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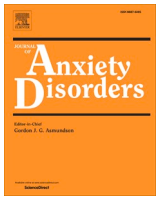

Better together? A randomized controlled microtrial comparing different levels of therapist and parental involvement in exposure-based treatment of childhood specific phobia

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ABSTRACT

Introduction: Exposure is often limited to homework assignments in routine clinical care. The current study compares minimally-guided (MGE) and parent-guided (PGE) out-session homework formats to the 'golden standard' of therapist-guided in-session exposure with minimally-guided exposure at home (TGE).
Methods: Children with specific phobia (N = 55, age 8–12, 56% girls) participated in a single-blind, randomized controlled microtrial with a four-week baseline-treatment period design. Clinical interviews, behavioral avoidance tests, and self-report measures were assessed at pre-treatment, post-treatment, and at one-month follow-up.
Results: TGE resulted in a larger decline of specific phobia severity from baseline to post-treatment compared to MGE but not compared to PGE. Parental anxiety was found to be a moderator of less treatment efficacy of PGE from baseline to post-treatment. Overall, there was no meaningful difference in efficacy of TGE versus MGE or PGE from baseline to follow-up.
Conclusions: These findings suggest that for improving short-term treatment gains, exposure exercises can best be conducted with the help of a therapist within the therapy session before they are conducted as homework assignments outside the therapy session. However, for long-term treatment gains exposure exercises can be handled by the child itself or with help of its parents.

1. Introduction

Childhood anxiety disorders (CADs) are often treated with exposure-based cognitive behavioral therapy (CBT), which creates the opportunity for children to learn to approach instead of avoid the feared object or situation. Although many children benefit from this type of treatment, a substantial proportion (9–50%) either refuse, drop out from, do not respond to, or fail to maintain long-term gains following CBT (Taylor et al., 2012). Exposure-based CBT protocols for CADs usually recommend to start with therapist-guided in-session exposure exercises before passing on the exposure exercises as self-guided or parent-guided homework assignments (Bouchard et al., 2004; Tiwari et al., 2013). Together these are considered the 'golden standard' for clinical practice, since children first need to get acquainted with exposure inside therapy before they know how to conduct exposure outside therapy, which in turn helps to generalize the exposure effects to different contexts (de Jong et al., 2019). The importance of therapist-guided in-session exposure is also stressed in a recent meta-analysis that showed that a greater amount of in-session exposure was related to significantly larger treatment effects post-treatment (Whiteside et al., 2020).

Nevertheless, it turns out that the balance between in- and out-session exposure varies greatly among different CBT manuals (Ale et al., 2015), with almost one-fourth of CBT protocols not including in-session exposure at all (Whiteside et al., 2020). This may leave the therapist with the impression that it does not matter whether exposure is practiced inside or outside therapy, or that this part of treatment can be handled by the child itself or with help of its parents. As a consequence, clinicians may choose to only discuss the exposure exercises in-session, and then prescribe these exercises as out-session self-guided or parent-guided homework assignments. Research seems to confirm this

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hypothesis, as exposure is delivered in only a third of the treatment sessions (Whiteside et al., 2020). Negative beliefs about exposure (Whiteside et al., 2016), lack of time to prepare or conduct exposure (Farrell et al., 2013), logistic challenges (McAleavey et al., 2014), and unavailability of resources (e.g., stimulus materials) (Ringle et al., 2015) are all factors found to be associated with limited use of therapist-guided in-session exposure. If - as suggested in the manuals - the 'golden' combination of therapist-guided in-session exposure followed by out-session exposure as homework is more effective than out-session exposure as homework alone, it might be worth trying to overcome these barriers to improve outcome of exposure-based CBT.

If, however, in-session exposure does not turn out to be crucial, one may wonder whether out-session exposure as homework can be practiced by the child itself, or only with help of its parents. A recent evidence base update clarified that parental involvement is a must for successful CBT for early CADs (child < 8 years old) (Comer et al., 2019), but for treatment of CADs in older children (child > 8 years old) the literature is inconclusive (Reuman et al., 2021).

On the one hand, there are good reasons to involve parents in the homework assignments. First, teaching parents how to encourage, model, and reinforce their children's approach behaviors is found to have a positive effect on the reduction of anxiety symptoms and avoidance behavior in the short (Silverman et al., 1999) and long term (Manassis et al., 2014). Thus, parents can promote short- and long- term benefits by promoting their children's approach behaviors during the exposure exercises at home. Also, parents can help their child stay engaged in treatment, which is important given that active engagement in treatment (e.g., good homework compliance) predicts better treatment outcome for CADs (Glenn et al., 2013).

On the other hand, there are a number of reasons to *not* involve parents in the homework assignments. First of all, many of the characteristic features of anxiety, such as avoidance and cognitive bias to threat, have been hypothesized to be transmitted by modelling, reinforcement, and overprotectiveness from parent to child (Barrett et al., 1996). Thus, depending on the level of parent's own anxiety as well as specific parenting practices that have shown to be associated with the onset and maintenance of anxiety in children (see Wei & Kendall, 2014 for a review), parental involvement can hinder instead of help improvement of symptoms following exposure (Breinholst et al., 2012; Cobham et al., 1998; Creswell et al., 2008). But even when the parent is not anxious or overprotective, including a parent in the exposure exercises might inadvertently hamper treatment outcome, for example when a child falsely attributes its success in exposure to their parent's presence or participation (Depestele et al., 2015; Ollendick et al., 2015). This will undermine the child's feeling of self-efficacy, whereas self-efficacy has been shown to be an important factor in treatment success (Lewis et al., 2020).

Studies that compared individual CBT with minimal parental involvement to CBT with parental involvement in at least half of the (exposure) sessions found no major differential outcomes between the two formats (e.g., In-Albon & Schneider, 2007; Reynolds et al., 2012; Ollendick et al., 2015). However, none of these studies specifically assessed whether exposure *should* be practiced in-session with the therapist, or whether parents can work as co-therapists and take responsibility for this part of treatment. And although the recent meta-analyses by Whiteside et al. (2020) suggests that CBT protocols for CADs that emphasize in-session exposure have the potential to improve the efficacy and effectiveness of treatment, no dismantling studies to directly test this hypothesis have been conducted.

Therefore, the current study examined whether the 'golden' combination of therapist-guided in-session exposure followed by out-session exposure as homework is more effective than out-session exposure as homework alone. Hence, in-session therapist-guided exposure combined with minimally-guided exposure at home (TGE) was compared to mere minimally-guided exposure at home (MMGE) and mere parent-guided exposure at home (PGE). The study was designed as a single-blind, randomized controlled microtrial, which has been proposed by Leijten et al. (2015) as the optimal design to test how one specific treatment element is most efficacious (not to be confused with a micro-randomized trial (MRT) (e.g., Bidargaddi et al., 2020). Three parallel groups followed a four-week waitlist-treatment period design. Children (age 8–12) with a specific phobia were randomized to a short treatment of three sessions consisting of either TGE, MGE, or PGE. We expected TGE to be more effective in reducing specific phobia severity (primary outcome), avoidance behavior, anxiety towards one's individualized goal, as well as comorbid anxiety and depression, and more effective in increasing self-efficacy (secondary outcomes) than MGE or PGE. Third, we explored parent-related predictors and/or moderators of treatment outcome to get more insight into non-responders of exposure-based treatment (Davis III et al., 2019). As predictors and/or moderators, we chose parental anxiety, avoidance, modeling/reassurance, and reinforcement of their children's approach behavior, as parental involvement has been found to limit the effectiveness of exposure-based treatment of specific phobia in children (Öst & Ollendick, 2017), but it is unclear which parental factor(s) is/are responsible.

2. Methods

2.1. Design

This study was a single-blind, randomized controlled microtrial comparing three parallel groups in a four-week baseline-treatment period design. The baseline period allowed us to test whether the treatment period resulted in a larger reduction in specific phobia severity than the no treatment baseline period. Between September 2017 and September 2019, interested parents and children could register for the study online. Participants started with an intake conducted by an experienced and certified CBT therapist consisting of a clinical interview, followed four weeks later by a pre-treatment assessment consisting of a clinical interview, behavior test, and self-report measures. After pre-treatment assessment, participants were randomly assigned to one of three conditions. The assessment was repeated one week after treatment (post-treatment assessment), and four weeks after treatment (follow-up assessment). The study was approved by the Medical Ethical Committee of the University Medical Centre in Groningen in the Netherlands (#METc2016/669) and was preregistered at the US National Institutes of Health (ClinicalTrials: #NCT03688360). Current report of the trial follows the CONSORT guidelines (Moher et al., 2010). A CONSORT-PSI checklist can be found in Appendix A.

2.2. Participants and procedure

After registration and active informed consent for the study, children were screened for eligibility and included if the following criteria were met: aged between 8 and 12 years old; suffering from a specific phobia that could be treated with the available phobic stimuli (e.g., fear of flying could not be treated due to absence of a nearby airport); not currently or recently (i.e., in the past 12 months) in treatment or receiving medication for (an) anxiety disorder(s); not showing (risk of) suicidality or suicidal ideation or warranting treatment for other mental health issues; showing willingness to travel to one of the treatment locations. All participants who scored at least a clinician severity rating (CSR) of 4 ($M = 6.15$; $SD = 0.81$; range 4–7) on the specific phobia section of the ADIS-IV-C/P at intake (N = 55; age 8–12 ($M = 9.25$; $SD = 1.11$); 56.4% girls) were included in the study. The majority of them had a dog phobia (60.6%) or another animal phobia (14.5%). Other types of phobias were blood-injury-injection (14.5%), situational (2%), natural environment (2%), and other (7%). The specific phobia could be their primary or secondary diagnosis. Table 1 provides an overview of baseline participant characteristics for each condition.

Table 1
Summary measures of baseline participant characteristics by condition.

	Therapist-guided exposure ($n = 19$)	Minimally-guided exposure ($n = 18$)	Parent-guided exposure ($n = 18$)
Gender (n (% girls))	10 (52.6)	11 (61.1)	10 (55.6)
Age in years (M (SD))	8.9 (1.0)	9.3 (1.1)	9.6 (1.2)
Specific phobia severity (M (SD))[1]	6.2 (0.7)	6.0 (1.0)	6.3 (0.7)

Note. [1]As measured by ADIS-IV-C/P-SP-CSR (range 0–8), clinical consensus composite rating of child and parent interview.

2.3. Treatments

All treatments started with an identical child and parent psycho-education session, see Fig. 1. During this session, participants created a fear hierarchy, and worked through their hierarchy from bottom to top in a step-by-step manner in the following sessions. In the *therapist-guided* exposure (TGE) format, participants engaged in two exposure sessions, in which at least 45 of 60 min were spent on conducting exposure exercises in or outside the *Dare clinic* treatment location together with the therapist. Participants were instructed to conduct the same exposure exercises, with a minimum of 45 min, as homework assignment before the next session. In the *minimally-guided* exposure (MGE) format as well as in the *parent-guided* exposure (PGE) format, participants did not engage in exposure exercises during the sessions, but spent all 60 min on preparing the exposure as homework exercises together with the therapist (i.e., therapist support sessions). Preparation included discussing every exposure exercise in detail by helping the child answer questions about it (see Appendix C). Participants were instructed to conduct the prepared exposure exercises, with a minimum of 90 min, as homework assignment before the next session. In this next session, therapist and child reflected back on each homework assignment in detail before preparing the exposure as homework exercises for the next week. In the TGE and MGE formats, parents did not sit in or observe any of the aspects of the two exposure sessions, and besides assisting children to access phobic stimuli or situations to practice with, they were not allowed to help their child with the homework assignments. In the PGE format, parents did sit in and observe all sessions. To help parents assist their children in the exposure exercises at home, they received instructions on how to reinforce appropriate approach behaviors and decrease avoidance behaviors and distress associated with the phobic object or situation (Ollendick et al., 2015).

2.4. Therapists and setting

All three treatments consisted of three weekly one-hour sessions, so total treatment duration was three weeks for all conditions. The sessions took place at the *Dare clinic* treatment location and were provided by therapists who were familiar with and experienced in CBT with anxious children. Therapists received a three-hour training in the treatment protocol and thereafter biweekly supervision by an experienced and certified CBT therapist. Therapists were assisted by bachelor students in psychology who were responsible for administration of in-session assessments and arrangement of the stimulus materials. To rule out therapist effects, all therapists provided all versions of the treatment.

2.5. Randomization

The research coordinator randomly assigned participants by balanced randomization (1:1:1) using a randomization program, based on the Sealed Envelope program. This program was accessed via the internet by the research coordinator only. Randomization took place with stratification on gender, age, and severity of the specific phobia. Research assistants, who were master students in psychology, were trained in the ADIS by a certified CBT therapist. Because research assistants conducted the assessments at pre- and post-treatment and at follow-up, they were blinded to treatment allocation. The research coordinator, therapists, treatment assistants, supervisor, and participants were not blinded to treatment allocation. Randomization was conducted after pre-treatment assessment, to make sure condition could not influence performance and willingness to participate.

2.6. Outcomes

2.6.1. Treatment measures

Treatment satisfaction was measured post-treatment ($\alpha = 0.97$) with the Service Satisfaction Scale for Children (SSS-C: Athay & Bickman, 2012). The original SSS-C contains four items rated on a 4-point scale ('No, definitely not' (1) to 'Yes, definitely' (4)). Because the current treatment was provided as RCT, we removed item (3) "If you were to seek help again, would you seek it from us?" The responses on the other three items were averaged to create a total score.

Therapeutic alliance was measured post-treatment ($\alpha = 0.74$) with the Therapeutic Alliance Scale for Children (TASC-r; Accurso et al., 2013). Twelve items were rated and summed on a 4-point scale from 'not true' (1) to 'very much true' (4).

Treatment adherence was assessed using a session checklist consisting of all agenda points. During each session a bachelor student in psychology observed the therapist, and ticked the boxes of all agenda points that were met according to the treatment protocol. In addition, the psychology student rated the duration of the entire session (in minutes). Adherence was considered sufficient when 80% of the aspects were administered.

Homework duration was assessed using a weekly checklist in which the child or parent stated how much time was spent on the exposure as homework (in minutes). Together with the session checklist this information was used to calculate total time spent on exposure (in minutes).

Understanding of rationale was checked by the therapist asking the participant to repeat the rationale of exposure at the end of the psycho-education session. Participants' answers were rated by the therapist on a VAS ratio scale from 'I do not believe the participant understands exposure at all' (0) to 'I completely believe the participant understands exposure' (100).

Note that the preregistration of this study also contained the Credibility and Expectancy Scale for Children (CEQ; Borkovec & Nau, 1972). Accidentally, this measure was assessed before treatment allocation, therefore we decided not to report on this measure.

2.6.2. Primary outcomes

Specific phobia severity was based on the Specific Phobia (SP) section of the child version of the semi-structured diagnostic interview the Anxiety Disorder Interview Schedule for Children (ADIS-C; Silverman, & Albano, 1996; Dutch version by Siebelink & Treffers, 2001) at intake, pre- and post-treatment and at follow-up. After the interview, and in line with recent clinical trial reporting recommendations (Creswell et al., 2020), a consensus-based clinician severity rating (CSR) was assigned by the research assistant together with the certified CBT therapist. A CSR of 0, 1, 2, or 3 indicates there is no clinical SP, a CSR of 4 and higher indicates that the participants met criteria for SP. The ADIS-C has exhibited excellent interrater and test-retest reliability (e.g., Silverman, Saavedra, & Pina, 2001) and concurrent validity (Wood et al., 2002).

2.6.3. Secondary outcomes

Avoidance behavior was measured using the Behavioral Avoidance Test (BAT) for feared and avoided objects or situations (Lang & Lazovik, 1963) at pre- and post-treatment and at follow-up. During the BAT, participants were asked to approach a phobic object or stay in a phobic

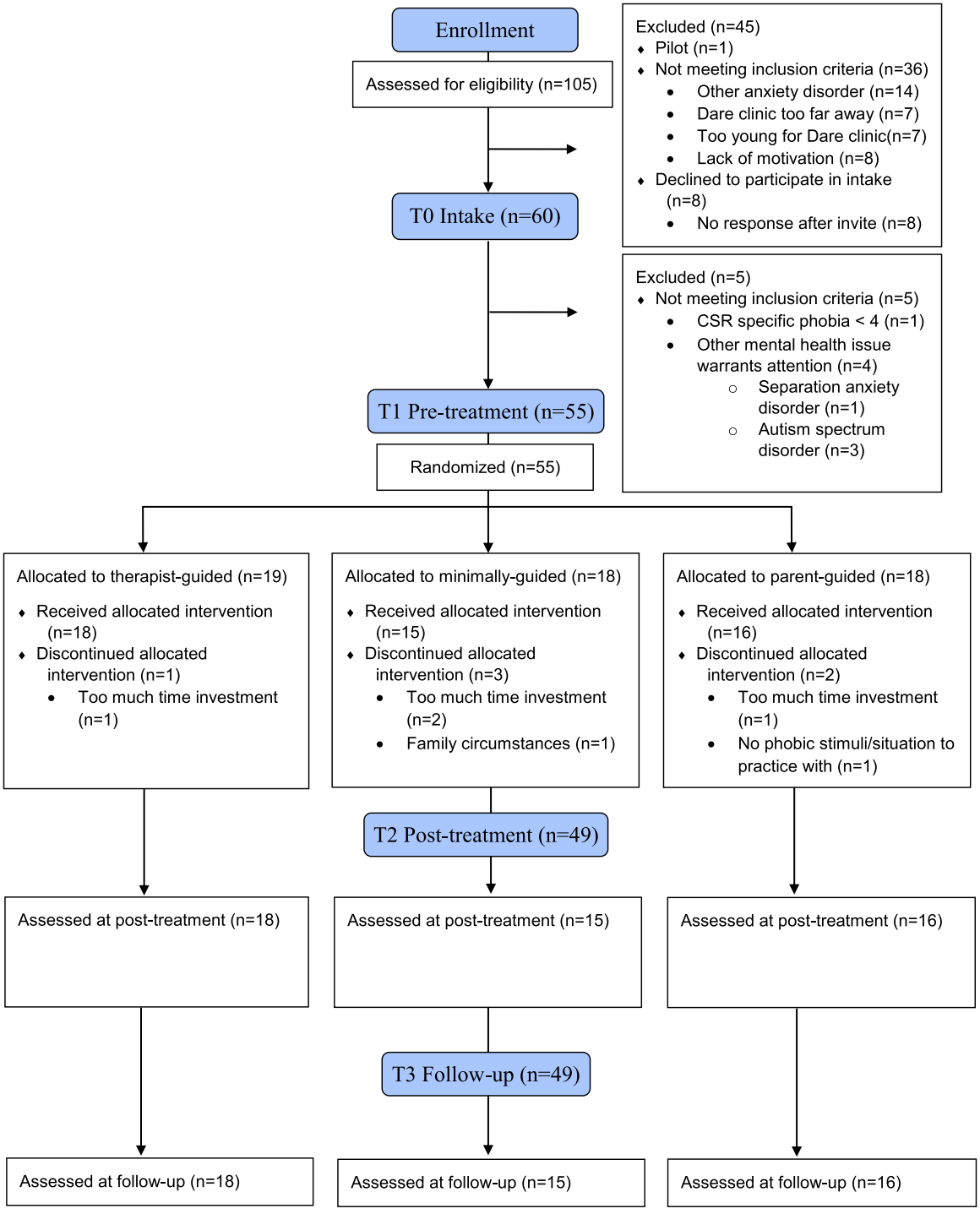

Fig. 1. CONSORT Participant flow diagram.

situation and were told they could stop the test at any time they wished to do so. In case of a phobic object (e.g., animal phobia), participants started on a 5-meter distance of the object and were asked to approach the object as close as possible in 60 s. Total score in this version of the BAT was calculated by multiplying distance in meters by time in seconds, with higher scores indicating more avoidance. In case of a phobic situation (e.g., claustrophobia), participants were asked to stay in the phobic situation for a maximum of 300 s. Total score in this version of the BAT was calculated by subtracting time in seconds from 300, so that higher scores indicated more avoidance. Three outliers were identified and winsorized by replacing the original scores with the 99th percentile score (DeCoster et al., 2009). The BAT has good test-retest reliability (Ollendick et al., 2011).

2.6.4. *Individualized goal*

During the first session, all participants set their individualized goal for the treatment. This goal always pertained being able to approach the phobic object or stay in the phobic situation (e.g., "Petting a dog for one minute"). Next, participants formulated their threat belief about the expected outcome when performing their goal (e.g., "When I pet a dog for one minute, it will bite me"). Using Visual Analogue Scales ranging from 0 to 100 (VAS; Bond et al., 1995), six questions were asked at the

start and end of every session (except at the start of session 1), at post-treatment and at follow-up. The first four questions started with "Imagine you have to perform [your goal] *right now*… 1) how anxious would you feel?" ('not anxious' (0) – 'extremely anxious' (100)); 2) "how often would you avoid this situation?" ('never' (0) – 'always' (100)); 3) "how well can you cope with this situation?" ('not at all' (100) – 'extremely well' (0)), and 4) "how tense would your body feel?" (not tense (0) – extremely tense (100)). The final two questions regarding the threat belief were 5) "how much do you believe this could actually happen?" ('not at all' (0) – 'very strongly' (100)) and 6) "how much would you mind if this actually happened?" ('not at all' (0) – 'a lot' (100)). A single individualized goal score (combined VAS) was computed by summing and averaging all six scales (standardized so that higher scores indicated more anxiety). Cronbach's alpha was $\alpha = 0.62$ for the combined VAS at pre-treatment, indicating questionable internal consistency with significantly lower scores on item 4 and 5. Internal consistency was good at post-treatment and follow-up with $\alpha = 0.88$ and $\alpha = 0.87$ respectively. VAS scales are found to be capable of validly and effectively capturing a reduction in anxiety (Williams et al., 2010).

Comorbid internalizing problems were assessed at pre- and post-treatment and at follow-up ($\alpha = 0.90$, $\alpha = 0.94$, and $\alpha = 0.92$ respectively) with the Revised Child Anxiety and Depression Scale for Children (RCADS; Chorpita et al., 2005) consisting of 47 items. All items were rated on a 4-point interval scale from 'never' (0) to 'always' (3). The RCADS is found to be a reliable and valid instrument for screening anxiety and depression in children from diverse backgrounds (Kösters et al., 2015).

Self-efficacy was measured by the Self Efficacy Questionnaire for Children (SEQ-C; Muris, 2001) at pre- and post-treatment and at follow-up ($\alpha = 0.92$, $\alpha = 0.93$, and $\alpha = 0.95$ respectively). This questionnaire contains 24 questions regarding academic, social, and emotional self-efficacy. Items were rated on a 5-point interval scale from 'not at all' (1) to 'very well' (5). Construct validity and reliability of the SEQ-C is good (Muris, 2001, 2002).

2.6.5. Predictors and moderators of change

Parental anxiety and avoidance were measured pre-treatment ($\alpha = 0.84$) with the Fear Questionnaire (FQ; Marks & Mathews, 1979). This 15-item questionnaire regarding phobia, avoidance, and associated anxiety contains different phobia all rated on an 8-point interval scale from 'no fear' (1) to 'in panic' (8) for anxiety and from 'never avoidance' (1) to 'always avoidance' (8) for avoidance.

Parental modeling and reinforcement behavior were assessed with the Child Development Questionnaire (CDQ; Challacombe & Salkovskis, 2009) at pre-treatment ($\alpha = 0.86$). The CDQ consists of 18 items in which a child is showing anxious behavior and the parent is asked how it would respond to the behavior of the child: with punishment, positive reinforcement, reinforcement of dependency, force, and/or with modeling/reassurance, on a scale from 'never' (1) to 'always' (5). In the current study, only the modeling/reassurance and positive reinforcement scales were used.

2.7. Sample size

Multilevel a priori power analyses in G*Power 3.1 (Faul et al., 2007) suggested that for a repeated measures MANOVA with three groups (therapist-guided vs. minimally-guided and parent-guided exposure), four time points (intake, pre-treatment, post-treatment, follow-up), alpha = .05 and power = 0.80, and detection of a medium (clinically relevant) time x condition interaction effect of 0.39 (active control: Reynolds et al., 2012) a total sample of 49 was required. To detect a medium time x condition x moderator interaction effect of 0.20 a total sample of 52 was required. To compensate for anticipated dropout, we increased the sample size by approximately 10%, resulting in 49 + 5 = 54 participants (18–19 in each condition). To correct for multiple comparisons a Simes Bonferroni correction was performed using $p_i' = (n + 1 - a)p_i$ (Simes, 1986).

2.8. Statistics

Multilevel analysis, using MlwiN Version 3.00 (Charlton et al., 2017) was used to test (1) whether the treatment period (post-treatment, follow-up) was more effective in reducing specific phobia severity than no treatment during a baseline period (intake, pre-treatment), and (2) whether TGE was more effective in reducing specific phobia severity than MGE or PGE. In addition, we explored (3) parental anxiety, parental avoidance, modelling/reassurance and positive reinforcement as predictors of treatment outcome (independent of condition). When found to be a significant predictor, we tested whether the variable also acted as a moderator of change (dependent of condition) of the primary outcome (i.e., specific phobia severity).

The data had a two-level structure, with the time points nested in participants. Multilevel modelling takes into account this hierarchical structure. In addition, multilevel modelling has the advantage of using all available data at all the time points without the need for imputation of missing values (Snijders & Bosker, 2011). Separate two-level models (level 1: time point; level 2: participant) were estimated for the primary outcome (ADIS) and for the secondary outcomes (BAT, VAS, RCADS, SEQ).

The analysis strategy for the primary outcome measure was as follows. First a random intercept model was built with the following predictors as fixed effects: (a) dummy variables representing time (intake, post-treatment, follow-up); and (b) the interactions post-treatment*condition and follow-up*condition. This random intercept model was built using three dummy variables for time with pre-treatment as reference category, and two dummy variables for condition with TGE as reference category. If the effect of intake was not significant, we proceeded with a model dropping the dummy for intake, yielding the intercept 'baseline' pertaining to intake and pre-treatment. Then the model was used to test the main effect of time (i.e., whether the treatment was more effective in reducing specific phobia severity than no treatment during a baseline period), and the differences in time effect across conditions (i.e., whether TGE was more effective in reducing specific phobia severity than MGE or PGE). No main effect of condition was included, because we expected no baseline differences between conditions.

For the secondary outcomes, we followed a similar procedure, yet entering only the dummy variables for post-treatment and follow-up, as we did not assess these outcomes at intake. Since the individualized goal and associated threat belief (VAS) were not assessed at pre-treatment, but at the end of session one, we built the random intercept model including a dummy variable for session one, followed by the dummy variables for time (post-treatment and follow-up). Predictor and moderator analyses were only done for the primary outcome, starting with the random intercept model including the main effect of time and the time*condition interactions, then adding the predictor*time interaction or moderator*time*condition interaction.

The statistical significance of fixed effects was tested using the approximate t-test and of random effects using the deviance test (e.g., Snijders & Bosker, 2011). Both tests were conducted one-tailed with the significance level set at $\alpha = .05$ with Simes Bonferroni correction. The reported effect sizes for significant effects over time were derived from the differences in sample means between time points for all participants together, divided by the estimated standard deviation at pre-treatment. Reported effect sizes for significant group differences at post-treatment or follow-up were derived from the differences in sample means between groups divided by the estimated pooled standard deviation (Feingold, 2013). All analyses were conducted following the intent-to-treat principle, including all 55 participants that started treatment.Post-hoc sensitivity analyses were conducted on the primary outcome measure (ADIS) to assess whether the pattern of findings remained the same with multiple imputation of missing values in the dataset or with including

the treatment location in the multilevel model.

3. Results

3.1. Preliminary analyses

3.1.1. Missing data

A detailed overview of the participant flow is provided in Fig. 1. The percentage of drop-out did not differ between conditions (TGE 5.3% versus MGE 16.7% or PGE 11.1%; X^2 (2) = 1.24, p = .54). There was some indication of selective attrition, with drop-outs reporting relatively lower severity scores at pre-treatment assessment than those who completed all assessments (mean ADIS CSR of 5.50 (SD = 0.55) in drop-outs, and mean ADIS CSR of 6.22 (SD = 0.78) in non-dropouts; t(53) = 2.18, p = .034).

3.1.2. Treatment measures

Treatment satisfaction and therapeutic alliance ratings did not differ significantly between conditions. TGE treatment participants had significantly higher therapist ratings for understanding the rationale of exposure than PGE treatment participants (t(28) = 2.63, p = .014). Session duration was the same for all treatments, and adherence checklists revealed that the majority of agenda points were checked off (always > 80%), although in a few cases the creation of the fear hierarchy was only finished at the start of session two. Total time spent on exposure (in-session and out-session together) did not differ significantly between conditions, see Table 2.

3.2. Main analyses

3.2.1. Descriptive statistics per time point and statistical testing of time effects

Specific phobia was present in 100% (n = 55) of the sample at intake and pre-treatment, in remission in 38.8% (n = 19 of 49) of the sample at post-treatment, and in remission in 55.1% (n = 27 of 49) of the sample at follow-up (n = 6 of 55 were missing at post-treatment and follow-up). The observed sample means (M) and standard deviations (SD) per time point for five outcome measures (ADIS to SEQ) are provided in Table 3. Table 4 provides the estimates of the multilevel modeling of these outcome measures, which are used for the statistical testing. Table 5 in Appendix B provides an overview of remission outcomes per condition.

3.2.2. Time effect following baseline period

Primary outcome. As expected, we found no significant difference between specific phobia severity at intake (M = 6.15, SD = 0.81, range 4–7) and after baseline at pre-treatment (M = 6.14, SD = 0.79, range 4–8), so specific phobia severity did not reduce significantly during baseline (X^2 (1) = 0.0, p = 1). Intake was therefore dropped from the random intercept model. The intercept thus pertained to intake and pre-treatment, further referred to as baseline, see Table 4.

Table 2
Summary measures of treatment characteristics by condition.

	Therapist-guided exposure (n = 19) *M (SD)*	Minimally-guided exposure (n = 18) *M (SD)*	Parent-guided exposure (n = 18) *M (SD)*
Treatment satisfaction (SSS)	3.77 (0.26)	3.60 (0.37)	3.88 (0.17)
Therapeutic alliance (TASC)	35.75 (3.15)	36.71 (3.63)	35.47 (3.11)
Understanding of rationale (VAS)	74.33 (13.48)	67.50 (17.77)	61.00 (14.29)
Session duration (in minutes)	64 (5)	62 (5)	61 (7)
Total time spent on exposure (in minutes)	257 (143)	207 (110)	250 (230)

Note. SSS = Service Satisfaction Scale (range 0–4), TASC = Therapeutic Alliance Scale for Children (range 0–48), VAS = Visual Analogue Scale (range 0–100).

Table 3
Means (M) and standard deviations (SD) for all outcomes as a function of time point.

	Therapist-guided exposure (n = 19) (*M (SD)*)	Minimally-guided exposure (n = 18) (*M (SD)*)	Parent-guided exposure (n = 18) (*M (SD)*)
Specific phobia severity (ADIS)			
Intake	6.18 (0.71)	5.97 (1.01)	6.28 (0.69)
Pre-treatment	6.03 (0.74)	6.14 (0.97)	6.27 (0.69)
Post-treatment	3.78 (1.79)	4.83 (1.25)	4.16 (2.05)
Follow-up	3.42 (1.96)	3.73 (1.62)	4.02 (1.83)
Avoidance behavior (BAT)			
Pre-treatment	51.80 (78.43)	34.99 (38.99)	63.51 (53.79)
Post-treatment	24.75 (37.30)	16.00 (20.56)	14.94 (24.28)
Follow-up	40.37 (78.04)	25.89 (39.48)	21.21 (37.09)
Individualized goal (VAS)			
Pre-treatment	72.63 (12.41)	74.10 (13.78)	76.75 (13.02)
Post-treatment	33.12 (21.47)	50.93 (25.09)	46.11 (26.19)
Follow-up	36.56 (23.04)	42.74 (21.79)	35.42 (24.81)
Comorbidity (RCADS)			
Pre-treatment	26.11 (12.83)	19.22 (12.49)	25.39 (15.72)
Post-treatment	21.22 (16.62)	21.93 (17.01)	23.39 (16.49)
Follow-up	16.33 (13.69)	16.00 (11.48)	17.71 (15.26)
Self efficacy (SEQ)			
Pre-treatment	92.50 (11.36)	89.67 (16.56)	89.20 (17.23)
Post-treatment	90.94 (12.99)	83.57 (16.02)	89.75 (17.20)
Follow-up	90.00 (13.96)	81.29 (20.12)	90.64 (18.21)

Note. ADIS = ADIS-SP-CSR (range 0–8, clinical range 4–8), BAT = Behavioral Avoidance Test (range 0–300 s) with 3 trimmed outliers (M + 1 SD), VAS = Visual Analogue Scale (range 0–100), RCADS = Revised Children Anxiety & Depression Scale (range 0–141), SEQ = Self-Efficacy Questionnaire (range 24–120)

3.2.3. Time effect following treatment period

Primary outcome. The random intercept model of specific phobia severity indicated that specific phobia severity reduced significantly from baseline to post-treatment (large Hedge's g = 1.43), and from baseline to one-month follow-up (large Hedge's g = 1.77).

Secondary outcomes. Avoidance behavior reduced significantly from pre-treatment to post-treatment (medium Hedge's g = 0.54), but not significantly from pre-treatment to one-month follow-up. In addition, participants' anxiety ratings towards their individualized goal reduced substantially from pre-treatment to post-treatment (large Hedge's g = 1.62), and from pre-treatment to one-month follow-up (large Hedge's g = 1.96). Comorbid anxiety and depression did not reduce significantly from baseline to post-treatment, but did reduce significantly from baseline to one-month follow-up (medium Hedge's g = 0.55). Self-efficacy ratings neither changed significantly from pre- to post-treatment, nor from pre-treatment to one-month follow-up.

3.2.4. Differences in time effect across conditions

Primary outcome. The random intercept model of specific phobia severity indicated that from baseline to post-treatment, specific phobia severity decreased significantly more following TGE compared to MGE (medium Hedge's g = 0.65), but at one-month follow-up the group difference was no longer significant. No significant group differences in specific phobia severity between TGE and PGE were found from baseline to post-treatment and from baseline to follow-up.

Secondary outcomes. At post-treatment, differences in avoidance behavior between TGE and MGE or PGE were non-significant. At both post-treatment and follow-up, differences in comorbidity or self-efficacy

Table 4
Estimated fixed and random effects for the conditional models between baseline – post-treatment and baseline – follow-up.

Parameter	Specific phobia severity (ADIS) β (*SE*)	Avoidance behavior (BAT) β (*SE*)	Individualized goal (VAS) β (*SE*)	Comorbidity (RCADS) β (*SE*)	Self-efficacy (SEQ) β (*SE*)
Fixed effects					
Time					
Intercept	6.14 (0.13)	50.38	74.46 (2.77)	23.62 (1.94)	90.58 (2.23)
Post-time effect	-2.37 (0.34)* **	-25.63 (13.64)	-41.34 (5.45)* **	-2.40 (3.90)	0.36 (4.36)
Follow-up time effect	-2.73 (0.34)* **	-10.01 (13.64)	-37.89 (5.45)* **	-7.29 (3.90)*	-0.58 (4.36)
Post x Minimally-guided	1.06 (0.46)* *	-8.75 (17.48)	17.81 (7.11)* *	0.71 (5.02)	-7.37 (5.58)
Follow-up x Minimally-guided	0.32 (0.46)	-14.48 (17.82)	6.18 (6.97)	-0.33 (5.02)	-8.71 (5.58)
Post x Parent-guided	0.38 (0.45)	-9.81 (18.20)	12.99 (6.97)* *	2.71 (5.02)	-1.19 (5.39)
Follow-up x Parent-guided	0.60 (0.45)	-19.16 (17.48)	-1.14 (6.97)	1.38 (5.12)	0.64 (5.58)
Random effects					
Variances of residual	1.79 (0.18)	2499.81 (292.58)	397.53 (46.37)	206.30 (23.82)	239.07 (28.57)

Note. * ** = significant at $p < .001$, one-tailed, * * = significant at $p < .01$, one-tailed, * = trend significant at $p < .05$, one-tailed. Therapist-guided is reference category. ADIS = ADIS-SP-CSR (range 0–8, clinical range 4–8), BAT = Behavioral Avoidance Test (range 0–300 s) with 3 trimmed outliers (M + 1 SD), VAS = Visual Analogue Scale (range 0–100), RCADS = Revised Children Anxiety & Depression Scale (range 0–141), SEQ = Self-Efficacy Questionnaire (range 24–120).

between TGE and MGE or PGE were non-significant. From pre-treatment to post-treatment, the participant's anxiety ratings towards their individualized goal reduced significantly more following TGE compared to MGE (medium Hedge's $g = 0.75$) and compared to PGE (medium Hedge's $g = 0.53$), but these group differences were no longer evident at follow-up.

3.2.5. Predictors and moderators of change

Parental anxiety was found to significantly predict specific phobia severity at post-treatment ($t(28) = 3.44$, $p < .001$), but not at follow-up ($t(28) = 1.11$, $p = .134$), indicating that children with parents with higher anxiety scores benefitted less from treatment on the short term. Approximate t-tests showed that parental anxiety was only moderating treatment outcome in PGE at post-treatment ($t(28) = 2.45$, $p = .006$), indicating that children of parents with higher anxiety scores benefitted less from PGE. Parental avoidance, parental modeling/reassurance, and parental reinforcement of their children's approach behavior were not found to be significant predictors of treatment outcome.

3.2.6. Post-hoc sensitivity analyses

The results on the primary outcome (ADIS) remained robust with multiple imputation of missing values in the dataset. However, adding treatment site as a moderator in the multilevel model revealed that specific phobia severity not only decreased significantly more following TGE compared to MGE at post-treatment ($t(36) = 2.45$, $p < .007$), but also at one-month follow-up ($t(36) = 1.80$, $p = .036$), with less symptom reduction reported in the MGE group on the main academic treatment site ($M = 4.50$ ($SD = 1.23$) at follow-up).

4. Discussion

We tested whether the 'golden standard' of in-session therapist-guided exposure combined with minimally-guided exposure at home (TGE) is more effective in treating specific phobia in children than mere minimally-guided exposure at home (MGE) and mere parent-guided exposure (PGE) at home. The results show that: (i) Independent of condition, there was a stronger decline of specific phobia severity during treatment period than waitlist period; (ii) there was a large-sized decline (Hedge's $g = 1.43$–1.77) of specific phobia severity that was maintained at one-month follow-up and that was even larger than effect sizes found in the treatment of specific phobia in adult population (Hedge's $g = 0.49$–0.72; Van Dis et al., 2020); (iii) there was a medium-sized decline of avoidance behavior post-treatment that was not maintained at follow-up, a large-sized decline of anxiety towards one's individualized goal at both post-treatment and follow-up, and a medium-sized decline of comorbid anxiety and depression only at follow-up (iv) a little over half of the participants (55%) was in remission at follow-up, indicating that treatment resulted in clinically relevant change comparable to the results in a similar study by Ollendick and colleagues (2015); (v) TGE resulted in a larger decline of specific phobia severity than MGE from baseline to post-treatment, and in a larger decline of anxiety towards one's individualized goal than MGE and PGE from baseline to post-treatment; (vi) there was no meaningful difference in efficacy of TGE versus MGE or PGE from baseline to follow-up, although TGE seemed to outperform MGE in reducing specific phobia severity when treatment location was taken into consideration; (vii) specifically for PGE, parental anxiety was found to be a moderator of less treatment efficacy from baseline to post-treatment.

4.1. Considerations regarding the different treatment formats

Zooming in on the different exposure formats assessed in this study, we found TGE to be slightly more efficacious than MGE or PGE on some outcome measures post-treatment, suggesting that the combination of therapist-guided in-session exposure followed by out-session exposure as homework has stronger short-term benefits than out-session exposure alone. This finding is in line with a recent meta-analysis that found that more therapist-guided in-session exposure was associated with larger treatment effects post-treatment (Whiteside et al., 2020). However, TGE was not found to be superior to MGE or PGE at follow-up, indicating that contrary to what is generally assumed (Bouchard et al., 2004; Tiwari et al., 2013), the combination of therapist-guided in-session exposure followed by out-session exposure (as homework) has the same long-term benefits as out-session exposure alone. Consistent with previous findings, minimally- and/or parent-guided exposure at home can be an appropriate treatment for childhood specific phobia as long as therapist support is provided (Vigerland et al., 2016). We found no difference in total time spent on exposure in the different treatment formats, which means that practicing exposure with the therapist inside therapy (TGE) as well as only discussing exposure with the therapist inside therapy (MGE and PGE) were both motivating and stimulating for children to keep practicing outside therapy.

An explanation for the short-term benefits of TGE might be that the children who followed this treatment format already got acquainted with exposure inside therapy, before conducting exposure outside therapy. Potentially, their familiarity with exposure improved the quality of their exposure practice at home (e.g., practicing with different stimuli), and the experiences during the session provided confidence in change, which improved their short-term treatment gains. Even if this was not the case, maybe the two therapist-guided exposure sessions ensured enough high-quality exposure practice in-session for short-term benefits. The children who followed MGE or PGE only got acquainted with exposure once they started practicing at home. Their unfamiliarity with exposure might have lowered theualityy of their exposure practice

at home (e.g., practicing with the same stimulus), and the lack of experience with in-session exposure may not have provided confidence in change, lowering their short-term treatment gains. However, TGE did not differ in efficacy from MGE or PGE at follow-up. An explanation for the comparable long-term benefits of all treatment formats might be that children who followed MGE or PGE got more practice in *multiple* and mainly *meaningful* contexts, compared to the children who followed TGE and mainly practiced in the context of the therapists' office. Given that the practice of exposure in multiple (meaningful) contexts has been found to enhance the effect of exposure (de Jong et al., 2019), the emphasis on practicing at home in the MGE and PGE formats might have better prepared children for confrontation with the feared stimulus in real-life settings.

4.2. Methodological considerations

There are a few methodological aspects that may account for the similar long-term outcomes across conditions. First, in all three conditions, children received at least the minimally required time of 120–180 min needed for exposure to result in clinically significant improvement of specific phobia (Öst et al., 2001). Second, children who followed MGE or PGE actually engaged in 60 min of in-session activities plus 90 min of out-session activities each week (i.e., total 150 min per week), while children who followed TGE engaged in 60 min of in-session activities plus 45 min of out-session activities each week (i.e., total 105 min per week). This may not represent clinical practice, as there is no reason to assume that therapists providing in-session exposure practice would prescribe fewer hours of weekly between-session practice than therapists who do not provide guided in-session practice. Third, even though the therapy sessions for children in the MGE or PGE conditions did not involve actual exposure exercises, discussion of and planning for exposures likely provided therapeutic benefit (Tiwari et al., 2013). For children, discussing their phobias can serve as exposure itself (Davis III et al., 2009). This may have led to greater change in children who followed MGE or PGE than would have occurred if the formats were assigned equal in- to out-session exposure time. Fourth, children in all conditions conducted a BAT prior to and after treatment, which can be therapeutic in itself (Ollendick et al., 2013), and might therefore have evened out differences in long-term treatment effect. Anecdotally, our therapists reported that conducting the BAT at pre-treatment increased motivation of the children to start with the exposure exercises. However, TGE seemed to outperform MGE in short- and long-term reduction of specific phobia severity when treatment location was taken into consideration, with less symptom reduction found at the mean academic treatment site. This could possibly be explained by the fact that the more complicated cases (e.g., with unusual phobia like phobia for fruits) were referred to the main academic treatment site instead of the peripheral non-academic treatment sites.

The study has several strengths including its preregistered RCT design and its use of a multi-informant and multimethod approach to assessment resulting in strong measurement variance. However, there were also some limitations that need to be considered. First and foremost, because a participant adherence check was missing, we could not evaluate cross-contamination (e.g., to verify that parents did not provide support at home in the TGE and MGE formats) However, due to the design of the study (RCT) and the markedly different protocols that were used in the different treatment groups (e.g., handbook for the therapist, workbook for the child), we could establish therapist fidelity for the on-site sessions (Moncher & Prinz, 1991). Unfortunately, we could not guarantee treatment fidelity for the off-site (homework) assignments. This could possibly explain the unexpected increase of avoidance behavior in the TGE versus MGE and PGE groups (see Table 3). It is possible that parents in both homework formats felt more responsible for the treatment outcome of their child, and thus provided more parental support. Maybe their parental support alone led to a further decrease in avoidance behavior from post-treatment to follow-up (Silverman et al., 1999; Manassis et al., 2014), whereas parents in the therapist guided format felt less responsible and thus provided less support of approach behavior during the follow-up period, resulting in a slight relapse or non-significant increase of avoidance behavior during follow-up assessment. In addition, the parental support at home during the follow-up period might have evened out differences in long-term treatment effect between conditions. Second, because a measure of quality of exposure was lacking (e.g., number of different stimuli used or contexts in which the child got practice), we cannot be certain whether this is indeed a differentiating factor in the short-term treatment efficacy between the formats. Third, our design lacked a long-term follow-up assessment, which rendered it impossible to assess longer term differences in treatment efficacy between the treatment formats and to assess whether further improvement or relapse rates of the current sample would be in line with other studies. Fourth, as the current study relied on a relatively small sample size, we could only include a limited number of predictors and moderators of change, and could only detect medium effects. Power did not allow to examine differences in remission rates between conditions or additional child variables like age, gender and comorbid internalizing problems of children that can act as potential predictors and/or moderators of change in anxiety symptoms (Davis III et al., 2019). We did include both parental anxiety (FQ) and anxious parenting behavior (CDQ) as moderators in the analyses. However, the CDQ specifically assesses parental modelling and reinforcement behavior, which might have been a too specific measure of anxious parenting behavior; perhaps this might explain why parental anxiety but not parental behavior was found to be a moderator of change. Moreover, our current design did not include assessments within each exercise, like the course of distress (subjective units of distress) or the feeling of self-efficacy (Zlomke & Davis III, 2008). Future studies may include such assessments not only during in-session exposure exercises, but also during out-session exposure exercises, to further study a potential differential change process. In addition, power did not allow to explore the differential efficacy between minimally-guided and parent-guided out-session exposure. Last, the opportunity to further examine differences in treatment efficacy across different types of specific phobia was limited, given the relatively low number of children in the current sample with a phobia other than animal phobia.

5. Conclusion

The current findings indicated that it is clinically worthwhile for a therapist to make time for in-session exposure practice, especially for improving overall short-term treatment gains. However, for long-term treatment gains it might be as beneficial to conduct the homework assignments outside the therapy session and only discuss them with the child in-session. Results suggest that minimally-guided exposure could be recommended over parent-guided exposure as minimally-guided exposure might be the preferred homework format for children of highly anxious parents.

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Declaration of Competing Interest

None.

Data availability

Data will be made available on request.

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Participating centers

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Data access and responsibility

RdJ, MJJL, and MHN have full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Trial Registration

The Facing Fears In-Session or Out-Session trial is registered at the US National Institutes of Health (ClinicalTrials.gov) #NCT03688360.

APPENDIX A

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CONSORT 2010 checklist of information to include when reporting a randomised trial* .

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4–6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7,10
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8–9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10–15
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	15
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	11
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	11
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	11
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	11
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	11
	11b	If relevant, description of the similarity of interventions	8–9
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15–17
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	15–17
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	8

(*continued on next page*)

(*continued*)

Section/Topic	Item No	Checklist item	Reported on page No
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	18–22
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	18–22
Harms	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	25,26
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	26
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	23–26
Other information			
Registration	23	Registration number and name of trial registry	7
Protocol	24	Where the full trial protocol can be accessed, if available	7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	2

APPENDIX B

Table 5
Remission rates per condition (ADIS).

	Therapist-guided exposure ($n = 19$) *n (%)*	**Self-guided exposure ($n = 18$) *n (%)***	**Parent-guided exposure ($n = 18$) *n (%)***
Post-treatment	8 (44.4%)	4 (26.6%)	7 (43.8%)
Missing post-treatment	1 (5.3%)	3 (16.7%)	2 (11.1%)
Follow-up	8 (44.4%)	10 (66.6%)	9 (56.3%)
Missing follow-up	1 (5.3%)	3 (16.7%)	2 (11.1%)

Note. All participants met criteria of a specific phobia diagnosis at baseline.

APPENDIX C

Table 6
Questions for preparation of exposure exercises.

1. What is the exposure exercise?
2. Where are you doing the exposure exercise?
3. What do you need to arrange to be able to do the exposure exercise?
4. How long or how often are you doing the exposure exercise?
5. What are you afraid of during the exposure exercise?
6. What do you get as a reward for doing the exposure exercise?

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