ISRCTN58327872 https://doi.org/10.1186/ISRCTN58327872

EMERGENT: Evaluating eMbErs: Digitally suppoRtinG childrEns meNtal healTh

Submission date
19/10/2023

Recruitment status
No longer recruiting

Registration date
25/10/2023

Overall study status
Completed

Last Edited
30/12/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims:
Embers the Dragon is a unique digital programme of animated stories, parent education videos and classroom resources. It is designed to help children and families experiencing common problems related to children's early emotional and behavioural development and resilience, around the time they start school (4-7 years). The aim of the study is to investigate the efficacy and acceptability of the programme by measuring its impact on 1) parenting style, confidence, and effectiveness, and 2) children's wellbeing and psychosocial development, when delivered in both home and school settings.

Who can participate?
Parents/guardians of children aged 4-7 years old

What does the study involve?
Participants will be randomly assigned to a control arm, or access to Embers arm to evaluate the use of Embers in a home, parent-led setting. To evaluate scalability in school settings, there will also be access to the Embers + school plan arm. This arm will comprise participants who were recruited via schools and are not randomised. All participants in the access to Embers arm or Embers + school plan arm will have access to the Embers platform, which includes animations, parenting advice videos, downloadable content, and games. Additionally, participants in the Embers + school plan arm will also receive lesson plans/resources. All participants are asked to complete a series of surveys online at 4 time points (baseline, 8 weeks, 16 weeks, and 24 weeks). Finally, participants in the access to Embers arm, and Embers + school plan arm are invited to take part in an interview to examine their lived experiences of using the Embers program. These interviews will be conducted either face-to-face or online.

What are the possible benefits and risks of participating?
1. Children would benefit from an intervention developed to promote resilience skills and the development of lifelong coping strategies

2. Parents would benefit from improving their parenting efficacy and confidence

3. Unlike the main alternative of professionally led parenting courses (which have significant waiting lists and dropout rates) Embers can be accessed directly by parents and teachers, either alone or while awaiting mental health assessment. It has the potential to reach a wider range of families at a fraction of the current costs of existing methods

4. There is a financial incentive to take part in the study. Specifically, everybody who takes part in the study will receive £10 for completing the baseline measures. Participants will receive a further £10 for completing the 8-week follow-up, £10 for completing the 16-week follow-up, and £10 for completing the 24-week follow-up. Participants will receive an additional £20 if they complete all the measures at each time point (i.e., baseline, 8-weeks, 16-weeks & 24 weeks). The full amount payable will be paid via Tango vouchers. This information regarding payment is provided to participants in the Information Sheet.

5. Parents may feel negatively when completing some of the surveys. To mitigate this risk, all participants are informed that they will be asked to complete a series of surveys that measure their parenting style using the following wording: "You may find reporting on your parenting style and your child's psychological well-being upsetting at times. Please note that the Embers programme aims to support children who experience mild to moderate issues with their mental well-being. If you have concerns about your child's psychological/general well-being, please contact your Health Care Professional (for instance your GP)." Based on this information, parents can choose to take part in the study or not. Additionally, all participants are signposted to various support resources at the end of the study information sheet, as well as at the end of all correspondence with the research team.

Where is the study run from?
London South Bank University (UK)

When is the study starting and how long is it expected to run for?
April 2023 to April 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) i4i [Invention for Innovation Connect programme] (Funder grant number: NIHR204516) (UK)

Who is the main contact?
1. Prof Daniel Frings, fringsd@lsbu.ac.uk (UK)
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
2024-000124-22

Integrated Research Application System (IRAS)
331410

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

IRAS 331410, CPMS 57350

Study information

Scientific Title
EMERGENT: Evaluating eMbErs: Digitally suppoRtinG childrEns meNtal healTh

Acronym
EMERGENT

Study objectives
It is hypothesised that Embers will be superior when delivered in both family and school settings over treatment as usual and non-inferior between school and family delivery settings.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 18/08/2023, London South Bank University Ethics Panel (103 Borough Rd, London, SE1 0AA, United Kingdom; +44 (0)20 7815 7815; ethics@lsbu.ac.uk), ref: ETH2324-0004

2. approved 20/02/2024, South West – Central Bristol (3 Piccadilly Place, Manchester, M1 3BN, United Kingdom; +44 (0)207 1048061; centralbristol.rec@hra.nhs.uk), ref: 24/SW/0003

Study design
Waitlist-controlled randomized pragmatic field study with a non-randomised testing element

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life

Health condition(s) or problem(s) studied
Parents/guardians of children aged 4-7 years old who are concerned about their children's mental health

Interventions
The current project is a waitlist-controlled pragmatic field trial with 3 arms: (i) a control arm comprising treatment as usual (TAU), (ii) access to Embers arm and (iii) access to Embers + school plan. Participants will be randomised into (i) or (ii) 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 and compare (iii) to both (ii) - to test the impact of the added school content and setting - and (i) to test efficacy against TAU.

All participants in the access to Embers arm or Embers + school plan arm will have access to the Embers platform, which includes animations, parenting advice videos, downloadable content, and games. Additionally, participants in the Embers + school plan arm will also receive lesson plans/resources. All participants will be asked to complete a series of surveys online at 4 time

points (baseline, 8 weeks, 16 weeks, and 24 weeks). Finally, participants in the access to Embers arm, and Embers + school plan arm are invited to take part in a face-to-face or online interview to examine their lived experiences of using the Embers program.

Primary measures:
1. Parental Self-efficacy Scale
The PSOC aims to measure parent's perceived confidence in their parental skill in supporting their children. The measure is comprised of 5 items, rated on a 5-point Likert. The items are summed to yield a total score, with higher scores indicating higher levels of parental self-efficacy. This measure is administered at baseline, week 8, week 16, and week 24.

2. Strengths and Difficulties Questionnaire (SDQ) (Goodman,1997)
The SDQ aims to assess the behaviours, emotions, and relationships of children and young people (aged 4-17 years old) over the past six months. The scale is comprised of 25 items, divided between 5 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 problems scales indicate a lower level of difficulty, whereas scoring is reversed for the prosocial behaviour scale, with higher scores indicating lower levels of difficulty. This measure is administered at baseline, week 8, week 16, and week 24.

3. Qualitative interviews
Interviews with parents/guardians and children will be conducted to explore the lived experience of the intervention. These interviews will be conducted using a visual-qualitative methodology, which involves using visual images and videos taken from Embers relating to key characters to be used as prompts to facilitate thought and memory (Reavey, 2021). These interviews will be conducted face-to-face or online. Participants will be invited to take part in the interviews at week 16.

Secondary measures:
1. Parenting Scale (PS) (Arnold, O'Leary, Wolff & Acker, 1993)
The PS aims to assess parental discipline responses over the last two months. The measure is comprised of 30 items, rated on a 7-point Likert scale. These items are divided into 3 scales (Laxness, Over-reactivity, and Verbosity). Lower scores indicate good parental responses and high scores indicate dysfunctional parental responses. This measure is administered at baseline, week 8, week 16, and week 24.

2. Health Questionnaire (EQ-5D-3L) (Herdman, et al., 2011)
The EQ-5D-3L is a widely used survey which assesses health-related quality of life. The measure is comprised of 5 scales (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 (VAS) 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 points). This measure is administered at baseline, week 8, week 16, and week 24.

3. 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 is comprised of three questions: 1) How many attendances to the GP, family school liaison, and social services have you made as a result of your 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 (e.g., 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 the three conditions (control arm, access to Embers arm, and access to Embers + school plan arm). This measure is administered at baseline, week 8, week 16, and week 24.

4. Need 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 Hopes questionnaire is comprised of three questions: 1) What do you think are your child's main needs at the moment that 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. This measure is administered at baseline, week 8, week 16, and week 24.

5. Access and Duration usage
How participants engage with the platform (e.g., number of logins, time spent during each log-in) 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. This data will be accessed at the end of week 24.

6. Programme component usage
How participants engage with the content offered on the platform (e.g., 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. This data will be accessed at the end of week 24.

7. 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. This data will be collected at week 24.

Intervention Type
Behavioural

Primary outcome(s)
1. Parent's perceived confidence in their parental skill in supporting their children measured using the Parental Self-efficacy Scale (PSOC) at baseline, week 8, week 16, and week 24
2. Behaviours, emotions, and relationships of children and young people (aged 4-17 years old) over the past six months measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline, week 8, week 16, and week 24
3. The lived experience of the intervention will be explored and measured using qualitative interviews conducted using a visual-qualitative methodology at week 16

Key secondary outcome(s))
1. Parental discipline responses over the last two months measured using the Parenting Scale (PS) at baseline, week 8, week 16, and week 24
2. Health-related quality of life measured using the Health Questionnaire (EQ-5D-3L) at baseline, week 8, week 16, and week 24

3. What impact their child's mental health has had on various aspects of the parents/guardians (and their families) lives measured using an Impact survey at baseline, week 8, week 16, and week 24
4. What led them to enrol in the study and what did they hope to achieve by using the Embers platform measured using the Need Hopes questionnaire at baseline, week 8, week 16, and week 24
5. How participants engage with the platform (e.g., number of logins, time spent during each log-in) measured using access and duration usage at the end of week 24
6. How participants engage with the content offered on the platform (e.g., the number of episodes watched, and exercises accessed) measured using programme component usage at the end of week 24
7. Parent engagement measured using engagement data at week 24

Completion date
30/04/2025

Eligibility

Key inclusion criteria
1. Parents/Guardians of children aged 4-7 who are concerned about their children's mental well-being, including both those who are and are not already actively seeking professional support
2. Parents/Guardians of children who are receiving the Embers intervention in a school setting (School condition only)
3. Both parent and child fluent in English
4. Access to a platform-compatible digital device
5. Willingness to complete follow-up measures

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit
7 years

Sex
All

Total final enrolment
733

Key exclusion criteria

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

Date of first enrolment
01/10/2023

Date of final enrolment
13/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
London South Bank University
103 Borough Road
London
England
SE1 0AA

Sponsor information

Organisation
London South Bank University

ROR
https://ror.org/02vwnat91

Funder(s)

Funder type
Not defined

Funder Name

Invention for Innovation Programme

Alternative Name(s)
NIHR Invention for Innovation Programme, i4i

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data, once drawn down from the Qualtrics data collection platform, will be stored on the LSBU cloud during the trial. Only the research team will have access to this file. Quantitative data will be stored in a csv master file. A copy of this will be time stamped at the end of the data extraction and collation phase of the project on the OSF. It will be made available to the public following the publication of the main trial paper. Analysis will be conducted on working files. Syntax will be recorded to aggregate any variables, data transformations, etc. to construct the analysis from the master file. These syntax files will be made available alongside the master data file and accompanied by a data dictionary. Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections- in line with participant consent. It will also be available for secondary research purposes with participant consent, following publication of the main study paper(s). Data for secondary use will be publicly available via the OSF and other repositories. Projecting archiving (protocol, data (inc. anonymous transcripts), ethics documentation analysis plans, outputs, other study materials) will be archived on the projects OSF site. Archived data will be available for at least 5 years from study completion date

IPD sharing plan summary
Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		05/03/2024	07/03/2024	Yes	No
Plain English results			30/12/2025	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes