One-session treatment compared with multisession CBT in children aged 7–16 years with specific phobias: the ASPECT non-inferiority RCT

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Scientific summary

The ASPECT non-inferiority RCT

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Scientific summary

Background

A specific phobia is an intense, enduring fear of an identifiable object or situation that leads to anxiety symptoms, distress and avoidance. Between 5% and 10% of children and young people (CYP) have a specific phobia that can significantly affect their mental health and development, and can result in considerable academic difficulties, personal distress and interference with daily functioning. Interventions based on the principles of cognitive–behavioural therapy (CBT) remain the dominant model of treatment for specific phobias. However, their limitations, including being time-consuming and costly to deliver and having limited availability, have warranted investigations into alternative, low-intensity psychological therapies. One such alternative to CBT with potential in this context is one-session treatment (OST). Although OST is based on many of the same principles as CBT, it does not require an extensive treatment period; the treatment techniques are consolidated into a single 3-hour session.

Research examining the use of OST for specific phobias in CYP has demonstrated efficacy when compared with active controls. However, to date, OST has not been compared with the primary treatment choice in England, namely multisession CBT.

Objectives

The primary aim was to examine the non-inferiority of OST compared with routinely used CBT-based interventions for treating specific phobias in CYP at the 6-month follow-up.

The secondary objectives were to:

- examine the cost-effectiveness of OST compared with CBT
- establish the relative impact of the interventions on CYP's quality of life
- establish the acceptability of OST from the perspectives of those receiving it, their parents/guardians and the clinicians delivering it.

Methods

The study was a two-arm, pragmatic, multicentre, non-inferiority randomised controlled trial, with a nested economic evaluation and qualitative investigation. Potentially eligible CYP were referred via gatekeepers in the NHS, schools and voluntary youth services. Research assistants assessed eligibility and obtained written consent from those interested and a parent/guardian. After completion of the baseline measures, participants were randomly allocated to receive either CBT or OST using an allocation ratio of 1 : 1, and were stratified according to age and phobia severity. The measures were repeated at 6 months post randomisation.

Setting

Thirteen sites comprising 12 NHS trusts [including 26 Children and Adolescent Mental Health Services (CAMHS) sites and three affiliated voluntary agency services] and one university-based CYP's well-being service took part in the study.

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Participants

Inclusion criteria

The target population was CYP aged 7–16 years at the date of consent, experiencing a specific phobia defined in accordance with *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition, criteria and assessed using the Anxiety Disorder Interview Schedule (ADIS).

Exclusion criteria

Potential participants were not considered for entry into ASPECT (Alleviating Specific Phobias Experienced by Children Trial) or were withdrawn from the study if:

- exposure therapy was not the best-available/first-line treatment (e.g. additional needs warranted the therapy unsuitable, such as psychosis and suicidality)
- exposure therapy could be unsafe for the individual or cause harm (e.g. when exposure to the feared stimulus could not be safely simulated).

This pragmatic trial sought to reflect usual care and, therefore, few exclusion criteria were applied.

Interventions

Cognitive–behavioural therapy

Those randomised to receive CBT received the usual CBT-based treatment for specific phobias as provided by their local service. Using a combination of cognitive and behavioural techniques, CBT helps individuals to change unhelpful beliefs and behaviours arising in feared situations. This involves exposure to the feared stimulus and the correction of unhelpful beliefs that maintain the phobia. Each CBT session comprises structured discussions with a therapist, has a specific agenda and sets homework tasks to be undertaken between sessions. There is currently no recommended number of CBT sessions for specific phobias; however, it can range from 4 to 20 sessions, often delivered weekly or fortnightly. Sessions can last 45–60 minutes over weeks or months.

One-session treatment

One-session treatment is a variant of CBT and, although comprising many of the same techniques (e.g. graduated exposure therapy, participant modelling, reinforcement, psychoeducation, cognitive challenges and skills training), it takes a more condensed and intensive approach. Unlike CBT, which is delivered over weekly sessions, those randomised to OST attended an initial functional assessment session used to plan treatment (lasting up to 1 hour) followed by an exposure session (lasting approximately 3 hours).

When possible, therapy sessions were audio-recorded to allow assessment of treatment fidelity using the Cognitive Behaviour Therapy Scale for Children and Young People and the One-Session Treatment Rating Scale.

Sample size

The initial target sample size was 286 participants (143 per group); this was reduced to 246 participants (123 per group) on application for an extension from the funder. The non-inferiority margin was set at a standardised mean difference of 0.4. Assuming a correlation of 0.6 between baseline and final Behavioural Avoidance Task (BAT) performance required 170 participants to achieve 90% power with a 2.5% one-sided significance level. We allowed for a modest therapist effect (intraclass correlation coefficient of 0.01) assuming that each therapist would treat up to five participants, and an attrition rate of 28%. This increased the required sample size to 246 participants.

Main outcome measures

The non-inferiority of OST was assessed at 6 months post randomisation using the BAT. The BAT is a widely used measure of treatment outcomes for phobias in CYP and measures how close an individual can get to their phobic stimulus across 10 predefined steps. Secondary outcome measures included the ADIS, the Child Anxiety Impact Scale, the Revised Children's Anxiety and Depression Scale and a goal-based outcome measure.

Economic evaluation

To investigate the cost-effectiveness of OST compared with CBT in CYP with specific phobias, a within-trial cost–utility analysis from the UK NHS and Personal Social Services perspective with a time horizon of 6 months was conducted. Effectiveness was measured using quality-adjusted life-years (QALYs) based on the EuroQol-5 Dimensions Youth version, and costs were measured using bespoke resource use questionnaires. The outcome was incremental cost per QALY, which was then compared with the national willingness-to-pay threshold of £20,000–30,000 per QALY gained to assess the cost-effectiveness of the OST intervention. Multiple imputation was used to allow for missing cost and effect data, and non-parametric bootstrap simulations were carried out to address the uncertainty surrounding the incremental cost-effectiveness ratio. A set of sensitivity analyses were performed using a societal perspective and QALYs measured by the Child Health Utility 9D to assess the robustness of the study findings.

Qualitative study

To examine the acceptability of OST, interviews were conducted with participants who had received the treatment within the trial, their parents/guardians and the clinicians who had delivered it. All interviews were digitally recorded and transcribed verbatim, with participant consent. Analysis followed a qualitative framework approach, a widely used method of analysing primary qualitative data pertaining to health-care practices with policy relevance.

Statistical analyses

Analyses were conducted on the primary outcome (BAT score at 6 months) using all analysis sets [intention-to-treat (ITT), per-protocol (PP) and sensitivity analysis]. For all secondary outcomes, the analysis was reported on the ITT population unless there were important differences between results based on the ITT set and results based on the PP set. As a guideline, differences between the ITT- and the PP-estimated treatment difference of > 0.1 standard deviation on any inventory were assessed further.

The primary outcome was compared between groups using mixed-effects linear regression with robust standard errors and exchangeable correlation to allow for the clustering of outcomes by the therapist. The null hypothesis of inferiority would have been rejected if the lower limit of the two-sided 95% confidence interval (CI) for the standardised difference was wholly below 0.4 (the range of clinical non-inferiority).

Secondary continuous outcomes were analysed using a mixed-effects regression model for the primary outcome, including the baseline measurement of the respective outcome as a covariate. Secondary binary outcomes were analysed using a mixed-effects logistic regression model adjusted for age, site, phobia severity and therapist as the random effect. Potential moderating effects of four predefined subgroups (BAT stimulus set-up, participant treatment preference, therapist treatment preference and phobia type) were explored used mixed-effects linear regression with BAT score at 6 months as the response.

Results

Between June 2017 and January 2020, a total of 340 individuals were screened for the study, of whom 274 consented to participate and 268 were randomised to receive either CBT ($n = 134$) or OST ($n = 134$).

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Behavioural Avoidance Task scores at the 6-month follow-up were similar for the ITT and PP populations, with a larger number of participants achieving 10 steps at 6 months than at baseline in both treatment groups. A marginally larger improvement was seen in the PP group in both treatment groups. Mean BAT scores at 6 months were similar across treatment groups when both ITT and PP analyses were applied [CBT: 7.1 (ITT), 7.4 (PP); OST: 7.4 (ITT), 7.6 (PP); on the standardised scale adjusted mean difference for CBT compared with OST –0.123, 95% CI –0.449 to 0.202 (ITT); mean difference –0.204, 95% CI –0.579 to 0.171 (PP)]. On the standardised scale, 95% CIs for both ITT and PP were wholly below the standardised non-inferiority limit of 0.4 and, therefore, there is evidence that OST is non-inferior to CBT.

Comparison of secondary outcomes at 6 months demonstrated that all treatment differences were small, with their corresponding CIs crossing zero, and, hence, were in keeping with the results for the primary outcome. The treatments appear comparable for the secondary outcomes. Some point estimates were slightly in favour of CBT and others were slightly in favour of OST; none was statistically significant. Based on ADIS CSR (clinical severity rating) scores, 73% of the ITT population were considered to still have a phobia diagnosis at 6 months; this was the same across treatment groups. Fewer PP participants had a specific phobia at 6 months; slightly more in the CBT group than in the OST group (odds ratio 1.41, 95% CI 0.60 to 3.32).

No reliable statistical evidence of subgroup effects or interactions were found between the treatment groups. The adjusted mean difference for treatment in BATs where the stimulus had to be simulated (e.g. blood injection injury) was similar to the BAT real stimuli and both CIs were wholly below the non-inferiority limit. The adjusted mean difference appeared larger in favour of OST when the participant preferred OST and when the therapist preferred OST.

The health economic analysis showed that, compared with CBT, OST marginally decreased the mean service use costs and increased the mean QALYs at 6 months' follow-up; however, reduced resource use and improved utility compared with baseline were observed in both groups. After imputing for missing data and adjusting for the imbalanced utility, cost and other characteristics at baseline, on average, the OST group incurred £302.96 (95% CI £28.61 to £598.86) less costs and gained 0.002 (95% CI 0.002 to 0.002) more QALYs than the CBT group. At a threshold of willingness to pay for a gain of 1 QALY of £20,000, the probability that OST was cost-effective was 98%. The sensitivity analyses provided similar results, suggesting that OST is likely to save on costs and maintain similar QALYs compared with CBT.

In total, 27 participants and 27 parent/guardians attended face-to-face interviews with a research assistant following their 6-month follow-up appointment. In addition, 16 clinicians participated in a telephone interview. Findings from the qualitative analysis demonstrated a good level of acceptability of and satisfaction with OST from the perspectives of participants, parents/guardians and clinicians. The core components consistently identified to influence treatment process and satisfaction were child readiness, therapist competency and collaboration. Several clinical challenges were identified during interviews. These included complexities associated with the provision of phobia treatments within services where, at times, phobia referrals were not routinely seen. Ensuring adequate resources, time allocation, training and administrative support were highlighted as important to ensure the successful implementation of OST.

Conclusions

ASPECT has demonstrated that OST for CYP with specific phobias in UK-based child mental health treatment centres is as clinically effective as multisession CBT and is highly likely to be a cost-saving alternative. The research has highlighted the need for future work in this area, particularly in developing service specifications, training and care pathways for specific phobias in CYP.

Trial registration

This trial is registered as ISRCTN19883421.

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