Interdisciplinary Development of a Transdiagnostic Mobile App to Enhance Children's Emotion Regulation: Sharing Insights and Lessons Learned.

Bettina Moltrecht, Praveetha Patalay, Holly Alice Bear, Jessica Deighton, Julian Edbrooke-Childs

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Bettina Moltrecht[1, 2] PhD; Praveetha Patalay[3] PhD; Holly Alice Bear[1, 2] PhD; Jessica Deighton[4] PhD; Julian Edbrooke-Childs[4] PhD

[1]Department of Clinical, Educational, and Health Psychology University College London London GB
[2]Department of Psychiatry University of Oxford Oxford GB
[3]Centre for Longitudinal Studies Institute of Education University College London London GB
[4]Evidence-based practice unit Department of Clinical, Educational and Health Psychology University College London London GB

Corresponding Author:
Julian Edbrooke-Childs PhD
Evidence-based practice unit
Department of Clinical, Educational and Health Psychology
University College London
4-8 Rodney Street
London
GB

Abstract

Background: Digital interventions, including mobile apps represent promising means to provide effective mental health support to young people. Despite the increased availability of mental health apps, there is a significant gap for this age group, especially for younger children. Research investigating the effectiveness and development process of child mental health apps is limited, and the field faces persistent issues in relation to low user up-take and engagement, which is assumed to be a result of lacking interdisciplinary approaches.

Objective: We present the development and design process of a new mental health app for children that targets their emotion regulation abilities. We describe the creation of a new interdisciplinary development framework, to guide the design process, and explain how each activity informed different app features.

Methods: The first two stages of the framework employed a variety of methods, including: 1) classroom observations, 2) public-engagement events with the target group (N=21), 3) synthesis of the existing evidence as part of a meta-analysis, 4) a series of co-design and participatory workshops with young users (N=33), clinicians (N=7), researchers (N=12), app developers (N=1) , designers (N=2), and lastly 5) testing of the first high-tech prototype (N=15).

Results: For the interdisciplinary framework we drew on methods derived from the medical research council framework for complex interventions, the patient-clinician-framework and Druin's cooperative inquiry. The classroom observations, public-engagement events, and synthesis of the existing evidence informed the first key pillars of the app and wireframes. Subsequently, a series of workshops shaped and reshaped the content and app features, including games, psychoeducational films, and practice modules. Based on the prototype testing sessions we made further adjustments to improve the app.

Conclusions: Although mobile apps could be highly suitable to support young people's mental health on a wider scale, there is little guidance on how these interventions could be designed. The involvement of the different methods and especially the young users was very valuable. We hope that the interdisciplinary framework and multiple methods that we applied will be helpful to others who are also aiming to develop suitable apps for young people.

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Conclusions:

Although mobile apps could be highly suitable to support children's mental health on a wider scale, there is little guidance on how these interventions could be designed and developed. The involvement of young users across different design activities was very valuable. We hope that our interdisciplinary framework and description of the employed methods will be helpful to others who are hoping to develop mental health apps for children and young people.

Keywords: mHealth; participatory design; emotion regulation; interdisciplinary development; child mental health

Introduction

It has been estimated that approximately 10-20% of children and young people worldwide experience mental health problems, making it one of the leading causes of disability in this population [1], [2]. Addressing the rising numbers of mental health problems in young people is a major public health concern. International studies indicate that more than 60% of young people do not have access to adequate (or any) treatment [3], highlighting the urgent need for innovative approaches to tackle the problem. Mental health apps present promising means to address this challenge by making mental health support more widely accessible to young people. Our research team developed a new mental health app that aims to support children (age 10-12 years) by enhancing their emotion regulation skills. Difficulties with emotion regulation are seen in a wide range of mental health problems and recent evidence suggests that enhancing emotion regulation in children and adolescents was related to improvements in mental health regardless of the type of disorder or intervention [4]. To this date, guidelines and studies on the development of mental health apps for children are lacking. The present paper aims to fill this gap.

Digital mental health landscape for youth

While it has been suggested that digital mental health interventions can be efficacious in both preventing and treating mental health problems in young people (age 12 and older) [5]–[7], recent systematic reviews found that in comparison to the adult literature, research investigating the effectiveness of digital interventions for children and young people is lagging [7], [8]. Only a few mental health apps have been designed and tested specifically for young people (age 12 and older), but even less are available for children younger than age 12. The latest systematic reviews identified only 2 mental health apps for children, thereby highlighting the significant evidence gap and limited availability of suitable digital interventions for this age group [7], [9]. Despite these considerable limitations, digital interventions are expected to be highly accepted by young people due to the high degree of anonymity they provide. Furthermore, they are cost-effective and, if designed appropriately, also highly applicable across different real-life contexts [10].

The majority of available mental health apps suffer from low uptake and engagement levels [11], [12], which is considered essential to securing their effectiveness [13], [14]. Various methods have been suggested to increase engagement levels with digital health interventions, including the involvement of users in the development and design process as part of user-centred design methods. A recent review of 30 studies and another meta-review of 21 studies have demonstrated that the majority of digital mental health interventions, that was aimed at children and young people, had neglected the use of such methods, which is also reflected in the highly uniform design across these interventions, where psychoeducation content often represents the main intervention component [15], [16]. In terms of specific mental health apps for children (<12 years), we were unable to identify any app that involved target users during the development and design stages, thereby further emphasizing the importance of the present paper.

A closer look at the digital mental health landscape indicates that the majority of interventions draws on evidence-based treatments that target specific symptoms or diagnoses [17], [18]. Initially, the recycling approach of taking existing interventions and transferring them to a digital platforms had helped the field to move forward quickly, however, this approach has increasingly been criticised as it provides little room for innovation and improvement [17]. Chandrashekar [19] has described key features of highly effective mental health apps, amongst high engagement levels and easy to use interfaces, the author highlighted app components targeting transdiagnostic mechanisms. Transdiagnostic mechanism are common across mental health problems and not specific to one disorder. Putting an additional focus on transdiagnostic mechanisms has previously enhanced

traditional psychotherapeutic approaches [20], [21], and is also expected to increase engagement with mental health apps [19]. One such mechanism that has repeatedly been emphasized as a highly promising treatment and prevention target is emotion dysregulation.

Emotion regulation as an intervention target

Deficits with emotion regulation - or the ability to monitor, evaluate, and modify one's emotional reactions in order to accomplish one's goals [22] - has been identified as a risk and maintenance factor for mental health difficulties. Developmental research has demonstrated that higher emotion dysregulation in children was associated with greater mental health difficulties concurrently and later in life. Additionally, recent meta-analyses indicated that interventions that effectively reduced emotion dysregulation in children also reduced psychopathological symptoms, irrespective of the intervention type or clinical diagnosis [4], [23]. With respect to our target group, children between age 10-12 years, the latter is of particular importance, because high comorbidity rates are common in this group and symptom presentations are often not clear-cut.

The transdiagnostic approach has also been deemed suitable for mental health prevention programs. Forbes and colleagues recently highlighted that targeting transdiagnostic factors in youth mental health prevention has the potential to activate a range of related, beneficial developmental cascades, such as social or academic development [24]. Furthermore, they argued that a transdiagnostic approach can reduce the burden on schools, which are often asked to provide a multitude of short-lived programs, each one trying to tackle a different problem [24].

To the best of our knowledge there is currently no app intervention that targets emotion regulation as a transdiagnostic factor in late childhood (age 10-12), although an increasing number of scholars have highlighted this period as a critical stage to achieve maximum impact in terms of youth mental health prevention [25]. Moreover, in the United Kingdom late childhood (age 10-12) is characterised by the transition from primary to secondary school, which is frequently experienced as stressful by children, thereby strengthening the case for an intervention that supports children prior and during to this transition period [26].

Present paper objectives

With respect to the existing limitations in the field, we aim to present the develop process of a new, transdiagnostic mental health app for children, which puts the young user group in the centre of the design process. To achieve this, we created a new development framework that drew on different methodologies from the fields of psychology, human computer interaction and user-design. In the following sections, we will (1) describe the interdisciplinary design, development and refinement process; (2) take the reader through the different stages and research activities; (3) describe the various app features and explain how they were informed by the research activities and lastly, (4) we share important lessons learned and considerations for future activities.

Formulation of our inter-disciplinary development framework

Developing a complex digital intervention

The present mental health app is considered a complex intervention, because it involves multiple, interconnected, and interacting components [27], [28]. In line with that, we used the first three stages of the Medical Research Council's (MRC, See Figure 1) framework for complex interventions to guide the development and evaluation process of the present mental health app. We first explored relevant theories and the existing evidence to identify promising intervention components. In the next stage, the researcher team focused on identifying underlying mechanisms that would influence the preferred outcome, which were then incorporated in the design of the intervention. As mentioned above this paper focuses primarily on the early development and design stages to address existing gaps in the literature. Therefore, we only present research activities that are part of the first two stages of

our development framework as depicted in Figure 2. Findings of the third stage, the exploratory trial are published elsewhere [29].

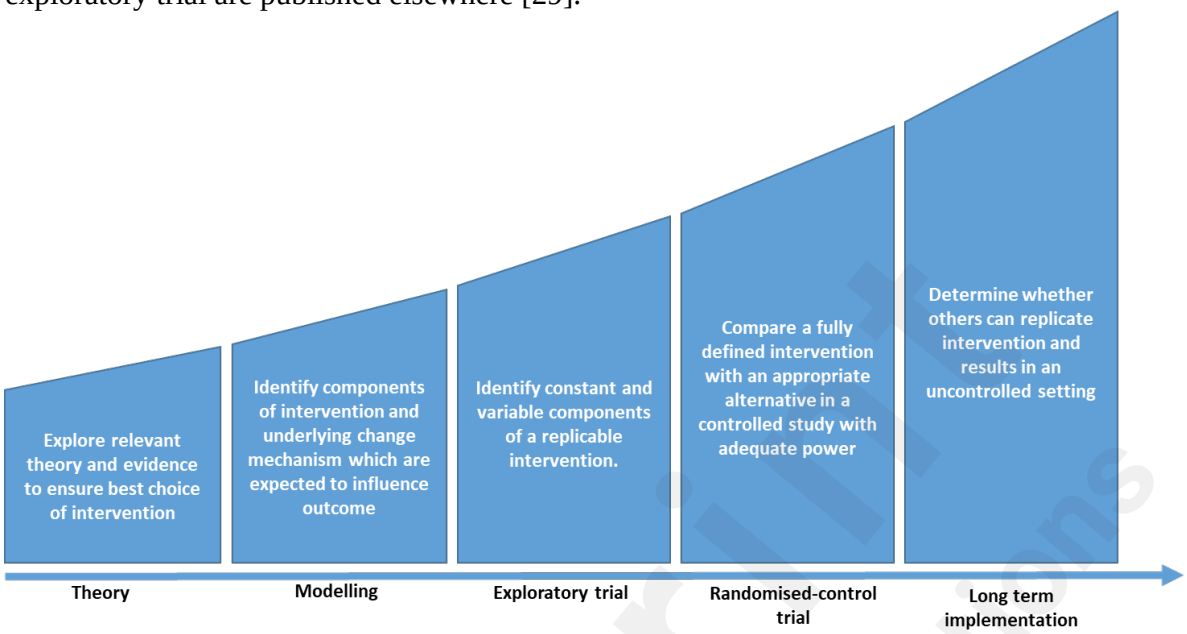

Figure 1 Medical Research Council framework for complex interventions

Designing a complex digital intervention

While the MRC framework provides valuable guidelines for the development and evaluation of complex interventions, it provides little information on how to design intervention components [30]. Hence, we drew on the following two frameworks rooted in the fields of HCI and user-centred design.

The Patient-Clinician-Designer (PCD) Framework provides guidance on how to structure the design and content creation process of digital interventions for mental illness [31]. It aims to meet the complex requirements when designing user-centred interventions for mental illness by taking into account different perspectives (i.e., patient vs clinician) and design goals. It describes how five key principles, based on user-centred design methodology, can be applied in the design process and divides it into four design phases: a) understanding the illness and its challenges, b) involving users in the design, c) mediating co-design activities between users and professionals and d) accommodating different evaluation goals.

With respect to our target user-group, children at the end of primary school (age 10-12), we decided to incorporate Druin's *cooperative inquiry* framework, which provides specific techniques on how to involve young users in the design process of technologies. It draws on years of experience and is widely used in the field [32]. This framework highlights the importance of involving children as partners in the whole process, instead of merely letting them test an almost finished prototype or end product. Druin emphasizes the benefits of conducting field work (i.e. "contextual inquiry")when working with children, which allows researchers to detect relevant contextual information, including patterns of activities, ways of communication and other artefacts. Additionally, it has been reported that discussing design features in the relevant context (e.g., school, home), makes it easier for children to express ideas and provide suggestions [33]. Lastly, the framework calls for the importance of visualizing ideas through low- and high-tech prototypes, as this offers children more concrete ways to elaborate on ideas, and reject or refine them.

The present development framework

Taken together, we combined three frameworks from different fields, which allowed us to take a highly interdisciplinary approach (see Figure 2). For each stage of the development

process, we employed a unique set of methodologies derived from the different disciplines. The research team was involved in all the activities as a linking point and served as mediator between the different stakeholders.

The research team consisted of five child and adolescent mental health researchers, of which two have extensive experience in conducting digital health research [BM, JED]; one has a background in clinical psychology [BM], and four have extensive experience in designing, delivering and evaluating school mental health programs [JD, JED, PP, HB]. Three authors [BM, JED, JD] are part of an international training network on technology-enabled mental health systems for young people, with experts from different disciplines (i.e., computer sciences, psychology, medicine, data privacy, design), who were consulted throughout the process. BM also has extensive training in applying HCI and UX techniques. Figure 2 depicts which other stakeholders were involved at each stage, including app developers, clinicians, UX and graphic designers, young people, teachers, and parents.

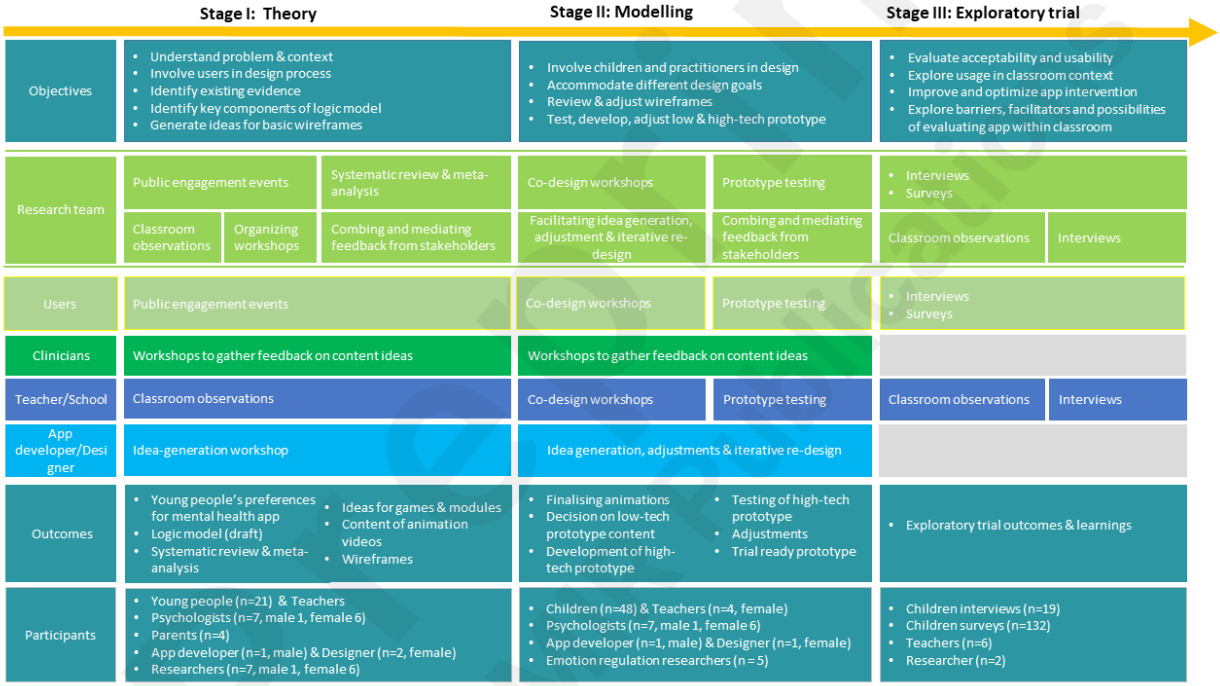

Figure 2Development framework and research activity outline of present app

METHODS

Stage I Identifying theory, evidence and challenges

Objectives

As shown in Error: Reference source not found, this stage focuses on understanding the context and the problem at hand. We generated some initial ideas with key stakeholders and tested the feasibility of potential research activities for Stage II. Furthermore, we identified the existing evidence to inform the underlying logic model of the resulting intervention in terms of its active ingredients and expected outcomes [34].

Activities and data analysis

In line with our framework we conducted a) multiple classroom observations, b) a systematic review and meta-analysis to summarise the evidence for existing psychological interventions and their effectiveness in enhancing emotion regulation skills in youth, and c) two consultation groups with young people. Notes and materials (i.e., drawings, stick-notes, outcomes of exercises, reflective notes) produced during (a) classroom observations and (c) consultation groups were analysed using reflexive thematic analysis as described by Braun

and Clarke [35], [36]. BM manually coded the data, detailing inductive descriptive codes by highlighting and categorising similar phrases, words or patterns across the data. This was done in NVivo11 or Excel (further specified below). Themes were created using mind-mapping exercises and refined further in discussions with all authors. Occasionally, we also involved app developers, designers and clinicians, as specified below.

School visits and classroom observations

Familiarisation with the user and their environment as part of a fieldwork exercise is a central tenet of the cooperative inquiry framework. Clinical research has also shown that the identification of user resources within the intervention context is a significant determining factor of an interventions' effectiveness [37].

Schools are considered a key player in youth mental health provision [38], [39]. We collaborated closely with two different schools for this project, resulting in weekly school visits across a 6-month period with a total of 20 observations. This allowed us to identify common challenges that children and teachers face, especially in relation to emotion dysregulation and resulting behavioural difficulties (e.g., not being able to concentrate, disrupting the teaching process, distracting other children). We became familiar with every-day practices and issues related to the school setting and gained valuable insights into what children and teachers already do to manage difficult emotions in the classroom.

The lead author [BM] was able to observe different lessons, classes and teachers in both schools. BM took notes during the observations, and reflective notes afterwards. BM was also able to ask teachers questions about their understanding of emotion dysregulation, what role it played in the classroom and how children and teachers currently managed situations were children experienced intense feelings. During the school visits, teachers and children reported one main strategy that was frequently applied to manage difficult behaviour in relation to emotion dysregulation in the classroom: the use of quiet corners or so called "time-out zones".

Time out zones are defined areas in the classroom. Students were directed to the area when they showed difficult behaviour, struggled to concentrate or distracted other pupils in class. Some classrooms were divided into different zones, which signalled a different type of support (e.g., zone closer to the front to facilitate concentration and zones closer to the back for time outs). The time out zones often included a sofa or pillows to sit on and children had access to books or other tools that could help them to calm down. Based on this observation, storing a tablet with the app intervention installed near the time-out zone, seemed to be a suitable approach to implement the app in the classroom context.

Furthermore, children reported that they themselves or together with a teacher had identified strategies to manage difficult feelings, such as playing with Blu Tack, stepping outside for a "breather", reading a book, or listening to music in the quiet corner. This list of emotion regulation strategies inspired the implementation of the digital tools box in the app (see Figure 11).

While the insights from the school visits significantly influenced some of the design concepts in the app, the collaboration with the schools also helped us to gain access to parents and other professionals, who we were able to consult on parent-teacher days about the app.

Table 1 Outcomes and implications based on school observations

Observation	Design implication and goals
• Teacher and children use different devices, including tablets, PCs and smart-boards during lessons.	• Web-based app that can be accessed from different devices.
• Children try different strategies that help them in the classroom. Sometimes these	• Let children create list of "tools" which contains personal strategies and provides

are agreed with the teacher.	suggestions.
• Children struggle to draw on strategies, when they have very intense emotions. Some teacher direct child in need to quiet corner.	• Add function that gives quick access to guided strategy to provide in the moment support.
• Children familiar with breathing exercises and time-out	• Guided relaxation, breathing and mindfulness exercises.
• Children report on certain situations in which they find it difficult to regulate their emotions and where this has impedes with their goals.	• Integrate children's stories as examples in content to make it more relevant for target group.
• Teachers employ a range of strategies, some that help specific individuals when needed and some that they apply to the whole class.	• Design an intervention that can be used with the whole class as well as for individual children

Public consultation groups

Two consultation groups were conducted as part of a patient and public engagement event (PPI). Participants were recruited through the centres network and existing collaborations with other third sector child mental health organisations. Organisation leads contacted young people or their parents who had previously consented to be contacted for PPI events.

The two PPI events involved 21 "young research advisors" between the ages of 12 and 19 and had an even distribution of female and male participants. The term 'young research advisor' is a special term that is used to describe a group of young people, who have been service users themselves and received specific training that prepares them to work with researchers. The research team worked with this specific group, despite them being slightly older than the target group, due to their prior training and experience of working with researchers. This has a number of benefits: they are familiar with common research processes and have an existing relationship with the workshop facilitators, which secures good engagement. This in turn allowed the researchers to ask more complex questions and to get direct feedback on the workshop activities.

The young advisors were reimbursed for their time in line with the organisation's internal arrangements. The lead author and two PPI leaders who were familiar to the young advisors facilitated the workshops.

Each PPI event included an ice-breaker exercise, an introduction to the topic (e.g. mental health and digital interventions) and a discussion of the following questions:

1) What is mental health for you and how do you take care of it?
2) How can technology support young people's mental health or emotion regulation?
3) What are young people's perceived barriers and facilitators to the use of mental health apps?
4) How can research involve children and young people in the design process of mental health technology?

For some exercises the groups were split into smaller teams first, where they brainstormed together and collected ideas on big sheets of paper. After that, each group presented their ideas and discussed them further in the larger group. A complete activity schedule is available in the supplements. BM was present at each PPI event to observe participants, ask follow-up questions and to take notes. Materials produced as part of the PPI groups (i.e., drawings and notes resulting from exercises) and written notes by the lead author were thematically

analysed [35], [36]. Based on the identified themes a list of “do’s and don’ts” for mental health apps was developed (see Table 2). If the young advisors had suggested possible solutions in the workshop, they were included; however, the research team also consulted the app developer and graphic designer afterwards to identify possible solutions (marked with * in Table 2 below).

Considerations and design implications

Table 2 Identified Do's and Don'ts for mental health apps based on PPI group

Theme	Please do	Please avoid	App solution
Accessibility	•Available across devices •Affordable for a young person •Available offline	• Advertisement • In-app purchases •Too much data or WIFI	• Web-based app* • No costs •Data/WIFI for first-time login/ updates*
Engagement	•Interactive, games, tracking •Social connection, community •Make use of users’ feedback and provide relevant updates	•Push notifications •Dead website/app •Information/text only	• Selection of games • Digital agent for interaction • Multi-media content • Feedback option in app
Design	•Customizable features •Age appropriate (language, design) •Intuitive, easy to use	• Childish • Clunky • Text only	• Customizable features • Designed and tested by users
Data & Technology	•Use cloud service to limit storage space •Transparent data tracking •User control over data/tracking •Data security and privacy	• Requires too much data • Crashes or is slow • Hidden data tracking	•Google analytics provides insight for general use of app content* • No individual data tracking through app*
Mental Health specific	•Teach and educate •Increase understanding •Opportunity to practice •Facilitate social connectedness •Sign-posting to services	•Sign posting only •Text only	•Content that educates and increases understanding •Practice modules •Digital agent to feel socially connected •Sign-posting

* suggested by app developer

The PCD and cooperative inquiry framework recommend including target users directly into the design process. We explored the usability of potential co-design methods with this group,

before employing them in workshops with younger, un-trained children. However, the PPI participants were significantly older (12 -19 years) than the expected user-group, which might explain some of the difficulties that we faced when working with younger children in the co-design workshops (see Co-design workshops section).

Systematic review and meta-analysis

We conducted a systematic review and meta-analysis that aimed to understand potential intervention mechanisms, best practices and suitable intervention components as well as ways to measure emotion regulation in youth [4]. We identified 21 studies of which two included some type of digital intervention. The results demonstrated a significant lack of technology-based interventions for youth and provided insights into the evidence-base of existing psychological interventions' and their impact on emotion dysregulation. Given the lack of any technology-based intervention for emotion regulation in our review, we had to rely on prior evidence that primarily focussed on face-to-face delivered interventions. A meta-regression suggested that changes in emotion dysregulation were associated with changes in psychopathology [4].

With respect to intervention components the evidence was the strongest for Cognitive-behaviour therapy (CBT) approaches. We created an overview of the different intervention components (e.g. psychoeducation, mindfulness and attention bias modification), which subsequently formed the first basic tenets of the app. CBT models and theories (e.g., thought-feelings-behaviour triangle) informed the content of a series of animated videos, which served as psychoeducational components. The animations also discussed strategies that are commonly addressed in CBT interventions to enhance emotion regulation, such as problem-solving, cognitive restructuring, mindfulness and relaxation. A more detailed description of the intervention components as identified in the systematic review, can be found in the supplements.

In contrast to existing interventions and in response to intervention limitations identified in the systematic review, the present app puts a greater focus on adaptive emotion regulation processes, as evidence from developmental studies suggested that the lack of adaptive emotion regulation in early childhood is associated with increased emotion dysregulation later in life [40].

Table 3 Design implications based on systematic review

Findings	Design implications and goals
• CBT interventions have the strongest evidence for face to face as well as digital interventions	• Integrate CBT concepts to the app, e.g. psychoeducation about feelings, behaviour and thoughts.
• Interventions that improve emotion regulation also improve mental health	• Integrate exercises that enhance emotion regulation, e.g. mindfulness
• Emotion literacy, understanding and differentiation is linked to better mental health	• Enhance children's emotional literacy and understanding.
• Adaptive and positive emotion regulation are associated with less emotion dysregulation	• Include games that increase positive emotions and introduce adaptive emotion regulation strategies (e.g. teach adaptive strategies).

Design Implications Stage I

Based on the Stage I findings, we outlined the different intervention components, change mechanisms, moderators and outcomes in a logic model (see Figure 3). The logic model was developed to clarify conceptual and logical underpinnings of complex interventions used in child mental health services [34]. Based on our logic model and the outcomes of the PPI groups and school observations, initial wireframes were created by an app designer and

developer. Furthermore, we decided on key criteria for the technology underlying the app (see tech specifications below).

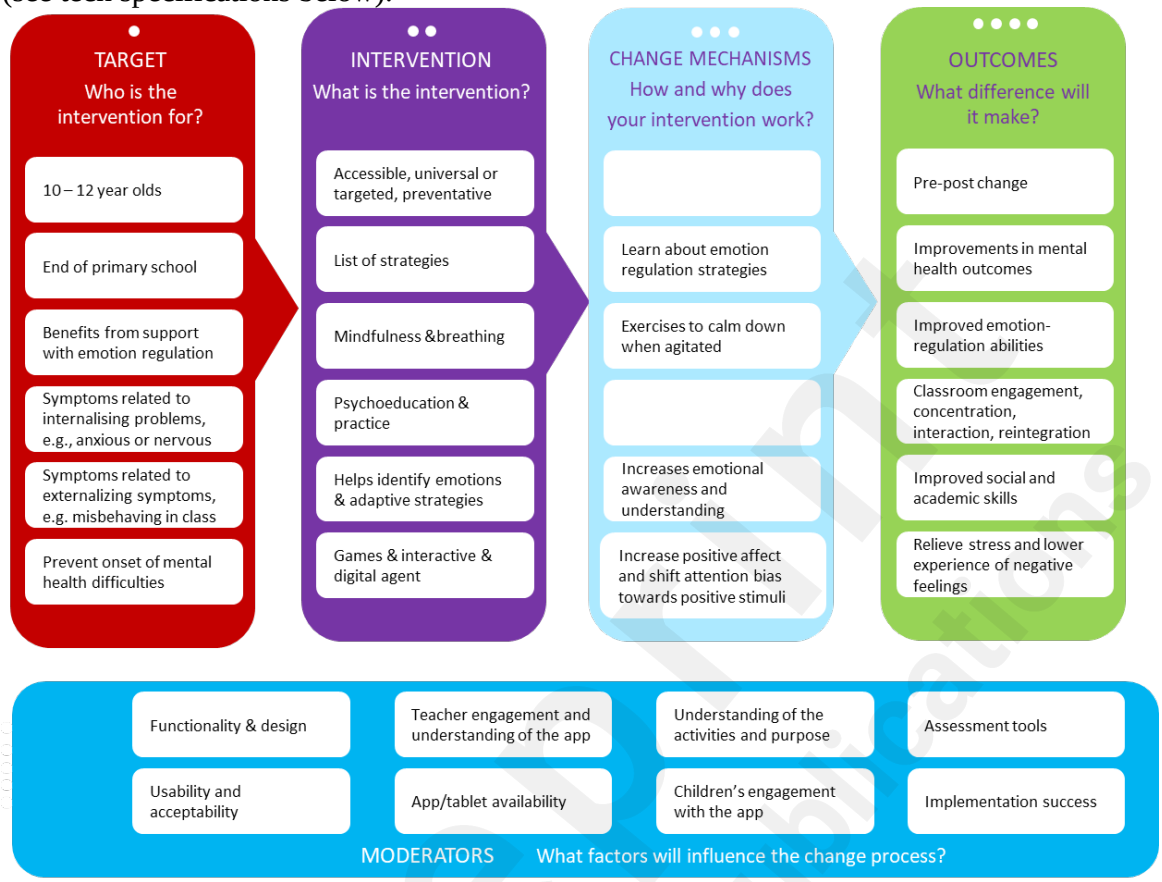

Figure 3 Stage I logic model of app intervention

Stage II Modelling and design

Objectives:

Stage II focused on involving children and the other key stakeholders including teachers, clinicians, researchers, the app developer and designer in the in design and modelling process. This included the identification of key modules in the app, as well as the development of content and design of each modules, such as psychoeducational content, games, and exercises.

Activities, data analysis and resulting design formulations

Stage II consisted of a highly iterative process, combining the results of the two PPI events (see Table 2), and three co-design and participatory workshops, followed by three testing sessions to make final design decisions and test the functionality and usability of the prototype. The combined use of PPI and user-centred design methods has been highly recommended for the development of complex interventions [41]. Ethical approval to conduct these workshops was obtained from the University College London Research Ethics Board (number 11701/001). We conducted three co-design (N=15) and three participatory workshops (N=18), across two primary schools with 33 children (age 10-12 years). Although, specific demographic data including age and gender of the children was not collected, the researcher team noticed that there was a slightly greater number of girls present in the workshops. Each workshop was conducted by the lead author and accompanied by a teacher.

The lead author [BM] took notes during each workshop and produced reflective notes afterwards. Materials and notes produced during the workshops were coded manually and mind-mapping exercises were used to organise the data further. Following this an excel sheet was created to provide an overview of all items raised in the workshops. Each item was discussed with the app developer and designer to identify whether and how they could be integrated into the app. Each item in the excel sheet was colour-coded accordingly: ‘green’ = can be done, ‘orange’ = might be possible/ alternative suggestion to be tested in next workshop and ‘red’= on hold or technology/ design do not allow for this.

Occasionally, other stakeholders and experts were involved, such as clinicians who provided feedback on the psychoeducation modules; their involvement is described in more detail in the respective sections.

Co-design workshops

The first co-design workshops introduced children to the project and their role as co-creators. After an icebreaker exercise, we explored what the children knew about mental health and emotions, including what strategies they use in different emotion-eliciting situations. The first workshop did not involve specific wireframes, as the focus for this stage was on exploring freely with children what activities and potentially app features could help them to regulate feelings.

Children wrote down what feelings they knew (on sticky-notes) and identified which feelings they found most difficult to regulate. Children reported that intense, negative as well as positive emotions had a negative impact on their behaviour in school (e.g., “*When I am super excited, I cannot concentrate*” or “*when I am angry, I don’t want to do stuff.”)*. In relation to that, children shared personal stories of situations that tend to elicit strong feelings in them either at school or at home.

Based on children’s suggestions we created a list of day-to-day strategies, which included strategies such as: “*playing games online”, “listening to music”, “drawing and painting”, “watching something funny on YouTube”, “playing with my pet”*, and physical activities like *“cycling”* or *“football with friends”*. As a next step, we discussed which activities could be supported through the app. The final list was then use to create overarching categories, which formed the core components of the app:

a) Games to play

b) Something to relax
c) Something to watch
Going forward we focused on these components as key modules while linking them to the Stage I findings.
For the games module we created a list of possible games with the children. They frequently mentioned existing popular video games (e.g. “Fortnite”), but also referred to other apps like music making, colouring in, drawing in sand and fast reaction games. In discussion with the app developer, each item was marked as ‘possible, ‘alternative game’ or ‘not possible’. Complex games with multiple levels, requiring frequent updates, large amounts of data or needing high resolution were discarded, as they conflicted with other design goals, such as a) slowing down the app, b) requiring too much data or c) not being suitable for a small mobile device. Due to this, we had to exclude game ideas suggested by children, such as: colouring in, music making, taking care/raising a pet, and a reaction game where the user smashes eggs by hitting them.
Simultaneously, the research team screened the literature to identify existing evidence for any of the game suggested or other games that have been developed in other contexts for this age group.
We asked children what activities they found relaxing. Many suggested mindfulness and breathing exercises, which they had learned about at school. Others suggested ‘*watching something online’* or ‘*listening to music’*. Which led to the idea to include a music and sounds feature and encouraged us to make animated videos that could guide children with mindfulness and breathing exercises.
For the “watch” modules, we decided to develop a series of animated films. The storylines were inspired by children’s reports about their emotion-eliciting situations and the associated feelings, thoughts and behaviours (e.g., having a fight with a friend and not being able to concentrate in class). The stories were complemented with theories grounded in cognitive behavioural therapy (e.g., the behaviour-thoughts-feelings triangle) so that they could serve as a psychoeducational component. The scripts and screens were developed by a clinical psychologist and an animator, who specialises in communicating mental health concepts to the public. Drafts of the films were reviewed by clinicians (N=7), who worked with children and in schools and a group of researchers specialised in child emotion regulation (N=5). Both provided feedback on the scripts and the visual presentation of the content, and helped to ensure that they were in line with current evidence and guidelines. Any changes to the script or content was presented to children in subsequent workshops to ensure that it was age-appropriate and children could identify with it.
For the second and third workshop, wireframes and potential screen designs were printed on A3 paper based on the three core modules. Children were provided with pens, stickers, and sticky-notes to add ideas for new feature and review existing features. In contrast to Druin’s reports [32], but in line with recent observations by Jones and colleagues, some children seemed to struggle with the creation of visual representations for potential app functions [42]. It seemed as if they could not visualise how something that was drawn on paper could later be transferred to an app. As a result, some children were hesitant to draw their ideas and preferred to describe them. Therefore, we decided to build a basic but high-tech prototype for subsequent workshops, which seemed to make it easier for children to provide suggestions for existing and new app features.

Participatory workshops

In the participatory workshops, children were asked to give feedback on the high-tech prototype that we had developed based on the outcomes of the co-design workshops. In comparison to the low-tech paper prototypes, the high-tech prototype made it significantly easier for children to find their role in the process and provide suggestions for and against

potential app features.
During the three participatory workshops (N=18), children raised the need for a feature that provides in-the-moment support. They reported that it can be difficult to remember the strategies when they are experiencing strong feelings. Following this, a "help button" was added, which children can press when they experience strong emotions and cannot remember the tools or strategies available to them.
Moreover, children suggested that it would help them if they could tell the app how they felt and it told them in return what they could do about a feelings ("*Can I tell it how I feel and it tells me what to do?*"). This possibility was first explored through a chatbot function, whereby children could tab on an animated agent on the home screen to open a chat window. When we tested this feature in subsequent workshops it became evident that some children seemed to think that they were speaking to an actual person (i.e. "*Who is on the other side*?"). Therefore, we decided against the chatbot function for this age group, as it involved potential risks, in case a child needed urgent help and tried to access it through the chatbot. While the chatbot function presents an exciting opportunity to engage children with the app, developing it further was beyond the scope of the present research. Hence, we decided to replace the chatbot with a "check-in function". With this feature children can select a feeling from a list to indicate their emotional state and in return they are provided with suggestions on what to do. This feature was considered a safer alternative by clinicians and the research team and also required less functionality and was therefore more feasible (see Figure 7).
For the check-in function, an initial list of 12 feelings was created based on the most common feelings that children had reported in the first round of the co-design workshops. We designed a set of images each representing one of the 12 feelings. We tested the validity by showing children the images without a description and letting them rate what emotions were represented. Based on children's feedback the images were further adjusted. Children also highlighted important emotions that were missing, so the list was extended. The final list aims to reflect a full range of feelings, ranging from emotions with positive, neutral to negative valence as well as different levels of arousal. For instance "feeling excited" represents an emotion of positive valence and high arousal, while "feeling grateful" is a state of positive emotional valence, but low arousal.
Consequently, the functionality of the animated agent was reduced to two main functions: a) "tell me something" – which activates a random selection of jokes or funny facts that are expected to increase the level of engagement and perceived level of interaction with the app – and b) the "check-in" function as presented above.
A summary of all items raised in the workshops and the resulting changes to the app are presented in Table 4 below.

Table 4 Observations and design implications based on participatory design workshops

Observations and feedback	Implications, solutions and actions
• Games to play and feel happy	• Created list of games to discuss with app developer. Solutions and suggestions, were tested and further adjusted with children in next workshop.
• Children suggest breathing and mindfulness exercises which they know from school	• Develop animated videos to guide them through exercises
• Children would like feature to create music	• Music making feature conflicts with usability of app
• Children listen to music to relax	• Added music and sounds to relax

	module
• Children frequently report to watch videos as a way to calm down, relax, be happy and distract themselves.	• Create video content for watch modules
• “Can I tell it how I feel and it tells me what to do?” indicated that children would like some guidance and support in difficult situations and with specific feelings.	• We explored chatbot function, which was then replaced with check-in function
• Children request in the moment support, when feelings are too intense.	• We added easy to reach help button to homescreen of the app. Once pressed a “stop and breathe” sign covers whole screen which is followed by guided breathing exercise.
• Children thought that they were talking with a real person in chat	• Replace chatbot with check-in- function
• Children liked to interact with the digital agent and wanted more of that.	• Keep the digital agent and add interactive features
• Children report to watch and listen to funny things to feel better.	• Asked children for jokes and fun-facts and added these to animated agent which was in line with our goal to increase opportunities for interaction.
• Speech bubbles of agent to fast	• We increased length of time of speech bubbles
• Onboarding process more colours and options	• We add background colours and a selection of different colour themes.
• Explainer on how to use app	• Add stars to highlight different functions in app for first time users. This was discarded as it was too complex to adjust position of stars on screen for different screen sizes. We added short explainer video as part of the onboarding process.

Prototype testing

The prototype was tested in another primary school with 15 children across three workshops. During these workshops broad design features, such as the flow of screens, as well as more detailed design questions regarding language and use of colours were discussed. The schools provided tablets, which allowed us to test the functionality of the app across different devices and the school’s technology-infrastructure (e.g., access to Wi-Fi, school’s digital safety policies). A teacher was present at each workshop.

At the beginning of the workshops, children were informed about the purpose of the app, but were not given any instructions on how to use the app. This allowed us to observe whether the current design was intuitive enough so that children could use it without much explanation. Children were encouraged to speak out loud their thoughts while navigating through the app. A researcher observed the children and took written notes about the ways they explored the app to identify pitfalls, popular items, technical difficulties, and features that they did not discover on their own. Following this, children received an in-depth

introduction and were asked to be tech-detectives who help us find any glitches and errors. All children were encouraged at all times to provide honest feedback and suggestions on the usability of the app and how it could be further improved.
BM took part in each workshop, asked follow-up questions and took notes. After each workshop BM made reflective notes and asked teachers about their observations. The collected data was organised in an excel spreadsheet according to specific app functions. The spreadsheet was used to discuss each item with the app developer and designer, who subsequently adjusted the app. A summary of the items raised and adjustments made is provided in Table 5.

Table 5 Observations and implications following prototype testing

Observations & feedback	Design implications & actions
• Difficulties with certain functions dependent on different use of browser	• Test web-app across different browsers and devices
• Screen and design do not adjust correctly for devices of different sizes	• Test with different screens and devices
• Animated videos were sometimes slow	• Improve video quality • Make available offline
• Add personalised tools to tools list	• Children can mark favourite tools in list
• Differentiate between in-class and out-of-class tools list, as some tools, e.g., go outside not suitable for classroom context	• Two tabs for different contexts
• Problems with login. Children either do not have an email address or forget login details.	• Add different logins for quick classroom access and use at home.
• Music does not stop when leaving the module	• App developer checks stop and pause function and music, videos pause automatically when leaving a module
• Some of the games do not start	• App developer adjusts underlying technology

Results: Intervention design and evidence base

Technical specifications

The intervention was developed as a responsive web-based app to increase accessibility of the app, and allow users to access it across different mobile devices, desktop computers and smartboards. While it works across multiple platforms, it was optimised for tablets, because children are more likely to have access to tablets at school and at home [43].

The app is delivered through a browser, meaning over-the-wire updates can be pushed out instantly, and the app uses advanced HTML5, CSS3, and JavaScript (ES6) techniques to render a smooth and performant user experience. The underlying development platform used was Meteor.js, a full-stack Node.js application development framework, hosted on a resilient AWS EC2 instance with a MongoDB database hosted via MongoDB Atlas. The app only requires internet connection when users access it for the first time, after which it can be saved to the home screen. This feature was chosen to mitigate risks that the intervention could not be accessed in case of reduced or limited Wi-Fi.

The app offers two different types of logins a guest login and a registered account login. The guest-login serves the following purposes: a) new users can explore the app without having to register, b) children without an email address can use the app, and c) it allows for easy and fast access. The second login allows users to set up a personal account that is registered through an email address and password. The app only remembers personalized features (e.g., design features) when users access it through their personal account. The app does not store any individual user data and adheres to existing general data protection regulations.

Intervention description

The latest version of the intervention includes four modules: Play, Relax, Watch, and Tools. The different modules provide users with opportunities to learn, practice and develop their emotion regulation skills. The content is presented through audio tracks, images, animated films and games. Based on the activities and findings outlined above we adjusted the logic model further (see Figure 4).

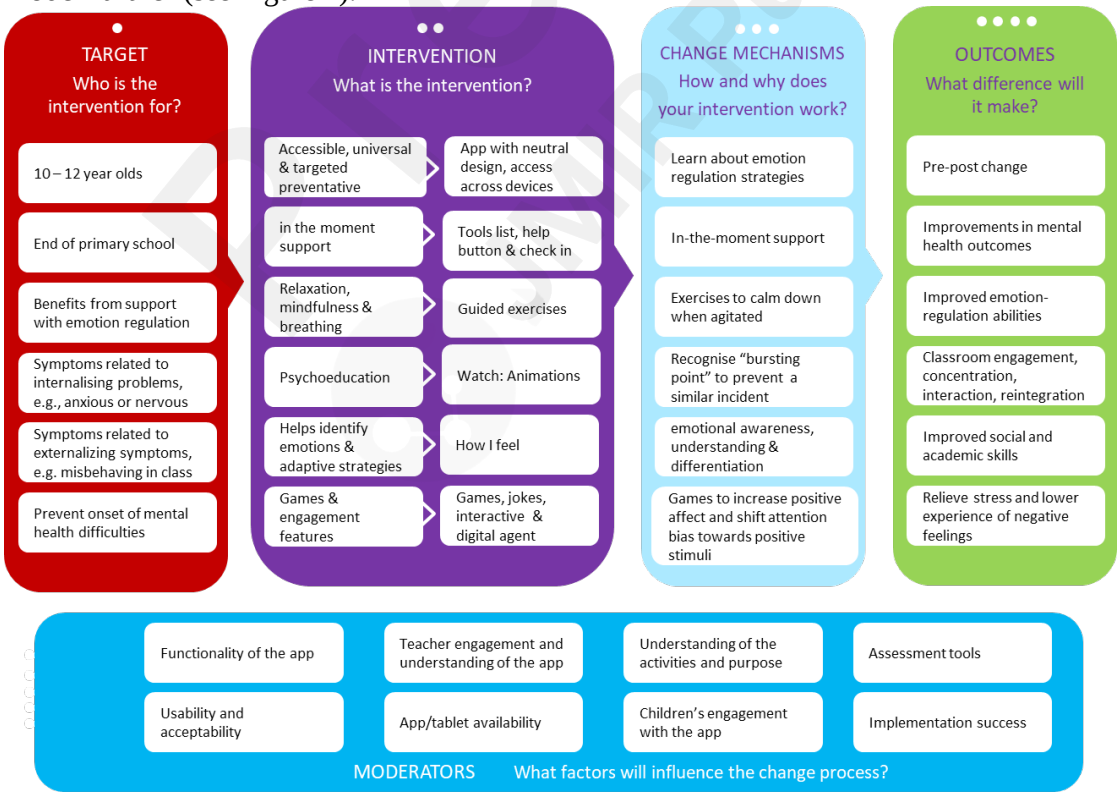

Figure 4 Finalised logic model for app intervention

Onboarding process and home screen

First time users go through an onboarding process, before they reach the homescreen of the app. During this process they learn about the purpose of the app, provide account details (e.g., user name), and select a preferred colour scheme and profile picture.

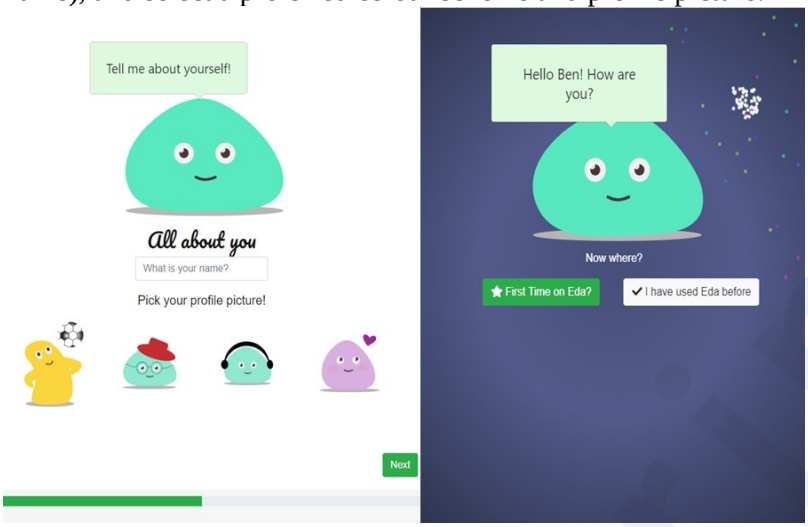

Figure 5 Onboarding screens of app

After the onboarding process, the user enters the home screen, where an animated, digital agent greets the user with their chosen username and encourages them to explore the app or tap on the body of the agent itself, which opens the “check-in-function” and “tell me something” – which activates a random selection of jokes or funny facts to increase the level of engagement with the app.

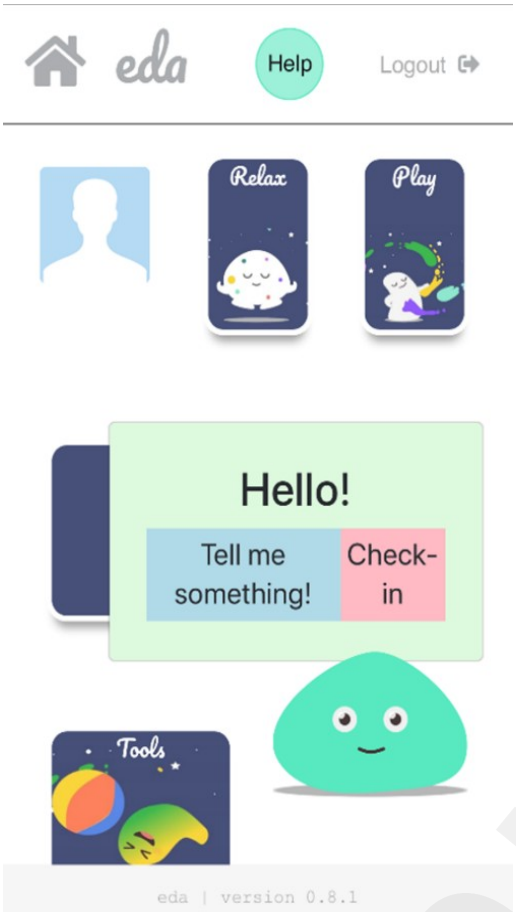

Figure 6 Homescreen of app with four main modules and digital agent

The digital agent

We aimed to design a gender-neutral, animated agent who accompanies the user through the different modules in the app. This feature was added based on children's requests to have someone to turn to in situations where strong emotions are experienced. Additionally, research has shown that the use of virtual agents can facilitate the experience having a personal relationship, which in turn increased long-term engagement with a digital intervention [44]. The digital agent was designed as a moving (or "wobbling") blob with big, blinking eyes to add a human-feel to it, which is hoped to enhance a feeling of connectedness and engagement in the user [45].

The check-in- function

The "Check-in" function (see Figure 7) displays a set of 18 different feelings to the user. When the user selects a specific feeling, a new window opens-up that provides more information about the chosen feeling and gives suggestions regarding potentially helpful emotion regulation strategies. Where appropriate cross-links to other modules in the app are provided (e.g., relax), so that the user has the opportunity to immediately apply or practice these strategies. This approach is in line with past research which has structured emotions along the two dimensions of arousal (high versus low) and valence (positive versus negative; [46]. Furthermore, it has been suggested that internalizing symptoms are associated with the primary experience of low arousal emotions, while externalizing symptoms are rather linked to high arousal emotions [47]. We believe that this function not only meets children's initial requests, but can also help them expand their emotional literacy and emotion differentiation skills, which has been linked to better mental health and is therefore in line with the purpose of the present app [48]–[50].

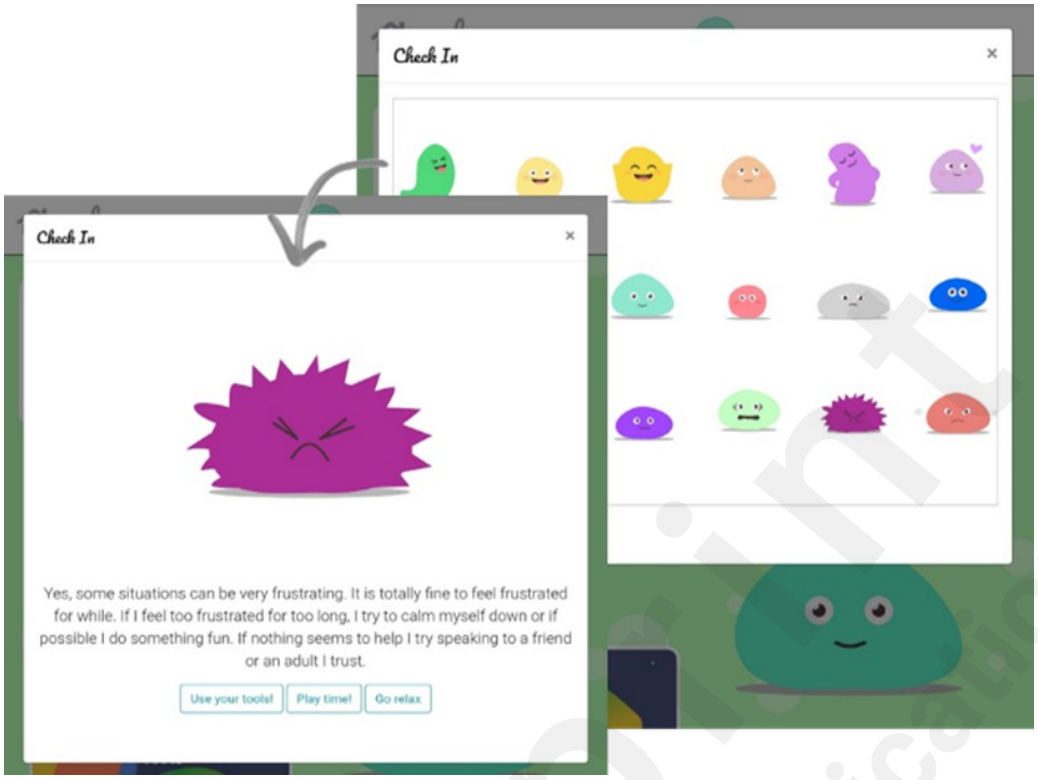

Figure 7 Check in function in app

Education and practice modules

Users can enter one of the four main modules manually via the home screen or by selecting an emotion in the check-in function, which subsequently forwards the user to one of the practice modules.

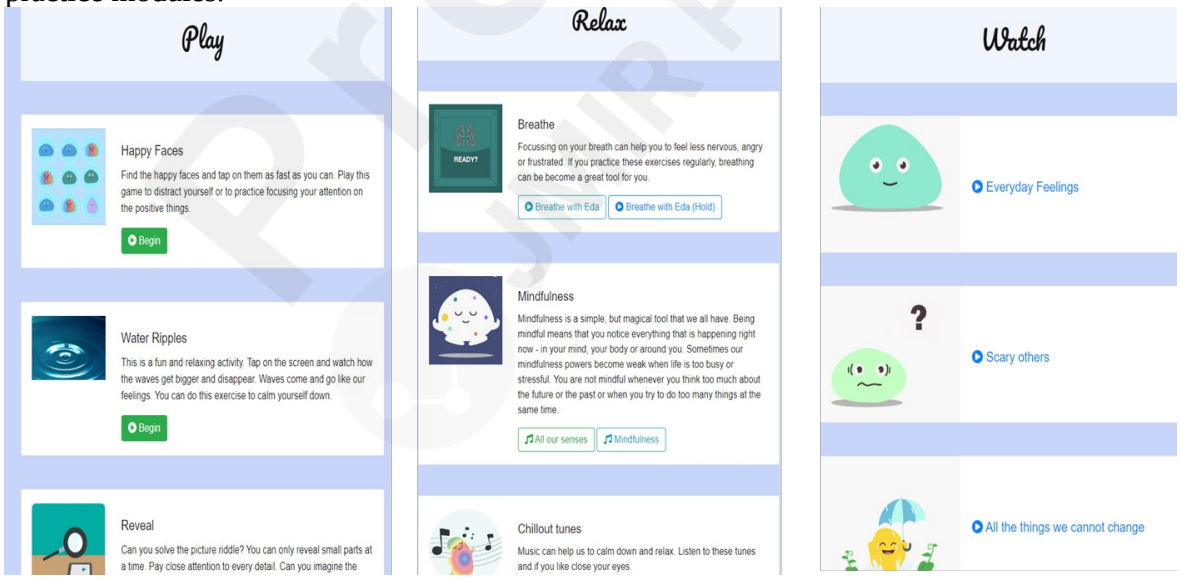

Figure 8 Content of Play, Relax and Watch module

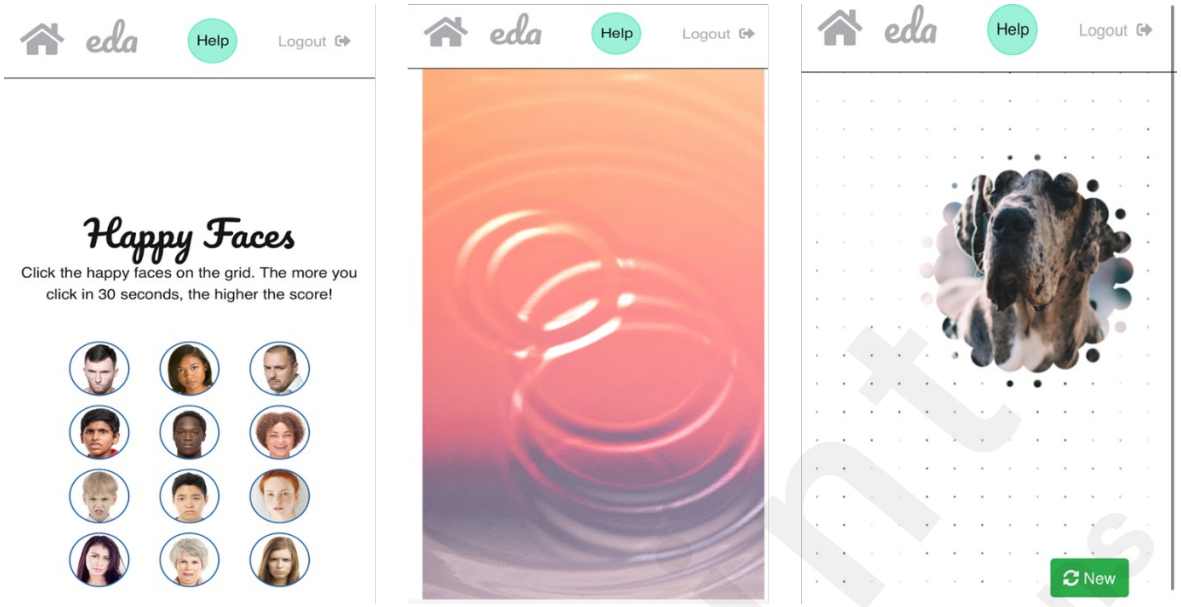

Figure 9 Overview of games including Happy Faces, Water ripples and Reveal

Play

This module contains three games. In the first game “Happy Faces”, the user has to identify one happy face amongst 12 neutral or angry faces. This design was chosen due to research showing that search tasks like these can result in an attention bias shift towards positive stimuli, which in turn increases the likelihood to experience more positive emotions [51]. During one of the workshops, some children suggested that the game should have a second level of increased difficulty, by animating the faces so that they move over the screen like balloons. In discussions with the app developer, this specific feature was considered as too complex for the present version of the app, but will be further explored in the future.

The second game “Water Ripples” presents a colourful picture with an animated water surface. Through tapping the screen, the water animation creates circular waves that slowly expand to the sides of the screen. The design evolved from the co-design workshops, where children reported that drawing in sand or water drops had a calming effect on them. Furthermore, it resembles a commonly employed mindfulness exercise, where the individual imagines their emotions as waves that come and go [52].

The third game “Reveal” shows a colourful picture that is covered by a white layer. By touching the layer with a finger, parts of the white layer disappear and reveal sections of the underlying picture. The user is encouraged to guess the theme/object of the underlying picture. While there was no specific psychological theory to guide the design of this game, especially in the context of a mental health intervention, research has shown that games like the ones chosen here foster engagement [53]. Furthermore, games have been shown to increase positive affect and wellbeing, although more research is needed to identify which specific aspects initiate the change and whether or how this might differ for different users [54], [55]. When testing this game with the children the first time, it became evident that they a) wanted to know whether they identified the correct underlying picture and that b) adding a point or reward system for correct answers could further increase their engagement with this game.

Relax

The relax module was inspired by the school observations and reports from children during the workshops, which indicated that most schools already used breathing and mindfulness

methods, hence many children were already familiar with relaxation exercises. In line with that, there is increasing evidence showing that mindfulness interventions enhance emotion regulation and exert positive effects on mental health and wellbeing [56], [57]. The relax module contains three sections that encourage the user to actively engage in some type of relaxation or mindfulness exercise. The user can choose from video animated breathing exercises, audio-guided mindfulness exercises and a selection of calming sounds (e.g., guitar or rain). The decision to include sounds or relaxing music was based on children's suggestions in the workshop, as well as classroom observations, where teachers used music to keep children concentrated during a task.

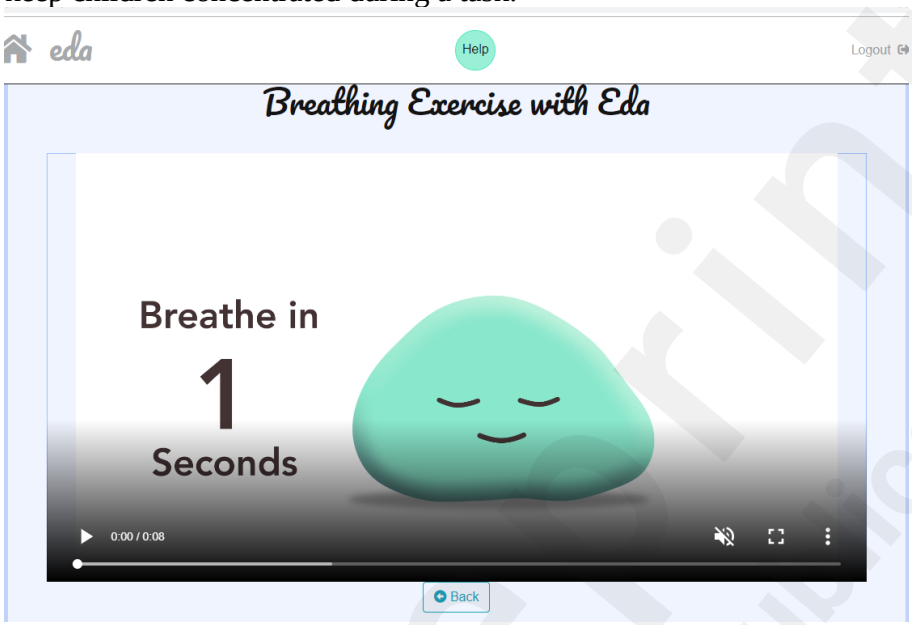

Figure 10 Screenshot of guided breathing animation

Tools list

The tools module evolved from conversations with children, who indicated that they used different methods to regulate their emotions, some of these methods were developed through the help of the teacher. Thus, the tools module consists of a list of behavioural and cognitive strategies that are expected to help with regulating intense emotions. The list is divided into a general tools list that can be referred to outside of the classroom (e.g., doing something fun, getting support from a friend) and a specific list of tools suitable for the classroom (e.g., going to the quiet zone). That list was created with the input from children and teachers, who stated certain tools that were already applied in the classroom.

With respect to existing evidence demonstrating that the lack of and limited access to appropriate emotion regulation strategies contributes to mental health difficulties, it was expected that by giving users increased access to these tools, it would positively influence their emotion regulation abilities [58]. Furthermore, research has shown that early school years represent a crucial time for children to expand their repertoire of emotion regulation strategies, including cognitive and behavioural strategies [59], hence, it was assumed that the tools list function could positively support this development.

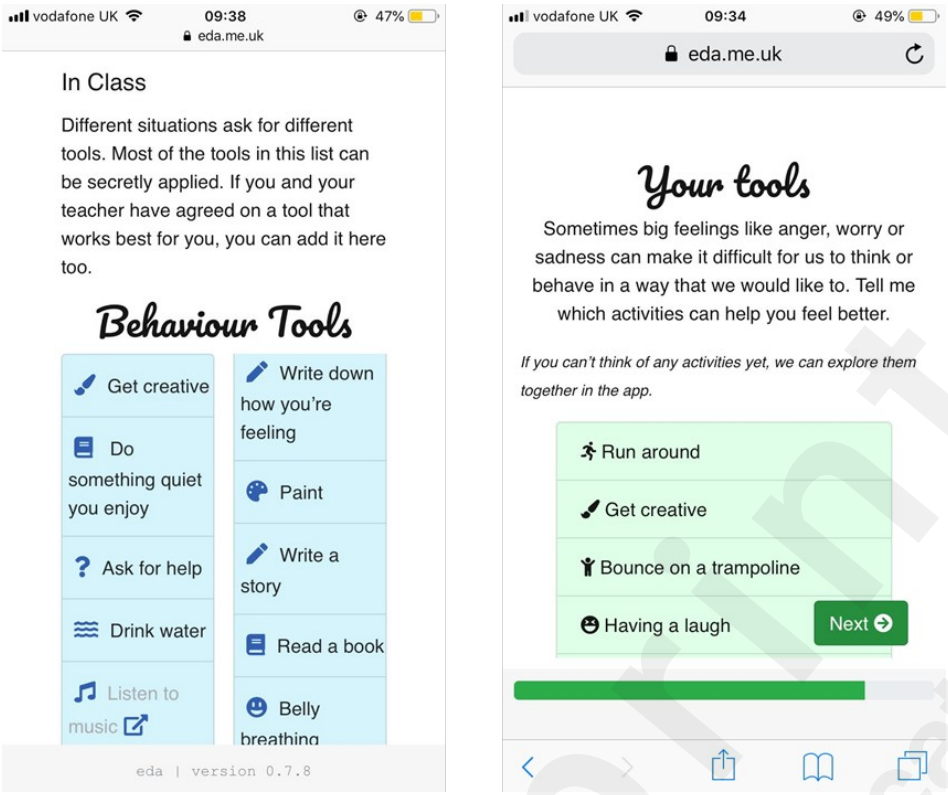

Figure 11 Tools list feature showing different tools for different contexts and personalized tools

Watch

Contains a set of psychoeducational animated films, with the primary aim to improve users' understanding of emotions, emotion regulation strategies and how thoughts and behaviours influence an emotional experience. This is achieved by explaining commonly applied CBT principles in simple terms and by introducing some of the more complex emotion regulation strategies, such as cognitively restructuring one's thoughts (i.e., cognitive reappraisal) or mindfulness [60], [61]. Research has shown that CBT based interventions successfully improve a variety of psychopathological symptoms, even if delivered through technology-based platforms [15]. Furthermore, the results of the systematic review demonstrated that CBT-based interventions were effective in improving emotion regulation difficulties in youth.

Help function

This function was included based on children's requests to have more in-the-moment- support when they experience high levels of negative emotions, which can prevent them from engaging in adaptive decision making.

Therefore, by clicking on the help button a series of emotion regulation methods is presented to the user (i.e., stop what you are doing, count to 3, and breathe), who is instructed to follow these until the initial emotional reaction decreases to allow for more adaptive actions. This functionality is also in line with research indicating that the duration of an emotional experiences is influenced by the type of emotion regulation strategy employed [62]. It was expected that the help function would support children to distract themselves from the emotion eliciting stimuli. Distraction is an emotion regulation strategy that been shown to quickly decrease levels of negative emotions [63], [64]. Similarly, the use of distraction strategies to regulate intense emotions is a substantial part of dialectic-behavioural therapy, which has been shown to effectively support individuals with severe emotion regulation problems [65], [66].

Discussion

Mobile apps for children represent a promising pathway to provide effective mental health support, yet there is a significant lack of mental health apps for this age group (age 10-12) [7], [9]. Only recently, the self-management intervention ReZone was developed for children (age 10-15 years) with the aim to reduce internalizing and externalizing symptoms [67].Early findings suggest that the app was perceived as helpful by pupils, but findings from a proposed randomised control trial have not been published yet. Additionally, Hides and colleagues' developed a new music app to enhance emotion regulation in adolescents [68], their initial findings with N= 169 young people (age 16 to 25) suggested that the app could potentially enhance emotion regulation; however further testing is required to determine its effectiveness.

Moreover, has highlighted above, for many child mental health apps information on the design and testing process is not available [7], hence we are addressing this gap by describing and sharing our development and design process, as we continue to develop the app further.

Strength, limitations and lessons learned

A significant strength of the present development process is the inclusion of children and young people at every stage. Due to existing collaborations, we were able to involve a group of young advisors (age 12-19 years) in the early stages of our project, which had numerous benefits. However, the inclusion of slightly older participants in the PPI events, may have also contributed to some issues that were experienced in subsequent workshops with younger children. We believe that the work with the young advisors was very valuable, but also want to highlight that the involvement of the actual target users should be a priority, when designing new digital interventions.

By combining methodologies from different fields, we adopted a highly interdisciplinary approach, the lack of which has been highlighted as significant limitations in existing digital mental health interventions. We hope that in doing so we increased the potential for sufficient user-engagement, while also providing a sound evidence-based for the content of the intervention [12], [15]. Despite our best efforts, it was not possible to get all the different experts into one room for the workshops. This can be particularly difficult in research including vulnerable populations, where additional safeguarding regulation are in place. Such access constraints impacting the work of HCI researchers and designers with vulnerable groups have been highlighted before [69]. In our project the lead researcher was already trained to work with children and had easier access to the target group. To facilitate our interdisciplinary approach BM undertook additional training to familiarise herself with the methods from the different disciplines and consulted experts from the other fields before and after each activity. Throughout the development process the lead author served as a linking point for all key stakeholder and tried to gain and share everyone's views and opinions. While in an ideal scenario experts from the different fields would be conducting the workshops together, we believe that we took the best possible approach by training the lead researchers in interdisciplinary methods and have regular consultations with experts from the respective fields.

While the inclusion of the various experts and stakeholders in the process is a significant strength of our development framework, we think that this aspect could be further improved by developing a decision-making tool with all stakeholders beforehand. Such a tool could be consulted whenever contradicting design goals from different stakeholders need to addressed. Our team did not develop such a tool and final decisions were made by the research team, which may have resulted in unwanted biases.

The collaborative approach with schools had various benefits, as it ensured regular access to the user group and helped us to identify context specific design goals at an early stage. Furthermore, the research team was able to conduct all of the design workshop within the

school context, as recommended in the cooperative inquiry framework [70]. However, during the workshop activities the research team noticed that children, who were reported to show most emotion and behavioural difficulties at school, were also less engaged in the workshop. The research team had the impression that some of these vulnerable children may have engaged more in a different context. Going forward we suggest to try and speak to these children outside of the school context or choose different workshop activities so that all voices can be taken into account. Furthermore, in most cases teachers decided which children would join the workshop activities. This could have caused an unwanted bias, as previous research suggests that adults were less likely to choose children with certain characteristics, (i.e. less sociable, externalizing symptoms, lower academic competences) [71]. In relation to that, it should be noted that the research team did not collect specific demographic or other sensitive category data, which could be useful in interpreting current but also future usage data. Collecting data on participant characteristics can provide insights on other mental health risk factors (e.g. existing mental health problems, living status, ethnicity), which can help make comparisons between different user groups that may be of the same age, but have different mental health profiles. Therefore, we suggest that future research collects relevant participant data in the early design stages.

Teachers contributed tremendously with their views and expertise. However, they had very limited time available and their role as intervention deliverers has not yet been fully addressed at this stage. We suggest to conduct more classroom observations with a specific focus on teachers' roles and needs to adjust the app accordingly. This could also be explored as part of an exploratory feasibility trial, which we suggest as a next step to develop and evaluate the present app further. We suggest a series of exploratory feasibility trials to uncover and iron out remaining technology and design issues. Moreover, with respect to one of the greatest limitations of today's digital mental health interventions [72], we suggest that the next stages need to focus primarily on usability, engagement and implementation of the present app, prior to any effectiveness testing.

Throughout the development process we noticed a tension between finding the right balance between a) guaranteeing an adequate evidence-base for each feature of the intervention while b) leaving enough room for creativity and innovation of new features. We strongly agree that evidence-based and evidence-informed concepts are of significant importance, however, there seems to be a common misconception that one can only achieve "evidence-based innovation" by "transforming" evidence-based non-digital interventions into digital ones [17]. We would like to encourage the field to free themselves from this notion as it can significantly hinders us in reaching the actual potential of digital mental health interventions [73]. In relation to this, we would like to refer the reader to the findings of our exploratory trial [29], where we discuss promising future directions for the present app.

Conclusion

Digital interventions that target transdiagnostic mechanisms like emotion regulation have the potential to support young people's mental health on a wider scale, regardless of the level or type of symptoms that they experience. Currently, little guidance exists on how to develop such a transdiagnostic, digital intervention for children. We highlighted existing limitations in the field and presented a new approach to address them in the current project. By developing a new interdisciplinary development framework we were able to incorporate methods from different fields. Although, more research is needed to evaluate and further improve the present app, we hope that by sharing our insights and lessons learned this paper will be a helpful guide to others.

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Praveetha Patalay supervised BM during her PhD and was involved in conceptualising and designing the study, and writing, editing and reviewing of the manuscript.

Holly Bear conducted her PhD alongside BM and was involved in conceptualising, writing, editing and reviewing the manuscript.

Jessica Deighton supervised BM during her PhD and was involved in conceptualising, writing, editing and reviewing of the manuscript.

Julian Edbrooke-Childs supervised BM during her PhD and was involved in conceptualising, writing, editing and reviewing of the manuscript.

Conflict of interest

None to declare. Neither the app development company nor any of the authors have ownership over the app. The app development company was contracted for the project. Any costs resulting from this project were covered by BM's scholarship, a grant from the EU's Horizon2020 Research and Innovation program. The project formed part of BM's independent PhD research, therefore the intellectual property rights of the content of the app lie with the first author.

Abbreviations

CBT: Cognitive Behavioural Therapy

HCI: Human Computer Interaction

MRC: Medical Research Council

PCD: Patient-Clinician-Designer

PPI: patient and public engagement

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