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Effectiveness of an online intervention for parents/guardians of children aged 4–7 years who are concerned about their child's emotional and behavioural development: protocol for an online randomised controlled trial (EMERGENT study)

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ABSTRACT

Introduction The demand for resources to support emotional and behavioural development in early childhood is ever increasing. However, conventional interventions are lacking in resources and have significant barriers. The Embers the Dragon programme helps address the growing unmet need of children requiring support. The delivery of the current project seeks to help support parents, reduce the burden placed on pressed services (eg, Child and Adolescent Mental Health Services) and to help improve the emotional and behavioural development of children.

Methods and analysis This project aims to investigate the efficacy and acceptability of Embers on parenting and children's psychosocial outcomes. 364 parents/guardians of children aged between 4 and 7 will be recruited via the internet, schools and general practitioners (GPs). This is an online waitlist-controlled trial with three arms: (1) control arm, (2) access to Embers arm and (3) access to Embers+school. Participants will be randomised (1:1) into (1) or (2) to evaluate the use of Embers at home. To evaluate scalability in schools, (3) will be compared with (2), and (1) to test efficacy against treatment as usual (not receiving the intervention). Qualitative interviews will also be conducted. Primary outcomes are the Parental Self-efficacy Scale, Strengths and Difficulties Questionnaire and qualitative interviews. Outcomes will be compared between the three groups at baseline, 8, 16 and 24 weeks.

Ethics and dissemination Ethical approval has been granted by the London South Bank University ethics panel (ETH2324-0004). To recruit via GPs, NHS ethical approval has been applied for, and the IRAS (331410) application is under consideration by the Central Bristol REC. The results of the project will be submitted for publication in a peer-reviewed journal. Parents/guardians will provide informed consent online prior to taking part in the study. For the interviews, assent will be taken from children by the researchers on the day.

Trial registration number ISRCTN58327872

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A key strength of the project is the use of a mixed method (qualitative and quantitative) process evaluation to understand the intervention's mechanisms of action and participants' experience of the intervention.
⇒ Patient and public involvement work has been used throughout the development and design of the project to help ensure that all aspects are as relevant, meaningful and appropriate as possible for end users.
⇒ This trial is only available to English-speaking participants with access to a computer/internet.
⇒ Given the nature of the study and data collection, participants will not be blinded to their condition allocation, and the research team will not be blinded to participant allocation for the purpose of data completion requests.

INTRODUCTION

Mental health issues in early childhood are a prevalent and ever-growing problem, further exacerbated by the COVID-19 pandemic.[1–4] Approximately one in six children (4–5 to 16–19 years old) in the UK experience mental health issues, which refer to any patterns and/or changes to their emotional and behavioural development that causes distress or interferes with their daily lives.[1 5 6] Despite this, children and young people's access to mental health support has deteriorated significantly since 2020/2021.[1 5 7 8] Mental health services currently offered to address children's mental health face financial and logistical barriers to provision at scale.[2 3 5 7 8] This increases the likelihood of medium and long-term detrimental

impacts on individuals and society.[3 7] Increasing access to early interventions that can be delivered at home and schools could considerably improve longer term health, well-being and societal function for children, as well as aid already overburdened services (eg, Child and Adolescent Mental Health Services; CAMHS), and help to support schools and parents/guardians.[9–11]

The Embers the Dragon programme was designed to provide an accessible, affordable intervention to help address the growing unmet need for children's mental health support. It is a psychoeducation digital platform developed to support parents/guardians, children aged 4–7 and schools in developing emotional well-being in early years. The programme is based on social learning theory[12] and uses activities focusing on modelling and reinforcement to encourage parent-supported development of social-emotional skills in children. One of the key features of the programme is a series of animated stories which follow the adventures of Embers and his friends as they explore the common challenges of childhood. Along with each animated story, the platform also offers psychoeducation videos and other resources for parents/guardians that cover topics such as child development, modelling, reinforcement and parent management techniques for behaviours of concern. To support schools, the programme offers lesson plans and classroom resources which can be distributed to a whole class, small group or 1:1 approach.

The results of a feasibility study for trialling the platform revealed that 98% of parents/guardians reported a significant improvement in their self-assessed parental effectiveness and confidence in responding to their children's emotional needs.[13] Qualitative feedback also demonstrated that children were able to successfully recall coping strategies highlighted in the programme.[13] Building on these findings, the current randomised controlled trial aims to evaluate the accessibility, efficacy and acceptability of the platform in real-world use, and to prepare for commercialisation. The main objectives of the project are the following:

- Deliver a pragmatic trial to establish real-world efficacy and acceptability of Embers by measuring impacts on (1) parenting style, confidence and effectiveness, and (2) children's psychosocial development, when delivered in both home and school settings.
- Via a comprehensive and mixed method process evaluation, examine in detail the context and lived experience of the intervention.
- To explore if the impact of the intervention varies as a function of (1) usage patterns and (2) user profile.
- To examine the health economic impacts of the intervention.

METHODS AND ANALYSIS

Study design

The current project is a waitlist-controlled pragmatic field trial with three arms: (1) a control arm comprising treatment as usual (TAU), (2) access to Embers arm and (3) access to Embers+school plan. Participants will be randomised into (1) or (2) to evaluate the use of Embers in a home, parent-led setting. To evaluate scalability in school settings, we will also recruit a (non-randomised) sample of classes from schools to receive the intervention to compare (3) to (2) to test the impact of the added school content and setting and (1) to test efficacy against TAU. The primary outcomes for the current study are the Parental Self-efficacy Scale (PSOC; Johnston and Marsh, 1989),[14] Strengths and Difficulties Questionnaire (SDQ; Goodman, 1999)[15] and the qualitative interviews. The secondary outcomes for the current study are EQ-5D-3L (Herdman *et al*, 2011)[16] and data collected to examine access and duration usage of the Embers app, user acceptability, parent engagement and health economic status. The study settings are in home environments (home, control conditions) and in primary school and home environments (school condition).

Study status

Recruitment for the study started in November 2023 via expressions of interest. No participants have consented at the time of this protocol submission. Recruitment to the study is expected to be open until December 2024, and the follow-up measures until March 2026.

Participant identification

Eligible participants will be identified via four channels: social media, schools, general practitioners (GPs) and third sector and community sites.

Social media channel

Recruitment materials will be posted on various social media platforms, including Facebook, X, TikTok, Instagram, etc. Interested individuals will be directed to the study landing page, which will include key info about the study, contact details of the research team, link to the screening questionnaire and consent form (see online supplemental material 1).

School channel

Collaborating schools in London, the Southeast and Yorkshire regions will distribute study brochures to parents/guardians of children that fall in the target age range (4–7 years old), which will direct them to the study landing page. The schools, as well as parents/guardians, are told that all children in the collaborating school will have access to the platform in the classroom, but only those parents/guardians who consent to take part in the project will be invited to provide data for the evaluation.

GP channel

Collaborating GPs based in London, the Southeast and Yorkshire will identify parents/guardians of children that fall in the target age range from electronic database searches of their clinical systems. Following this, GPs will distribute study brochures to these individuals, which will direct them to the study landing page.

Third sector and community site channel

Similar to the approach taken via the social media channel, recruitment materials will be posted on various third sector and community platforms, including YoungMinds, Little Lives, Mumsnet, Family Rights Group, etc. Interested individuals will be directed to the study landing page.

Screening process

All individuals will be screened against the following inclusion and exclusion criteria:

Inclusion criteria

- Parents/guardians of children aged 4–7 who are concerned about their children's mental/emotional well-being, including both those who are and are not already actively seeking professional support.
- Parents/guardians of children who will receive the Embers intervention in a school setting (school condition only).
- Both parent and child fluent in English.
- Access to a platform-compatible digital device.
- Willingness to complete follow-up measures.

Exclusion criteria

- Previous experience with the Embers programme.
- Currently undergoing a treatment intervention with CAMHS or social care.
- Shares parenting/caring duties for the same child for which a parent/guardian is already recruited.
- Already recruited to the study in relation to a different child.
- Previous involvement in Patient and Public Involvement and Engagement (PPIE) work associated with Embers.

Randomisation

Participants will be randomised to either the control arm or access to Embers arm stratifying by age and gender of the child using block randomisation. To achieve this, the *blockrand* command from the blockrand R package was used. The block size was randomised between 1 and 4, and 68 slots per stratification permutation generated. The randomisation ratio is 1:1 between the access at home and control conditions. Children in the school condition will not be randomised.

Participants in the access to Embers+school plan arm are not randomised.

Participant timeline

Participant flow through the study is shown in figure 1. Participants recruited via the social media or the third sector community site channels will access the screening survey via a link on the study landing page. Participants recruited via schools and GPs will access the screening survey via a QR code on the study brochure. Once eligibility has been confirmed, participants will complete the consent form online via Qualtrics (see online supplemental material 1). Once consent has been attained, participants will be randomised to either the access to Embers arm or the control arm. The access to Embers arm (school condition) comprised participants who were recruited via schools and are not randomised. Participants are asked to complete a series of surveys online at four time points (baseline, 8 weeks, 16 weeks and 24 weeks). Additionally, participants in the access to Embers arm, and access to Embers (school condition) arm are invited to take part in an interview to examine their lived experiences of using the Embers programme. These interviews will be conducted either face to face or online.

Sample size calculation

We will aim to recruit n=364 completed cases. Pilot feasibility work revealed an effect size of d=0.51 (a medium effect size, equivalent to effect size f=0.26) between premeasures and postmeasures in the intervention group in parental confidence and no difference over time in the control. In the current study, a sample of n=364 allows detection of within/between interactions in repeated measures analysis of variance at f=>0.07 (ie, small effect size interactions) as well as comparisons within such an analysis between any one-time point at any two conditions at f=0.17 (a small-medium effect size). Power calculations were calculated at α=0.05 and power=0.90 using GPower V.3.1. A previous attrition rate of 14% between consent (n=129) and the final follow-up point (n=111) was observed in our feasibility work. As we are targeting a community sample, including from seldom heard populations, we anticipate that this rate may increase to around 33%. Thus, to reach the final sample of n=364 will require us to consent 543 parents/guardians.

Outcomes

Table 1 shows all the measures and when they are completed.

Primary outcomes

Parental Self-efficacy Scale

The PSOC aims to measure parents' perceived confidence in their parental skill in supporting their children. The measure comprises five items rated on a 5-point Likert scale. The items are summed to yield a total score, with higher scores indicating higher levels of parental self-efficacy (Johnston and Marsh, 1989).[14]

Strengths and Difficulties Questionnaire

The SDQ aims to assess the behaviours, emotions and relationships of children and young people (aged 4–17 years) over the past 6 months. The scale comprised 25 items, divided between five scales (emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and prosocial behaviour). Lower scores on the emotional symptoms, conduct problems, hyperactivity/inattention and peer relationship problem scales indicate a lower level of difficulty, whereas scoring is reversed for the prosocial behaviour scale, with higher scores indicating lower levels of difficulty (Goodman, 1997).[17]

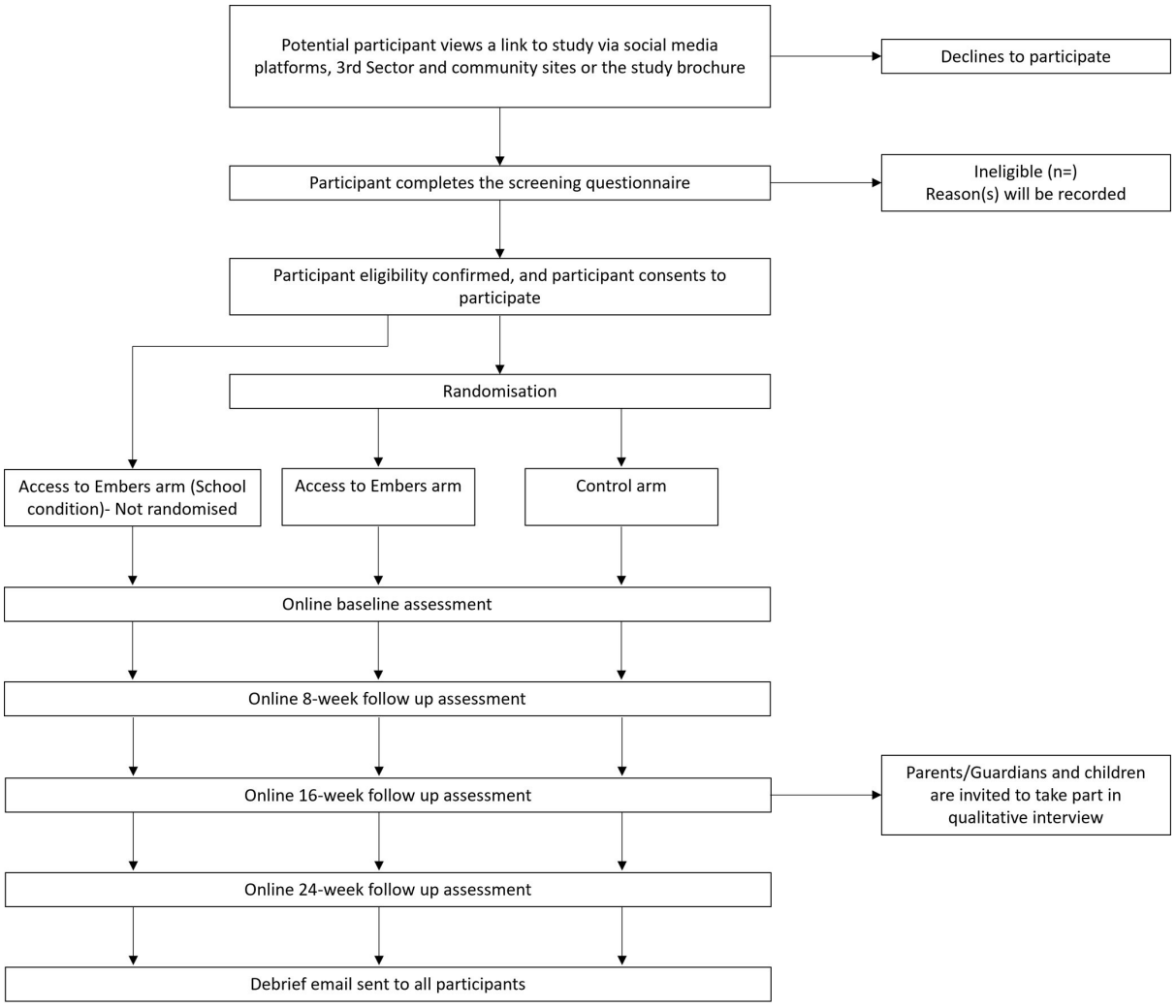

Figure 1 Participant progress through the study.

Qualitative interviews

Interviews with parents/guardians and children will be conducted face to face or online to explore the lived experience of the intervention. These interviews will use a visual-qualitative technique involving images and video excerpts from Embers relating to key characters and storylines. The visual element is part of an elicitation technique to help prompt and facilitate thought and memory recall (Reavey, 2020).[18]

Secondary outcomes

Parenting Scale

The Parenting Scale aims to assess parental discipline responses over the last 2 months. The measure comprised 30 items rated on a 7-point Likert scale. These items are divided into three subscales (laxness, over-reactivity and verbosity). Lower scores indicate good parental responses, and high scores indicate dysfunctional parental responses (Arnold, O'Leary, Wolff and Acker, 1993).[19]

Health Questionnaire (EQ-5D-3L)

The EQ-5D-3L is a widely used survey which assesses health-related quality of life. The measure comprised six subscales (mobility, self-care, usual activities, pain, discomfort and anxiety/depression). Individuals rate their level of problems for each scale (no problems, moderate problems and severe problems). Additionally, the measure includes a visual analogue scale where the highest endpoint is labelled as 'The best health you can imagine' (100 points) and the lowest as 'The worst health you can imagine' (0 point) (Herdman *et al*, 2011).

Health Impact Survey

Participants will be asked to indicate what impact their child's mental health has had on various aspects of the parents/guardians' (and their families) lives. The impact survey comprised three questions: (1) how many attendances to the GP, family school liaison and social services have you made resulting from concerns over your child's mental health? (2) details of any other interventions used (if any)? and (3) an estimate of any additional financial cost associated with managing your child's mental health (eg, including loss of time at work, appointment travel or additional care)?. This information will be used for a sensitivity analysis to control for any differences between

Table 1 Schedule of study measures

	Study stage			
Outcome measure	Baseline	Week 8	Week 16	Week 24
PSOC	X	X	X	X
SDQ	X	X	X	X
Qualitative interviews			X	
PS	X	X	X	X
EQ-5D-3L	X	X	X	X
Health Impact Survey	X	X	X	X
Needs and Hopes Questionnaire	X	X	X	X
Access and duration usage				X
Programme component usage				X
Parent engagement data	X			X

EQ-5D-3L, Health Questionnaire; PS, Parenting Scale; PSOC, Parental Self-efficacy Scale; SDQ, Strengths and Difficulties Questionnaire.

the three conditions (control arm, access to Embers arm and access to Embers+school plan arm) at baseline, and for a health economic evaluation.

Needs and Hopes Questionnaire

Participants will be asked to indicate what led them to enrol in the study and what they hope to achieve by using the Embers platform. The Needs and Hopes Questionnaire comprised three questions: (1) what do you think are your child's main needs at the moment which you might want to focus on supporting, (2) what do you hope will be different after using the Embers platform and (3) what areas do you most want to work on? This information will be used to explore the lived experience of the intervention. Participants in the control arm will only be administered the first question, while participants in the access to Embers arm and access to Embers+school plan arm will be administered all three questions.

Access and duration of usage

How participants engage with the platform (eg, number of logins, time spent during each login) will be measured and used to inform a sensitivity analysis to control for any differences between the access to Embers arm and access to Embers+school plan arm, and to assess how individuals interact with the platform.

Programme component usage

How participants engage with the content offered on the platform (eg, the number of episodes watched, and exercises accessed) will be measured and used to inform a sensitivity analysis to control for any differences between the access to Embers arm and access to Embers+school plan arm.

Parent engagement data

Parent engagement data will be used to inform the sensitivity analysis to control for any differences between the three conditions (control arm, access to Embers arm and access to Embers+school plan arm). This includes: (1) hours spent playing with children, (2) hours spent reading with children, (3) average time (hours) of shared TV watching per week and (4) number of meals shared per week.

Data analysis plan

Preparatory checks and approaches

Success of randomisation stratification (age and gender) will be checked. If it has not been successful, the failed variable(s) will be included as covariates as an adjusted analysis. Where possible, bootstrapping approaches will be used to account for potential skew, kurtosis or outlying scores. Missing data will be coded as such, and partial cases will be used where the partial data allow for inclusion in each analysis. The primary outcome analysis will be on an intention-to-treat basis (all participants, as randomised). Deviations from the final statistical analysis plan will be described as exploratory or deviations from the plan.

Primary outcome analysis

Differences between conditions, across time among primary outcomes, will be tested using a restrictive likelihood mixed effect model, with intervention condition and time as fixed effects and school and participant as random effects. We will focus on within differences at 24 weeks as the primary difference of interest.

Sensitivity analysis of primary analyses

We will undertake both intention to treat and sensitivity analysis, including checking effects excluding protocol violators. Protocol violations may include (but are not limited to) the following:

- Inclusion/exclusion criteria not met.
- Participants having not completed the two-core modules (titled 'Introduction' and 'Positive Attention') of the Embers programme by 24 weeks.

If any violation occurs during the study, these will be documented and reported to the sponsor and trial steering committee.

Secondary analysis

Secondary analyses will compare if responses from families who chose to use all parts of the intervention versus just the episodes differ in levels of change. This will allow us to positively identify the key 'active ingredients'. To explore the potential confounding impact of

trial effects (ie, being a child, whose parent has engaged with enrolling their child in the study programme), we use measured levels of parental engagement with children, joint TV viewing, etc, to allow sensitivity analysis to test if any present effects are as strong for children with engaged parents/guardians in the TAU group.

We will also conduct an analysis comparing the efficacy of the intervention (in terms of pre-post change) among different demographics to allow initial evaluation of the levels of health equity achieved. We will also produce a COHORT flow diagram.

Qualitative analysis

Given the visual element of this data collection is for elicitation purposes only, the qualitative visual and verbal data will be combined and analysed thematically, based on transcription of the verbal interview responses only. All data will be transcribed verbatim and subject to stringent coding using up to three team members to ensure reliability. Stringent coding refers to the recognised practice within the thematic analysis literature of analysing the data systematically (ie, line by line). This coding will also be cross-checked with each member of the research team. The aim will be to examine common patterns of sense making across the data sets, thematically analyse children's data separately from parental data and then combine the data sets to explore common themes. The analysis will be steered by the theoretical domains framework to investigate any barriers or facilitators of implementation relating specifically to user experiences reported in this qualitative element. This will also be triangulated by checking qualitative data against the quantitative outcome measures, to see if there is coherency between data sets, or to explore whether there are arising inconsistencies (eg, positive outcome measures but negative reports regarding user experience).

Economic evaluation

Alongside the evaluation of the Embers platform in terms of mental health outcomes, a robust health economic benefits evaluation is essential to inform future funders and decision-makers and to support the estimated impact of scaling up the intervention. The overall aims of our health economic evaluation package are to (1) estimate the monetary cost per unit of identified health outcome improvement, (2) examine wider cost implications (ie, savings made elsewhere, such as fewer workdays missed for appointments at parenting classes, fewer GP appointments, etc), (3) differentiate the cost benefits deploying at home versus home and school and (4) provide comparative data in a way that can be examined in relation to the cost-effectiveness of other interventions. Specifically, we will measure occurrences of self-reported GP, school-family liaison and social service appointments by arm, including estimates of mental health-related indirect/out-of-pocket expenses incurred by families. These will be combined with direct delivery cost information, plus estimates of downstream savings related to the outcome benefits realised. We will also measure quality of life using the EQ-5D-3L (a standard measure of quality of life). Data will be collected from the same sample who undertake the evaluation (in both intervention arms and control arm). As this is an area of specialist expertise, we will appoint a health economist to the team who, in consultation with the PPIE group, will finalise the measures taken and undertake the resulting analysis.

Patient and public involvement

Patient and public involvement (PPI) is extensive and fully integrated into the project design, including recruitment, methodology, animation and resource development, testing, promotion and dissemination. All programme content was developed with PPI groups to ensure that they are relevant, meaningful and appropriate. Additionally, all process evaluation materials will be developed in collaboration with PPI groups and piloted. Inclusive and representative parent/carer and child involvement was imperative to the development of the study by ensuring that key themes and content developed are reflective of the needs and points raised by the community they are designed to support.

ETHICS AND DISSEMINATION

Ethical considerations

Ethical approval has been granted by the London South Bank University ethics panel (ETH2324-0004), which covers all aspects of the study except for recruitment via GPs. To recruit participants via GPs, NHS/HRA ethical approval has been applied for, and the IRAS (331410) application is currently under review by the Central Bristol REC. Informed consent will be obtained from all parents/guardians before participating in the trial (see online supplemental material 1), and all individuals will have the opportunity to ask any questions about the study before deciding to take part. Children aged 4–7 years will not provide their consent to take part in the trial, as they do not provide any data beyond intervention usage data. To take part in the qualitative interviews, informed consent will be obtained from all parents/guardians (see online supplemental material 2). Children aged 4–7 years will be asked to provide assent on the day of the interview by the researcher reading the assent form adapted from Simonoff E, Palmer M, Chandler S. 'Child Assent Form, aged 4–8'[20] aloud to the child (see online supplemental material 3). The whole interview will be recorded from the beginning. This approach is in line with the London South Bank University ethics panel recommendations.

Dissemination

Results will be disseminated in academic peer-reviewed journals and in platforms/formats that are accessible to the public.

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Competing interests None declared.

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