent methodology.
- Outcomes for quantitative data such as app usage metrics will be integrated with qualitative findings.
- Inclusion of members from the OPTIMA patient and public involvement panel to advise on best practice in working with participants as well as assisting in data analysis and interpretation of the study results.
- All eligible participants were invited to partake in interviews, including those who did not complete all timepoints and those who did not download or use the app, to further understand barriers to uptake and usage of the STEPS app.
- A potential limitation of this study is the crossover of team members working on both the RCT and the process evaluation which may influence the interpretation of the qualitative data.

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INTRODUCTION

Attention-deficit/hyperactivity disorder (ADHD) is a common neuro-developmental condition characterised by symptoms of inattention and/or impulsivity-hyperactivity (1). Children referred for ADHD assessment may also present with co-morbidities such as symptoms of conduct problems (2), which can negatively impact the family (3). The National Institute for Health and Care Excellence (NICE) recommends families should receive support as soon as possible after their referral, however, despite these recommendations, parents frequently endure long waiting times for diagnostic assessment and treatment. The average time between seeking help and receiving an ADHD diagnosis has been estimated as 18.3 months in the UK: the longest average interval compared to other European countries (4). Lengthy waiting times and scarcity of services are the most common barriers to accessing mental health services for children and adolescents as reported by parents (5). Furthermore, these waiting times are likely to get even longer, given consistent rises in the number of referrals to Child and Adolescent Mental Health Services (CAMHS) (6).

A robust body of research has established the efficacy of parent training as a psychosocial intervention for children and young people (7). Research has found that parent training may reduce conduct problems in children with ADHD (8). Moreover, Daley et al. (9) conducted a meta-analysis on behavioural interventions that established improvements in parenting quality as well as a reduction in child ADHD symptoms and conduct problems. However, despite evidence of its efficacy, parent training may not be made available until a diagnosis has been established, leaving parents without support during the lengthy waiting period which can have a detrimental effect on children and their families (10).

Considering evidence that parent training can have a positive outcome for both parent and child, and to provide families with much-needed timely and accessible support, we have developed a digital parenting application called Structured E-Parenting Support (STEPS). Research suggests that digital health interventions (DHIs), such as mobile apps, may have great potential to deliver large-scale, cost-effective support (11). However, there is a real need to understand how health and digital research can work together for effective implementation (12).

The STEPS app and OPTIMA trial

STEPS has been designed to support parents of children with ADHD-type symptoms that are accompanied by challenging behaviour and who are awaiting clinical diagnostic assessment. Its structure, content and approach are described in Appendix A. STEPS draws inspiration from some of the principles underpinning the New Forest Parenting Program (NFPP) (13), an

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established face-to-face parent program based on a long track record of research and clinical practice relating to parenting of child behaviour problems. However, its content, structure and approach, tailored to the digital delivery, are substantively different from the NFPP.
STEPS is delivered via a mobile app that aims to improve parents' understanding of their child's challenging behaviour and increase their perceived self-efficacy to manage such behaviours, as well as facilitate effective parent-child communication. STEPS has one preparatory module, "Introduction", followed by eight separate intervention modules (steps) to be followed in order. Each of the eight steps is designed to take about 20 minutes if completed in one go. The content is delivered via short, pre-recorded videos, audio clips and text, and parents can download resources as well as make notes on their own reflections within each of the modules (steps) (Table 1).

Table 1.

The STEPS app modules' titles and aims.

MODULE Title	Module Aim
1. Make a fresh start	To encourage parents to see their child and themselves in a new, more positive way.
2. Look after yourself	To emphasize the importance for parents to find time for themselves and to make links with other parents.
3. Get their cooperation	To explain ways parents can communicate more effectively with their children
4. Build their confidence	To highlight the importance for parents to create situations in which they can praise their child
5. Lead by example	To help parents think of ways they can avoid losing their temper with their children when they are being difficult.
6. Guide & support them	To show how parents can help their children navigate difficult situations where they may find themselves getting upset.
7. Give them structure	To demonstrate how vital it is that everyone signs up to and follows the house rules
8. Reducing conflict	To explain how using rewards and sanctions can promote better behaviour in children.

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In our previous study, parents rated the app's usability level as very high; the overall STEPS usability score on the System Usability Scale was 94.8 (SD 4.8) out of 100 (14). Moreover, feedback received was used to optimise the app in preparation for the trial. For example, we improved and simplified the registration process, improved video playback and added captions to videos. We also let parents know that study administrators would be on hand to help with any technical issues if the app visual download guide was insufficient. As part of the screening process, researchers checked whether parents had a phone with an operating system that was compatible with the app and were sufficiently proficient in English to be able to use the app and understand it.

The efficacy and cost-effectiveness of STEPS is currently being evaluated in the Online Parent Training for The Initial Management of ADHD referrals (OPTIMA) randomized controlled trial (14). Optima is a two-arm, superiority parallel randomised controlled trial with an internal pilot (15). Parents (n=352) are randomly assigned to either the intervention group (access to the STEPS app for 3 months) or the Wait as Usual comparison group (WAU) on completion of baseline measures. Randomisation will be carried out online via a secure platform provided by Sealed Envelope in a 1:1 ratio and stratification by trial centre location (London, Nottingham, Southampton) using random permuted blocks procedure with varying block sizes. The randomisation system will use a unique identifying number. Questionnaires are administered via Sealed Envelope, every three months at five timepoints. Participants are recruited from mental health services across London, Nottingham, Portsmouth, Southampton and Gloucester, after initial eligibility has been established via a positive screen for high levels of hyperactivity (≥8) and conduct problems (≥4) as measured by the Strengths and Difficulties Questionnaire (16). Participation in the study does not impact clinical care the family receives, or the time spent on the waitlist. There will be no restrictions on concomitant care, which will be monitored carefully during the trial through the child and adolescent service use questionnaire (17). Participant recruitment took place from May 2022 to July 2023.

The primary outcome of the OPTIMA trial is the severity of behaviour problems at 3 months post-randomisation compared to WAU care using parent-reported child behaviour problems measured with the eight-item ODD subscale of the Swanson Nolan and Pelham Rating Scale (SNAP-IV) (18). For the process evaluation, the mean difference between timepoint one and

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two of the primary outcome will be measured for the intervention arm only. Data relating to the study outcomes comparing the two groups will be published in separate papers.

Process Evaluation Aims and Objectives

Establishing a methodology by which the process evaluation will adhere to a priori is useful to ensure rigour and improve trial quality. Using Medical Research Council (MRC) guidelines (19) this protocol describes the method for the process evaluation of STEPS within the OPTIMA trial. Furthermore, the Standard Protocol Items: recommendations for interventional trials (SPIRIT) checklist has been utilised to provide evidence-based guidance in producing this protocol and is a widely accepted standard for trial protocols (20). Specific objectives are to:

1. To assess the i) reach ii) dose iii) fidelity iv) impact and v) context of the intervention. Table 2 defines the components of process evaluation and shows the methods by which the required information is gathered.
2. To describe how parents implement STEPS.
3. To explore parents' and clinicians' views concerning the value of STEPS and to describe this in the context of their respective needs.
4. To explore external factors that may have acted as barriers to, or facilitators of, STEPS uptake and engagement.
5. To consider the sustainability of the STEPS app beyond the trial and, if shown to be effective, the possible ways it could be incorporated into the clinical pathways.
6. Evaluation of mechanisms of impact (mediating factors contributing to the outcome) and context (intrapersonal and environmental factors influencing app usage).

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Table 2.

The STEPS Process evaluation components and methodology.

	Description	Data collected	Method of evaluation
Reach	The extent to which the intervention reached the intended participants as outlined above in criteria	Data capture via a secure web platform (SE) including age, ethnic origin, education and income of parents and age, gender and ethnicity of child collected at baseline.	Basic statistics including means, ranges and standard deviations. Attrition rates to be calculated at each timepoint.
Dose	Level of intervention delivered and received	STEPS app data downloaded via the application developers Bitjam.	STEPS usage data including time spent per STEP before moving on to the next one, time spent within each STEP and number of STEPS completed. Mean times, ranges and standard deviations will be calculated.
Fidelity	Was the intervention delivered as intended including exploring adaptations or changes made during the study	Data from captured via a secure web platform (SE) on trial expectations. Recordings and minutes from regular PPI panel meetings.	Trial expectations collected at baseline as multiple choice and free text boxes. PPI panel feedback on suggestions for change/adaptations.
Impact	Did the intervention produce change? If so, how?	Parent and clinician interviews. Quantitative data exploring changes in outcome measures (ODD) between timepoint 1 and 2.	30-45 minute parent interviews on the experiences of using the STEPS app including technology, engagement with the STEPS, effect on child behaviour and suggestions of adaptions to the app (see appendix B). Interviews with clinicians on any noticed effects on patients if applicable, barriers to use within the service and suggestions on effective implementation. SNAP-IV ODD subscales measured at baseline and 3 months
Context	External factors influencing change in parent and/or child behaviour and intervention uptake.	Parent interviews exploring changes in child behaviour.	Interviews as above.

Note. ODD=Oppositional Defiance Disorder; PPI=Patient and Public involvement; SE=Sealed Envelope; SNAP IV O (oppositional problems) (20,21)

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Following MRC guidelines for process evaluations (19), a logic model has been developed (Table 3) to elucidate the mechanisms by which the STEPS intervention will produce an outcome and inform the framework of the qualitative analysis. A logic model can be useful in representing the theory of the intervention and its outcomes and helps to clarify the main aspects of the intervention as well as aid in data collection and analysis (21). The STEPS logic model clarifies the current issues in parent support for those waiting on a diagnosis for their child as well as expands on the implications for STEPS use beyond the study. Moreover, by providing a step-by-step process from developing the research question to understanding how outcomes were achieved, it ensures that researchers adhere to the pre-determined process of delivery and analysis.

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Table 3.

STEPS Logic Model

Problem	Proposed Solution	Input and intervention	Mechanisms of impact	Intended outcomes	Intended impact
ADHD is accompanied by Oppositional Defiant Disorder in up to 90% of referred cases. This is associated with child and parent distress and impairment which often drives referrals. Lengthy waiting times to receive assessment and diagnosis which can add to parent and child stress.	To provide low-intensity, unguided support for parents to help them better manage their children's challenging behaviour while they are awaiting formal clinical assessment.	Parents are screened via a secure hosting platform (MHE) or through local health services utilising the SDQ (≥4 conduct problems and ≥8 attention and hyperactive problems). Access to STEPS is given post randomization to the intervention group (n=172) via research administrators and supported via text/email to download and utilise the app. The self-guided, parent training intervention, STEPS, is delivered via a mobile phone application. Parents work through 8 modules (steps) with content delivered via short videos and audio clips. Parents can download additional resources	STEPS draws on the evidence-based NFPP. It includes education about ADHD and uses behavioural techniques, including an emphasis on praise. The delivery of the intervention is underpinned by social learning theory. Modelling techniques are used to develop parenting skills (mastery) and to increase confidence (self-efficacy).	Increased parental understanding of ADHD and its impact on child behaviour. Increased knowledge of strategies to manage challenging child behaviour. Development of a positive parenting style. Improved parent-child communication Improved parental well-being and confidence in managing their child's oppositional behaviour. Reduced levels of oppositionality and defiance in children.	Improved support for parents while waiting on an assessment and diagnosis for their child. Cost-effective and time-efficient delivery of parent training, potentially reducing load on stretched child mental health services. Implementation of STEPS into the care pathway for children with symptoms of ADHD. Extension of parent training to more difficult-to-reach families and those too busy to attend training sessions. Engagement of a broader range of family members and key adults (e.g., fathers/grandparents/childminders)

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Problem	Proposed Solution	Input and intervention	Mechanisms of impact	Intended outcomes	Intended impact
Lack of parenting support during waiting times can further add to parent stress and unwanted child behaviour.		and are prompted to reflect on progress via written or audio notes. Engagement is encouraged through use of pre-recorded digital buddies. Parents receive text reminders to engage with the app, tips on app usage and encouragement on completion of a STEP. These are sent via automated text and emails from research admins.	A range of pre-recorded scripts using digital buddies to describe scenarios allows parents to choose a family dynamic that feels relatable to them.	By using digital buddies parents feel less alone and more supported in their journey by being able to relate to their chosen buddy.	

ADHD=Attention Deficit Hyperactive Disorder; MHE=myHealthe; NFPP=New Forest Parenting Program; SDQ=Strength and Difficulties Questionnaire; STEPS= Structured E-parenting support

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METHOD

Design

This mixed-method process evaluation integrates qualitative and quantitative data. Qualitative data will be gathered from semi-structured interviews with parents and clinicians to explore the implementation of the intervention and the perceived impact of the intervention on parenting and child behaviour as well as expectations about the trial as reported by participants via free text responses on the trial questionnaires. Parallel to this, we will use quantitative data such as demographic data and app usage metrics. Table 2 describes the methods and evaluation of data collection.

Qualitative data collection

Qualitative data collection will include semi-structured interviews with parents and clinicians and text gathered from Sealed Envelope asking parents about their trial expectations.

Parent Interviews

Participants who meet the following criteria will be invited to interview; i) have consented to be contacted for interviews via the study consent form (optional consent statement), ii) have been randomised to the STEPS arm. Participants will be invited to take part in interviews irrespective of whether they engaged with the STEPS app or not. Views of participants who have not completed any of the steps are very important in the context of understanding barriers to usage. We aim to recruit n=50 parents for interviews.

Participants who have consented to be contacted about interviews will be approached by a researcher other than the one who has enrolled them on the trial to avoid unblinding. Selection and allocation of eligible participants is completed by the trial manager and trial administrators. Researchers invite participants via email explaining the interview process. The default method for conducting interviews will be a video/phone call (30-45 minutes duration). Participants who wish to complete the interview via email will be sent an adapted interview schedule. Offering a range of ways to engage in the interviews will ensure that those who feel unable to speak with a researcher on the phone will also be able to take part to give a breadth of views from parents.

The interview schedule has been developed by a team of experienced qualitative researchers in collaboration with the OPTIMA Patient and Public Involvement group (PPI). Once the team had finalised the interview schedule, the three researchers involved in conducting the

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interviews, piloted the interviews with members from the PPI group and colleagues. Initially up to an hour had been allocated for the interviews but the pilot showed that 30-45 was adequate time to cover all the questions. Furthermore, the PPI group felt that a decrease in the time required from the parents was more commensurate with the compensation for participation, a £20 Amazon gift voucher. The interview schedules remained dynamic and in the early stage of interviewing, the qualitative team worked together to adapt and add questions.

Questions explore the technical experience of downloading and using the app, views on content and features of the app, such as the STEPS buddies, and feedback on if/how the app influenced aspects of parenting and child behaviour management. They will also ask participants about their thoughts on the effectiveness of STEPS in reducing their child's behavioural challenges and, if applicable, the perceived mechanisms by which STEPS is effective (see appendix B for full interview schedule). Interviews with parents took place between October 2022 and November 2023. All parents who were recruited into the intervention arm were invited to take part in interviews whether they had downloaded the app or not. Invitations went out three months after randomization, ensuring parents had the full three-month usage period of the app. All de-identified transcripts and email responses will be stored in electronic form on a KCL OneDrive for Business and SharePoint location. The original recordings or emails will be deleted from OneDrive for Business after transcription.

Clinician Interviews

Clinicians form no active part in the OPTIMA RCT with the study being independent of any clinical input from CAMHS or other healthcare providers. Parents must be on a current wait list for their child to take part in OPTIMA and clinics have been informed of the nature of the OPTIMA RCT. It is therefore important to gain clinical perspectives to effectively evaluate the STEPS app in terms of future directions and implementation. Managers in the clinical services that have supported OPTIMA RCT recruitment will be approached with a request to circulate the clinician information sheet to members of the team. Clinicians interested in taking part are asked to contact the team directly. The clinicians who are interviewed have no active involvement in the trial, the STEPS intervention or the collection of outcome data. Some participants may disclose their use of the STEPS app but the clinician is not asked to probe for this. The purpose of the interviews with clinicians is to get their views about the

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impact of STEPS, potential factors influencing parent engagement and perceived barriers to effectiveness with the aim of facilitating implementation into clinical services.

Clinician interviews can help add depth to the qualitative data in terms of understanding the clinical context in relation to any outcomes shared by parents in terms of contact with services or receiving an assessment and/or diagnosis. Our aim is to include n=10 interviews from clinicians to give adequate representation across the three sites although if more clinicians come forward to be interviewed they will be able to partake. Clinicians will all be interviewed via phone/video call and data stored as per the participants' data above. There is no incentive for clinicians to take part.

Quantitative data collection

To establish intervention adherence, the number of completed STEPS modules will be measured (min = 0; max = 8), with completion of two modules constituting adherence to the intervention. Other collected app usage events will include: the number of started modules, the number of videos watched, the time spent watching videos (in seconds), the number of audio clips listened to and the time spent listening to audio clips (in seconds), the number of reflections recorded, the number of items saved to favourites, and the number of accessed text resources. These will be used to provide descriptive information about app usage patterns. To determine the intervention's reach, the process evaluation will use data collected from parents at baseline (pre-randomisation) via Sealed Envelope, including demographic data about the parent, such as parent's gender, parent ethnicity, parental education, parent employment status, parent relationship status and family socioeconomic status based on total household income as well as child's age, sex and ethnicity. To describe the severity of oppositional and defiant disorder symptoms and hyperactivity/impulsivity and inattention symptoms in the sample, the respective subscales from the parent-completed SNAP questionnaire will be used (22,23). The 8 items of the SNAP-IV ODD subscale have excellent internal consistency (α=0.93) and has been shown to be sensitive to change in clinical trials (24). Furthermore, given that ADHD and ASD often co-occur, parent-rated scores for the Social Communication Questionnaire-Lifetime (SCQ-L) will be included (25). The SCQ-L, used in this study to characterise the sample of participants receiving the intervention, has been found to have good internal consistency (Cronbach α=0.82). A cutoff =>15 differentiated young people with a clinical diagnosis of ASD from those without ASD (sensitivity = 0.70 and specificity = 0.67) (26). At baseline, parents are asked about their trial

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expectations. Parents are also asked about previous engagement in parent training (yes/no answer), expectations of receiving parent training (strongly disagree to strongly agree), and expectations of the STEPS app (strongly disagree to strongly agree).

DATA ANALYSIS

Qualitative data analysis

Our objectives are to explore the reach, dose, fidelity, impact and context of the intervention. Qualitative analysis will use a framework approach (27), utilising NVivo version 14, complemented by quantitative analysis. Framework analysis sits within the broader qualitative methodology of thematic analysis and allows researchers to compare data across cases as well as within cases, ensuring the individual's view is retained (27). Framework analysis is a flexible but rigorous method used in health research to integrate qualitative data from different informants and sources. It uses inductive or deductive approaches to identify, describe and interpret patterns (28). Three researchers will take part in both interviewing, transcribing and analysing transcripts with two senior members of the research team taking part in verifying a selection of transcripts. PPI members will work with the research team during the interpretation and verification stages of analysis. Specifically, PPI members will individually review a selection of transcripts to verify the researchers' interpretation of the data and also take part in group meetings to discuss codes and meanings. Although several members of the PPI team have prior experience in qualitative research, 2-3 hours of training on the introduction to qualitative research and how to read and code transcripts will be provided by the research team. Finally, the analysis will be overseen by experts in framework analysis and regular meetings between the researchers analysing the transcripts and the larger qualitative team, will ensure fidelity and cohesiveness in the coding process. The team will start by identifying a coding framework that aligns with the objectives of the study. Creating a data set, researchers will map out the codes and start looking for themes and relationships in the data set. As data moves from codes to themes, the original research questions as well as existing literature will be referred to and discussed and reviewed within the multidisciplinary team to ensure transparency and avoid bias. The method is appropriate for incorporating data from semi-structured interviews, PPI panel discussions and free text box data from questionnaires.

Quantitative data analysis

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Descriptive data on the study sample will be presented to include means, SD, medians, ranges, n values and percentages. Quantitative data measuring changes in oppositional behaviour (SNAP-IV ODD) between baseline and 3 months and making within-group comparisons will also help to assess the impact of the app.

Data integration

The qualitative data extracted from interviews with parents and clinicians as well as text box data exploring parents' expectations from the study will provide the main source of data to explore the aims and objectives of the process evaluation. Alongside this descriptive data from the online questionnaires will be used, both to provide context to the qualitative data in terms of demographics, but also to help refine the themes emerging from the qualitative data analysis. Mixed methods afford multiple perspectives and seek to converge the findings (29). Researchers will analyse the data synchronously and integrate the outcomes from the different datasets to provide a holistic overview of the results.

Patient and Public Involvement (PPI)

The OPTIMA RCT and STEPS app were developed in conjunction with an advisory board made up of parents of children with neurodevelopmental disorders including ADHD. The PPI group was established early on in the overall OPTIMA programme of research prior to the RCT taking place. The group advised the team about how the design and functionality of the app could be optimised as part of the panel group discussions as well as individually in the usability study (14). This was implemented and piloted before the RCT. The PPI group also supported the team in ensuring that the trial procedures were acceptable to the participants and that any participant-facing documents were written in clear and accessible language. Finally, they also helped with the development of the schedules for the parent interviews. In addition to regular PPI panel meetings throughout the study period, panel members advised on subjects such as how to most effectively communicate with parents, suggestions of how best to reward parents for their time in the study and other study questions. Further, members will be involved in the data analysis process, reading transcripts and taking part in meetings to discuss codes and meanings with OPTIMA researchers.

Ethics and Dissemination

All participants in the study consented to take part via e-consent on Sealed Envelope after having received written and oral information about the study including a brief participant information sheet (PIS) with condensed information in an easy-to-understand format and as well as a full PIS for their reference. All parents received a counter-signed, by the researcher, copy of their consent form. The study received ethical approval from the North West -

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Liverpool Central Research Ethics Committee on 26 November 2021, reference number 21/NW/0319. Findings will be published in open-access, peer-reviewed scientific journals as well as be presented at conferences.

DISCUSSION

STEPS is a digital, self-guided app that is currently being evaluated in the OPTIMA RCT (15). To better understand the study outcomes and contextual factors influencing these, we are conducting a process evaluation using qualitative and quantitative data gathered from parents, clinicians, app usage and demographic data. We expect the results to allow us to understand how the app has worked, such as if it worked as intended, with the aim of understanding the implications of the potential wider use of STEPS, especially within a clinical setting. In understanding the strengths and weaknesses of the intervention, how the intervention was delivered and whether the intended audience received the intervention and how the app can be further developed and improved to attain its intended purpose, we aim to provide a cost-effective and self-guided support to parents awaiting clinical assessment and/or diagnosis for their child.

Research suggests that DHIs may have great potential to deliver large-scale, cost-effective support (11). The STEPS app may be able to bridge the gap between lengthy waiting times for a diagnosis of ADHD and the strains of managing difficult child behaviour. Furthermore, the study will contribute to a body of research that aims to understand how digital interventions work and the factors that contribute to their efficacy, with the aim of improving and understanding the practical implication of using STEPS as a viable DHI to be accessed by a wider population.

Strength and limitations

Integrating qualitative and quantitative data provides a comprehensive evaluation of the way in which the intervention has worked. Capturing the lived experience of parents through interviews will give valuable insight into both the mechanics of how the app works as well as the impact on parenting and child behaviour. The data from the app provide detailed measures of how the app was used by participants and will help to better understand how the app was utilised (e.g., the number of times app was used or the length of time per each app use). Some caution must be exercised when analysing these data in terms of potential errors such as parents opening the app but not actually using it.

Limitations in terms of breadth of participant involvement may occur, for example, participants who do not engage with the study may be less likely to respond to invites to take part in interviews. Participants' interview invites clearly state that the researchers are

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interested in all views, including those who did not engage with the STEPS app to ensure as wide reach as possible is attained.

Interviews with clinicians may provide limited data as many parents in the study will not yet have been assessed, even after completing the final 12-month timepoint, meaning clinicians may have limited feedback/views from the parents regarding the app.

Conclusion

Process evaluations are an essential part of evaluating complex interventions to understand the potential causal mechanisms within the study. Within research, transparency of implementation and rigour and validity throughout the trial is essential. A process evaluation can further the understanding of the mechanisms by which an intervention is successful and for whom it is successful and in what circumstances. Preparing a protocol prior to the process evaluation taking place will further ensure that the planned methodology is adhered to, adding to the validity of the process evaluation. Furthermore, a process evaluation may establish fidelity and quality of the implementation and mechanisms of change and help to understand the context in which the intervention is effective (30).

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Authors' contributions

ESB led the overall conception and design of the study and is the overall OPTIMA Chief Investigator. EH, KKA and ESB led the drafting of this manuscript. KKA is responsible for coordinating the study. BF and EH are responsible for enrolling participants and administering outcome measures and coordinating recruitment. EH and NL are responsible participant interviews, transcription and qualitative data analysis. NL provides administrative support for the project and for the patient and public involvement activities. CH, HK and CG contributed to the conception and design of the study. HK and CG had overall responsibility for qualitative data analysis. All authors have read and approved the final version of this manuscript.

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Competing interests

STEPS concepts and content were designed by ESB together with other members of the OPTIMA team. STEPS visual design and digital implementation were completed by TOAD with funding provided to ESB by the South London & Maudsley NHS Trust. Videos were produced by Eye Witness Productions Ltd. funded by Solent NHS Trust. ESB has received speaker fees, consultancy or research funding from Takeda, Neurotech Solutions, QBtech and Medice. He has received royalties from the New Forest Parenting Programme.

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Structured E-Parenting Support (STEPS)

What is STEPS?

STEPS is a parenting support intervention delivered in the form of a digital application (app).

What is STEPS aiming to do?

STEPS has been designed to decrease conflict in the family by reducing levels of children's oppositionality and defiance. It helps parents to be more effective and self-confident in managing these problems. It 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. It is aimed at supporting parents of primary school-aged children.

How was STEPS developed?

STEPS is evidence based. 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.

How is STEPS implemented?

STEPS can be accessed through a variety of devices. Parents can move through the content (steps) at their own pace and at any time of day. The order of the steps is fixed (see 'How is STEPS structured?'), although there is a degree of choice within each step. STEPS is an unguided intervention, which means there is no personal clinical support for parents progressing through STEPS. The content is delivered mainly using short videos and audio clips. During onboarding each parent will register with the app and choose one of four 'buddies' – a parent character played by an actor, who will accompany them on their STEPS journey.

How is STEPS structured?

STEPS has two preparatory modules, "onboarding" and "introduction", followed by eight separate intervention modules (steps). These steps must be followed in order.

What are the eight steps?

1. **Make a fresh start –** Encourages parents to see their child and themselves in a new, more positive way.
2. **Look after yourself** – Emphasizes how important it is for parents to find time for themselves and to make links with other parents.
3. **Get co-operation** – Explains ways parents can communicate more effectively with their children.
4. **Build confidence** – Highlights how important it is for parents to create situations in which they can praise their child.
5. **Keep it cool** – Helps parents to think of ways they can avoid losing their temper with their children when they are being difficult.
6. **Guide & support** – Shows how parents can help their children navigate around difficult situations where they may find themselves getting upset.

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7. **Structure & boundaries you can trust** – Demonstrates how vital it is that everyone signs up to and follows the house rules.
8. **Reduce conflict and improve behaviour** – Explains how using rewards and sanctions can promote better behaviour in children.

What elements are included in the steps?

Each step has a similar structure and includes the following common elements:

i) **Aims**: sets out the themes to be covered in a step presented by Buddy.
ii) **Science**: provides a short and easy to understand video-description of the evidence behind a step's message presented by a real-life expert.
iii) **Examples:** videos of parents (played by actors) discussing their parenting experiences.
iv) **Skills:** audio presentations of specific skills in simple short sentences accompanied by graphical illustrations.
v) **Reflections:** a chance for parents to write or talk about their experiences.
vi) **Resources:** downloadable aides and guides relating to each step.

How long will STEPS take to complete?

This will depend on the pace and frequency of usage. However, each of the 8 steps are designed to take about 20 minutes if completed in one go.

How will engagement be encouraged?

The app has an attractive design and is easy to use. The use of buddies and pre-recorded prompts automatically sent to parents' devices will help maintain engagement and remind users to reconnect (see table 1).

What happens if parents are having difficulty?

There will be support for parents encountering technical difficulties. For any serious clinical concerns, parents will be provided with contact details for the clinical service to whom they were referred as well as direct contact details for crisis services.

What information will be recorded?

Each parent will be assigned a unique ID, which will be used to link app usage data with the offline study information. Usage data including the number of steps, elements completed, the amount of time parents were engaged with the app and the time of day the app was accessed will be collected.

Who created STEPS?

STEPS concepts and content was designed by Edmund Sonuga-Barke, David Daley, Johnny Downs, Hanna Kovshoff, Jana Kreppner and Margaret Thompson with Samuele Cortese and Cathy Laver-Bradbury providing advice. STEPS visual design and digital implementation was completed by TOAD with funding provided to Sonuga-Barke by the South London & Maudsley NHS Trust. Videos were produced by Eye Witness Productions Ltd. funded by Solent NHS Trust. Special thanks go to Catherine Thompson for her work on an earlier prototype – *New Forest On-Line*.

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Table 1. All prompts sent to app users (grey fill – messages sent via the app; white fill – messages sent via the team).

When?	Seven days from randomisation	One day after download	One week after download	One day after completing Step 1	One week after completing Step 1	Seven days from last activity	Two months to go	After about 6 weeks from download (half-way through access period)	One month to go	One week to go
What?	Hi [Name] Thanks for taking part in OPTIMA. We noticed that you haven't downloaded the STEPS app yet. It is available via the App Store [link] or Google Play [link] If you are having any problems, please reply to this message and we will contact you as soon as we can to help.	Thanks for downloading the STEPS app. Just using it for a few minutes a day can be very useful. We hope you find it helpful.	STEPS TIP: All reflections recorded within the app remain completely private to you and will not be seen by anyone else.	Well done for completing Step 1. Step 2 is all about looking after yourself and includes tips from other parents on finding 'me time'. Click here to have a go now.	Hi [Name] Well done for completing Step 1. Step 2 is all about looking after yourself and includes tips from other parents on finding 'me time'. Click here to have a go now. If you are unsure how to do it or need any help with the app, please reply to this message and we will contact you as soon as we can.	STEPS TIP: When finding time to complete a whole step in one go is tricky, breaking it down into small 'bite-sized' chunks can be helpful.	STEPS UPDATE: You have 2 months left to go on STEPS. Use it while you can.	Hi [name] Thanks for taking part in OPTIMA. It's great to see that you downloaded STEPS. Just dip in and out when you can, at your own pace. If you are unsure how to do it or need any help with the app, please reply to this message and we will contact you as soon as we can.	STEPS UPDATE: You have 1 month left to go on STEPS. There is still time for you to get a lot of out of the app.	STEPS UPDATE: You have 1 week left to go on STEPS. There is still time for you to get a lot of out of the app.
How?	From the research team	Via the app	Via the app	Via the app	From the research team	Via the app	Via the app	From the research team	Via the app	Via the app
How many times?	Two/three times	Once	Once	Once	Once	Twice	Once	Once	Once	Once
Conditional?	Yes, has not downloaded the app	No	No	Yes, has not started Step 2.	Yes, has not started Step 2.	Yes, has not completed the whole app.	No	Yes, downloaded the app but not using it.	No	No

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PARENT INTERVIEW SCHEDULE

Preamble

- Check that the interviewee has received the information sheet, has initialled the box stating they are happy to be contacted for an interview on consent form, understands the OPTIMA trial project and his/her role in it.

- Explain that:
    - The aim of the OPTIMA study is to investigate whether a digital parent education programme, STEPS, can help parents to become more confident and effective in managing their children's difficult behaviour.
    - The research team is talking to some of the parents who are taking part in the study to see how they feel about participating in the trial and using the STEPS app.
    - We are interested in individual experiences and thoughts about STEPS, so please give honest responses, as both positive and negative feedback will help us improve the intervention.
    - We will ask questions relating to your expectations of STEPS, its impact on your parenting and on your child.
    - We will combine all our interview responses so that we can provide an overall picture of parents' views about STEPS. Any comments in the study report are attributed very generally, for example, "A parent commented that…" All comments/opinions will be strictly confidential.

Ask: Do you have any initial questions about the project?

Ethics

- The interview will take about 30-45 minutes
- You do not have to answer any questions that you are not comfortable with and there are no 'right' or 'wrong' answers.
- You can turn your camera off, if you prefer.
- You can stop at any time, no explanation needed
- If you need a comfort break, please just say, that's absolutely fine
- If any question doesn't make sense, ask for an explanation.
- You will receive a £20 shopping voucher as a thank you for taking part. A voucher will be emailed to you within the next 5-7 days.

With your permission we are going to audio/video (if you keep your camera on) record the interview so that we can focus on what you are saying. The interviews will be transcribed by a member of our research team. We remove any reference to any places, clinicians/therapists/family members that may give away your (or others) identity during transcription.

For peer review only

The original transcription will be stored in a restricted-access folder restricted-access folder on the King's College London (KCL) cloud server, and no one other than immediate members of the research team can access this.

Anonymised quotes from transcripts will be used in written reports, published journal articles and presentations including online. Again, any reference to places/family members/clinicians and so on will be removed.

Ask: Do you have any questions about how we use your comments? Please feel free to ask anything however minor it may seem at this stage or at any time later.

Ask: Is it okay to record the interview?

- If participant not satisfied: answer any questions they have. If they do not want to participate, thank them for their time and finish the interview at this point.

Explain procedure

I will begin the interview with my name, the date, time and the identifying code we have assigned to you and your child - this is just to keep the recordings organised. All your identifying details will be removed when the data is transcribed. The first part will be a little about yourself and your family, followed by general questions about the project such as how you were recruited and your expectations, then moving on to the STEPS programme more specifically and then ending with any recommendations and your overall experience of being involved in OPTIMA.

Ask: Do you have any questions before we start?

Ask: Is it okay for me to start recording now?

State researcher's name, date, time, and identifying code (for data management)

Warm up

Please tell me a bit about your family. Where do you live? How many children do you have?

Can you tell me why you went for an assessment for your child (name).Did you go via school? Did you self-refer? GP?

Thinking about the last three months you have taken part in the trial, have you noticed any changes in your child's behaviour? Types of behaviour? Severity of behaviour? Frequency and so on.

I am now going to ask you some questions about being part of the OPTIMA trial and using the STEPS app.

1) Tell me a bit more about your technical experience of using the app
    - How did you feel about the downloading/logging on process?
    - Was it technically easy to use/easy to understand?
    - How did you feel about the way the material was presented? Was it easy to navigate each STEP
    - Did you receive reminders to use the app? If so, how did you feel about these (eg length, regularity)

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2) Tell me a bit more about what you thought about the content of STEPS
   - What did you think about what was included? (thinking about the videos/text)
   - How did you decide which buddy to choose? Did you change buddies at all while using the app? What did you think about the buddies? (If they did not like the buddies, probe asking what would have made them like them better/what type of buddy would they like to see).
   - If you used the STEPS that included examples with children, what did you think about these examples? (Probe would they have like to see more of the children? If they did not like these examples, why?)
   - Was there any content that you felt worked particularly well? Anything that could have done better?

3) Using the app
   - At the time of using the app, what did your life look like? Would you say it was as normal, busier, quieter?
   - Did you go through all the STEPS? If not, which/how many STEPS did you do?
   - If you did not complete all STEPS was there a reason for this? What, if anything, would have made you complete all 8 STEPS?
   - How did you find fitting the recommendations/strategies into everday life?
   - Were there any times of day in particular that you used the app?
   - Were there any particular places that you used the app? Prompt: At home, car, on school run etc
   - Did you use the STEP in the order it was set out or did you move around within each STEP (eg download resources before watching the film clip).
   - Did you complete a STEP all in one go or did you dip in and out?
   - Did you show the app or talk about it to anyone in your family such as partner or grandparents? Did anyone else interact with the app? If so, how often?

4) Implementing the app
   - Did STEPS influence the way you approached your child´s behaviour? If yes, in what way. If no, why do you think this was?
   - Did you use any of the strategies in the app? If so which ones? If you did not make any changes to parenting or your thinking, why?

5) Expectations and reality of using the app
   - Thinking about your **expectations** of STEPS prior to usage. How effective did you **expect** it to be? Prompt for expected effects
   - Did you expect benefits in any other aspects of life?
   - Thinking about the **reality** of using the STEPS once you had started using it. How effective did you find it to be? Prompt for impact on child's behaviour.
   - Did you find benefits in any other aspects of life?
   - Which aspects of the STEPS programme were particularly helpful/unhelpful?

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Follow up question depending on answer: You have mentioned that the programme impacted on X (Follow-up from previous questions). How do you think STEPS influenced that? Was there anything that influenced the impact that STEPS had? If no impacts prompt why?

6) Would you change anything about the STEPS intervention?
   - What additional information, if any, should be included?
   - Was anything included that was unnecessary?

7) How did you feel about receiving STEPS as a digital intervention?
- Would you have preferred another format? If so what?

8)Had you received any parent training prior to (or during) being offered STEPS? If no move on to next question. If yes, ask

- What type of parenting training did you receive? When did you receive it?
- Did the other PT change the way you viewed STEPS? Probe: Was it helpful? Different?

Thank you for answering these questions. We only have a few questions left now and these will focus on the future of STEPS:

Future Direction

8) If the STEPS programme is found to be effective, are there any changes you can think of that we should make before it is routinely offered to parents seeking help for their child's behavioural difficulties?

9) At what point in seeking support from a service do you think it would be most helpful for parents to be given access to STEPS?
- How should this access be given (e.g. through the school, GP, CAMHS)
- Would you recommend the STEPS programme to other parents whose children need support?
- Can you give me a few words that you would use to describe the STEPS app to someone else?

For the final questions I wanted to ask about your experiences of the recruitment process into the OPTIMA trial. The OPTIMA trial is a study where we are testing whether providing support to parents on a service waitlist via a mobile phone app is an effective way of helping them to deal with some parenting challenges.

10) How did you feel about the way you were approached to take part? If you remember how long you had been on the waiting list when we contacted you, would you have preferred to be contacted earlier or later on?

11) What made you decide to take part in the study? What were your initial thoughts about the OPTIMA study?

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12) How did you feel when you were told you would be testing the STEPS app?
    - What did you hope to get out of testing the app from both you and your child's point of view?

13) Finally, what did you think of the online questionnaires such as how long they took, the ease of understanding the questions and getting a voucher as an incentive.

End of questions

That reaches the end of the interview and questions I wanted to ask you.

Thank you so much for giving me your time.

- Do you have anything else you wish to speak about that hasn't been mentioned?
    - Let interviewee talk if they have anything else to add
    - If nothing else – then close interview

If you are okay to end the interview there, I will stop recording now.

Stop recording

Mood Repair

Ask the participant if they have anything nice planned for the rest of the day. If they have any family plans for the weekend (or similar ensuring the participants mood is lifted before you close the interview).

Debriefing

- Ask how they are feeling – whether anything in the interview has troubled them or distressed them or if anything requires clarification
- They can email me if they have any follow up questions
- Thank them again, and ask if they are feeling okay to end interview here.
- Remind about the voucher.

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CLINICIAN INTERVIEW SCHEDULE

Preamble

Check that the interviewee has received the information sheet, understands the OPTIMA project and his/her role in it

Explain that:

The aim of the OPTIMA trial was to investigate whether a parenting programme (STEPS) delivered online to parents seeking help from CAMHS for their child's behavioural difficulties was effective in reducing rates of oppositional defiant disorder.

The research team is speaking to parents and clinicians who were involved in the trial.

We are interested in individual experiences and thoughts about the OPTIMA trial so please give honest responses, as both positive and negative feedback will help us improve the intervention. Explain that they will be asked questions relating to their involvement in the OPTIMA, experiences with recruitment, and factors relating to their institution e.g. NHS However, we combine all the data we collect to provide an overall picture of OPTIMA and its implementation and any comments in the report are attributed very generally, for example, "A clinician commented that…" All comments/opinions will be strictly confidential.

Ask: Do you have any initial questions about the project?

Ethics

Remind interviewee:

- The interview will take about 20 minutes
- You do not have to answer any questions that you are not comfortable with and there are no 'right' or 'wrong' answers
- You can turn your camera off if you wish
- You can stop at any time, no explanation needed
- If you need a comfort break, please just say, that's absolutely fine
- If any question doesn't make sense, ask for an explanation

With your permission we are going to record the interview so that we can focus on what you are saying. This will be transcribed by a member of the research team.

We remove any reference to any places, therapists/family members that may give away yours (or others) identity during transcription.

The original transcription will be stored in a restricted-access folder restricted-access folder on the King's College London (KCL) cloud server and no one other than immediate members of the research team can access this.

Ask: Do you have any questions about how we use your comments?

Ask: Is it okay to record the interview?

- If participant not satisfied: answer any questions they have. If they do not want to participate, thank them for their time and finish the interview at this point.

Explain procedure

I will begin the interview with my name, the date, and time - this is just to keep the recordings organised. All your details will be anonymised when the data is transcribed. The first part will be a little about yourself, followed by general questions about the OPTIMA trial, moving on to your views on recruitment, and ending with institutional issues and future direction.

Ask: Do you have any questions before we start?

Ask: Is it okay for me to start recording now?

Start Interview

State researcher's name, date, and time (for data management)

I want to start by asking some questions about you:

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Background Questions

Please briefly describe your professional background

Prompt (if not covered)

- What is your job title?
- How long have you worked as a clinician with children/young people?

What treatment recommendations would you normally make for young people with …

Prompt (if not covered)

- Referral to a specialist therapist?
- Behavioural treatments and/or medication (referred for? Or given by themselves?)

Now I am going to ask you questions about being part of the OPTIMA trial (if Clinician has not heard about the OPTIMA trial, move on to the next question).

Questions about OPTIMA trial

How did you find out about the STEPS intervention?

What were your expectations of the OPTIMA trial?

- Did it sound like something that would be effective?
- Did you expect people to take part?

Thank you for these answers, that's been really helpful. I'd now like to move on and ask about your thoughts on the STEPS intervention (give a brief summary of the STEPS intervention here).

Questions about the STEPS intervention

What do you think about offering parents on the waiting list for assessment child behavioural difficulties the opportunity to take part in the OPTIMA trial and receive STEPS?

Why do you think parents may have agreed to take part?

Why do you think parents may have declined to take part?

Why do you think parents may not have persisted with the STEPS intervention?

How might STEPS impact on child behaviour?

What factors might influence the effectiveness of the STEPS intervention? Prompt parent factors. Prompt child factors

What might be the barriers to engaging with an online intervention such as STEPS (if not covered) .

How can we better engage parents and families in future work?

Have you received any feedback from parents about the STEPS intervention? If so, what was it?

How do you think online parenting programmes compare to face to face programmes?

Thank you for answering those questions. We only have a few questions left now and these will focus on institutional factors:

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Institutional factors

How do you think the NHS could incorporate the STEPS programme into everyday practice?

Prompt

- Feasibility
- Benefits
- Obstacles

Do you think the NHS would be able to/willing to fund such a project?

Prompt

- Costs versus benefits
- Good use of money?

Future Direction

Overall, would you recommend the STEPS intervention to parents?

Prompt

- Why?
- At what point of referral/child age?

End of questions

That reaches the end of the interview and questions I wanted to ask you.

Thank you very much for your time.

- Do you have anything else you wish to speak about that hasn't been mentioned?
  - Let interviewee talk if they have anything else to add
  - If nothing else – then close interview

If you are okay to end the interview there, I will turn the recording off.

Turn recording off

Debriefing

- They can email me if they have any follow up questions/comments
- Thank them again, and ask if they are feeling okay to end interview here.

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BMJ Open

A protocol for the process evaluation of a Structured E-parenting Support (STEPS) in the OPTIMA randomised controlled trial.

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Secondary Subject Heading:	Evidence based practice, Health economics
Keywords:	Randomized Controlled Trial, Behavior, Clinical Trial, eHealth, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™
Manuscripts

A protocol for the process evaluation of a Structured E-parenting Support (STEPS) in the OPTIMA randomised controlled trial.

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Abstract

Introduction: *Structured E-parenting Support* (STEPS) is a digital application (app) designed to help parents manage behaviour of their children who are referred to mental health services and are waiting for an assessment or treatment. STEPS is currently being evaluated in The Online Parent Training for the Initial Management of ADHD (OPTIMA) randomized controlled trial. Alongside the examination of STEPS' clinical and cost-effectiveness, we are conducting a process evaluation to better understand the contextual factors that may influence study outcomes. The purpose of this protocol is to describe the aims, objectives, and methodology of the process evaluation prior to it taking place to add to the fidelity and rigour of the trial process and outcomes. Our goal is to adapt STEPS to optimise its benefits in future applications. **Methods:** In line with the Medical Research Council guidelines for evaluating complex interventions, the process evaluation will adopt a mixed method design using qualitative data collected from clinicians and parent interviews and app usage data from participants assigned to the intervention arm. **Analysis:** Qualitative data from semi-structured interviews and free text box responses included in trial questionnaires will be analysed thematically using framework analysis to better understand how parents use STEPS, how it works and key factors that could aid or hinder its effective implementation in routine clinical practice. **Ethics:** The application for ethical approval for the study was submitted to the North West - Liverpool Central Research Ethics Committee and received a favourable opinion on further information on 26 November 2021, reference number 21/NW/0319. **Dissemination:** The process evaluation aims to explore how a digital app might support parents in managing their child's behaviour. Implications for policy and research will be explored and the clinical implications of offering the app to a wider audience to address the lack of support to parents as highlighted in this paper. We plan to publish findings in international, peer-reviewed journals as well as present at conferences.

Trial registration: The trial has been prospectively registered on 18 November 2021; ISRCTN 8 16523503. https://www.isrctn.com/ISRCTN16523503.

Keywords: Process evaluation, ADHD, Conduct problems, Randomized Controlled Trial, Digital health, Parenting intervention

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Strengths and Limitations of this study

- Framework analysis allows for in-depth data analysis using a rigorous and transparent methodology.
- Outcomes for quantitative data such as app usage metrics will be integrated with qualitative findings.
- Inclusion of members from the OPTIMA patient and public involvement panel to advise on best practice in working with participants as well as assisting in data analysis and interpretation of the study results.
- All eligible participants were invited to partake in interviews, including those who did not complete all timepoints and those who did not download or use the app, to further understand barriers to uptake and usage of the STEPS app.
- A potential limitation of this study is the crossover of team members working on both the RCT and the process evaluation which may influence the interpretation of the qualitative data.

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INTRODUCTION

Attention-deficit/hyperactivity disorder (ADHD) is a common neuro-developmental condition characterised by symptoms of inattention and/or impulsivity-hyperactivity (1). Children referred for ADHD assessment may also present with co-morbidities such as symptoms of conduct problems (2), which can negatively impact the family (3). The National Institute for Health and Care Excellence (NICE) recommends families should receive support as soon as possible after their referral, however, despite these recommendations, parents frequently endure long waiting times for diagnostic assessment and treatment. The average time between seeking help and receiving an ADHD diagnosis has been estimated as 18.3 months in the UK: the longest average interval compared to other European countries (4). Lengthy waiting times and scarcity of services are the most common barriers to accessing mental health services for children and adolescents as reported by parents (5). Furthermore, these waiting times are likely to get even longer, given consistent rises in the number of referrals to Child and Adolescent Mental Health Services (CAMHS) (6).

A robust body of research has established the efficacy of parent training as a psychosocial intervention for children and young people (7). Research has found that parent training may reduce conduct problems in children with ADHD (8). Moreover, Daley et al. (9) conducted a meta-analysis on behavioural interventions that established improvements in parenting quality as well as a reduction in child ADHD symptoms and conduct problems. However, despite evidence of its efficacy, parent training may not be made available until a diagnosis has been established, leaving parents without support during the lengthy waiting period which can have a detrimental effect on children and their families (10).

Considering evidence that parent training can have a positive outcome for both parent and child, and to provide families with much-needed timely and accessible support, we have developed a digital parenting application called Structured E-Parenting Support (STEPS). Research suggests that digital health interventions (DHIs), such as mobile apps, may have great potential to deliver large-scale, cost-effective support (11). However, there is a real need to understand how health and digital research can work together for effective implementation (12).

The STEPS app and OPTIMA trial

STEPS has been designed to support parents of children with ADHD-type symptoms that are accompanied by challenging behaviour and who are awaiting clinical diagnostic assessment. Its structure, content and approach are described in Appendix A. STEPS draws inspiration from some of the principles underpinning the New Forest Parenting Program (NFPP) (13), an

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established face-to-face parent program based on a long track record of research and clinical practice relating to parenting of child behaviour problems. However, its content, structure, and approach, tailored to the digital delivery, are substantively different from the NFPP. STEPS is delivered via a mobile app that aims to improve parents' understanding of their child's challenging behaviour and increase their perceived self-efficacy to manage such behaviours, as well as facilitate effective parent-child communication. STEPS has one preparatory module, "Introduction", followed by eight separate intervention modules (steps) to be followed in order. Each of the eight steps is designed to take about 20 minutes if completed in one go. The content is delivered via short, pre-recorded videos, audio clips and text, and parents can download resources as well as make notes on their own reflections within each of the modules (steps) (Table 1).

Table 1.

The STEPS app modules' titles and aims.

MODULE Title	Module Aim
1. Make a fresh start	To encourage parents to see their child and themselves in a new, more positive way.
2. Look after yourself	To emphasize the importance for parents to find time for themselves and to make links with other parents.
3. Get their cooperation	To explain ways parents can communicate more effectively with their children
4. Build their confidence	To highlight the importance for parents to create situations in which they can praise their child
5. Lead by example	To help parents think of ways they can avoid losing their temper with their children when they are being difficult.
6. Guide & support them	To show how parents can help their children navigate difficult situations where they may find themselves getting upset.
7. Give them structure	To demonstrate how vital it is that everyone signs up to and follows the house rules
8. Reducing conflict	To explain how using rewards and sanctions can promote better behaviour in children.

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In our previous study, parents rated the app's usability level as very high; the overall STEPS usability score on the System Usability Scale was 94.8 (SD 4.8) out of 100 (14). Moreover, feedback received was used to optimise the app in preparation for the trial. For example, we improved and simplified the registration process, improved video playback and added captions to videos.

The efficacy and cost-effectiveness of STEPS is currently being evaluated in the Online Parent Training for The Initial Management of ADHD referrals (OPTIMA) randomized controlled trial (15). Optima is a two-arm, superiority parallel randomised controlled trial with an internal pilot (14). Participant recruitment took place from May 2022 to July 2023 and during this time 352 parents were randomly assigned to either the intervention group (access to the STEPS app for 3 months) or the Wait as Usual comparison group (WAU) on completion of baseline measures. Randomisation was carried out online via a secure platform provided by Sealed Envelope in a 1:1 ratio and stratification by trial centre location (London, Nottingham, Southampton) using random permuted blocks procedure with varying block sizes. The randomisation system used a unique identifying number.

Questionnaires are administered via Sealed Envelope, every three months at five timepoints. Participants were recruited from mental health services across London, Nottingham, Portsmouth, Southampton and Gloucester, after initial eligibility has been established via a positive screen for high levels of hyperactivity (≥8) and conduct problems (≥4) as measured by the Strengths and Difficulties Questionnaire (16). As part of the screening process, researchers checked whether parents had a phone with an operating system that was compatible with the app and were sufficiently proficient in English to be able to use the app and understand it. Participation in the study does not impact clinical care the family receives, or the time spent on the waitlist. There are no restrictions on concomitant care, which has been monitored carefully during the trial through the child and adolescent service use questionnaire (17). During the study, trial administrators have been on hand to help parents with any technical issues if the app visual download and use guide, which they received from the study team, was insufficient.

The primary outcome of the OPTIMA trial is the severity of behaviour problems at 3 months post-randomisation compared to WAU care using parent-reported child behaviour problems measured with the eight-item ODD subscale of the Swanson Nolan and Pelham Rating Scale (SNAP-IV) (18). For the process evaluation, the mean difference between timepoint one and

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two of the primary outcome will be measured for the intervention arm only. Data relating to the study outcomes comparing the two groups will be published in separate papers.

Process Evaluation Aims and Objectives

Establishing a methodology by which the process evaluation will adhere to a priori is useful to ensure rigour and improve trial quality. Using Medical Research Council (MRC) guidelines (19), this protocol describes the method for the process evaluation of STEPS within the OPTIMA trial. Furthermore, the Standard Protocol Items: recommendations for interventional trials (SPIRIT) checklist has been utilised to provide evidence-based guidance in producing this protocol and is a widely accepted standard for trial protocols (20). Specific objectives are to:

1. To assess the i) reach ii) dose iii) fidelity iv) impact and v) context of the intervention. Table 2 defines the components of process evaluation and shows the methods by which the required information is gathered.
2. To describe how parents implement STEPS.
3. To explore parents' and clinicians' views concerning the value of STEPS and to describe this in the context of their respective needs.
4. To explore external factors that may have acted as barriers to, or facilitators of, STEPS uptake and engagement.
5. To consider the sustainability of the STEPS app beyond the trial and, if shown to be effective, the possible ways it could be incorporated into the clinical pathways.
6. Evaluation of mechanisms of impact (mediating factors contributing to the outcome) and context (intrapersonal and environmental factors influencing app usage).

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Table 2.

The STEPS Process evaluation components and methodology.

	Description	Data collected	Method of evaluation
Reach	The extent to which the intervention reached the intended participants as outlined above in criteria	Data capture via a secure web platform (SE) including age, ethnic origin, education and income of parents and age, gender and ethnicity of child collected at baseline.	Basic statistics including means, ranges and standard deviations. Attrition rates to be calculated at each timepoint.
Dose	Level of intervention delivered and received	STEPS app data downloaded via the application developers Bitjam.	STEPS usage data including time spent per STEP before moving on to the next one, time spent within each STEP and number of STEPS completed. Mean times, ranges and standard deviations will be calculated.
Fidelity	Was the intervention delivered as intended including exploring adaptations or changes made during the study	Data from captured via a secure web platform (SE) on trial expectations. Recordings and minutes from regular PPI panel meetings. Participant feedback on app communication/support	Trial expectations collected at baseline as multiple choice and free text boxes. PPI panel feedback on suggestions for change/adaptations. Participant responses to support material provided throughout the app usage (written instructions/video guides)
Impact	Did the intervention produce change? If so, how?	Parent and clinician interviews. Quantitative data exploring changes in outcome measures (ODD) between timepoint 1 and 2.	30-45 minute parent interviews on the experiences of using the STEPS app including technology, engagement with the STEPS, effect on child behaviour and suggestions of adaptions to the app (see appendix B). Interviews with clinicians on any noticed effects on patients if applicable, barriers to use within the service and suggestions on effective implementation. SNAP-IV ODD subscales measured at baseline and 3 months
Context	External factors influencing change in parent and/or child behaviour and intervention uptake.	Parent interviews exploring changes in child behaviour.	Interviews as above.

Note. ODD=Oppositional Defiance Disorder; PPI=Patient and Public involvement; SE=Sealed Envelope; SNAP IV O (oppositional problems) (20,21)

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Following MRC guidelines for process evaluations (19), a logic model has been developed (Table 3) to elucidate the mechanisms by which the STEPS intervention will produce an outcome and inform the framework of the qualitative analysis. A logic model can be useful in representing the theory of the intervention and its outcomes and helps to clarify the main aspects of the intervention as well as aid in data collection and analysis (21). The STEPS logic model clarifies the current issues in parent support for those waiting on a diagnosis for their child as well as expands on the implications for STEPS use beyond the study. Moreover, by providing a step-by-step process from developing the research question to understanding how outcomes were achieved, it ensures that researchers adhere to the pre-determined process of delivery and analysis.

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Table 3.

STEPS Logic Model

Problem	Proposed Solution	Input and intervention	Mechanisms of impact	Intended outcomes	Intended impact
ADHD is accompanied by Oppositional Defiant Disorder in up to 90% of referred cases. This is associated with child and parent distress and impairment which often drives referrals. Lengthy waiting times to receive assessment and diagnosis which can add to parent and child stress.	To provide low-intensity, unguided support for parents to help them better manage their children's challenging behaviour while they are awaiting formal clinical assessment.	Parents are screened via a secure hosting platform (MHE) or through local health services utilising the SDQ (≥4 conduct problems and ≥8 attention and hyperactive problems). Access to STEPS is given post randomization to the intervention group (n=172) via research administrators and supported via text/email to download and utilise the app. The self-guided, parent training intervention, STEPS, is delivered via a mobile phone application. Parents work through 8 modules (steps) with content delivered via short videos and audio clips. Parents can download additional resources	STEPS draws on the evidence-based NFPP. It includes education about ADHD and uses behavioural techniques, including an emphasis on praise. The delivery of the intervention is underpinned by social learning theory. Modelling techniques are used to develop parenting skills (mastery) and to increase confidence (self-efficacy).	Increased parental understanding of ADHD and its impact on child behaviour. Increased knowledge of strategies to manage challenging child behaviour. Development of a positive parenting style. Improved parent-child communication Improved parental well-being and confidence in managing their child's oppositional behaviour. Reduced levels of oppositionality and defiance in children.	Improved support for parents while waiting on an assessment and diagnosis for their child. Cost-effective and time-efficient delivery of parent training, potentially reducing load on stretched child mental health services. Implementation of STEPS into the care pathway for children with symptoms of ADHD. Extension of parent training to more difficult-to-reach families and those too busy to attend training sessions. Impact on a broader range of family members and key adults (e.g., fathers/grandparents/childminders)

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Problem	Proposed Solution	Input and intervention	Mechanisms of impact	Intended outcomes	Intended impact
Lack of parenting support during waiting times can further add to parent stress and unwanted child behaviour.		and are prompted to reflect on progress via written or audio notes. Engagement is encouraged through use of pre-recorded digital buddies. Parents receive text reminders to engage with the app, tips on app usage and encouragement on completion of a STEP. These are sent via automated text and emails from research admins.	A range of pre-recorded scripts using digital buddies to describe scenarios allows parents to choose a family dynamic that feels relatable to them.	By using digital buddies parents feel less alone and more supported in their journey by being able to relate to their chosen buddy.	

ADHD=Attention Deficit Hyperactive Disorder; MHE=myHealthe; NFPP=New Forest Parenting Program; SDQ=Strength and Difficulties Questionnaire; STEPS= Structured E-parenting support

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METHOD

Design

This mixed-method process evaluation integrates qualitative and quantitative data. Qualitative data will be gathered from semi-structured interviews with parents and clinicians to explore the implementation of the intervention and the perceived impact of the intervention on parenting and child behaviour as well as expectations about the trial as reported by participants via free text responses on the trial questionnaires. Parallel to this, we will use quantitative data such as demographic data and app usage metrics. Table 2 describes the methods and evaluation of data collection.

Qualitative data collection

Qualitative data collection will include semi-structured interviews with parents and clinicians and text gathered from Sealed Envelope asking parents about their trial expectations.

Parent Interviews

Participants who meet the following criteria will be invited to interview; i) have consented to be contacted for interviews via the study consent form (optional consent statement), ii) have been randomised to the STEPS arm. Participants will be invited to take part in interviews irrespective of whether they engaged with the STEPS app or not. Views of participants who have not completed any of the steps are very important in the context of understanding barriers to usage. We aim to recruit n=50 parents for interviews.

Participants who have consented to be contacted about interviews will be approached by a researcher other than the one who has enrolled them on the trial to avoid unblinding. Selection and allocation of eligible participants is completed by the trial manager and trial administrators. Researchers invite participants via email explaining the interview process. The default method for conducting interviews will be a video/phone call (30-45 minutes duration). Participants who wish to complete the interview via email will be sent an adapted interview schedule. Offering a range of ways to engage in the interviews will ensure that those who feel unable to speak with a researcher on the phone will also be able to take part to give a breadth of views from parents.

The interview schedule has been developed by a team of experienced qualitative researchers in collaboration with the OPTIMA Patient and Public Involvement group (PPI). Once the team had finalised the interview schedule, the three researchers involved in conducting the

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interviews, piloted the interviews with members from the PPI group and colleagues. Initially up to an hour had been allocated for the interviews but the pilot showed that 30-45 minutes was adequate time to cover all the questions. Furthermore, the PPI group felt that a decrease in the time required from the parents was more commensurate with the compensation for participation, a £20 Amazon gift voucher. The interview schedules remained dynamic and in the early stage of interviewing, the qualitative team worked together to adapt and add questions.

Questions explore the technical experience of downloading and using the app, views on content and features of the app, such as the STEPS buddies, and feedback on if/how the app influenced aspects of parenting and child behaviour management. They will also ask participants about their thoughts on the effectiveness of STEPS in reducing their child's behavioural challenges and, if applicable, the perceived mechanisms by which STEPS is effective (see appendix B for full interview schedule). Interviews with parents took place between October 2022 and November 2023. All parents who were recruited into the intervention arm were invited to take part in interviews whether they had downloaded the app or not. Invitations went out three months after randomization, ensuring parents had the full three-month usage period of the app. All de-identified transcripts and email responses will be stored in electronic form on a KCL OneDrive for Business and SharePoint location. The original recordings or emails will be deleted from OneDrive for Business after transcription.

Clinician Interviews

Clinicians form no active part in the OPTIMA RCT with the study being independent of any clinical input from CAMHS or other healthcare providers. However, to be eligible for participation in the OPTIMA trial, parents must be on a current wait list for their child to receive clinical support and clinics have been informed of the nature of the OPTIMA RCT. It is therefore important to gain clinical perspectives to effectively evaluate the STEPS app in terms of future directions and implementation. Managers in the clinical services that have supported OPTIMA RCT recruitment will be approached with a request to circulate the clinician information sheet to members of the team. Clinicians interested in taking part are asked to contact the team directly. The clinicians who are interviewed have no active involvement in the trial, the STEPS intervention or the collection of outcome data. Some participants may disclose their use of the STEPS app but the clinician is not asked to probe for this. The purpose of the interviews with clinicians is to get their views about the impact of

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STEPS, potential factors influencing parent engagement and perceived barriers to effectiveness with the aim of facilitating implementation into clinical services.

Clinician interviews can help add depth to the qualitative data in terms of understanding the clinical context in relation to any outcomes shared by parents in terms of contact with services or receiving an assessment and/or diagnosis. Our aim is to include n=10 interviews from clinicians to give adequate representation across the three sites although if more clinicians come forward to be interviewed, they will be able to partake. Clinicians will all be interviewed via phone/video call and data stored as per the participants' data above. There is no incentive for clinicians to take part.

Quantitative data collection

To establish intervention adherence, the number of completed STEPS modules will be measured (min = 0; max = 8), with completion of two modules constituting adherence to the intervention. Other collected app usage events will include: the number of started modules, the number of videos watched, the time spent watching videos (in seconds), the number of audio clips listened to and the time spent listening to audio clips (in seconds), the number of reflections recorded, the number of items saved to favourites, and the number of accessed text resources. These will be used to provide descriptive information about app usage patterns. To determine the intervention's reach, the process evaluation will use data collected from parents at baseline (pre-randomisation) via Sealed Envelope, including demographic data about the parent, such as parent's gender, parent ethnicity, parental education, parent employment status, parent relationship status and family socioeconomic status based on total household income as well as child's age, sex and ethnicity. To describe the severity of oppositional and defiant disorder symptoms and hyperactivity/impulsivity and inattention symptoms in the sample, the respective subscales from the parent-completed SNAP questionnaire will be used (22,23). The 8 items of the SNAP-IV ODD subscale have excellent internal consistency (α=0.93) and the subscale has been shown to be sensitive to change in clinical trials (24). Furthermore, given that ADHD and ASD often co-occur, parent-rated scores for the Social Communication Questionnaire-Lifetime (SCQ-L) will be included (25). The SCQ-L, used in this study to characterise the sample of participants receiving the intervention, has been found to have good internal consistency (Cronbach α=0.82). A cut-off =>15 differentiated young people with a clinical diagnosis of ASD from those without ASD (sensitivity = 0.70 and specificity = 0.67) (26). At baseline, parents are

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asked about their trial expectations. Parents are also asked about previous engagement in parent training (yes/no answer), expectations of receiving parent training (strongly disagree to strongly agree), and expectations of the STEPS app (strongly disagree to strongly agree).

DATA ANALYSIS

Qualitative data analysis

Our objectives are to explore the reach, dose, fidelity, impact and context of the intervention. Qualitative analysis will use a framework approach (27), utilising NVivo version 14, complemented by quantitative analysis. Framework analysis sits within the broader qualitative methodology of thematic analysis and allows researchers to compare data across cases as well as within cases, ensuring the individual's view is retained (27). Framework analysis is a flexible but rigorous method used in health research to integrate qualitative data from different informants and sources. It uses inductive or deductive approaches to identify, describe and interpret patterns (28). Three researchers will take part in both interviewing, transcribing and analysing transcripts with two senior members of the research team taking part in verifying a selection of transcripts. PPI members will work with the research team during the interpretation and verification stages of analysis. Specifically, PPI members will individually review a selection of transcripts to verify the researchers' interpretation of the data and also take part in group meetings to discuss codes and meanings. Although several members of the PPI team have prior experience in qualitative research, 2-3 hours of training on the introduction to qualitative research and how to read and code transcripts will be provided by the research team. Finally, the analysis will be overseen by experts in framework analysis and regular meetings between the researchers analysing the transcripts and the larger qualitative team, will ensure fidelity and cohesiveness in the coding process. The team will start by identifying a coding framework that aligns with the objectives of the study. Creating a data set, researchers will map out the codes and start looking for themes and relationships in the data set. As data moves from codes to themes, the original research questions as well as existing literature will be referred to and discussed and reviewed within the multidisciplinary team to ensure transparency and avoid bias. The method is appropriate for incorporating data from semi-structured interviews, PPI panel discussions and free text box data from questionnaires.

Quantitative data analysis

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Descriptive data on the study sample will be presented to include means, SD, medians, ranges, n values and percentages. Quantitative data measuring changes in oppositional behaviour (SNAP-IV ODD) between baseline and 3 months and making within-group comparisons will also help to assess the impact of the app.

Data integration

The qualitative data extracted from interviews with parents and clinicians as well as text box data exploring parents' expectations about the study will provide the main source of data to explore the aims and objectives of the process evaluation. Alongside this, descriptive data from the online questionnaires will be used, both to provide context to the qualitative data in terms of demographics, but also to help refine the themes emerging from the qualitative data analysis. Mixed methods afford multiple perspectives and seek to converge the findings (29). Researchers will analyse the data synchronously and integrate the outcomes from the different datasets to provide a holistic overview of the results.

Patient and Public Involvement (PPI)

The OPTIMA RCT and STEPS app were developed in conjunction with an advisory board made up of parents of children with neurodevelopmental disorders including ADHD. The PPI group was established early on in the overall OPTIMA programme of research prior to the RCT taking place. The group advised the team about how the design and functionality of the app could be optimised as part of the panel group discussions as well as individually in the usability study (14). This was implemented and piloted before the RCT. The PPI group also supported the team in ensuring that the trial procedures were acceptable to the participants and that any participant-facing documents were written in clear and accessible language. Finally, they also helped with the development of the schedules for the parent interviews. In addition to regular PPI panel meetings throughout the study period, panel members advised on subjects such as how to communicate with parents most effectively, how to structure compensation for participating parents' time in the study and other study management-related questions. Further, members will be involved in the data analysis process, reading transcripts and taking part in meetings to discuss codes and meanings with OPTIMA researchers.

Ethics and Dissemination

All participants in the study consented to take part via e-consent on Sealed Envelope after having received written and oral information about the study including a brief participant information sheet (PIS) with condensed information in an easy-to-understand format and as well as a full PIS for their reference. All parents received a counter-signed, by the researcher,

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copy of their consent form. The study received ethical approval from the North West - Liverpool Central Research Ethics Committee on 26 November 2021, reference number 21/NW/0319. Findings will be published in open-access, peer-reviewed scientific journals as well as be presented at conferences.

DISCUSSION

STEPS is a digital, self-guided app that is currently being evaluated in the OPTIMA RCT (15). To better understand the study outcomes and contextual factors influencing these, we are conducting a process evaluation using qualitative and quantitative data gathered from parents, clinicians, app usage and demographic data. We expect the results to allow us to understand how the app has worked, such as if it worked as intended, with the aim of understanding the implications of the potential wider use of STEPS, especially within a clinical setting. In understanding the strengths and weaknesses of the intervention, how the intervention was delivered and whether the intended audience received the intervention and how the app can be further developed and improved to attain its intended purpose, we aim to provide a cost-effective and self-guided support to parents awaiting clinical assessment and/or diagnosis for their child.

Research suggests that DHIs may have great potential to deliver large-scale, cost-effective support (11). The STEPS app may be able to bridge the gap between lengthy waiting times for a diagnosis of ADHD and the strains of managing difficult child behaviour. Furthermore, the study will contribute to a body of research that aims to understand how digital interventions work and the factors that contribute to their efficacy, with the aim of improving and understanding the practical implication of using STEPS as a viable DHI to be accessed by a wider population.

Strength and limitations

Integrating qualitative and quantitative data provides a comprehensive evaluation of the way in which the intervention has worked. Capturing the lived experience of parents through interviews will give valuable insight into both the mechanisms of how the app works as well as the impact on parenting and child behaviour. The data from the app provide detailed measures of how the app was used by participants and will help to better understand how the app was utilised (e.g., the number of times app was used or the length of time per each app use). Some caution must be exercised when analysing these data in terms of potential errors such as parents opening the app but not actually using it.

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Limitations in terms of breadth of participant involvement may occur, for example, participants who do not engage with the study may be less likely to respond to invites to take part in interviews. Participants' interview invites clearly state that the researchers are interested in all views, including those who did not engage with the STEPS app to ensure as wide reach as possible is attained.

Interviews with clinicians may provide limited data as many parents in the study will not yet have been assessed, even after completing the final 12-month timepoint, meaning clinicians may have limited feedback/views from the parents regarding the app.

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Authors' contributions

ESB led the overall conception and design of the study and is the overall OPTIMA Chief Investigator. EH, KKA and ESB led the drafting of this manuscript. KKA is responsible for coordinating the study. BF and EH are responsible for enrolling participants and administering outcome measures and coordinating recruitment. EH and NL are responsible for participant interviews, transcription and qualitative data analysis. NL provides administrative support for the project and for the patient and public involvement activities. CH, HK and CG contributed to the conception and design of the study. HK and CG had overall responsibility for qualitative data analysis. All authors have read and approved the final version of this manuscript.

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Competing interests

STEPS concepts and content were designed by Edmund Sonuga-Barke together with other members of the OPTIMA team; David Daley, Johnny Downs, Jana Kreppner, Hanna Kovshoff and Margaret Thompson. STEPS visual design and digital implementation were completed by TOAD with funding provided to ESB by the South London& Maudsley NHS Trust. Videos were produced by EyeWitness Productions Ltd. funded by Solent NHS Trust. ESB has received speaker fees, consultancy or research funding from Takeda, Neurotech Solutions, QBtech and Medice. He has received royalties from the New Forest Parenting Programme.

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Structured E-Parenting Support (STEPS)

What is STEPS?

STEPS is a parenting support intervention delivered in the form of a digital application (app).

What is STEPS aiming to do?

STEPS has been designed to decrease conflict in the family by reducing levels of children's oppositionality and defiance. It helps parents to be more effective and self-confident in managing these problems. It 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. It is aimed at supporting parents of primary school-aged children.

How was STEPS developed?

STEPS is evidence based. 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.

How is STEPS implemented?

STEPS can be accessed through a variety of devices. Parents can move through the content (steps) at their own pace and at any time of day. The order of the steps is fixed (see 'How is STEPS structured?'), although there is a degree of choice within each step. STEPS is an unguided intervention, which means there is no personal clinical support for parents progressing through STEPS. The content is delivered mainly using short videos and audio clips. During onboarding each parent will register with the app and choose one of four 'buddies' – a parent character played by an actor, who will accompany them on their STEPS journey.

How is STEPS structured?

STEPS has two preparatory modules, "onboarding" and "introduction", followed by eight separate intervention modules (steps). These steps must be followed in order.

What are the eight steps?

1. **Make a fresh start –** Encourages parents to see their child and themselves in a new, more positive way.
2. **Look after yourself** – Emphasizes how important it is for parents to find time for themselves and to make links with other parents.
3. **Get co-operation** – Explains ways parents can communicate more effectively with their children.
4. **Build confidence** – Highlights how important it is for parents to create situations in which they can praise their child.
5. **Keep it cool** – Helps parents to think of ways they can avoid losing their temper with their children when they are being difficult.
6. **Guide & support** – Shows how parents can help their children navigate around difficult situations where they may find themselves getting upset.

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7. **Structure & boundaries you can trust** – Demonstrates how vital it is that everyone signs up to and follows the house rules.
8. **Reduce conflict and improve behaviour** – Explains how using rewards and sanctions can promote better behaviour in children.

What elements are included in the steps?

Each step has a similar structure and includes the following common elements:

i) **Aims**: sets out the themes to be covered in a step presented by Buddy.
ii) **Science**: provides a short and easy to understand video-description of the evidence behind a step's message presented by a real-life expert.
iii) **Examples:** videos of parents (played by actors) discussing their parenting experiences.
iv) **Skills:** audio presentations of specific skills in simple short sentences accompanied by graphical illustrations.
v) **Reflections:** a chance for parents to write or talk about their experiences.
vi) **Resources:** downloadable aides and guides relating to each step.

How long will STEPS take to complete?

This will depend on the pace and frequency of usage. However, each of the 8 steps are designed to take about 20 minutes if completed in one go.

How will engagement be encouraged?

The app has an attractive design and is easy to use. The use of buddies and pre-recorded prompts automatically sent to parents' devices will help maintain engagement and remind users to reconnect (see table 1).

What happens if parents are having difficulty?

There will be support for parents encountering technical difficulties. For any serious clinical concerns, parents will be provided with contact details for the clinical service to whom they were referred as well as direct contact details for crisis services.

What information will be recorded?

Each parent will be assigned a unique ID, which will be used to link app usage data with the offline study information. Usage data including the number of steps, elements completed, the amount of time parents were engaged with the app and the time of day the app was accessed will be collected.

Who created STEPS?

STEPS concepts and content was designed by Edmund Sonuga-Barke, David Daley, Johnny Downs, Hanna Kovshoff, Jana Kreppner and Margaret Thompson with Samuele Cortese and Cathy Laver-Bradbury providing advice. STEPS visual design and digital implementation was completed by TOAD with funding provided to Sonuga-Barke by the South London & Maudsley NHS Trust. Videos were produced by Eye Witness Productions Ltd. funded by Solent NHS Trust. Special thanks go to Catherine Thompson for her work on an earlier prototype – *New Forest On-Line*.

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Table 1. All prompts sent to app users (grey fill – messages sent via the app; white fill – messages sent via the team).

When?	Seven days from randomisation	One day after download	One week after download	One day after completing Step 1	One week after completing Step 1	Seven days from last activity	Two months to go	After about 6 weeks from download (half-way through access period)	One month to go	One week to go
What?	Hi [Name] Thanks for taking part in OPTIMA. We noticed that you haven't downloaded the STEPS app yet. It is available via the App Store [link] or Google Play [link] If you are having any problems, please reply to this message and we will contact you as soon as we can to help.	Thanks for downloading the STEPS app. Just using it for a few minutes a day can be very useful. We hope you find it helpful.	STEPS TIP: All reflections recorded within the app remain completely private to you and will not be seen by anyone else.	Well done for completing Step 1. Step 2 is all about looking after yourself and includes tips from other parents on finding 'me time'. Click here to have a go now.	Hi [Name] Well done for completing Step 1. Step 2 is all about looking after yourself and includes tips from other parents on finding 'me time'. Click here to have a go now. If you are unsure how to do it or need any help with the app, please reply to this message and we will contact you as soon as we can.	STEPS TIP: When finding time to complete a whole step in one go is tricky, breaking it down into small 'bite-sized' chunks can be helpful.	STEPS UPDATE: You have 2 months left to go on STEPS. Use it while you can.	Hi [name] Thanks for taking part in OPTIMA. It's great to see that you downloaded STEPS. Just dip in and out when you can, at your own pace. If you are unsure how to do it or need any help with the app, please reply to this message and we will contact you as soon as we can.	STEPS UPDATE: You have 1 month left to go on STEPS. There is still time for you to get a lot of out of the app.	STEPS UPDATE: You have 1 week left to go on STEPS. There is still time for you to get a lot of out of the app.
How?	From the research team	Via the app	Via the app	Via the app	From the research team	Via the app	Via the app	From the research team	Via the app	Via the app
How many times?	Two/three times	Once	Once	Once	Once	Twice	Once	Once	Once	Once
Conditional?	Yes, has not downloaded the app	No	No	Yes, has not started Step 2.	Yes, has not started Step 2.	Yes, has not completed the whole app.	No	Yes, downloaded the app but not using it.	No	No

For peer review only

PARENT INTERVIEW SCHEDULE

Preamble

- Check that the interviewee has received the information sheet, has initialled the box stating they are happy to be contacted for an interview on consent form, understands the OPTIMA trial project and his/her role in it.

- Explain that:
    - The aim of the OPTIMA study is to investigate whether a digital parent education programme, STEPS, can help parents to become more confident and effective in managing their children's difficult behaviour.
    - The research team is talking to some of the parents who are taking part in the study to see how they feel about participating in the trial and using the STEPS app.
    - We are interested in individual experiences and thoughts about STEPS, so please give honest responses, as both positive and negative feedback will help us improve the intervention.
    - We will ask questions relating to your expectations of STEPS, its impact on your parenting and on your child.
    - We will combine all our interview responses so that we can provide an overall picture of parents' views about STEPS. Any comments in the study report are attributed very generally, for example, "A parent commented that…" All comments/opinions will be strictly confidential.

Ask: Do you have any initial questions about the project?

Ethics

- The interview will take about 30-45 minutes
- You do not have to answer any questions that you are not comfortable with and there are no 'right' or 'wrong' answers.
- You can turn your camera off, if you prefer.
- You can stop at any time, no explanation needed
- If you need a comfort break, please just say, that's absolutely fine
- If any question doesn't make sense, ask for an explanation.
- You will receive a £20 shopping voucher as a thank you for taking part. A voucher will be emailed to you within the next 5-7 days.

With your permission we are going to audio/video (if you keep your camera on) record the interview so that we can focus on what you are saying. The interviews will be transcribed by a member of our research team. We remove any reference to any places, clinicians/therapists/family members that may give away your (or others) identity during transcription.

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The original transcription will be stored in a restricted-access folder restricted-access folder on the King's College London (KCL) cloud server, and no one other than immediate members of the research team can access this.

Anonymised quotes from transcripts will be used in written reports, published journal articles and presentations including online. Again, any reference to places/family members/clinicians and so on will be removed.

Ask: Do you have any questions about how we use your comments? Please feel free to ask anything however minor it may seem at this stage or at any time later.

Ask: Is it okay to record the interview?

- If participant not satisfied: answer any questions they have. If they do not want to participate, thank them for their time and finish the interview at this point.

Explain procedure

I will begin the interview with my name, the date, time and the identifying code we have assigned to you and your child - this is just to keep the recordings organised. All your identifying details will be removed when the data is transcribed. The first part will be a little about yourself and your family, followed by general questions about the project such as how you were recruited and your expectations, then moving on to the STEPS programme more specifically and then ending with any recommendations and your overall experience of being involved in OPTIMA.

Ask: Do you have any questions before we start?

Ask: Is it okay for me to start recording now?

State researcher's name, date, time, and identifying code (for data management)

Warm up

Please tell me a bit about your family. Where do you live? How many children do you have?

Can you tell me why you went for an assessment for your child (name).Did you go via school? Did you self-refer? GP?

Thinking about the last three months you have taken part in the trial, have you noticed any changes in your child's behaviour? Types of behaviour? Severity of behaviour? Frequency and so on.

I am now going to ask you some questions about being part of the OPTIMA trial and using the STEPS app.

1) Tell me a bit more about your technical experience of using the app
    - How did you feel about the downloading/logging on process?
    - Was it technically easy to use/easy to understand?
    - How did you feel about the way the material was presented? Was it easy to navigate each STEP
    - Did you receive reminders to use the app? If so, how did you feel about these (eg length, regularity)

For review only

2) Tell me a bit more about what you thought about the content of STEPS
   - What did you think about what was included? (thinking about the videos/text)
   - How did you decide which buddy to choose? Did you change buddies at all while using the app? What did you think about the buddies? (If they did not like the buddies, probe asking what would have made them like them better/what type of buddy would they like to see).
   - If you used the STEPS that included examples with children, what did you think about these examples? (Probe would they have like to see more of the children? If they did not like these examples, why?)
   - Was there any content that you felt worked particularly well? Anything that could have done better?

3) Using the app
   - At the time of using the app, what did your life look like? Would you say it was as normal, busier, quieter?
   - Did you go through all the STEPS? If not, which/how many STEPS did you do?
   - If you did not complete all STEPS was there a reason for this? What, if anything, would have made you complete all 8 STEPS?
   - How did you find fitting the recommendations/strategies into everday life?
   - Were there any times of day in particular that you used the app?
   - Were there any particular places that you used the app? Prompt: At home, car, on school run etc
   - Did you use the STEP in the order it was set out or did you move around within each STEP (eg download resources before watching the film clip).
   - Did you complete a STEP all in one go or did you dip in and out?
   - Did you show the app or talk about it to anyone in your family such as partner or grandparents? Did anyone else interact with the app? If so, how often?

4) Implementing the app
   - Did STEPS influence the way you approached your child´s behaviour? If yes, in what way. If no, why do you think this was?
   - Did you use any of the strategies in the app? If so which ones? If you did not make any changes to parenting or your thinking, why?

5) Expectations and reality of using the app
   - Thinking about your **expectations** of STEPS prior to usage. How effective did you **expect** it to be? Prompt for expected effects
   - Did you expect benefits in any other aspects of life?
   - Thinking about the **reality** of using the STEPS once you had started using it. How effective did you find it to be? Prompt for impact on child's behaviour.
   - Did you find benefits in any other aspects of life?
   - Which aspects of the STEPS programme were particularly helpful/unhelpful?

For peer review only

Follow up question depending on answer: You have mentioned that the programme impacted on X (Follow-up from previous questions). How do you think STEPS influenced that? Was there anything that influenced the impact that STEPS had? If no impacts prompt why?

6) Would you change anything about the STEPS intervention?
   - What additional information, if any, should be included?
   - Was anything included that was unnecessary?

7) How did you feel about receiving STEPS as a digital intervention?
- Would you have preferred another format? If so what?

8)Had you received any parent training prior to (or during) being offered STEPS? If no move on to next question. If yes, ask

- What type of parenting training did you receive? When did you receive it?
- Did the other PT change the way you viewed STEPS? Probe: Was it helpful? Different?

Thank you for answering these questions. We only have a few questions left now and these will focus on the future of STEPS:

Future Direction

8) If the STEPS programme is found to be effective, are there any changes you can think of that we should make before it is routinely offered to parents seeking help for their child's behavioural difficulties?

9) At what point in seeking support from a service do you think it would be most helpful for parents to be given access to STEPS?
- How should this access be given (e.g. through the school, GP, CAMHS)
- Would you recommend the STEPS programme to other parents whose children need support?
- Can you give me a few words that you would use to describe the STEPS app to someone else?

For the final questions I wanted to ask about your experiences of the recruitment process into the OPTIMA trial. The OPTIMA trial is a study where we are testing whether providing support to parents on a service waitlist via a mobile phone app is an effective way of helping them to deal with some parenting challenges.

10) How did you feel about the way you were approached to take part? If you remember how long you had been on the waiting list when we contacted you, would you have preferred to be contacted earlier or later on?

11) What made you decide to take part in the study? What were your initial thoughts about the OPTIMA study?

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12) How did you feel when you were told you would be testing the STEPS app?
    - What did you hope to get out of testing the app from both you and your child's point of view?

13) Finally, what did you think of the online questionnaires such as how long they took, the ease of understanding the questions and getting a voucher as an incentive.

End of questions

That reaches the end of the interview and questions I wanted to ask you.

Thank you so much for giving me your time.

- Do you have anything else you wish to speak about that hasn't been mentioned?
    - Let interviewee talk if they have anything else to add
    - If nothing else – then close interview

If you are okay to end the interview there, I will stop recording now.

Stop recording

Mood Repair

Ask the participant if they have anything nice planned for the rest of the day. If they have any family plans for the weekend (or similar ensuring the participants mood is lifted before you close the interview).

Debriefing

- Ask how they are feeling – whether anything in the interview has troubled them or distressed them or if anything requires clarification
- They can email me if they have any follow up questions
- Thank them again, and ask if they are feeling okay to end interview here.
- Remind about the voucher.

For peer review only

CLINICIAN INTERVIEW SCHEDULE

Preamble

Check that the interviewee has received the information sheet, understands the OPTIMA project and his/her role in it

Explain that:

The aim of the OPTIMA trial was to investigate whether a parenting programme (STEPS) delivered online to parents seeking help from CAMHS for their child's behavioural difficulties was effective in reducing rates of oppositional defiant disorder.

The research team is speaking to parents and clinicians who were involved in the trial.

We are interested in individual experiences and thoughts about the OPTIMA trial so please give honest responses, as both positive and negative feedback will help us improve the intervention. Explain that they will be asked questions relating to their involvement in the OPTIMA, experiences with recruitment, and factors relating to their institution e.g. NHS However, we combine all the data we collect to provide an overall picture of OPTIMA and its implementation and any comments in the report are attributed very generally, for example, "A clinician commented that…" All comments/opinions will be strictly confidential.

Ask: Do you have any initial questions about the project?

Ethics

Remind interviewee:

- The interview will take about 20 minutes
- You do not have to answer any questions that you are not comfortable with and there are no 'right' or 'wrong' answers
- You can turn your camera off if you wish
- You can stop at any time, no explanation needed
- If you need a comfort break, please just say, that's absolutely fine
- If any question doesn't make sense, ask for an explanation

With your permission we are going to record the interview so that we can focus on what you are saying. This will be transcribed by a member of the research team.

We remove any reference to any places, therapists/family members that may give away yours (or others) identity during transcription.

The original transcription will be stored in a restricted-access folder restricted-access folder on the King's College London (KCL) cloud server and no one other than immediate members of the research team can access this.

Ask: Do you have any questions about how we use your comments?

Ask: Is it okay to record the interview?

- If participant not satisfied: answer any questions they have. If they do not want to participate, thank them for their time and finish the interview at this point.

Explain procedure

I will begin the interview with my name, the date, and time - this is just to keep the recordings organised. All your details will be anonymised when the data is transcribed. The first part will be a little about yourself, followed by general questions about the OPTIMA trial, moving on to your views on recruitment, and ending with institutional issues and future direction.

Ask: Do you have any questions before we start?

Ask: Is it okay for me to start recording now?

Start Interview

State researcher's name, date, and time (for data management)

I want to start by asking some questions about you:

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Background Questions

Please briefly describe your professional background

Prompt (if not covered)

- What is your job title?
- How long have you worked as a clinician with children/young people?

What treatment recommendations would you normally make for young people with …

Prompt (if not covered)

- Referral to a specialist therapist?
- Behavioural treatments and/or medication (referred for? Or given by themselves?)

Now I am going to ask you questions about being part of the OPTIMA trial (if Clinician has not heard about the OPTIMA trial, move on to the next question).

Questions about OPTIMA trial

How did you find out about the STEPS intervention?

What were your expectations of the OPTIMA trial?

- Did it sound like something that would be effective?
- Did you expect people to take part?

Thank you for these answers, that's been really helpful. I'd now like to move on and ask about your thoughts on the STEPS intervention (give a brief summary of the STEPS intervention here).

Questions about the STEPS intervention

What do you think about offering parents on the waiting list for assessment child behavioural difficulties the opportunity to take part in the OPTIMA trial and receive STEPS?

Why do you think parents may have agreed to take part?

Why do you think parents may have declined to take part?

Why do you think parents may not have persisted with the STEPS intervention?

How might STEPS impact on child behaviour?

What factors might influence the effectiveness of the STEPS intervention? Prompt parent factors. Prompt child factors

What might be the barriers to engaging with an online intervention such as STEPS (if not covered) .

How can we better engage parents and families in future work?

Have you received any feedback from parents about the STEPS intervention? If so, what was it?

How do you think online parenting programmes compare to face to face programmes?

Thank you for answering those questions. We only have a few questions left now and these will focus on institutional factors:

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Institutional factors

How do you think the NHS could incorporate the STEPS programme into everyday practice?

Prompt

- Feasibility
- Benefits
- Obstacles

Do you think the NHS would be able to/willing to fund such a project?

Prompt

- Costs versus benefits
- Good use of money?

Future Direction

Overall, would you recommend the STEPS intervention to parents?

Prompt

- Why?
- At what point of referral/child age?

End of questions

That reaches the end of the interview and questions I wanted to ask you.

Thank you very much for your time.

- Do you have anything else you wish to speak about that hasn't been mentioned?
  - Let interviewee talk if they have anything else to add
  - If nothing else – then close interview

If you are okay to end the interview there, I will turn the recording off.

Turn recording off

Debriefing

- They can email me if they have any follow up questions/comments
- Thank them again, and ask if they are feeling okay to end interview here.

For peer review only