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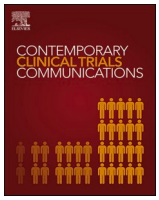

Combining one-session treatment with a homework program including app-based technology to enhance the treatment of childhood specific phobias: A study protocol of a multicenter pragmatic randomized controlled trial

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ABSTRACT

Introduction: Childhood specific phobias are among the most common and earliest onset mental disorders with a lifetime prevalence of more than ten percent. Brief intensive cognitive behavioral therapy (CBT) programs such as the One-Session Treatment (OST) are found to be effective in the remission of the specific phobias following treatment, but there is still room for improvement. The goal of the current study is to examine whether the long-term efficacy of OST increases by using a homework program supported by an app specifically designed for children; the Kids Beat Anxiety (KibA) homework program.

Methods: Children aged between 7 and 14 years with a specific phobia receive OST preceded by a three-week baseline phase to control for time-effects. Directly following OST, children are randomized to either a four-week homework period supported by an app (OST + app), or standard One-Session Treatment with a four-week homework period that is only supported by therapist instructions (OST-only). Primary outcome variables are diagnosis and severity of the specific phobia. Secondary outcomes include behavioral avoidance, self-reported fear, and functional impairment. Data will be analyzed based on intention-to-treat and per protocol samples using mixed-effects multilevel linear models.

Ethics and dissemination: The current study was approved by the METC of the Academic Medical Center, Amsterdam, The Netherlands (number: NL72697.018.20) and the Ethical Committee of the Ruhr University, Bochum, Germany (number: 663). Results of this trial will be published in peer-reviewed journals.

Trial registration: The study was pre-registered at the Dutch Trial Register, number: NL 9216.

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1. Article summary

Strengths and limitations of this study.

- The pre-registered trial uses a randomized design in which only a structured homework program differs between conditions.
- The treatment and app include exposure exercises combined with positive reinforcement that are personalized to the child's needs and fears, aiming to enhance short and long-term outcomes.
- Children are randomized following the OST-session.
- Blinding of the therapists and participants is not possible.

2. Background

Specific phobias are characterized by an excessive and persistent fear and avoidance of specific objects or situations and are among the most common mental disorders [1] with a lifetime prevalence of more than ten percent [2–5]. Specific phobias are associated with significant life interference and are strong predictors for the onset of a range of other disorders [6]. Cognitive behavioral treatments have been shown to be efficacious in treating children with specific phobias [7,8]. However, these effective treatments are often not easily accessible and many children with specific phobias do not receive the treatment they need [9,10]. Research clearly shows that this is a disadvantage, as disorders get worse and more comorbidity is developed without help [6], resulting in longer and more expensive treatment trajectories [11]. Hence, there is a need for an accessible, evidence-based intervention for children.

Brief intensive interventions might be particularly useful to reach more children with a specific phobia. It is common for such treatments to be delivered in very few therapist-led sessions, therefore requiring fewer visits from families. Despite having fewer therapist led sessions than traditional treatment, several studies have shown strong support for the efficacy of (brief) intensive interventions for specific phobias (for a review, see [12]). A brief intervention approach that has been shown to be effective is the exposure-based One-Session Treatment (OST; [13,14]). OST is an individualized intensive form of CBT and is centered around a single 3-h exposure session. Social learning principles of instruction, modeling, reinforcement, and psychoeducation are incorporated throughout the exposure-based treatment. Several studies showed that OST is an effective intervention for treating childhood specific phobia (e.g., 15,16,12) and it is therefore an excellent form of therapy for improving treatment efficiency in this group of children.

Even though short-term effects of CBT including intensive forms are relatively strong with remission rates of 60 % on the primary disorder, there is still room for improvement (for a review, see [17]). An important way to enhance treatment outcome and reduce relapse may be to practice relevant exposure in different contexts both during the treatment session and at home during and following treatment ([18,19]; for a review also see [20]). Indeed, previous studies in adults showed a positive relation between homework compliance and treatment outcome [21]. These results indicate that adults who comply with their homework have a more favorable treatment outcome. Unfortunately, there are only a few studies that examined the effect of homework on treatment outcome in children, with most studies examining homework following the content of each therapy session using a paper workbook. These studies showed only limited effects of homework on treatment outcome and reported that children sometimes found it difficult to comply with homework, for example because the instructions were too difficult or that the content was not appealing enough (e.g. [22]). Indeed, a recent review concluded that it is currently unclear how and under which circumstances homework could enhance treatment [20]. Augmenting and personalizing homework during and following cognitive behavioral therapy, including OST, could be a fruitful way to boost compliance, which might improve longer-term treatment effects.

Digital health innovations might be particularly useful to help children (and their families) comply with homework, as these innovations can support personalization options and include motivational features. For example, providing children with points, tracking their progress in practice, and sending reminders to practice can enhance engagement. Additional possible features, such as immediate feedback, game elements, or built-in reward features can motivate children to practice newly learned skills in different contexts [23,24]. By increasing motivation in children to do homework, it becomes easier for caregivers to involve them in homework, thereby making it more likely that caregivers will support homework progress. The use of digital health innovations is expected to facilitate home practice and enhance the quality of exposure children engage in after treatment. Therefore, the current study includes a homework program including an individualized app specifically designed for children to facilitate the practice and transition of newly acquired skills from the OST program into everyday life and relevant contexts, aiming to increase the amount of exposure practice following treatment. This program is called the Kids beat Anxiety (KibA) homework program.

3. Objective

Our primary aim is to test whether a personalized homework program, supported by the use of an app (OST + app), increases the short- and long-term efficacy of OST for specific phobias in children compared to the usual homework instructions (OST). For this primary aim, we expect that OST combined with an individualized homework program, including an app, is more effective than the care-as-usual OST procedure in terms of treatment outcomes and relapse rates. As a secondary objective, we aim to replicate the efficacy of standard OST for childhood specific phobias in Dutch and German samples. For this secondary aim, it is hypothesized that OST will be superior to a three-week waiting period. Furthermore, various secondary outcomes, mediators, and moderators have been included to examine active mechanisms of treatment (see appendix A for an overview of all secondary measures).

4. Methods

4.1. Study design

This study employs a multicenter pragmatic randomized controlled superiority trial with two active treatments: 1) One-Session Treatment with a four-week-homework program supported by an app (OST + app), 2) One-Session Treatment delivered in its usual manner (OST-only). To address the secondary research aim, both conditions are preceded by a three-week waiting baseline control period. The study has 6 time-points in total: T1 (baseline 1) – *3 weeks waiting* – T2 (baseline 2) – *1 week* – T3 (OST session) – *1 week* – T4 (post OST session + pre-homework) – *4 weeks* – T5 (post homework) – T6 (6 months follow-up). We used the SPIRIT reporting guidelines and checklist for this study ([25]; see Appendix B). See Fig. 1 for the trial flow.

4.2. Eligibility criteria

Children are included in the study if: 1) they meet criteria for a specific phobia according to the Diagnostic and Statistical Manual 5th edition criteria (DSM-5, [1]) as a primary or secondary diagnosis with a clinician severity rating of 4 or higher on the Kinder-DIPS [26] for the Germany sites. For the Dutch sites the most comparable interview to the Kinder-DIPS is used, namely the Anxiety Disorders Interview Schedule fourth edition (ADIS-IV, [27]) Unfortunately the ADIS-5 is not available in Dutch, and we therefore compared the ADIS-IV to the DSM-5 criteria and made a few very minor alterations to fit the criteria for DSM-5 (e.g., DSM-IV states: 'in individuals under 18 years, the duration is at least 6 months', whereas the DSM-5 states: 'the fear or avoidance is persistent, typically lasting for 6 months or more'). In case there is more than one specific phobia present, the focus will be on the most interfering specific phobia only, 2) at least one parent or caregiver is willing to be involved

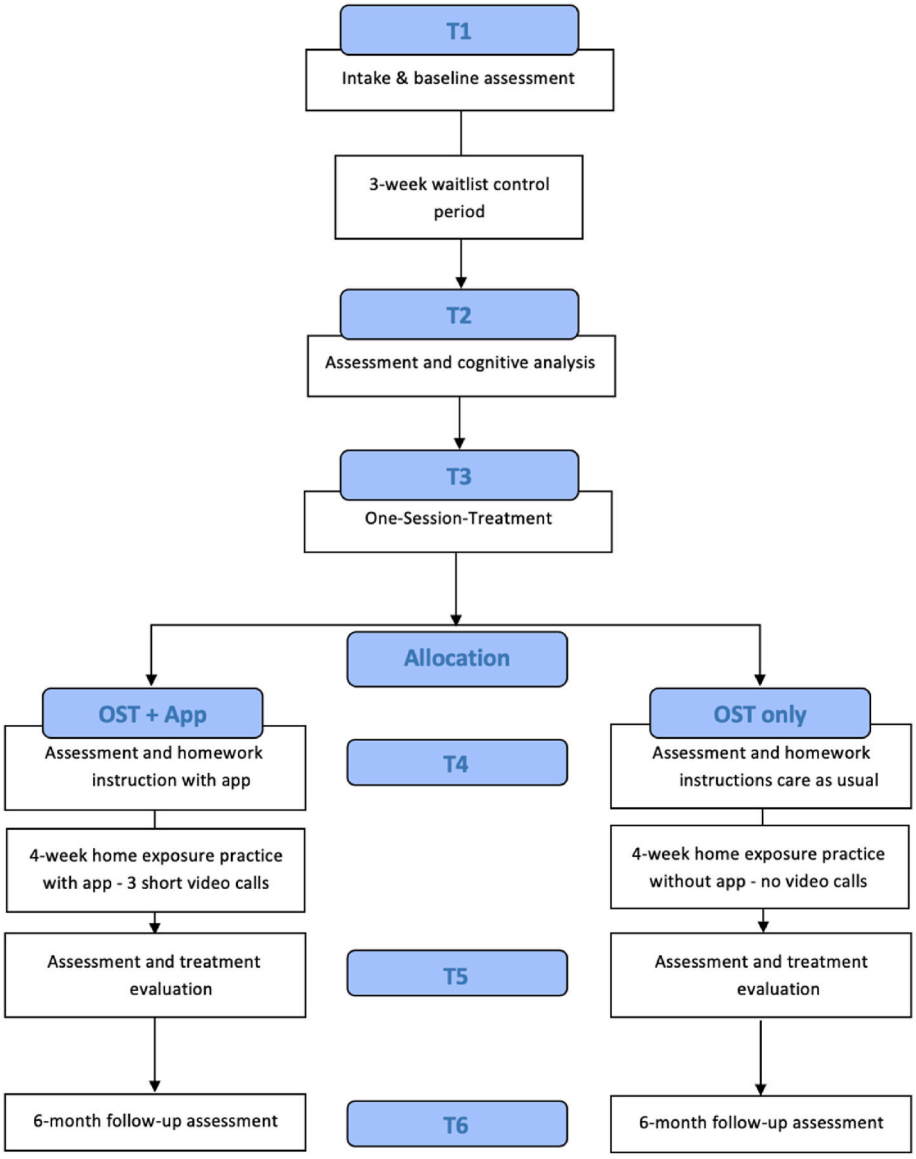

Fig. 1. Flow of the study.

in the study, and active consent is obtained from both legal guardians and the child when 12 years or older, 3) they are fluent in German, Dutch or English, and 4) aged between 7 and 14 years. Children are excluded from participation in the study if they meet any of the following criteria: 1) A comorbid problem that requires attention/-treatment more immediate than the specific phobia either before or during the participation in the study (e.g., severe depressive symptoms, suicidal ideation, psychosis, trauma), 2) child risk (e.g., suspected child maltreatment), 3) problems with understanding the procedure, 4) other treatment targeting anxiety complaints at the time of the study (children are allowed to start with treatment targeting other anxiety complaints after the post-assessment if necessary).

4.3. Recruitment

Children and their parents are recruited at six outpatient clinics, five centers in The Netherlands and one center in Germany. Three of these clinics are affiliated with a university, the other three clinics are smaller community-based centers.

Children are recruited in multiple ways: Announcements about the project are posted on several websites and social media, while flyers are distributed in public places. Parents seeking help for their child are invited to participate in a short 20-min telephone screening.

If the child is eligible to participate in the study, children and their parents receive written information and an informed consent form from the researchers (see Appendix C). Depending on the age of the child they either receive information for young children (aged between 7 and 12 years), or for older children (aged between 12 and 14 years), and information for the parent. Next, parents and children are invited for an intake session, where all inclusion and exclusion criteria are thoroughly checked before the family is enrolled in the study. During the enrollment phase, all families are explicitly informed that they can stop with the study at any time. The researchers will note down the reason for drop-out. In case of any adverse events, the study participation of the child will be immediately stopped and the child will be referred to care as usual.

4.4. Randomization, blinding and treatment allocation

Participants are randomly assigned to either the OST + app or the OST-only condition (1:1 allocation) following the three-week baseline and the massed exposure (OST) session, but before the start of the four-

week home practice period. Randomization is stratified by treatment center, phobia type and clinical severity as measured with the clinical severity rating (CSR) of the structured diagnostic interview (see below). More specifically, CSR scores of 4 and 5 are categorized as mild, while scores of 6, 7, and 8 are grouped as severe. Participant number generation and treatment allocation are done through LOTUS - a web tool designed to help researchers build and manage longitudinal research. Participants and therapists are blinded to the assigned treatment condition during the OST.

4.5. Intervention

Children in both treatment conditions visit the clinic five times in a period of approximately ten weeks with one additional visit six months following treatment. The intervention used in this study is the One-Session Treatment for childhood specific phobia [28,13,14] with and without a homework program including an app to assist with home practice after the OST. OST is an individualized intensive form of cognitive behavioral therapy, involving a single 3-h exposure session. Social learning principles of instruction, modeling, and reinforcement, and psychoeducation are incorporated throughout the treatment. The intervention is delivered by therapists with different backgrounds and experience (Bachelor level, <1 years of experience to Master level, >20 years of experience) and are trained and supervised by AH, THO, KK, and AB. All sessions are videotaped in order to enable protocol adherence checks. Adherence checks are done by reviewing 20 % of all 3-h exposure sessions. At least one video (chosen at random) is rated of each participating therapist and more from therapists who treat more participants.

As part of the standard procedure, the therapist conducts a 1-h functional behavioral analysis interview assessment with the child, a week before the 3-h exposure session. In addition, the treatment rationale is explained to the child and his/her caregiver. A week following the interview, the child visits the clinic for the 3-h exposure session in which the child is gradually exposed to the feared stimulus/situation. The cognitive behavior analysis of the child's catastrophic cognitions is used to set up the exposure as a series of behavioral experiments in which these cognitions are tested and disconfirmed. Directly following the OST session, the children are randomized to the homework conditions. The children in the OST-only condition do not receive specific information, other than that they will come back to the clinic for measurement and to receive instructions for the homework phase one week later. The children in the OST + app condition receive an information sheet with more information about the homework phase and are asked to already think of rewards to be added to the app and to watch some instruction videos on how the app works.

One week following the exposure session, the child and caregiver(s) in both conditions come to the clinic together for assessment and homework instructions. Children and their parents in the OST-only condition receive verbal instructions and receive a take home sheet on the importance of practice and what to do in case of a setback, and they are encouraged to keep practicing regularly for at least four weeks. Children in the OST + app condition are provided with an app to assist them with exposure practice exercises during the four-week period. The therapist and child (with the parental input) collaboratively think of ten exposure exercises that are relevant for the individual child and take place in various contexts. Additionally, the therapist and child enter a list of ten individualized rewards that they can earn while using the app. The therapist discusses everything with the child, but the parents are present during the session and can help when needed. The therapist in the OST + app condition conducts a weekly phone call with the child during the four weeks of practice, lasting approximately 15 min, to check in on the child and address any questions about the app. In total, three phone or video calls are made. Participating children and their caregivers in both conditions are informed that they can contact the therapist in case they run into major problems or setbacks while practicing at home, regardless of condition.

Following the four weeks of practice, the child and caregiver(s) in both conditions come back to the clinic for a post-treatment evaluation of the program. If children have other complaints, they may be referred for additional care. If children still fulfill the inclusion criteria for the study including a clinical specific phobia and want more help with their phobia, children and parents are usually asked to first practice for another four weeks (see also [17]). If this is not sufficient, up to two booster OST sessions including the 4-week homework following each OST session can be offered. If children still have significant complaints following these two boosters, children are referred to regular care.

4.6. App

The app that is used in this study is developed in collaboration with IT-company Trifork. The app is designed by a team of researchers, therapists, children, and parents to follow OST and is fully personalized to each child's specific phobia. It also includes an individualized motivational system to engage children as effectively as possible. Specifically developed for children aged 7–14 years, it incorporates age-appropriate language and gamification elements. The app is available in the commonly used app stores and children can download the app by themselves on their own phone or tablet. When downloaded, the app asks for an individual username and code which the child receives from their therapist (for more details, see also [20]). Children can borrow a phone from the project team if they do not own one.

4.7. Assessments

The RCT includes six assessment points: (T1): a baseline assessment including a diagnostic interview and questionnaires, (T2) a second baseline assessment three weeks following the first baseline, an assessment during the OST session (T3), a mid-assessment one week following the OST session and prior to the homework period (T5), a post-assessment following the four weeks of home practice (T5), and (T6) a follow-up assessment six months following T3. See Fig. 1 for the flow chart, Table 1 for the primary measures, and Appendix A for a full overview of all measures per time point. Throughout the OST session and the homework period, therapists, assessors and researchers encourage the children and parents to adhere to the prescribed treatment and to complete all assessments. Children receive a certificate at T5 and a small gift (worth 5 euro) at T6. Parts of the assessments, the ADIS interviews and Behavioral Approach Tests (BAT) are videotaped for data quality checks.

4.8. Primary outcomes

Presence and severity of the specific phobia. The presence of a clinical diagnosis and the severity of the specific phobia is measured with combined diagnosis derived (as recommended in trial reports [29]) from reliable and valid structured interviews: the specific phobia module of the Anxiety Disorders Interview Schedule for DSM-IV: Child and Parent Versions (ADIS-IV-C/P [27]). The clinician severity rating (CSR) of the phobia is rated on a 0–8 scale on the ADIS-IV. A score of four is the clinical cut-off, where scores of 4 or higher are indicative of a diagnosis with a specific phobia. The ADIS-IV has good test-retest reliability [30–32] and concurrent validity [33].

4.9. Secondary outcomes

Behavioral avoidance. Behavioral avoidance is measured with a Behavioral Approach Test (BAT; adapted from [34]). The BAT is individualized to the child's fear that is being targeted in treatment and consists of a number of steps in which the child is asked to approach their phobic object or situation. Children are instructed that they can stop whenever they like, the highest step that is completed is used as the

Table 1
Overview of the primary outcome measures separately for each assessment point.

Construct	Questionnaire	Source	Assessment point				
			Baseline 1 (t1)	Baseline 2 (t2)	Post-OST (t4)	Post-homework (t5)	Follow-up (t6)
Phobia severity	SP-ADIS-IV	P + C	X	X	X	X	X
Behavioral avoidance	BAT (+SUDS)	C		X	X	X	X
Daily life interference	SDS	P + C	X	X	X	X	X
Phobia fear and avoidance	AVAC	P + C	X	X	X	X	X

P = parent, C = child.

outcome measure. In addition, the child is asked to rate their fear level prior to this task, at the last step, and for the hardest point during the BAT on a 0–8 scale (subjective units of distress [35]).

Self-reported fear and avoidance. An adapted version of the Anxiety and Avoidance Scale for Children (AVAC [36]) is used to measure level of fear and avoidance for specific objects and situations. For each fear, both parent and child individually rate how scared the child is for this object or situation on a five-point scale ranging from 'no fear' to 'very strong fear'. In addition, parents and children rate how often the child avoids this object or situation on a five-point scale from 'avoids never' to 'avoids always'.

Functional impairment. To assess functional impairment in school, social and family life an adapted version of the Sheehan Disability Scale (SDS [37]) is administered. This is a three-item questionnaire in which the child and parent indicate how much the child feels burdened because of his or her fear in school, social and family life. Ratings are given on a 0–3 scale.

4.10. Other outcomes

During the course of the treatment study several other measures are administered including demographics, comorbidity, self-efficacy, sensation-seeking, positive mental health, emotional problems, number of needed booster sessions, and parental measures (parental coping, mentalization, mental health problems, self-efficacy). In addition, the study also assesses treatment-related outcomes including treatment improvement, adherence, motivation, credibility, compliance, and satisfaction - also with regard to the app - reported by both children and parents. Finally, we include some measures to study treatment mechanisms including interpretation bias, expectation violation and harm beliefs, habituation and imagery (see Appendix A for a full list of measures).

4.11. Statistical analyses

Sample size calculation. The primary hypothesis is that the OST + app condition will be superior to the care-as-usual condition (OST-only) at post-treatment and at follow-up (six months). (H0) Is: Changes in primary outcome do not differ between OST + app and OST-only. Timepoints 4 (post OST session + pre-homework), 5 (post homework) and 6 (6-months follow-up) are needed to answer this question. Power and necessary sample size were computed for this 2 (OST + app/OST-only) x 3 (pre-homework, post-homework, 6-months follow-up) mixed-factors interaction, using an alpha error of $p = 0.05$, a correlation between the repeated measures of $r = 0.50$, and a desired power of $1\text{-}\beta = 0.80$. Using the software G*Power, it was determined that 138 participants are needed to detect the expected small interaction effect ($f = 0.10$) with sufficient power of $1\text{-}\beta = 0.80$. For a medium-sized effect ($f = 0.25$), this sample size yields excellent power of $1\text{-}\beta > 0.99$. Based on previous similar trials, drop-out rates during treatment of approx. 20 % are expected [7]. Thus, total sample size to be enrolled is $N = 173$. For the secondary hypothesis, it is hypothesized that the active treatment phase will yield superior outcomes as compared to the 3-week baseline phase on primary and secondary outcome measures. Timepoints 1 (baseline 1), 2 (baseline 2) and 4 (post OST session + pre-homework) are needed to answer this question This results in a condition x 3 timepoints design. With $N = 138$, a Cohen's f of 0.22 or higher is required to achieve a power of at least 80 % using a one-tailed paired t-test.

Statistical Clinical analyses. The primary analysis consists of evaluating the effect of the interventions (OST + app/OST-only) on the presence of a phobia diagnosis (yes/no) and severity of the phobia (CSR score 0–8; on SP module of the ADIS-IV) from pre- to post homework intervention, and six-months follow-up. This will be tested using two generalized multilevel mixed-effects models with a restricted maximum likelihood algorithm. The post-intervention phobia diagnosis (yes/no) and CSR severity scores (0–8) will be used as dependent variables in the respective generalized mixed effects models. The fixed effects of trial arm condition (OST + app/OST-only) and Timepoint (pre-homework, post-homework, six-month follow-up), as well as their interaction, will be included as independent variables, while adjusting for baseline anxiety severity. Random slopes of the interaction between, and main effects of, trial arm condition and timepoint, as well as the interaction with baseline anxiety severity will be included in the model. A random intercept will be included for participant ID. A maximum random-effects structure will be adhered to, following guidelines by Barr [38]. These analyses will be repeated for behavioral avoidance, self-reported fear and avoidance, and functional impairment. Significant interactions will be followed-up by post-hoc analyses. Results will be considered significant whenever confidence intervals do not contain a zero. Data will be analyzed based on intention-to-treat, and per protocol samples using mixed-effects multilevel linear models.

5. Discussion

Even though specific phobias are among the most common disorders in children and are precursors for comorbid mental disorder in adulthood, approximately half of the young people who need help do not receive adequate care [2,=4,39]. Effective and early intervention is important to prevent a chronic course or the development of other problems, such as other anxiety disorders, depression and eating disorders [6]. The current study aims to further develop an easily accessible early intervention for children with a specific phobia, adding the potential benefits of using a newly developed homework program supported by an app following treatment.

Treating children with a specific phobia may also be beneficial for children with multiple problems ('comorbidity'), such as other anxieties, as treatment may generalize to reduce other problems as well, oftentimes better than treatments that focus on all problems simultaneously [40,41]. This generalization to other anxieties might be because other anxiety disorders share similar underlying maintenance processes with specific phobias, for example avoidance and cognitive biases [40,41]. Moreover, experiencing positive treatment success might increase self-esteem in children and could encourage parents and children to seek help earlier for other problems (e.g. [42]).

A major strength of this study is that it includes a pragmatic randomized controlled trial in which all children receive evidence-based treatment. It includes children with all kinds of specific phobias and includes children with comorbid problems, enhancing the ecological validity of the trial results. This approach reflects clinical practice, where comorbidity rates are high [4]. Additionally, the study is a

multi-center trial, including both academic and community clinics. This design resembles a less controlled and more realistic environment, providing an opportunity to further study the efficacy of the One-Session Treatment (OST) protocol and the four-week homework period supported by a newly developed app. The app is specially designed by a team of researchers, therapists, children, and parents to follow OST and is fully personalized to each child's specific phobia. It also includes an individualized motivational system to engage children as much as possible. This unique approach in developing an app to support therapy addresses societal needs and is expected to optimally enhance therapy outcomes, both directly following therapy as well as in the longer term.

The current study also has several limitations. Firstly, there is insufficient power to analyze each specific phobia separately, given that children with various specific phobias are included in the study. Also, we only include children aged between 7 and 14 years due to the app being only suitable for a limited age-range (due to wording and use of pictures that are only appealing for a certain age range). Consequently, no conclusions can be drawn regarding the efficacy of OST and the homework program with the app for separate specific phobias or for younger or older children. Additionally, therapists are not blinded to the treatment condition, as they are involved in instructing the children on how to use the app and in creating exposure exercises for the app together with the child. This lack of blinding might influence outcomes, as therapists may have a preference for one condition over the other. We did try to minimize this impact by not revealing the homework condition until after the OST session and by having blinded assessors assess the treatment outcomes. Another limitation of this study is that the children in the OST + app condition have more therapist contact than in the OST-only condition. In total, the children and the therapist spend around 45 min extra in the OST + app condition to explain the app and to create the exposure exercises and rewards. Also, the children in the OST + app condition are called for approximately 15 min per week to check if the app is still working and to discuss the exposure exercises. This results in approximately 90min of extra therapist time in the OST + app condition. We decided to not add this extra time to the OST-only group, as we wanted to compare the OST + app group to how the OST is carried out in regular care. If an effect of the app condition is found, it cannot be ruled out that this effect is entirely based on this extra therapist contact and superior homework delivery. Further research is then warranted to study the specific mechanisms underlying the improved treatment outcome.

In summary, the current study contributes to the development of affordable, accessible, and effective interventions for childhood specific phobia and provides new insights in the potential benefit of using mobile applications in treatment. Furthermore, the study may contribute to new insights into how and for whom this type of intervention works best. With these insights, we could provide local governments, schools, health care providers, parents, and children with evidence-based recommendations for the treatment of specific phobias in children.

Ethical approval, consent, involvement and dissemination

The current study was approved by the METC of the Academic Medical Center, Amsterdam, The Netherlands (number: NL72697.018.20) on March 24, 2020 and the Ethical Committee of the Ruhr University, Bochum, Germany (number: 663). Any changes to the protocol will be submitted to the ethical committees for approval and updated in the trial registry. The study follows all Dutch ethical legislations and is in accordance with the latest version of the Helsinki declaration. Changes or unintended effects will be reported to the METC, participating centers and if relevant to participants. Active informed consent from participants is asked for the entire procedure. A focus group from the Anxiety OCD and Phobia patient foundation helped with writing the consent letters, writing the website texts, and verifying the clarity of all instructions. Additionally, a focus group of children and their parents helped with the design of the app.

Data protection, data access and data management

The current project meets the standards of the European General Data Protection Regulations (EGDPR) requirements, since participants are recruited in The Netherlands and Germany. Members of the research team have access to the data. A data management plan was developed and approved by an external data privacy officer of Leiden University. Data and the data-management plan can be shared upon request by contacting the corresponding author. Most of the questionnaire data is collected through Qualtrics (Dutch sites) or on paper-and-pencil and LimeSurvey (German site), a few in-session questionnaires, the BAT information and interview data are collected on paper. All digital and paper data is collected under a participant number. The paper data is entered into the database regularly, usually in teams of 2. Data entry is checked randomly to ensure quality. In addition, a script is written to do range checks on all the data values. All participants are informed about which data is stored, how it is stored and who can access this information and are asked to read and consent with the terms of use and privacy regulations.

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Trial registration and trial status

Dutch Trial register number: NL 9216 and was pre-registered on 29-01-2021. The starting date of the recruitment was 12-02-2021 and the study runs until December 2024. Principal investigator AK, associate professor at Leiden University, is the contact person for both public and scientific queries, email: a.m.klein@fsw.leidenuniv.nl, phone: +31715276673, postal address: Pieter de La Court building, Wassenaarseweg 52, 2333AK Leiden, The Netherlands.

CRediT authorship contribution statement

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Declaration of competing interest

The authors state that they have no conflict of interest.

Data availability

No data was used for the research described in the article.

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Appendix A. Supplementary data

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