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A gamified, family-based program for children with mental illness: Protocol for a feasibility study toward a transdiagnostic intervention

Running title: Interactive, gamified therapy for children

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Abstract

Background: Mental illness is a leading global health burden, with a peak onset in childhood and adolescence, a period marked by heightened vulnerability due to neurodevelopmental changes and increasing psychosocial demands. Rising prevalence rates, long waiting times for treatment, and the lasting effects of adverse childhood experiences highlight the urgent need for accessible early interventions. Digital and blended therapeutic approaches, especially gamified tools, show promise in supporting emotional regulation, strengthening self-esteem, and reducing strain on healthcare systems.

Methods: EnTree is an interactive, family-oriented, digital picture-book intervention for children aged 6-11 years with mental illness, their families, and therapists. EnTree incorporates principles of cognitive behavioral therapy (CBT), is conceptually aligned with a transdiagnostic framework, and integrates nature-based activities. Thereby, it aims to strengthen emotion regulation, cognition, problem-solving, and general mental well-being, integrating a playful approach while simultaneously implementing protective factors for functional digital media use. The primary study objectives, including development, implementation, and delivery of the behavioral intervention, as well as feasibility of conducting a subsequent fully-powered randomized controlled trial (RCT), will be evaluated with help of a small feasibility study. Thirty affected families will be recruited to participate in the intervention over a duration of 8 weeks. Secondary objectives will investigate changes in mental health symptoms (e.g., emotion regulation, general psychopathology) in children and caregivers, and family functioning. Exploratory objectives will examine potential changes in digital media use patterns and assess acceptability as well as tolerability of the intervention in families and therapists. Outcomes will be assessed using standardized questionnaires and semi-structured interviews. Data analysis will include descriptive

statistics, repeated measures t-test, longitudinal linear mixed effects models, repeated-measures ANOVA, and qualitative analyses.

Conclusions: EnTree addresses an unmet need for accessible, family-based programs for children with mental illness and may serve as a foundation for a future transdiagnostic intervention adaptable to various clinical settings.

Clinical trial registration: DRKS00040158 (German Registry of Clinical Studies)

Keywords: Child, Mental Disorders, Family, Cognitive Behavioral Therapy, Emotional Regulation, Psychotherapy, Mental Health Teletherapy

Introduction

Description of Research Problems/Questions

Globally, 1 in 7 children is estimated to be affected by mental illness [1], which has been associated with reduced life expectancy compared to the general population [2]. The peak age of onset of mental illness lies in childhood and adolescence [3], which is attributed to significant neuronal changes and psychosocial demands, thus increasing vulnerability to mental disorders during early development [4]. Globally and in Germany, the prevalence of mental illness in children is rising, with up to 1 in 5 children reporting mental health concerns [5–8].

The growing need for accessible mental health care leads to new challenges within a healthcare system facing long waiting times for therapeutic treatment slots, economic pressure, and a decreasing number of mental health specialists. According to a recent analysis performed by the German Federal Diet, waiting times in Germany average six months (WD9-3000-059/22). Without support, affected caregivers often feel overwhelmed, while children face developmental risks and impairment in key life areas during a critical period of life [9].

Transdiagnostic approaches address mechanisms that contribute to a wide range of disorders, thus accounting for broad symptom clusters [10,11]. Emotion regulation represents a key transdiagnostic construct, with difficulties contributing to mental health impairment and chronicity [12,13]. Particularly, children report high rates of emotional difficulties, which are prone to develop into emotional disorders during adolescence if left untreated [6]. In addition, children's difficulties in emotion regulation and internalizing symptoms are directly linked to their parents' emotion regulation skills and the quality of parenting behaviors [14]. Early intervention and treatment of childhood transdiagnostic symptoms can improve the course of and prevent

progression to more severe mental disorders [15,16], i.e., relieving the healthcare system and reducing long-term personal and economic cost [17–20].

Digital interventions, particularly blended therapeutic approaches, i.e., the use of web/digital applications adjunct to regular therapeutic appointments, are well-suited as early intervention approaches and may improve transdiagnostic outcomes in affected children while reducing the burden on therapists [21–23]. For younger children, a playful, digital approach to transdiagnostic topics such as emotion regulation, cognition, and problem-solving may also be more accessible compared to traditional psychotherapy. For instance, gamification applications have demonstrated significantly positive effects on emotion regulation in children [24] and have shown superiority in treating internalizing disorders compared to non-gamified approaches [25,26].

Internet-enabled devices are increasingly available in German households, even for young age groups [27]. At the same time, early and excessive digital media use has been associated with sleep problems [28] and emotion dysregulation in young children [29]. Therefore, supporting functional digital media use should be considered an integral component of interventions targeting younger children, rather than treating digital engagement solely as a risk factor.

Parent involvement is a key component of effective interventions for children with mental health difficulties. Parents play a central role in shaping children's emotion regulation development, and combined parent-child treatments have been shown to produce benefits beyond individual child therapy alone [30]. Parent-mediated interventions, which equip caregivers with skills to enhance their children's emotional and behavioral outcomes, have emerged as a promising strategy to address difficulties in child emotion regulation across early and middle childhood [14,31]. A family-based approach, therefore, addresses not only the child's symptoms but also the broader relational context in which they occur.

Exposure to green environments has mental-health-promoting effects on children [32]. For instance, exposure to nature has been shown to positively influence attention [33,34], cognitive performance [35], positive affect [36], and stress reduction [37].

Considering stagnating effect sizes of therapeutic interventions [38], high dropout rates [39], and frequent psychiatric comorbidities [40], the development of more effective treatments tailored to the needs of children and families is increasingly important. A shift toward transdiagnostic digital approaches offers several advantages, including early treatment of transdiagnostic symptoms, flexible treatment models, reduced burden on the healthcare system, and increased engagement of children using playful methods.

Study Aims and Hypotheses

Following aims will be investigated:

1) Assess the feasibility of developing, implementing, and delivering a 6-chapter digital picture-book program for children aged 6-11 years and their caregivers.
2) Explore changes in children's emotional and behavioral experiences (e.g., emotion regulation) and family functioning between baseline and the 8-week follow-up among 30 children aged 6-11 years and their caregivers.
3) Assess acceptability, tolerability of the intervention, and protocol adherence in families and therapists.

Based on the results, conclusions will be drawn regarding the feasibility of a subsequent fully-powered randomized-controlled trial.

Aim 1 (feasibility) will be investigated using following primary hypotheses:

a) Dropout due to lack of intervention acceptance or therapeutic approach, or unexpected events, does not exceed 20% (6 families) [41].

b) Dropout due to technical issues does not exceed 20% (6 families).

c) Dropout due to non-adherence to the study protocol (less than 80% of the chapters are completed over the study period) does not exceed 20% (6 families).

d) No families will withdraw or be withdrawn due to unforeseen events.

e) At least 30 families (100%) will successfully complete study participation.

Secondary hypotheses (aim 2) include:

a) Participation in the EnTree educational program is expected to be associated with changes between baseline and week 8 in questionnaire-reported emotion regulation, children's and caregivers' emotional and behavioral experiences, family functioning, and children's nature-related knowledge and connectedness to nature. Given the absence of a control group, these findings should be considered preliminary and cannot be interpreted as evidence of causal effects.

b) From baseline to week 8, participation in the EnTree educational program is expected to be associated with changes in caregivers' confidence in guiding their children's digital media use, children's self-regulation and media-use habits, and reported family functioning. Caregiver depressive and anxiety symptoms, emotion regulation, and children's digital media use patterns are considered covariates in this context.

Explorative hypotheses (aim 3) include:

a) The implementation of the EnTree intervention over 8 weeks is acceptable and well-tolerated by participating children, caregivers, and therapists according to semi-structured interviews (SSI) and questionnaires. This includes acceptability and tolerance of the

content, technical aspects, and delivery, adherence/ protocol compliance, as well as the frequency of adverse events during the implementation of the EnTree program.

Methods

This study is registered with the German Clinical Trials Register (DRKS-ID: DRKS00040158).

Study Design

This study is an open-label, phase 2 study investigating the feasibility, preliminary outcomes and acceptability of the EnTree intervention, and the integrity of its study protocol. The study will be conducted within the Department of Child and Adolescent Psychiatry.

Participant Recruitment

Recruitment will be conducted in the outpatient clinic of the Child and Adolescent Psychiatry and Psychotherapy Department. Newly presenting, interested families will be referred to the study team. Families will be provided with study information, including a schedule of study assessments, intervention appointments, risks and benefits of participation, and data management. They will be informed about the voluntary nature of research participation. Informed assent or consent will be obtained from all involved parties (child, all legally assigned caregivers) prior to study inclusion. If eligible, participating families will continue to receive treatment as usual by their assigned clinicians. A sample size of 30 families will be pursued in line with recommendations for feasibility studies [42]. The intervention will be piloted with up to 8 families from October 2026-December 2026. Participants for the feasibility study will be recruited between January 2027 (First Person First Visit) and February 2028 (Last Person Last Visit).

Participant Eligibility

Families will be considered eligible for inclusion if the following criteria apply:

Children:

- Aged 6-11 years inclusive at the time of consent;
- Currently presenting to the Department of Child and Adolescent Psychiatry and Psychotherapy;
- Currently undergoing diagnostics within the department;
- German fluency;
- Ability to comply with the study protocol as assessed by the treating clinician;
- Ability to provide assent.

Caregivers:

- Currently presenting with one child to the Department of Child and Adolescent Psychiatry and Psychotherapy;
- German fluency;
- Ability to comply with the study protocol;
- Ability to provide informed consent for both them and the child.

To assess ability to provide informed consent caregivers and children will be asked to repeat the study information (including risks, benefits, voluntary nature of participation) in their own words.

Participants will be excluded based on the following criteria

Children:

- Acute risk of harm to self or others;
- Presence of medical or psychiatric contraindications that, in the opinion of the treating clinician, would compromise participant safety or the ability to engage with the

intervention. This includes all conditions that preclude meaningful app use (i.e., severe visual impairment, acute psychiatric instability requiring immediate intensive treatment);

- Insufficient proficiency in German;
- Cognitive impairments (i.e., intellectual disability, IQ below 70) that would prevent meaningful participation in the intervention.

Caregivers:

- Acute risk of harm to self or others;
- Presence of medical or psychiatric contraindications that, in the opinion of the treating clinician of the child, would compromise the safety of the caretaker/child or the ability to engage with the intervention. This includes all conditions that preclude meaningful app use (i.e., severe visual impairment, acute psychiatric instability requiring immediate intensive treatment);
- Insufficient proficiency in German;
- Cognitive contraindications (e.g., IQ below 70, illiteracy) and lack of capacity to provide informed consent (i.e., acute intoxication).

EnTree Program

EnTree encompasses a digital picture-book app, accompanied by an analog card game, a therapeutic anchor (customizable card sleeve for the playing cards), and an online portal. The app offers an immersive, narrative experience (based on the Meander Book[43]), presenting age-appropriate content through interactive stories and activities. The digital book incorporates educational elements informed by the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders in Children (UP-C) and selected CBT concepts [44], providing a conceptual

basis for the potential future development of a separate therapeutic program, including mindfulness exercises, and family-based psychoeducation to support emotion regulation, decrease general psychopathology, and improve family functioning using shared experiences. Increased exposure to nature will be aspired by providing regular outdoor challenges. Intervention engagement will be increased using gamification elements, while protective elements (e.g., time limits, unit structure, parental monitoring, no manipulative design mechanisms) will avoid negative usage patterns connected to the digital tool. Integrated protective elements are intended to further promote functional digital media use in children and strengthen caregivers' confidence in managing their children's digital media use (digital parental self-efficacy; see Table 1 for an overview of the intervention content). The analog playing cards and therapy anchor support blended therapy, memory consolidation, real-life links, and daily use. Therapists have access to a secure online portal that provides real-time monitoring of patients' app engagement and outcomes. The portal stores app-derived data and enables therapists to tailor usage of the digital book programs individual patient needs (e.g., by optimizing the sequence of intervention modules) while facilitating continuous monitoring of treatment progress.

Table 1

Intervention content for children and caregivers

Book Chapter	Content for children	Content for caregivers	Recurring content (All chapters)
Onboarding	Personalization of main characters & landing page (‘safe space’)	Introduction to the intervention, guidance on healthy digital media use	• Customization features • Gamification elements (e.g., mini games, interactive story elements) • Protective features regarding excessive digital media use (e.g., time limits, unit structure,
Chapter 1	Introduction to recurrent content and main features (e.g., basic emotions, mini games, mindfulness, outdoor challenges)	Psychoeducation on basic emotions and supportive parenting behaviors (i.e., expressing empathy, consistent use of disciplinary measures and praise, facilitating healthy	

		independence, and healthy emotional modeling)	parental monitoring, no manipulative design mechanisms) • Outdoor challenges • Mindfulness exercises
Chapter 2	Emotional awareness (purpose, structure, and components of emotions) & scaling	Additional information on the purpose, structure, and components of emotions, emotional child behaviors, instructions on how to scale emotions	
Chapter 3	Vicious circle of avoidance & acting opposite	Additional information on the vicious circle of avoidance and the benefits of emotional exposure, instructions on adaptive reinforcement	
Chapter 4	Physiological sensations during strong emotions & mindful awareness	Additional information on physiological sensations during strong emotions, psychosomatic expressions of emotional disorders, instructions on how conduct a body scan	
Chapter 5	Thinking traps & flexible thinking	Additional information on thinking traps and how to identify cognitive distortions, instructions on cognitive reappraisal	
Chapter 6	Problem solving	Additional information on the steps of problem solving, instructions on how to support child in using them	

Data Collection

Data on sociodemographic information (e.g., age, sex, gender, siblings (child), health status (presence of chronic illness of child), highest education level (caregivers), employment status (caregivers), migration backgrounds, income, household residency, distribution of childcare responsibility, geographic environment) will be obtained at baseline. Emotion regulation, general psychopathology (child and caregivers), family functioning (caregivers), digital media use (general information on usage times (caregiver), restrictive mediation (caregiver), conflicts due to digital media use (caregiver), digital parenting self-efficacy (caregiver), problematic digital media use pattern (child and caregiver)), connectedness to nature, nature-based knowledge, and app acceptability and usability will be collected for caregivers and children using self-report and

caregivers-report measures at baseline, post and/or follow-up (4 weeks post-intervention). Child mood will be assessed at all timepoints, and sleep will be measured at baseline and post-intervention. SSIs assessing technical feasibility, usability, acceptability, and safety of the intervention will be conducted via phone calls at every two weeks check-in sessions during the intervention period (from week one to eight). Treating therapists will rate the usability of the app and online portal via questionnaires. For a detailed list of measures and timepoints, see Table 2. Questionnaires will be provided via the secure, open-source software *REDCap*. Data will be alphanumerically coded and stored in de-identified format on a secure server for the duration of 10 years. Members of the research team only will have access to de-identified research as per data management plan. Data will be handled in accordance with the General Data Protection Regulation (GDPR).

[Insert Table 2 here]

Outcome Measures

The primary outcome will assess the feasibility of implementing and delivering the digital interactive book program, including analog playing cards and an online portal, as a standalone resource for children aged 6-11 years and their caregivers. The study will also generate preliminary evidence on whether the program could, following separate evaluation and appropriate adaptation, be integrated into a future therapeutic program or routine therapeutic care. Based on the study results, a decision will be made on whether to proceed with a subsequent large-scale randomized controlled trial (RCT).

Feasibility will be defined by rates of recruitment, dropout, retention, recruitment efforts and technical feasibility:

- Recruitment rate: Number of families who consent to participate in the study (over the course of the study).
- Dropout rate: Proportion of consented participating families who do not complete the entire study process, including follow-up (with discontinuation).
- Retention rate: Proportion of consented participating families who complete the entire study process, including follow-up (without discontinuation).
- Recruitment effort: Total number of recruitment attempts required to enroll 30 participating families.
- **Technical feasibility** refers to the successful development, deployment, and reliable operation of a stable, functional, and usable demonstrator comprising the digital children's book, analog playing cards, the online portal, and the study database. It will be assessed using predefined technical performance criteria that examine whether all components work together as intended, whether users can complete core tasks, and whether data are processed securely and reliably. Technical success will be assessed through the following criteria:

  - System stability: Absence of critical system crashes, prolonged outages, or interruptions to core functions.

  - Functional performance: Successful completion of predefined user journeys, including accessing the digital book, using the online portal, and completing relevant entries or activities.

  - Data flow and integrity: Accurate, complete, and data-protection-compliant transfer, storage, and retrieval of data between the digital children's book, online portal, and database.

- **Access and compatibility:** Reliable access across the intended devices, operating systems, and web browsers.
- **User and access management:** Appropriate authentication, role-based access, and protection of participant data.
- **Technical usability:** Users can access, navigate, and use core functions with minimal technical support.
- **Error and support management:** Documentation of technical errors, interruptions, crashes, and support requests, including their frequency, type, and time to resolution.
- **Data protection and security:** No critical data-protection or information-security incidents during the study period.

Technical feasibility will be considered established if the core functions remain continuously available, predefined user journeys can be completed successfully, data are transferred and stored correctly, and no critical technical or data-protection-related incidents occur during the study period.

Secondary outcomes investigate changes from baseline in mental health symptoms, psychological well-being, family functioning, digital media use patterns, parenting competencies, and nature-related variables in children and caregivers. For children, these include:

- Change from baseline (week 0) to week 8 in emotion regulation, assessed with the *Emotion Regulation Questionnaire* for Children and Adolescents (ERQ-CA, self-report) and P-ERQ (CR, from age 6) [45–47].

- Change from baseline (week 0) to week 8 in general psychopathology, assessed with the *Strengths and Difficulties Questionnaire* (SDQ, CR) [48].
- Change from baseline (week 0) to week 8 in nature-related knowledge, assessed with a custom-developed nature-related knowledge test (child SR).
- Change from baseline (week 0) to week 8 in nature connectedness, assessed with the German version of the *Connectedness to Nature Index* (CNI, child SR) [49,50].
- Change from baseline (week 0) to week 8 in mood, assessed with custom-developed CR items.
- Daily child-reported mood (SR): Real-time assessment of the child's emotional state during each app session, using a custom-developed 5-point facial Likert scale (Smileys) to track mood fluctuations throughout the intervention period.
- Change from baseline (week 0) to week 8 in sleep, assessed with a combination of items of a validated instrument and self-generated items as child SR and CR items [51]. Specifically, time in bed, wake-up time, rise time, sleep latency, sleep duration, subjective sleep quality, daytime sleepiness, sleep aids will be assessed.
- Change from baseline (week 0) to week 8 in problematic digital media use patterns, assessed with the *Compulsive Internet Use Scale* for Children (CIUS-10, self-report from age 8 years) and the short form German version of the Problematic Media Use Measure (PMUM-SF, caregiver report, from age 8) [52,53] both adapted for digital media use.

In caregivers, secondary outcomes include:

- Change from baseline (week 0) to week 8 in emotion regulation, assessed with the *Emotion Regulation Questionnaire* (ERQ, self-report) [45,54].

- Change from baseline (week 0) to week 8 in family functioning, assessed with the *Family Adaptation, Partnership, Growth, Affection, and Resolve* (APGAR) questionnaire [55].
- Change from baseline (week 0) to week 8 in digital parenting self-efficacy, assessed with the *Digital Parenting Self-Efficacy Scale* (DPSES, self-report) [56].
- Change from baseline (week 0) to week 8 in restrictive mediation, assessed with the Media Rules Questionnaire (MR-6, self-report) [66].

Covariates include:

- Change from baseline (week 0) to week 8 in psychological distress (depressive and anxiety symptoms), assessed with the *Patient Health Questionnaire-4* (PHQ-4, self-report) [57].
- Change from baseline (week 0) to week 8 in problematic digital media use patterns, assessed with the *Compulsive Internet Use Scale* adapted for digital media use (CIUS-5, self-report) [58].

Tertiary, exploratory outcomes include the acceptance, usability, tolerance and adherence/ protocol compliance of the intervention by children, parents, and therapists.

- Study Acceptance: Proportion of all eligible families who agree to participate in the study.
- Acceptance and Subjective User Experience (Caregivers and Child): Assessed at check-in sessions (T1, T2, T3) via SSIs. The SSI covers technical feasibility, app usage patterns, and subjective experience of the intervention, with separate components for caregivers and children.
- Usability: Usability and user experience of the digital components (storybook app and communication portal) will be assessed at intervention end using standardized questionnaires:

- Parents: The German version of the *mHealth App Usability Questionnaire* (GER-MAUQ) will be completed at the end of the intervention [59].
- Therapists: The German version of *the Mobile App Rating Scale* (MARS-G) will be completed once at the beginning of the study and at the end of the intervention [60].

- Burden and Safety: Assessment of whether the app was perceived as exhausting for the child as a parental proxy-report, using custom-developed items at intervention end.
- Tolerance: Absence of intervention-related adverse events (AEs) or other undesirable events.
- Adherence/ Protocol compliance: Number of participating families who independently completed the book chapters at home between the check-in sessions. Completion of outdoor missions will be tracked automatically via the app, based on photo uploads taken during the mission.

Data Analysis

Data analysis will be conducted after the study (Last Person Last Visit). Interim analyses may be conducted, if needed, to reassess the planned sample size in relation to study progress and for grant applications. In addition, data quality will be automatically monitored and assessed throughout the study to identify incomplete, inconsistent, or implausible entries.

Primary analyses: Feasibility measures, such as recruitment rate, dropout, and retention, and technical feasibility will be evaluated descriptively.

Secondary analyses: Change from baseline to week 8 in secondary outcomes will be assessed using repeated-measures t-test. Continuous secondary outcome measures that are repeated at several time points will be analyzed using longitudinal linear mixed effects models or repeated-measures ANOVA. The number of completed book chapters will be included as a covariate.

Tertiary analyses: Acceptability, usability, tolerance, and adherence/ protocol compliance by children, parents, and therapists will be analyzed descriptively and using qualitative content analysis. Depending on data availability, technical feasibility and technological use patterns will be analyzed descriptively and quantitatively.

Study Oversight and Quality Assurance

This study will be conducted in accordance with the European Code of Conduct for Research Integrity, research guidelines of the German Federal Ministry of Research, Technology and Space (BMFTR), and the ethical principles of the Declaration of Helsinki. The study team, a team of experienced child and adolescent psychiatrists, clinical psychologists, and therapists for children and adolescents, will closely monitor all recruitment and study processes, including adherence to the inclusion criteria, study documentation and filing practices, protocol deviations, and adverse events.

Safety

Data security complies with ISO/IEC 27001:2013 (Declaration of Applicability v2.0, 22/10/2019) and covers the development and management of e-health applications for monitoring and treating psychological and physical symptoms. Data collection, transfer, and storage are detailed in the data management plan.

Participant safety is ensured through continuous monitoring by the study team and the treating clinician team. Adverse events (AEs) and serious adverse events (SAEs) are assessed in each appointment and documented in the respective report forms. (S)AEs are classified according to the NCI (National Cancer Institute) Common Terminology Criteria for Adverse Events (CTCAE) and

will be reported to the principal investigator, the hospital's safety representative, and the local ethics committee within 24 hours. All children will be monitored and continue to receive treatment as usual by their treating team during the duration of study participation. For families whose circumstances change such that continued participation is no longer considered to be in their best interest, as assessed by their treating team throughout the study, participation will be discontinued. This includes a) Withdrawal of consent; b) evidence of adverse consequences related to study participation; c) requirement for inpatient hospital treatment; d) acute suicidality; e) worsening of mental health symptoms.

Discussion

Children's mental health is increasingly challenged by a combination of developmental and environmental factors, highlighting the need for interventional approaches that target common mechanisms underlying psychopathology. The peak age of onset for mental disorders lies in minors, with transdiagnostic symptoms often initially presenting during childhood. At the same time, digital media are already widely available for this young age group [61], with early excessive use having been linked to sleep problems and emotion dysregulation [28,29]. Concurrently, children are spending less time engaging in outdoor play [62–64], often in favor of screen-based activities [65], reducing opportunities for experiences that support emotional, cognitive, and social development. Together, these trends highlight the need for engaging, developmentally appropriate digital resources that support children and caregivers in discussing emotions, everyday challenges, and family interactions at an early stage. The EnTree system, comprising the app, online portal, and analog playing cards, is designed as such a family-oriented resource and may provide a

conceptual and technical foundation for the future development of a separate digital therapeutic intervention, subject to further development, evaluation, and regulatory assessment.

EnTree represents a demonstrator of a digital health intervention designed as a children's ebook and incorporating evidence-based methods designed to address transdiagnostic symptoms in children aged 6 to 11 years and their parents. The app is intended to improve emotion regulation competencies in children and parents and support family functioning. While families will be closely monitored by their treatment team (including a therapist) during study participation, EnTree may help bridge waiting times for therapy in the future and, when used alongside ongoing treatment, potentially reduce the frequency of face-to-face sessions, thereby increasing access to therapeutic support for more families while allowing them to engage in playful and immersive therapeutic exercises independently of place and time.

Considering previous evidence on the beneficial effects of gamification and playful approaches on mental health and self-efficacy in children, and the evidence-based therapy manuals, EnTree holds promise as a transdiagnostic program for children with an existing mental health diagnosis, potentially complementing ongoing treatment in a blended-care approach and addressing symptoms before they progress to greater severity. If proven feasible, the intervention will be developed further to conduct a fully-powered, randomized-controlled trial and streamline the implementation of EnTree into regular care for children.

Strengths and Limitations

The study has several notable strengths. Outcomes will be assessed using a multi-informant approach, integrating both self-report and third-party report measures. In addition, technology-derived outcomes will provide an objective dimension of assessment. Furthermore, the

intervention will be conducted in a naturalistic clinical setting, reflecting routine therapist–patient appointment schedules and thereby enhancing the ecological validity of the findings.

Limitations include: No power analyses will be performed due to the study type. Study results can therefore not be generalized beyond the participant population. While indicators of efficacy will be investigated (e.g., change from baseline in psychopathology), no conclusions regarding intervention efficacy can be drawn due to the lack of a control group. All outcomes will be assessed using self-report measures, caregivers' reports, and qualitative interviews; thus, reporting bias and social desirability need to be considered. As data collection will be performed by one and the same member of the research team, data analyses will be conducted by a second researcher to minimize the risk of overestimation of preliminary intervention effects. Selection bias needs to be considered due to the self-selection of participating families into the study.

Conclusion

EnTree aims to address current challenges within the healthcare system (e.g., long wait times) and to provide an accessible, immersive, and playful therapeutic intervention for children with mental illness and their parents, aiming to improve emotion regulation competency directly and family functioning indirectly. If proven feasible and acceptable to both families and therapists, this study will be a critical step toward conducting a fully powered randomized-controlled trial to investigate intervention effects and implement EnTree into routine care for affected families.

Declarations

Authors' Contributions (CRediT): Each author certifies that their contribution to this work meets the standards of the International Committee of Medical Journal Editors. SH: Supervision, Funding acquisition, Conceptualization, Methodology, Writing - Review & Editing; KP: Supervision, Funding acquisition, Conceptualization, Methodology, Writing – Review & Editing; LK: Conceptualization, Methodology, Writing - Original Draft, Writing - Review & Editing, Visualization, Project administration; JC: Methodology, Writing - Review & Editing, Visualization, Project administration; EO: Methodology, Writing - Review & Editing, Visualization, Project administration; GI: Review Editing, JP: Review; SK: Review; AK: Review; JG: Review; MK: Review; SWG: Review.

Ethics Approval and Consent to Participate: The study was reviewed and approved by the local Human Research Ethics Committee (LPEK-1058). All participants and their legal guardians will undergo a predefined informed consent process, with written informed consent obtained from guardians and age-appropriate written assent obtained from participating children before study participation.

Consent for Publication: Consent for the publication of consolidated, de-identified study data will be obtained as part of the informed consent process.

Availability of Data and Materials: Not applicable.

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List of Abbreviations

AE = Adverse event

ANOVA = Analysis of variance

APGAR = Family Adaptation, Partnership, Growth, Affection, and Resolve

BMFTR = German Federal Ministry of Research, Technology and Space

CBT = Cognitive behavioral therapy

CIUS = Compulsive Internet Use Scale

CNI = Connectedness to Nature Index

CR = Caregiver report

CTCAE = Common Terminology Criteria for Adverse Events

DPSES = Digital Parenting Self-Efficacy Scale

DRKS = Deutsches Register Klinischer Studien (German Registry of Clinical Studies)

DZSKJ = German Center for Addiction Research in Childhood and Adolescence

ERQ = Emotion Regulation Questionnaire

ERQ-CA = Emotion Regulation Questionnaire for Children and Adolescents

GER-MAUQ = German m Health App Usability Questionnaire

GDPR = General Data Protection Regulation

KJP = Department of Child and Adolescent Psychiatry and Psychotherapy

KPP = Department of Psychiatry and Psychotherapy

MARS-G = Mobile App Rating Scale (German version)

MR-6 = Restrictive Mediation Scale

NCI = National Cancer Institute

P-ERQ = Parent-rated Emotion Regulation Questionnaire

PHQ-4 = Patient Health Questionnaire-4

PMUM = Problematic Media Use Measure

RCT = Randomized controlled trial

SAE = Serious adverse event

SDQ = Strengths and Difficulties Questionnaire

SR = Self-report

SSI = Semi-structured interview

UKE = University Medical Center Hamburg-Eppendorf

UP-C = Unified Protocols for Transdiagnostic Treatment of Emotional Disorders in Children

Table 2

Table of study assessment

Timepoint	**T-2**	**T-1**	**T0**	**T1**	**T2**	**T3**	**T4**	**T5**
Study Phase	**Recruitment**		**Intervention Start**	**Intervention Period**			**Intervention End**	**Study End**
Appointment	**Study Information** Week -2	**Phone call** Week -1	**Baseline** Week 0	**Check-in 1** Week 2	**Check-in 2** Week 4	**Check-in 3** Week 6	**Post-Intervention** Week 8	**Follow-Up** Week 12
Duration	1 h	15 Min	25 Min	12 Min	12 Min	12 Min	25 Min	11 Min
Eligibility Criteria	X							
Informed Consent		X						
Caregivers								
Sociodemographics			X					
Family Dynamics								
Family Functioning (APGAR)			X				X	X
General Play Behavior			X				X	
Digital Media Use								
General Digital Media Use			X				X	
Restrictive Mediation (MR-6)			X				X	
Conflict due to Digital Media Use			X				X	
Digital Parenting Self-Efficacy (DPSES)			X				X	
Problematic Digital Media Use (CIUS-5 adapted)			X				X	
Clinical Measures								
General Psychopathology (PHQ-4)			X				X	X
Emotion Regulation (ERQ)			X				X	X
Acceptability/Usability								
General Attitude toward health applications			X				X	
App User Experience (GER-MAUQ)							X	
Evaluation of App + Card Game							X	

Children								
Sociodemographics			X					
Family Dynamics								
General Play Behavior, CR			X				X	
Digital Media Use								
General Digital Media Use, CR			X				X	
Problematic Digital Media Use (CIUS-10 adapted)			X				X	
Problematic Media Use Measure (PMUM-SF), CR			X				X	
Clinical Measures								
General Psychopathology, CR (SDQ)			X				X	X
Emotion Regulation (ERQ-CA)			X				X	X
Emotion Regulation, CR (P-ERQ)			X				X	X
Mood (App)				Several points throughout App-use				
Mood, CR			X	X	X	X	X	X
Sleep			X				X	
Sleep, CR			X				X	
Nature-Environment Interaction								
Nature Exposure, CR			X	X	X	X	X	X
Outdoor-Missions, Child's mood CR				X	X	X	X	X (except 1 item)
Nature Connectedness (CNI)			X				X	X
Nature-related Knowledge Test			X				X	
Acceptability/Usability								
Technical feasibility, CR				X	X	X	X	
Usability, CR				X	X	X	X	
Acceptability / Safety, CR				X	X	X	X	
Acceptability				X	X	X	X	
Therapists								
Acceptability/Usability								
App Usability (MARS-G)	X						X	

Note. This table outlines the recruitment process and assessment schedule from screening (T-2) to follow-up (T 5). '*X'* indicates the administration of an instrument or a study activity. **MR-6** = Restrictive Mediation Scale; **CIUS-5** = Compulsive Internet Use Scale, adapted; **CIUS-10** = Compulsive Internet Use Scale, adapted; **DPSES** = Digital Parenting Self-Efficacy Scale; **PMUM** = Problematic Media Use Measure; **ERQ**= Emotion Regulation Questionnaire; **APGAR** = Family Adaptation, Partnership, Growth, Affection, and Resolve; **CNI** = Connectedness to Nature Index; **ERQ-CA** = Emotion Regulation Questionnaire for Children and Adolescents; **GER-MAUQ** = German m Health App Usability Questionnaire; **MARS-G** = Mobile App Rating Scale (German version); **P-ERQ** = Parent-rated Emotion Regulation Questionnaire; **PHQ-4** = Patient Health Questionnaire-4; **CR** = Caregiver-report; **SDQ** = Strengths and Difficulties Questionnaire. Non-standardized and adapted instruments are described in the Outcome Measures section.