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Article (Accepted Version)

Vreeken-Ross, Stefanie C, Cartwright-Hatton, Samantha, Harris, Sally A, Hanna, Paul and Jones, Christina J (2021) Feasibility of an online CBT group intervention for parents of children with food allergy. Clinical and Experimental Allergy. ISSN 0954-7894

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Feasibility of an online CBT group intervention for parents of children with food allergy

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Conflict of interest statement: Vreeken-Ross, Cartwright-Hatton, Harris, Hanna, and Jones have no conflicts of interest to declare.

Funding: No funding was received for this work

Statement of contribution: Jones, Cartwright-Hatton and Harris conceived of the study idea. Vreeken-Ross developed the protocol with assistance from all authors. Vreeken-Ross undertook the intervention with regular supervision from Jones and Hanna. Vreeken-Ross, Hanna and Jones undertook analysis. Vreeken-Ross and Jones drafted the manuscript with all authors contributing to reading and approving the final version.

Acknowledgements: The authors would like to thank the Anaphylaxis Campaign and their members for supporting the development and delivery of this research project.
Data sharing: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Word count: 1577, table count: 1, figure count: 1, refs: 9

KEY WORDS: Allergy; Anaphylaxis; Anxiety; Cognitive Behavioural Therapy; Emotions; Group; Intervention; Online; Parent; Support.

Key messages:
- A remote, manualised, CBT group intervention appeared acceptable, feasible, and improved parental anxiety and self-efficacy
- Although small numbers, parent-rated child anxiety and QoL showed improvements for some age groups
- Future research should determine replicability in an appropriately powered, age-stratified RCT with longer-term assessment

To the Editor,
Food allergy (FA) is a source of anxiety which affects the quality of life (QoL) of individuals and their caregivers (1). Furthermore, parental anxiety is a risk factor for anxiety development in children with offspring of anxious parents being seven times more likely to meet the criteria for an anxiety disorder (2). Recommendations have been made to address parental anxiety and its associated restrictive behaviours specifically for children with FA (3). Anxiety in general clinical practice is often addressed using Cognitive Behavioural Therapy (CBT) of which there is some evidence in mothers of children with FA (1,4). The present study adapted a CBT-based group intervention for parents with anxiety disorders (5) to assess the acceptability, feasibility and signal of efficacy (i.e. an indication that the intervention may improve outcomes) of a two-session online intervention for a FA-parent population on improving both parent and child-outcomes. The adapted intervention aimed at minimising anxiety transmission from parent to child and empowering parents to raise confident children hence the rationale for measuring child outcomes (5). The content of the sessions included psychoeducation, managing early signs of anxiety (e.g. graded exposure to situational avoidance, challenging negative thoughts) and parenting skills (e.g. managing parenting hotspots (such as overprotection and perfectionism) and emotion coaching).

This feasibility study adopted an experimental, repeated measures, within-participant design. The outcome measures examined parental depression, anxiety and stress (DASS-21;6), FA self-efficacy
(FASE-P;7) which measures parental confidence in managing FA, and parent-reported child QoL (PedsQL;8) and anxiety (SPAS-P and SCAS-P;9) at baseline, immediately after the second intervention session, and 1- and 3-months post-intervention. Information about acceptability was collected through a feedback form. Recruitment took place through opportunistic sampling via the Anaphylaxis Campaign. All parents screened had children aged from 2 to 16 with parent-reported FA and none met the exclusion criteria which were an inability to interact in English and current involvement with another intervention-based research project. Verbal consent was obtained during the screening call when participants had the opportunity to ask further questions and informed consent was recorded online via Qualtrics. Ethical approval was obtained through the NHS REC (20/NE/0051). Due to COVID-19 restrictions the intervention was delivered over two online intervention sessions of two hours each, held at the same time on consecutive weeks and were facilitated by a trainee clinical psychologist (SVR).

An *a priori* power calculation was calculated in order to obtain an estimate of the intervention’s efficacy to improve outcomes in parents and children with FA. A previous trial of a brief CBT intervention for FA parents (4) reported an effect size of $d=0.50$ on anxiety which was converted to $f=0.25$ for use in this power calculation. Using these values with power at 0.95, $\alpha=0.05$ in a repeated measures ANOVA resulted in a required sample size of 36. As the data did not meet parametric assumptions, Friedman’s Test was utilised for analysis. Significant results were followed up using Wilcoxon tests. A Bonferroni correction to control for type I errors was used ($\alpha/3$; representing the three baseline to follow up assessments), which set the significance level at $p < 0.01667$. The scores of the parent-rated child measures (SPAS-P, SCAS-P and PedsQL) were converted to z-scores to ensure the different age groups were comparable. Analyses also investigated the scores per age group.

There were two recruitment rounds and out of the 68 parents who were invited or expressed an interest having seen the advert, 41 participated in screening (60% recruitment rate; Figure 1). Of the parents who opted in, two parents dropped out after they completed the baseline questionnaires, with 95% (39/41) attending both intervention sessions. All participants were female, aged between 28-50 years (mean age 40.13, standard deviation 5.17) with 89% being educated to at least undergraduate university level. The majority of participants baseline scores fell within the non-clinical range on the anxiety (54% in “normal” range), stress (59%), and depression (67%) on the subscales of the DASS21 (6). The majority of their children had multiple allergies, only 18% reported allergy to a single food group with almost a third (32%) reporting allergies to at least 6 food groups.
All had a prescription of auto-injectable epinephrine. In terms of outcomes, there was a statistically significant decrease in parental anxiety ($\chi^2(3)=17.883, p < 0.001$) across all follow up time points. There was a medium effect size reduction in anxiety sustained between baseline and 3-months post-intervention ($d=.57$). No significant effect was found for the stress and depression subscales. A statistically significant increase in parental FA self-efficacy was found ($\chi^2(3) = 47.463, p < 0.001$) again across all follow up assessments, which translated to a medium-large effect sustained between baseline and 3-months post-intervention ($d=.76$) (Table 1).

On the parent-rated child measures, no significant effects were found for QoL or anxiety when all ages combined (Table 1). However, improvement in QoL was observed on the PedsQL measure for 8 to 12 year olds ($n=17$) which through further exploration, was found only between baseline and 1 month post-intervention ($Z=-3.264, p=0.001$). Additionally, a statistically significant decrease was found in parent-rated child anxiety ($n=25$) which was sustained across all follow-up assessments ($\chi^2(3)=26.813, p < 0.001$), for 6.5 to 16 year olds but not for younger children. Furthermore, the feedback form showed satisfaction as the majority of parents rated that they found the intervention helpful (97%), enjoyable (100%), informative (100%), and they would recommend it to other parents (97%).

The aim of this study was to determine if a remote, manualised CBT-based parent group intervention was acceptable and feasible to deliver, and provided a signal of efficacy in reducing levels of anxiety for parents and, indirectly, their children. The intervention was deemed to be feasible and acceptable as evidenced through high recruitment, retention and outcome completion rates as well as positive ratings on the feedback forms. As found for previous CBT-based interventions for this population (4), a significant reduction in parental anxiety scores was observed. An additional significant increase in parental self-efficacy regarding FA management was found. However, there was no significant change on parental stress and depression measures. These findings could be explained by the nature of the intervention, which was mostly focused on anxiety management in relation to fears, worries, and unnecessary restrictions around navigating their child’s FA. Only a few intervention elements attended to overall parental stress and wellbeing, and there was no content aimed at mitigating depression or low mood.

Parent-rated child outcome measures overall did not yield any significant results when all child ages were combined. There were some significant trends for specific age groups, with an apparent short-lived improvement in QoL for 8-12 year olds and a potential more sustained decrease in anxiety for
6.5-16 year olds. However, due to the smaller sample sizes of the specific age groups, these results must be interpreted with caution. It is possible that indirect parent-driven interventions for child anxiety may take longer to have an observable effect on child outcomes. Future research could include longer term follow up of outcome measures and consider the addition of booster sessions. This would determine whether the effects found of reduced parental anxiety and improved perceived self-efficacy around FA management are maintained, as well as provide information around possible effects on child wellbeing following a longer assessment period.

A main strength of this study is that it adds evidence to a field with limited evidence on the acceptability and efficacy of CBT for anxiety in the context of FA, despite it being recommended as the preferred intervention and reviews requesting this (1). However, the design was a short-term, small-scale study with a focus on acceptability and feasibility. Therefore, the main limitations are the lack of a control condition, the self-reported nature of a FA diagnosis and the limited sample size in relation to child age-specific outcome measures. Moreover, this intervention was delivered during the global COVID-19 pandemic at a time when stricter lockdowns and school closures were implemented in the United Kingdom, with no control group meaning we cannot ascertain how this context contributed to the results.

Future research should attempt to replicate using a similar intervention protocol with a larger sample size and a control group, creating an appropriately powered randomised controlled trial design with stratification of duration of child’s FA diagnosis (clinician-verified) and mental health difficulties as both may affect coping strategies. Given the accessibility and potential cost-savings of this type of intervention, a definitive trial should also include a health economic analysis. Questionnaires were also kept to a minimum; future studies may consider including additional FA specific measures of QoL as well as child-reported (instead of the proxy-reported measures used in this study). Further limitations included self-selection bias due to the recruitment method (e.g. those already engaged with a supportive allergy charitable organisation) which may have favourably skewed the retention rate and feedback ratings, as well as limits generalisability. There was also lack of diversity in the current sample, specifically around gender and educational status (ethnicity was not recorded), which needs to be carefully addressed in future trials.

Despite these limitations, the approach adopted has offered initial insights into the efficacy of an online CBT intervention for parents with children with FA. This study demonstrated that a two-session, CBT-based parent group intervention adapted for FA parents appeared acceptable, feasible
and provided a signal of efficacy on parental anxiety, similar to other studies (4). Manualised CBT interventions are likely to benefit teams without dedicated allergy specialist support. Further research into this type of intervention with an adequately powered RCT and longer term follow up is recommended.
References


## Table 1. Descriptive statistics and Friedman’s Test results.

<table>
<thead>
<tr>
<th>Scale</th>
<th>n</th>
<th>Time</th>
<th>Median (IQR)</th>
<th>Friedman’s Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>DASS21 stress</td>
<td>38</td>
<td>Baseline</td>
<td>13 (7.5-18)</td>
<td>$\chi^2(3) = 2.304, p = 0.512$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immediate post</td>
<td>12 (10-26.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 month post</td>
<td>12 (8-16)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 months post</td>
<td>12 (10-16.5)</td>
<td></td>
</tr>
<tr>
<td>DASS21 anxiety</td>
<td>38</td>
<td>Baseline</td>
<td>6 (2-10)</td>
<td>$\chi^2(3) = 17.883, p &lt; 0.001$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immediate post</td>
<td>2 (0-8.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 month post</td>
<td>2 (0-4.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 months post</td>
<td>2 (0-6)</td>
<td></td>
</tr>
<tr>
<td>DASS21 depression</td>
<td>38</td>
<td>Baseline</td>
<td>4 (2-12)</td>
<td>$\chi^2(3) = 3.055, p = 0.38$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immediate post</td>
<td>4 (2-10.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 month post</td>
<td>6 (2-10)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 months post</td>
<td>6 (2-10)</td>
<td></td>
</tr>
<tr>
<td>FASE-P</td>
<td>38</td>
<td>Baseline</td>
<td>69.81 (61.64-83.56)</td>
<td>$\chi^2(3) = 47.463, p &lt; 0.001$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immediate post</td>
<td>80.19 (71.54-90.43)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>1 month post</td>
<td>80.67 (70.1-89.27)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>3 months post</td>
<td>88 (73.8-95)</td>
<td></td>
</tr>
<tr>
<td>PedsQL</td>
<td>38</td>
<td>Baseline</td>
<td>0.13 (-0.79-0.84)</td>
<td>$\chi^2(3) = 1.611, p = 0.657$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immediate post</td>
<td>0.04 (-0.80-0.82)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>1 month post</td>
<td>0.32 (-0.76-0.75)</td>
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<tr>
<td></td>
<td></td>
<td>3 months post</td>
<td>-0.08 (-0.60-0.73)</td>
<td></td>
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<tr>
<td>SCAS-P + SPAS-P</td>
<td>38</td>
<td>Baseline</td>
<td>-0.18 (-0.90-0.64)</td>
<td>$\chi^2(3) = 0.158, p = 0.984$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Immediate post</td>
<td>-0.14 (-0.65-0.58)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 month post</td>
<td>-0.26 (-0.82-0.91)</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>3 months post</td>
<td>-0.70 (-0.81-0.42)</td>
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</tbody>
</table>

Note: For the Depression, Anxiety and Stress Scale (DASS21), Spence Children’s Anxiety Scale Parent-reported (SCAS-P) and Spence Preschool Anxiety Scale Parent reported (SPAS-P) a higher score indicates greater impairment. For Food Allergy Self-Efficacy for Parents (FASE-P) and The Pediatric Quality of Life Inventory (PedsQL), a higher score indicates improvement. The PedsQL, SCAS-P and SPAS-P were z-transformed to facilitate comparison across age groups.
Round 1. Anaphylaxis Campaign emailed peer support leaders invitation letters and information sheets (n=24)

Parents opted in (n=7)

Participants offered screening telephone call (n=0 excluded), and choice of intervention dates (n=41)

Dropped out (n=2)
- Due to work commitments (n=1)
- Due to COVID illness (n=1)

Participants given a choice of workshop:
- Evening 7.30pm-9.30pm (n=28)
- Morning 10am-12pm (n=11)

Demographic characteristics and questionnaires
Parent measures Parent-reported child measures
- DASS-21<sup>a</sup>
- FASE-P<sup>b</sup>
- SCAS-P and SPAS-P<sup>c,d</sup>
- PedsQL<sup>e</sup>

2 x 2 hour workshop intervention (n=39)

Follow-up assessment
- Immediate post intervention (n=39) 28% reminded*
- 1-month post intervention (n=38) 46% reminded*
- 3-month post intervention (n=39) 72% reminded*

*Participants required reminding via email and telephone to complete measures

<sup>a</sup>Depression, Anxiety and Stress Scale; <sup>b</sup>Food Allergy Self-Efficacy for Parents; <sup>c</sup>Spence Children’s Anxiety Scale Parent-reported; <sup>d</sup>Spence Preschool Anxiety Scale Parent reported; <sup>e</sup>Pediatric Quality of Life Inventory (PedsQL)