For the version of record, please see: Sugunasingha, N., Jones, F. W., & Jones, C. J. (in press). Interventions for caregivers of children with food allergy: a systematic review. *Pediatric Allergy and Immunology.* https://doi.org/10.1111/pai.13255

Interventions for caregivers of children with food allergy: a systematic review

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Conflict of interest statement: Drs Sugunasingha, Jones and Jones have no conflicts of interest to declare.

Author contribution: All authors contributed to the design and development of the systematic review protocol. NS conducted initial searches and data extraction with secondary checks conducted by CJ and FW. All authors contributed to the synthesis of study results. NS completed first draft of manuscript with significant editing by CJ and FW. All authors have read and approved the final version.

33Funding: No funding was received for this work.

Abstract

Background: Studies have identified that food allergy (FA) in children is related to poorer caregiver quality of life (QoL). However, it is unclear which interventions are most effective at improving outcomes for caregivers of children with FA. This review aimed to identify and determine the efficacy, acceptability and quality of interventions for caregivers of children with FA.

Methods: A systematic search of four databases was conducted to identify studies evaluating any intervention that targeted wellbeing and support in caregivers of children with FA. Studies were not excluded based on design and were rated for quality using the mixed method appraisal tool (MMAT) and the Cochrane risk of bias tool for randomised controlled trials (RCTs).

Results: Fifteen studies met inclusion; eight studies used a pre-test post-test design, four used a post-test design, two were RCTs and one a case-control design. Seven studies were educational interventions, five were psychological, and three involved peer/professional support. All interventions had high participant acceptability; some evidence for cognitive behavioural interventions in supporting mothers was observed. Educational interventions tended to be associated with improvements in FA knowledge. With exception of three studies, most studies were assessed as poor or moderate in terms of quality.

Conclusion: There is a paucity of high-quality research evaluating interventions to improve outcomes in parents of children with FA. Limited evidence suggest that cognitive behavioural interventions could benefit some mothers, but this has not been tested in other populations. Future research should use methodologically sound designs with validated outcome measures.

Keywords: Food allergy, Parents**,** Caregivers, Intervention, Quality of Life, Wellbeing

Abbreviations

FA	Food allergy
QoL	Quality of life
MMAT	Mixed methods appraisal tool
RCT	Randomised controlled trial
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
AAI	Adrenaline auto-injector
CBT	Cognitive behavioural therapy

INTRODUCTION

Like all chronic illnesses, a food allergy (FA) diagnosis has emotional, psychological and financial implications[1-3]. Research has highlighted three challenges unique to caregivers of children with FA[4]. Firstly, children are generally asymptomatic in the absence of the allergen. Some caregivers have stated that the "invisibility" of the FA can result in others not recognising the importance of management plans or responding to requested accommodations for the child with hostility (e.g., accusing parents of being neurotic)[3,5]. Parents have reported that these negative social interactions increase anxiety and fear of "handing over" care to others[3]. Numerous studies have reported that although burdensome, parents often feel safer managing the ever-present threat of anaphylaxis alone[6-7]. This sense of responsibility may have consequences not only for the child, who may miss out on social interactions, but also for the whole family. Gupta et al. identified mothers who stopped working to stay at home with their child due to fears that caregivers in other settings would not provide adequate care[7].

Secondly, parents who are instructed to maintain a high level of vigilance as a part of FA management may experience anxiety and impose excessive restrictions on their child. Vigilance behaviours are enhanced in states of anxiety and can often result in unhelpful coping strategies (such as avoiding all situations, regardless of risk of exposure) [8]; reducing these behaviours is sometimes a component of psychological interventions for anxiety (e.g., dropping safety behaviours in cognitive behavioural therapy for Panic)[9]. Moreover, reactions from accidental exposure to allergens are not uncommon, even when numerous preventative steps have been taken, which may exacerbate parental anxiety and reinforce the perceived need for further vigilance[10,11].

Finally, the unpredictability of FA reactions can provoke negative beliefs around ambiguity among parents. In an analysis of parental understanding of allergy risk and management, Stjerna et al. found that parents feel the need to manage a "death risk", which depends both on context and on those who are interacting with their child[5]. As this risk is easier to manage when both aspects are familiar, caregivers may actively avoid uncertain environments, even when the overall risk of fatal anaphylaxis is low[12]. Given these

challenges, it is perhaps unsurprising that caregivers regularly report poorer mental health, lower self-confidence and impaired quality of life (QoL) [4,6,13,14].

In summary, allergy diagnoses are a serious and potentially chronic health difficulty that can negatively impact the lives of those affected as well as their caregivers. The current lack of curative treatments for FA requires caregivers to engage in vigilance behaviours to avoid the allergen, which may be burdensome. Further, these behaviours can impair QoL and provoke anxiety among parents, in turn potentially hindering the child's development and impacting caregivers' relationships. Given the increasing prevalence of allergy diagnosis[15], and the related consequences for individuals with FA and their families, there is a need to better understand what support is helpful to improve caregiver wellbeing. There are no published reviews examining interventions aimed at improving wellbeing in caregivers of children with FA. Improved support for this population has the potential to improve not only caregiver wellbeing, but also allergy management outcomes for children with FA. This study aimed to conduct a review based on a systematic search of the literature examining interventions targeted at improving wellbeing and support in caregivers of children with FA. Specifically, the review sought to summarise the reported efficacy, acceptability and quality of these interventions.

METHODS

This systematic review follows the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines (PRISMA)[16] and was prospectively published (PROSPERO ID: CRD42019140734).

Eligibility criteria

Studies were included on the basis that i) interventions targeted the wellbeing and support of primary caregivers (biological or adoptive or foster) of children with FA (clinician diagnosed or parent-reported), ii) interventions targeting non-primary caregivers (e.g. school staff) or children were included so long as they contained a component addressing parental needs, iii) studies could involve any type of intervention (e.g. psychological, social, behavioural, educational) irrespective of study design, and iv) studies were published in an English-language, peer-reviewed journal. Studies were excluded if i) children had other

chronic health difficulties (with the exception of comorbid atopic conditions) or did not have a diagnosis of FA, ii) caregivers were of children over 18 years (as adult children are less likely to be under the primary care of their parents), or iii) the intervention did not directly target parental outcomes (e.g. studies evaluating adherence to medical treatment plans to benefit children or medical professionals).

Search strategy

Databases were searched from inception and included Web of Science, Psychinfo, Pubmed and CINAHL up until December 18th 2018 (search terms available in supplementary file 1). Papers were screened against the eligibility criteria, initially by title and then abstract, and finally full text where necessary (Figure 1). Additional articles were searched for in reference sections of included studies and using Google scholar.

Data extraction, analysis and synthesis

A standardised data extraction form was created and data were extracted for important characteristics (Table 1 Online Repository). Data from the included studies were initially extracted by the first author and repeated for a randomly selected 20% percent of studies, by the last author with no disagreements observed. The same approach was used for conducting the assessment of study quality. A narrative synthesis of the data structured around the nature and type of intervention was undertaken.

Quality assessment of studies

As studies eligible for this review incorporated both qualitative and quantitative designs, quality assessment was guided by the Mixed Methods Appraisal Tool (MMAT)[17]. This is an effective and practical tool for systematic reviews that include varied study designs and mixed methods and has been used in recent reviews in the allergy literature[17]. The tool consists of two screening questions, followed by four criteria for appraising study design. The MMAT scores range from 0-100% (where all four criteria are met). For randomised controlled trials (RCTs), quality was also assessed using the Cochrane Risk of Bias tool[18]. This tool addresses six domains of potential bias, and assessments are made for multiple items under each domain. These assessments inform an overall judgement about whether the potential risk of bias is low, unclear or high.

RESULTS

Study characteristics

Of the 15 studies involving 6511 participants, seven were conducted in the United States[10,11,20-24], three were conducted in the United Kingdom[25-27], three in mainland Europe[28-30], one in Canada[31], and one in Australia[32]. Eight used a single-group pre-test post-test design[10,11,21,22,27,28,30,32] and four used a single-group post-test design[23,24,29,31]. Two studies were RCTs[20,25] and one used a non-random case control design[26]. Broadly, the studies' interventions focused on providing education, psychological support to mothers or families, or peer/professional support (Table 1).

Quality assessment

Of the 15 studies which were assessed using the MMAT, one scored 100%[25], one scored 75%[26], six scored 50%[10,20,22,28,30,31], four scored 25%[11,21,27,32] and three did not meet any of the appraisal criteria and scored 0%[23,24,29](supplementary file 2). Two studies used a randomised controlled trial design. Boyle et al. was rated as having an overall low risk of bias[25] (supplementary file 3). The primary methodological concerns were the lack of blinding of participants, experimenters and outcome assessors. Additionally, outcome measures were primarily self-reported and unvalidated, with a corroborating measure (salivary response) provided for one outcome in one study[25]. The authors attempted to reduce bias where possible and reported processes appropriately. Baptist et al. was rated as "unclear" due to failing to report processes such as randomisation, reducing confidence in the reported results[20] (supplementary file 3).

Educational interventions

Seven of the 15 reviewed studies reported on the implementation of an educational intervention aimed at parents and caregivers. One study created and ran an educational campaign across a US State, aiming to improve allergy management knowledge both in the public and to caregivers[22]. They reported a significant increase in knowledge scores at post-test, concluding that provision of information via media outlets was effective. Three studies presented information through varying formats, with one running two face-to-face

workshops, another showing participants educational videos, and the final through engagement with a 2-week online programme (consisting of interactive question and answer sessions and discussion threads)[10,28,30]. Despite the variation in presentation format and length of intervention, all studies reported increases in food allergy knowledge in participants between pre-test and post-test measures, as well as reporting high levels of satisfaction.

Wahl et al. created a face-to-face training session that was conducted in 247 schools[24]. Authors aimed to increase food allergy knowledge, as well as increasing perceived competence to care for children with FA. The primary demographic in this study was teachers, but workshops were also attended by parents, caregivers, nurses and administrators. This study did not measure confidence or knowledge increase with formal measures but reported participant feedback on the workshop. They concluded that respondents reported an increase both in knowledge and in confidence in managing FA as a result of the training.

The sixth study used a pre/post-test design to assess whether knowledge of food allergy and psychological wellbeing improved following diagnostic tests and appropriate information and advice given by an allergy specialist. At four-six weeks after the clinic appointment, knowledge of food allergy was significantly greater but there was no significant difference in psychological wellbeing between baseline and follow-up[27]. Finally, Sicherer et al. targeted the role of information in improving practical provision of care to children with FA[11]. They assessed correct administering of an adrenaline auto-injector (AAI) as the primary outcome, but also measured reported comfort with treatment and FA knowledge. They reported improvements in the administering of AAIs, with fewer errors made by participants, as well as increased FA knowledge and high participant satisfaction that was maintained at one-year follow-up.

Psychological interventions

Five studies evaluated psychological interventions for caregivers of children with FA. Two studies aimed to improve outcomes by targeting parental self-efficacy. The first study ran a series of psychologist-led workshops aiming to present relevant information about allergy

management and facilitate discussion[21]. They reported that the intervention resulted in increased perceived parental competence (self-efficacy) and a reduction in parental burden between pre and post-workshop measures.

The second study ran an RCT aimed at improving self-regulation and QoL[20]. The authors designed their intervention based on a self-regulation model to support health-related behaviour change[33]. Participants in the intervention group received three 25-minute telephone sessions with a trained clinician, to help them to set goals, problem solve and implement coping behaviours. The authors found that QoL improved across four domains (helplessness, anxiety, frustration and confidence), and they concluded that interventions targeting self-efficacy had the potential to improve FA related QoL in caregivers.

Two studies explicitly evaluated the role of Cognitive Behaviour Therapy (CBT) in improving psychological outcomes for mothers of children with FA. Knibb provided a 12-week course of individualised CBT to mothers and found that participants reported a decrease in depression and anxiety symptoms compared to treatment-as-usual control participants[26]. Another study ran an RCT to evaluate whether a brief, single session of CBT could support a reduction in maternal state anxiety[25]. They identified a decrease in anxiety only in a subgroup of mothers whose baseline scores were “moderate to severe”.

One additional study assessed the usefulness of psychological therapy for caregivers; Polloni et al. reviewed chart data for therapy offered to 100 attendees at an allergy referral centre[29]. Although they did not evaluate individual outcomes for type of therapy, they identified the most common reasons for referral (emotional/social problems, difficulties managing food allergies, eating problems and behavioural problems) and observed that 67% of cases reported that psychological therapy made them feel “a bit better”, and 33% “much better”.

Peer/professional support

The final three studies in this review used supportive interventions that did not include formal educational or psychological therapy. Stewart et al. evaluated an online support group for parents of children with FA and assessed qualitative outcomes post-test using

semi-structured interviews[31]. Attendees reported that the group helped them to feel less isolated and allowed them to ask for advice from peers. Rather than targeting parental wellbeing directly, one study examined the role of specialist input in improving psychological wellbeing in parents. Sharma et al. found that the presence of an allergy specialist in a face-to-face support group reduced reported anxiety and helped participants feel more comfortable asking their allergy specialist questions about their child's care[23].

The final study aimed to improve the mental health of parents of children with no previous diagnosis or management of FA by an allergy specialist, by providing training to community paediatricians[32]. The intervention was developed and delivered by paediatric allergists and dermatologists to address reports that inadequate clinician training results in contradictory medical advice, contributing to parental anxiety[13]. Following the training intervention, the clinicians' consultation plans were assessed for accurate medical guidance. The authors measured knowledge change in clinicians, as well as reported QoL, psychological wellbeing and satisfaction levels among parents who were registered with the clinicians. Although the authors reported that parent participants' mental health improved marginally, these changes were not statistically significant.

DISCUSSION

This review identified 15 studies which aimed to improve the wellbeing and support of caregivers of children with FA. The interventions identified were categorised into three broad themes; educational, psychological and peer/professional support. The majority of educational interventions aimed to address discrepancies in FA knowledge; these studies all reported increased knowledge among their participants. The studies mobilising psychological interventions provided tentative support for the use of a cognitive behavioural models to inform acceptable and effective interventions for mothers of children with FA. Further psychological evidence suggested that targeting parental self-efficacy may be beneficial for improved QoL. Evidence was mixed for the provision of peer/professional support with more convincing findings for support groups with or without specialist input compared with the impact of specialist input alone. Despite the mixed findings, participants largely reported the interventions as acceptable.

Taken together, the 15 studies evaluated in this review point to the relative lack of robust research evaluating psycho-social interventions for this population. When assessed for quality, seven scored between 0 and 25% on the MMAT, six scored 50% and two scored 75-100%. Only two RCTs met the inclusion criteria; of these, only one had low risk of bias. The generally poor methodological quality of reviewed studies, reflected in problematic designs, sampling bias and unvalidated outcome measures, prevent any definitive conclusions about these interventions' efficacy, despite this being one of the main aims of the review.

Nonetheless, these studies suggest implications for researchers and clinicians seeking to improve the psychological wellbeing and support in caregivers of children with FA. These results also imply there is a need for educational input for caregivers and are in line with the broader literature evaluating the needs of parents of children with chronic health difficulties, which suggests that illness-specific education interventions improve parental mental health outcomes[34]. CBT has been shown to facilitate improvements in the wellbeing of parents of children with other health difficulties (e.g., chronic pain)[35] and is currently the recommended treatment in the UK for people struggling with low mood or anxiety[36-37].

All the studies evaluating educational interventions lacked a control group, greatly reducing their internal validity. It is unclear whether the observed outcomes would have occurred in the absence of the intervention. Given that participants were not randomly allocated to the treatment, observed changes might have been the result of particular group characteristics. Additionally, none of the studies considered the implications of increased knowledge on parental wellbeing. Existing research reports that parents of children with FA have unmet informational needs and that improving access to clear and concise information from a credible source would positively influence parental QoL and reduce perceived stress[38-40]. However, this mechanism needs to be empirically evaluated as does the hypothesis that improved knowledge and self-efficacy leads to improvements in ability, given the propensity for current interventions to focus on the former. Finally, all studies may suffer from sampling bias. Each of the reviewed studies used an opportunistic sampling strategy to recruit participants, which may have resulted in a participant pool of caregivers with an interest in the study area, or with higher than average needs. Participation through self-selection reduced the validity of these studies' outcomes. That this problem was constant

across all studies points to a broader challenge in defining the population of interest and accessing a representative sample.

To the authors' knowledge this is the first review seeking to evaluate the efficacy of interventions to improve wellbeing and support in caregivers of children with FA. Although there may be value in considering the separate influence of interventions by "type" (for example, psychological versus educational), this review included all intervention types, which introduced difficulties when comparing studies and prevented meta-analysis. However, this approach was deemed necessary due to the paucity of studies evaluating a single intervention type or therapeutic model. Furthermore, the review included two studies that were aimed at a variety of caregivers (including teachers and the public), which meant that it was not possible to know the extent to which the intervention results applied specifically to parents. However, it was felt that the dearth of research in this area meant that a broader scope was ultimately useful in understanding the wider literature aimed at this population. The heterogeneity of both intervention type and study design also meant meta-analysis was not appropriate.

One of the primary issues with the studies included in this review is the lack of validated outcomes measures utilised. Only a third of studies used FA-specific outcomes; four of which used the Food Allergy Quality of Life-Parental Burden[20,21,26,32] and one study utilised both the Food Allergy Quality of Life and the Food Allergy Impact Scale[25]. The lack of utilisation may in part reflect the lack of FA-specific measures outside of quality of life where much existing research has focussed. Clinicians and academics should consider designing and developing, including psychometric evaluation, FA-specific measures to include a diverse range of experiences and participant demographics to ensure validity and reliability. With more holistic measures in place to capture the experiences of individuals living with FA and their caregivers, the academic and clinical community should move towards agreeing a standardised set of outcomes which represent the minimum that should be measured in all trials of FA-interventions which would also enable meta-analysis. Indeed there does exist a Core Outcome Measures in Effectiveness Trials (COMET) Initiative for food allergy although the project is currently underway with results expected in 2023[41].

The results of this review provide tentative suggestions for interventions to benefit parents of children with FA. However, it remains unclear whether the promising results demonstrated in these early studies are replicable elsewhere. In particular, there is a need for research which uses methodologically robust designs (e.g. RCTs) to test the efficacy of educational and psychological interventions in supporting parents of children with FA. Future research should attempt to recruit more representative samples and determine differences in intervention effects between type of caregiver (e.g. mother, father, adoptive, grandparent), age of child or type of allergen. The samples studied in the literature are disproportionately comprised of white, female, educated and middle-to-high income individuals. FA prevalence rates amongst diverse groups are still unknown[42]. However, preliminary research has suggested that those from minority groups are more likely to experience FA-related anxiety[43], and that non-Caucasian children are less likely to be prescribed AAIs[42]. Considering the growing consensus of the increased burden on parents of children with FA[4], it may be important to study populations who might have access to fewer supportive resources. Until these groups are better represented in this literature, alternative research designs may help overcome this problem: for example, online interventions can increase under-represented groups' access to services[31,44-45]. Adequately powered RCTs would be beneficial to evaluate whether these interventions are efficacious among such sub-groups.

The results of this review are not sufficiently conclusive to make strong recommendations for interventions that might be implemented in clinical settings. However, despite the limited evidence for parental interventions, the literature is clear about the increasing prevalence of allergies[46-49] and the negative implications for affected individuals and their caregivers[50]. Although strong recommendations cannot currently be made regarding the most efficacious intervention, clinicians must be aware of the growing needs of this population and of the current evidence. There is increasing emphasis on the integration of physical health and mental health provision[51]. With increasing understanding of the interrelatedness of these sectors, policy-makers have reported that failing to address individual needs in a holistic way results in worse outcomes that are socially and economically costly[52]. This is reflected in the allergy literature; numerous studies have noted

388the negative consequences for poorly supported parents that could be addressed by
389adequate provision of social, practical and psychological support[4,53-55].
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391In conclusion, the paucity of high-quality research evaluating interventions to support
392parents of children with food allergies is apparent. However, the studies summarised in this
393review suggest that future research should develop interventions that provide educational
394input to caregivers, which may influence their psychological wellbeing. Although limited, the
395evidence provides an indication that further support in the form of CBT could also offer
396mothers some benefits, but CBT has not been tested on other groups. However, the
397reviewed research suffers from methodological constraints which limit the validity of
398reported outcomes. Therefore, future research should use more methodologically sound
399designs and use validated outcome measures.
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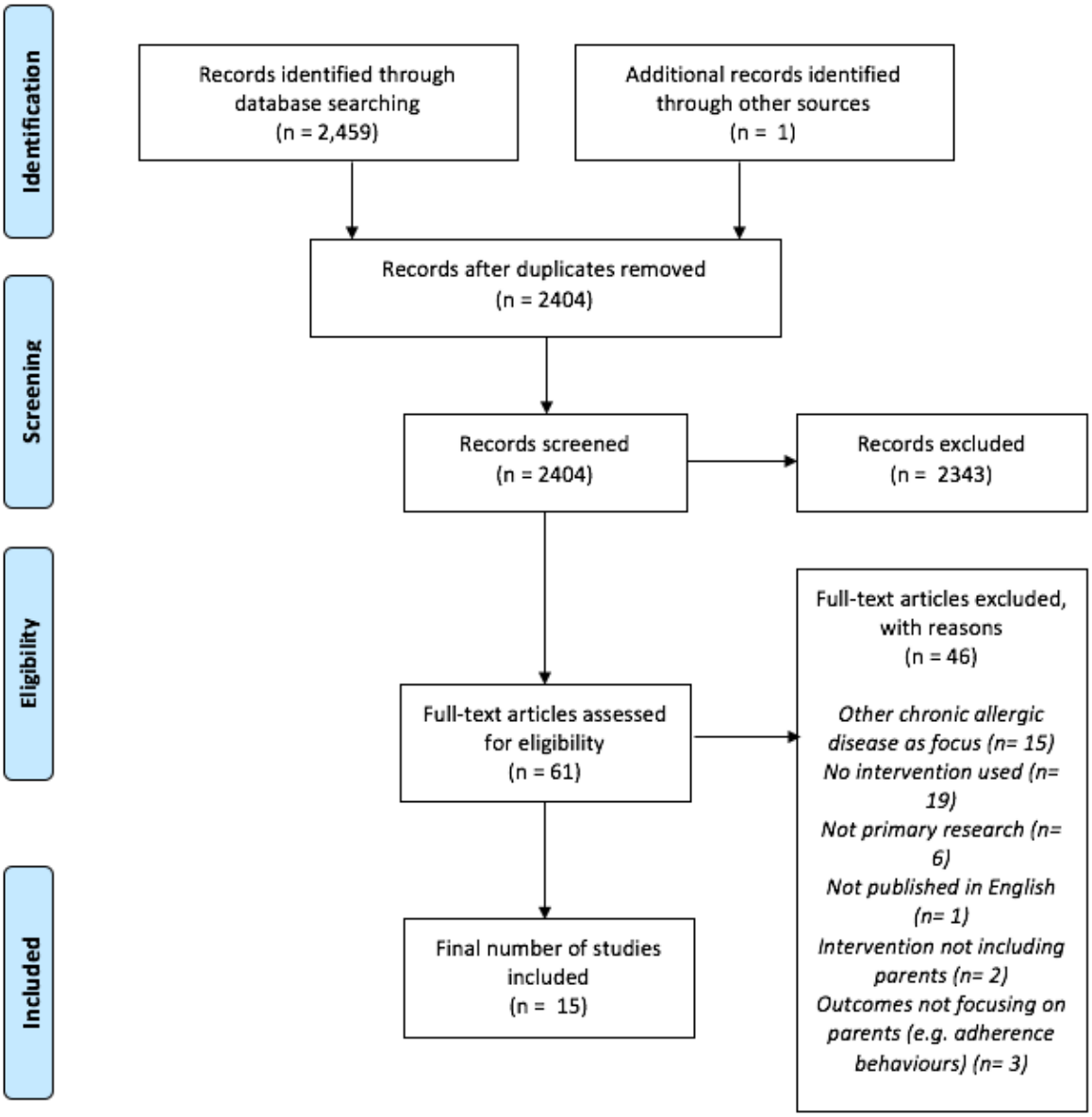

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588gure 1*:* PRISMA diagram of literature search[16]

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590 Table 1 Online Repository: Summary of reviewed studies

First author (year); quality score	Population	Design	Study summary	Intervention type	Outcome measures	Results
Maurer et al. (2007)[1] **MMAT: 50%**	667 participants completed pre-test measures and 474 completed post-test measures. Participants were 58% female, 59% over-50, 83% white. The campaign ran in all counties across the state of New Jersey, USA.	Pre-test post-test	Authors created an educational campaign to better inform caregivers of food-allergic children and the general public of best practice food allergy management. The campaign was released and publicised in numerous media outlets including via newspapers, radio and in a PSA video that was shown across supermarkets and cinemas in the State.	Educational intervention for caregivers and the general public	An unvalidated 8-item criterion referenced knowledge test based on campaign materials. Reliability calculated as 0.77 (Livingston's coefficient) Acceptability was not assessed.	Authors contacted State residents randomly before and after the campaign broadcast. Post-test scores showed a statistically significant increase in knowledge scores, and authors concluded that the campaign was an effective way of providing information to caregivers in the general public.
LeBovidge et al. (2008) **MMAT: 25%**	61 food allergic-children and their parent(s) attended a half day workshop. Participants were primarily white, female and university educated. The study was set in a hospital in Boston, USA.	Pre-test post-test	Authors developed and implemented a group intervention to improve perceived parental competence to manage food allergies.	Psychological group intervention for parents	- Medical information (ad-hoc questionnaire) - Family Coping with Food Allergy Questionnaire; 18 item measure developed by authors to assess perceived competence. Reported internal consistency (α = 0.91). - FAQoL-PB; 17 item validated measure of QoL.	Authors reported that higher levels of burden were associated with lower levels of information in pre-workshop measures. Authors concluded that parental confidence improved significantly from preworkshop to postworkshop, and again at follow up. They also found a significant decrease in parental burden from preworkshop to follow up. Authors reported the intervention was acceptable for

1[1] Study reported development of educational materials, but these are not discussed in this review

						participants.
Stewart et al. (2011) **MMAT: 50%**	Participants were 19 parents of food allergic children (7-11 y/o) based in Canada. Most participants came from high income households, attended university (>90%) and lived in urban settings.	Qualitative study using a post-test evaluation	Researchers developed and evaluated the perceived usefulness and acceptability of an online allergy support group for parents of food-allergic children.	Supportive intervention, no psychological component	Outcomes gathered via individual semi-structured interviews, no formal outcome measures were used.	Participants reported that they benefitted from the support group, highlighting reduced feelings of social isolation, and the ability to ask sympathetic peers questions and gain advice as helpful.
Baptist et al. (2012) **MMAT: 50%** **Cochrane risk of bias: Some concerns/unclear risk of bias[2]**	58 participants (47 at 3-month follow up) were recruited from an allergy clinic in Michigan, USA. Most participants were white, and from middle class households.	Pilot single blind RCT	Authors implemented a self-regulation intervention to improve food allergy related quality of life in parents of food-allergic children. The intervention group received phone calls from a trained clinician at 2 week intervals to discuss allergy management strategies.	Individual psychological intervention for parents	- FAQoL-PB; validated questionnaire to assess QoL - Unvalidated 8-item self-efficacy questionnaire developed by the authors. No reporting on reliability.	At 3 months, the intervention group had a statistically significant improvement in 4 domains (helplessness, anxiety, frustration and confidence in the FAQoL-PB questionnaire and on 1 item in the self-efficacy questionnaire. Did not report acceptability.
Sharma et al. (2012) **MMAT: 0%**	29/98 individuals affiliated with the institution in Pennsylvania, USA, and in attendance of the support groups completed an online survey.	Post-test questionnaire	Authors evaluated whether having a food allergy specialist present in support groups reduces parental anxiety and improves the relationship between parents and their allergy specialist.	Supportive intervention, no psychological component	Acceptability of intervention and anxiety related to caring for a food-allergic child was assessed in a 30-item unvalidated questionnaire designed by the authors.	77% respondents reported a decrease in food allergy anxiety and most reported an improvement in their child's QoL. More than 90% reported that it was beneficial to have an allergy specialist present in support group meetings, and that this made it easier for

[2] Cochrane risk of bias completed for only two studies which implemented a RCT design

	97% participants were female, 79% were university educated.					them to discuss concerns with their own specialists.
Sicherer et al. (2012) **MMAT: 25%**	A convenience sample of 32 parents attending an allergy clinic were recruited to trial educational materials. Sample was selected from New York, USA.	Pre-test post-test	Authors aimed to explore the effectiveness of educational materials for parents of food-allergic children.	Educational intervention for parents	- Authors assessed participant knowledge and correct administration of auto-injector to assess effectiveness of educational materials. - Acceptability was assessed using a 4-point Likert scale satisfaction questionnaire developed by the authors.	Results demonstrated an improvement in technique for administering epinephrine pens, increased comfort with treatment, improvement in food allergy knowledge and overall satisfaction with educational materials. These benefits were maintained at follow-up 1 year later. Authors reported high acceptability and efficacy of the intervention.
Knibb & Semper (2013) **MMAT: 25%**	Participants were 124 parents attending an allergy clinic for diagnostic tests. 50 participants completed post-test measures 6 weeks later. The sample was drawn from an allergy clinic in the UK. Participants were primarily female (80%), and white	Pre-test post-test questionnaire	Study authors aimed to assess whether visiting an allergy clinic (for support and a diagnosis) influences parental anxiety and depression. Measures were completed before and after the visit, and visit outcomes were also measured (i.e., if a food allergy diagnosis was given)	Educational intervention for parents	- Study specific demographic questionnaire to assess allergies, knowledge and acceptability of support offered at their allergy clinic. - The Hospital Anxiety and Depression scale (HADS) is a 14-item validated measure to assess anxiety and depression.	Authors reported that 86.4% of parents reported suspected food allergy had an impact on their family prior to attendance, 76% had made changes to their child's diet, 32.5% had mild to severe anxiety and 13.1% had mild to severe depression. However, researchers observed no changes in outcomes at follow up. Knowledge of food allergy significantly improved after clinic attendance.

	British (77.6%)					
Rosen et al. (2014) **MMAT: 50%**	Participants were 50 caregivers of food-allergic children. Individuals were recruited from an allergy clinic in NY, USA. Sample consisted of a white (66%), upper-income (82% >80,000 per annum), female (76%) individuals. Additionally, sample was well educated, with 90% of the sample completing undergraduate or post graduate university degrees.	Pre-test post-test questionnaire	Authors aimed to develop and validate audio-visual based food allergy educational materials for parents of food-allergic children.	Audi-visual educational intervention for parents	- Outcomes were assessed in a food-allergy knowledge questionnaire designed by authors. - Acceptability of the materials and interventions were assessed in a 7-point Likert scale satisfaction questionnaire designed by study authors.	Results identified an improvement in food allergy knowledge between pre and post knowledge scores, and high levels of satisfaction for the materials amongst participants (a mean score above 6).
Knibb (2015) **MMAT: 75%**	Participants were 11 mothers (5 CBT intervention; 6 control), attending a local allergy clinic. All participants were white British and female.	Non-randomised case control study	Evaluating the benefits of CBT to improve psychological outcomes for mothers of food-allergic children.	Psychological intervention for mothers	- 14-item HADS questionnaire to assess depression and anxiety. - Perceived Stress Scale (PSS), validated 14 item measure for stress. - FAQoL-PB to assess QoL. - WHO QoL scale- 26-item validated questionnaire.	At baseline CBT group had significantly higher anxiety and depression, and poorer general mental health than the control group but these differences no longer existed following the intervention. The control group maintained significantly lower general mental health, and the intervention group demonstrated decreased depression, anxiety and worry (with large effect sizes r > 0.6).

					-Penn State Worry questionnaire: 16-item validated measure. - General Health Questionnaire; a validated questionnaire assessing general mental health	Authors concluded that CBT seems to be an appropriate and effective intervention for mothers.
Polloni et al. (2015) **<u>MMAT: 0%</u>**	100 consecutive psychological treatments held at a food allergy referral centre were selected. 26% of these were family intervention, 9% individually for mothers and 2% individually for fathers. All treatments were conducted by a psychologist. The study was conducted in Italy. No demographic details were reported.	Post-test questionnaire design	Authors analysed the data for psychological treatments offered to individuals and their families attending a food allergy referral centre. They were interested in the reasons that individuals would access support from the service, and to identify the usefulness of psychological interventions to support this population. All interventions were grouped together (individual, parental, group session, etc.)	Psychological intervention for parents and families	Authors assessed effectiveness of psychological interventions using a measure with two questions, adapted from the Strengths and Difficulties questionnaire.	Authors reported that that requests for support were due to emotional/social problems (40%), difficulties managing food allergy (40%), eating problems (18%) and behavioural problems (2%). Authors indicated that participants reported that psychological interventions made them feel “a bit better” (67%) or “much better” (33%).
Wahl et al. (2015) **<u>MMAT: 0%</u>**	4818 individuals at 247 schools and community sites based in Seattle,	Post-test design	Aimed to increase food allergy knowledge and self-efficacy for all caregivers of food-allergic children through in-person	Educational intervention for caregivers	Outcomes were assessed with a feedback questionnaire asking	Results identified that respondents felt more confident to manage food allergies after their training, and

	Washington (USA) participated. 15% of the sample was reported to consist of parents, volunteers, coaches and food service workers. No demographic details were reported.		training.		participants about changes to knowledge levels following the intervention. No formal, objective knowledge questionnaire was administered.	suggested that attendees retained information about food allergy management. However, no baseline measures were recorded to demonstrate actual change.
Contreras-Porta et al. (2016) **<u>MMAT: 50%</u>**	174/184 participants completed both workshops and were recruited through social media websites. Sample were 56% mothers, 39% fathers and 4.9% caregivers. All were recruited in Spain. No other demographic details were reported.	Pre-test post-test study	Authors aimed to evaluate the provision of in-person educational workshops in improving QoL in food-allergic children and their parents	Educational intervention for parents	- Outcomes were measured using a 40-item knowledge questionnaire developed by the authors. - Acceptability of the intervention was assessed with a 5-point Likert scale satisfaction questionnaire designed by the authors.	Authors reported that 74/184 participants completed both workshops and were recruited through social media websites. Participants demonstrated improvements in food allergy management knowledge in 72.5% items on the knowledge questionnaire. Authors concluded that workshops were both acceptable and effective at improving food allergy management knowledge but they were unable to assess QoL due to lack of validated measures.
Danchin et al. (2016) **<u>MMAT: 25%</u>**	Participants were 10-12 paediatricians in Victoria, Australia. They opted in to the study and had no	Pre-test post-test study	Study aimed to provide GPs with training to better diagnose and manage food allergies, and that this would improve child QoL and parental mental health in parents of children with mild-	Supportive intervention, no psychological component	- Outcomes for paediatricians were assessed using the Chicago Food Allergy Research Survey. - Parents completed	Clinicians reported improved competency in managing food allergy their food allergy knowledge increased by 69-75%. 82% families returned baseline

	previous training in allergy management. Participants also included allergy patients (n=32) belonging to allocated clinicians who were taken from the clinic waiting lists.		moderate allergy presentations who might wait longer to access specialist appointments.		validated measures including the Depression Anxiety Stress Scales 21 (DASS), FAQoL-PB, PeDQL Family impact scale. - Satisfaction measured in a follow-up questionnaire designed by study authors.	surveys and 92% were satisfied with the care they received. Authors reported that parental mental health improved, (particularly anxiety) but that gains were small and this result was not significant. Mean scores for parental stress were below clinical cut-off in both timepoints.
Boyle et al. (2017) **MMAT: 100%** **Cochrane risk of bias: Low risk of bias**	Participants were 200 mothers, recruited from allergy clinics in London, UK. All participants were female, 53% participants had a university degree and 59% were non-white.	RCT	Authors aimed to examine whether a brief single session of CBT would help reduce maternal state anxiety	Psychological intervention for mothers	- The following outcome measures were used: Stait Trait Anxiety Inventory Scale (STAI), PSS, Strengths and Difficulties Questionnaire (SDQ), Screen for Child Anxiety Related Emotional Disorders (SCARED), Food Allergy Impact Scale (FAIS), Food Allergy Quality of Life Questionnaire. - Objective measure of stress; salivary cortisol levels	Authors reported that there was no difference in state anxiety between intervention and control group 6 weeks, except for a subgroup that started with moderate/high levels of anxiety at Time 1 (with a moderate effect size r = 0.5). Authors also found that the intervention educed risk perception and salivary cortisol response (however with a low effect size). In conclusion, authors identified that a brief intervention that incorporates risk perception may have an effect on parental anxiety for those reporting higher levels of distress.

Table 1: Summary of reviewed studies, continued

Interventions for caregivers of children with FA

Ruiz-Baques et al. (2018) **<u>MMAT: 50%</u>**	Participants were 135 carers and parents (75.4% mothers, 14.6% fathers, 10% caregivers) of food allergic children. Individuals were recruited online via social media websites, and the study was conducted in Spain.	Pre-test post-test questionnaire	Authors aimed to identify whether a 2-week online educational programme could improve QoL in parents of food-allergic children.	Educational intervention for parents	- Outcomes were measured using an ad-hoc 40-item knowledge questionnaire designed by the authors. - Acceptability of the intervention was assessed with a 5-point Likert satisfaction questionnaire.	Authors reported improvements on15/30 items on their knowledge test, and there was a significant improvement in 8 items. Engagement in the programme was good, with 76.2% participants visiting the website up to 25 times and 23. 8% more than 26 times in 2 weeks. Slightly lower attendance for live streams (27.5%, 18.3% and 15.9%). Authors reported a high level of satisfaction with the programme.

Supplementary file 1: Search terms

(allerg* OR anaphyla*) AND (parent* OR mother* OR father* OR care* OR mom* OR mum* OR dad* OR famil*) AND (intervention* OR psycholog* OR therap* OR experiment* OR education* OR psycho-education* OR psych* OR support “psychological education” OR treatment OR “psycho-social” OR psychosocial OR therapy OR group OR course OR “self-help” OR management OR plan).

611**Supplementary file 2**: Mixed Methods Appraisal Tool (MMAT)[16] for reviewed studies

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DESIGN	METHODOLOGICAL QUALITY CRITERIA
All types	A) Are there clear qualitative and quantitative research questions (or objectives*), or a clear mixed methods question (or objective*)? B) Do the collected data allow address the research question (objective)? E.g., consider whether the follow-up period is long enough for the outcome to occur (for longitudinal studies or study components).
Qualitative	1.1. Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question (objective)? 1.2. Is the process for analyzing qualitative data relevant to address the research question (objective)? 1.3. Is appropriate consideration given to how findings relate to the context, e.g., the setting, in which the data were collected? 1.4. Is appropriate consideration given to how findings relate to researchers' influence, e.g., through their interactions with participants?
Quantitative- Randomised controlled (trials)	2.1. Is there a clear description of the randomization (or an appropriate sequence generation)? 2.2. Is there a clear description of the allocation concealment (or blinding when applicable)? 2.3. Are there complete outcome data (80% or above)? 2.4. Is there low withdrawal/drop-out (below 20%)?
Quantitative non-randomised	3.1. Are participants (organizations) recruited in a way that minimizes selection bias? 3.2. Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups when appropriate) regarding the exposure/intervention and outcomes? 3.3. In the groups being compared (exposed vs. non-exposed; with intervention vs. without; cases vs. controls), are the participants comparable, or do researchers take into account (control for) the difference between these groups? 3.4. Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?
Quantitative descriptive	4.1. Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)? 4.2. Is the sample representative of the population understudy? 4.3. Are measurements appropriate (clear origin, or validity known, or standard instrument)? 4.4. Is there an acceptable response rate (60% or above)?
Mixed methods	5.1. Is the mixed methods research design relevant to address the qualitative and quantitative research questions (or

		objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective)? 5.2. Is the integration of qualitative and quantitative data (or results*) relevant to address the research question (objective)? 5.3. Is appropriate consideration given to the limitations associated with this integration, e.g., the divergence of qualitative and quantitative data (or results*) in a triangulation design? *Criteria for the qualitative component (1.1 to 1.4), and appropriate criteria for the quantitative component (2.1 to 2.4, or 3.1 to 3.4, or 4.1 to 4.4), must be also applied.*	
Study	Design (type)		Score
1) Maurer et al. (2007)	Single-group pre-test post-test design (Quantitative non-randomised)	A) YES. Authors identified a clear objective for the study: to develop and evaluate an educational campaign aimed at individuals who provide care for food-allergic children. B) YES. The authors recruited a sample of the population in a single US State to evaluate their intervention (n=474). Post-test measures were administered only a week after the campaign, which may have been sufficient to identify any changes to knowledge, however it would not be able to assess the retainment of information without a larger follow-up time period. 3.1) Selection bias was limited in recruitment for the evaluation—individuals were contacted by telephone. Numbers were generated using a "random-digit-dial" procedure that ensured that all state residents were equally likely to be contacted. However the study does not outline what time during the day calls were made, and what efforts were made to access individuals who were difficult to reach. The final sample however was biased towards white (83%), older (59% 50 years or older) women (58%). It is unclear how representative the sample is of the local population, and whether results can be generalised outside of these settings. (*) 3.2) Researchers collected demographic information, and administered an unvalidated 8-item knowledge test based on the campaign materials. Reliability of the knowledge test was ascertained by researchers at pre-test stage (0.77). 3.3) A single group design was used with no comparison or control group. This greatly limits the conclusions that might be drawn from the study, as confounding and external variables could not be controlled for (for example, individuals may have been inspired to complete additional research due to the allergy marketing materials, and a change in score	**

		cannot be causally linked to the intervention). 3.4) 474/667 (71%) participants completed the measures at both time points. (*)	
2) LeBovidge et al. (2008)	Single-group pre-test post-test design (Quantitative non-randomised)	A) YES. Authors identified a clear objective for the study: to develop and evaluate a group intervention for parents and children to improve competence in coping with food allergy management . B) YES. Collected data was appropriate to address the objectives of the study. Follow up questionnaires were also sent to participants to better assess with any changes could be maintained. 3.1) Individuals were recruited using opportunistic sampling strategies. All eligible attendees of an allergy programme were invited to attend the workshops. The sample was biased towards parents who could speak English, and had access to healthcare (United States) via insurance. This is reflected in their non-diverse sample, which was primarily white, well-educated, mothers. 3.2) Authors used a mix of unvalidated measures and data was all self-report. Their primary variable (competence) was measured by an unvalidated questionnaire that they had created, but demonstrated good internal reliability (0.91). Parental burden was measured using the FAQL-PB, which is a measured validated for use with UK populations (Knibb & Stalker, 2013). It is also unclear which components of the workshop might have been useful/ not useful for attendees. 3.3) A single group design was used with no comparison or control group. This greatly limits the conclusions that might be drawn from the study, as confounding and external variables could not be controlled for and any changes in outcomes cannot be causally linked to the group intervention. 3.4) All individuals who attended the workshop completed measures at Time 1 and 2, and 83% completed measures at follow-up. Authors did not identify any differences between completers and non-completers (based on demographic characteristics, medical information or scores on outcome measures). (*)	*
3) Stewart et al. (2011)	Single-group post-test design (Qualitative)	A) YES. Objectives are not directly stated, however it appears as though authors want to understand the effects of an online peer support group for parents of food-allergic children, and explore whether this support is in line with their support preferences. B) YES. A small sample of 19 parents attended	**

		the support group intervention, however the study has been able to adequately answer their question regarding the preferences and experience of this online support group. Results from this group cannot be generalised to other populations and settings. 1.1) Detailed telephone interviews with participants were the only source of data used in this study. Authors indicated that interviews were recorded, transcribed and coded using suitable software. This was appropriate and relevant to explore the aforementioned research objective. (*) 1.2) Qualitative description and thematic content analysis was used to analyse interview data. Authors briefly describe the development of themes in conjunction with the coding framework derived from the research questions. Authors outline how coding disagreements were addressed, and detailed notes around memos and rationale for codes were kept (although these were not accessible). (*) 1.3) Authors do not discuss the influence of context on their findings. There is little discussion about the role of income, ethnic/racial diversity or geographical location of participants. Authors reflect on the role of complexity in diagnosis and management that influences how useful any single intervention might be. 1.4) Although some consideration is giving to coding practice in analysis, authors do not discuss the role of facilitators or researchers and their influence on findings.	
4) Baptist et al. (2012)	Pilot single blind randomised control trial	A) YES. Researchers identified a clear research question whether FA related QoL in parents of food-allergic children could be improved through a self-regulation intervention. B) MAYBE. Data collected may identify whether an intervention (delivered by a trained clinician) improves self-regulation. Authors also collected data at a 3 month follow up to identify whether changes had been maintained. However all data is reliant on participant self-report, and measure self-efficacy using an unvalidated questionnaire. Additionally the sample consisted of predominantly white, middle class subjects. 2.1) Authors state that individuals were randomly allocated to intervention and control arms, however they fail to detail the randomisation schedule. 2.2.) Authors did not provide a description of the blinding process- it is unclear how this was achieved. 2.3) 47/58 participants were retained (81%) and	**

		completed measures at the 3 month follow up. (*) 2.4) 19% participants did not complete the full set of measures. (*)	
5) Sharma et al. (2012)	Single-group post-test design (Quantitative non-randomised)	A) YES. Authors aimed to evaluate whether having a food allergy specialist present in an allergy support group improves the relationship between parents and their child's allergist and their quality of life. B) NO. Although the questionnaire may provide researchers with some information about the preferences of group members, response rate was very low. Additionally, the questionnaire used was unvalidated so it is unclear whether the research questions posed by authors have been adequately answered. 3.1) All participants identified as Caucasian women and 79% of them had a university education, and it is unclear how representative this sample is of the population. The lack of diversity in the sample means that more diverse narratives are lacking. Participants were recruited via an email mailing list, and self-selected into the study. 3.2) Participants were provided with an unvalidated 30-item questionnaire devised by study authors. A sample of this questionnaire was not provided, and it is unclear whether questions collected quantitative data or whether they asked for some qualitative feedback. 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) Only 29.6% of contacted attendees completed the questionnaire, leaving the study with a small sample size.	
6) Sicherer et al. (2012)	Single-group pre-test post-test design (Quantitative non-randomised)	A) YES. The authors aimed to develop and evaluate a food allergy education programme. Their primary measure was correct administration of an auto-injector. Secondary outcomes were comfort with auto-injector administration and a reduction in allergic reactions. B) YES. The authors considered the necessary numbers of participants for the study, and accounted for predicted attrition. They completed follow-up 1 year later, and found that improvements had been maintained. 3.1) The study used a convenience sample of parents presenting at an allergy clinic. Although the sample was primarily Caucasian (81%), minority groups were better represented than other studies in the area with 17% African American's, 2% Asian, 3% Hispanic. The	*

		sample also consisted of mostly well-educated individuals from middle class backgrounds. 3.2) Recorded outcomes for food-allergy knowledge, demographic information, auto-injector competency and comfort were appropriate to answer the question posed by researchers. However, outcomes were gathered using (unvalidated) measures devised by the authors, and thus difficult to replicate. It is unclear how valid or reliable these measures were. As there was no control group, it is not possible to make causal claims about the efficacy of the study's intervention. 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) All 60 participants completed measures at Time 1 and Time 2. 33 (55%) of these participants were retained at the 1 year follow up. (*)	
7) Knibb & Semper (2013)	Single-group pre-test post-test observational design (Quantitative non-randomised)	A) YES. Authors aimed to evaluate parental anxiety and depression in parents before and after a visit to an allergy clinic in order to ascertain whether the provision of a diagnosis influenced parental wellbeing. B) YES/MAYBE. Data were appropriate to answer the question posed, however there was a short follow up period, and problems with the study design mean that it authors cannot determine whether any changes or lack of changes are associated with the visit to the clinic. 3.1) The study used a convenience sample- parents attending an allergy clinic were approached in the waiting room and given information about the study. The sample consisted of mainly white British (77.6%) mothers (80%). Authors did not attempt to minimise selection bias. 3.2) Authors gathered information about allergy knowledge and management behaviours using a self-devised questionnaire, but an established and validated measure (Hospital Anxiety and Depression Scale [HADS]) was used to measure levels of anxiety and depression. The authors compared their responses to norm data from a clinical sample of parents of children with a chronic illness. (*) 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) Sample consisted of 124 individuals at pre-test and post-test, and 50 individuals (40%) responded at follow up, 6 weeks later. This follow up period may have been too short for any effect to be noticed.	*

8) Rosen et al. (2014)	Single-group pre-test post-test design (Quantitative descriptive study)	A) YES. The study aimed to create, validate and evaluate web-based audio-visual educational materials for parents of food-allergic children. B) YES. Data were suitable to answer the question posed by researchers, but problems with the study design limit the conclusions that can be drawn from the study. 4.1) A convenience sample (n=50) was recruited from a hospital-based allergy clinic in NY, USA. The authors did not take action to reduce sampling bias, however they ensured that the sample validating their educational materials had not been involved in the development of the content. 4.2) Although the sample was predominantly White (66%), some ethnic and racial diversity was represented with 12% of the sample identifying as Black, 12% as Asian and 8% as other. 94% of the sample had college/university degrees, and 82% reported a household income above $80,000 per year. 4.3) The authors sought to validate their educational materials using pre and post knowledge tests, and ascertain satisfaction with the materials using a likert-scale based questionnaires devised by the authors. These measures were based on needs assessments and consultation with allergy experts. These measures were appropriate. (*) 4.4) The 50 participants were recruited in order to adequately power the study. All participants completed the measures before and after viewing educational materials. The study would have benefitted from a follow up to ascertain whether knowledge improvements were maintained. (*)	**
9) Knibb (2015)	Non-randomised case control study (Quantitative non-randomised)	A) YES. The study had a clear aim to examine the appropriateness and effectiveness of CBT to improve psychological outcomes in parents of food-allergic children. B) YES. The collected data are appropriate to address the question posed by researchers. 3.1) All participants were recruited from a local allergy clinic (Midlands, UK). All participants were included under the constraints of the same exclusion and inclusion criteria. However, the sample was small, and not representative of the local population; all participants were white women. 3.2) All outcomes were measured using established and validated measures of depression, anxiety, stress, parental burden and quality of life. These measures were appropriate to answer the question posed by the researchers. However, for ethical reasons participants self-selected into the experimental or control group. Although the control group participants opted in to	***

		the control group because they were not interested in CBT (and those currently accessing psychological support were excluded), it is possible that these could have sought support during the course of the study. However, there was no indication that individuals could have been exposed to the treatment(*) 3.3) Authors considered differences across groups, and reported descriptives. No obvious differences existed between groups, except for in numbers of egg and tree nut allergy. They were unable to check for statistical differences between groups due to small sample size. (*) 3.4) No participants withdrew from the study, but 2 (18%) participants were lost to follow-up. (*)	
10) Polloni et al . (2015)	Single-group post-test design (Quantitative descriptive studies)	A) YES. Authors aimed to investigate psychological treatments offered to food-allergic children and their families. B) YES. The collected data addresses the question raised by researchers. 4.1) Participants were selected by convenience- the first 100 consecutive treatments held at an allergy research centre in Italy were chosen. This service is dedicated to providing support for families and patients to alleviate the psycho-social burden of food allergy. Data were collected from hospital records. (*) 4.2) Demographic details of the sample were not reported, so it is not possible to determine whether the sample was representative. The study did not describe inclusion or exclusion criteria as sample was drawn from the group of interest. 4.3) Effectiveness of treatments were measured using a 2-question adaptation of the follow up questions to the strengths and difficulties questionnaire. It is unclear whether any other outcome measures were used, and authors did not identify or make comparisons between treatment types. 4.4) Not applicable as the study drew from pre-reported data.	
11) Wahl et al. (2015)	Single-group post-test design (Quantitative descriptive study)	A) YES. Study aims were clear: to develop and evaluate the effectiveness of educational workshops in improving QoL and self-efficacy in food-allergic children and their caregivers. B) YES/MAYBE. Participants completed appropriate measures at three time points following their attendance at a workshop. These were appropriate in answering the questions posed by the researchers. 3.1) Authors did not select participants based on explicit criteria. Details of the workshops were mailed to school nurses, administrators and child-care centres	

		in the Greater Seattle area. Researchers conducted 247 presentations, with a total of 4818 attendees. No inclusion or exclusion criteria was noted, and all interested caregivers were invited to attend. Demographic data was not reported, so ethic/racial diversity and average income is unknown. Primary attendees were teachers. 3.2) All outcomes were measured using self-report questionnaires about reported confidence in use of workshop content (e.g. administering auto-injectors, recognising symptoms), and no validated or objective measure of increased knowledge (e.g. knowledge test) was administered, although some questions aiming to measure knowledge retention and a request for participants to identify "three key messages" was asked at the secondary online survey. It is unclear what questions were asked. Furthermore, authors adjusted a question "whether they were likely to change the way they managed children with food allergies" so that earlier forms of the questionnaire had additional options that were later removed for participants in order to simplify the survey. 3.3) The authors did not use a control or comparison group. Additionally, the lack of pre-intervention measures further impacts the ability to draw conclusions about the effectiveness of the study and make any causal claims. 3.4) The study started with a sample size of 4818 attendees. Although 1586 (33%) individuals consented to being contacted for the second questionnaire, only 332 (21%) of individuals completed this measure. 94 (29%) of respondents at time 2 indicated that they had been involved in a food allergy incident and 53 of these individuals completed a phone interview (time 3).	
12) Contreras-Porta et al. (2016)	Single-group pre-test post-test design (Quantitative descriptive study)	A) YES. The authors aimed to develop and evaluate an educational programme for families of food-allergic children. B) YES. The data collected are appropriate to answer the question posed by the researchers. 3.1) Authors recruited participants from 7 different urban locations in Spain, via social media networks (opportunistic sampling). Individuals were recruited through "patient association" networks, where members would have already had information about appropriate allergy management. The majority of the sample were mothers (56%, with 36% fathers and 4.9% caregivers. Details around income or ethnic/racial diversity was reported. It is unclear how representative the sample is.	**

		3.2) Authors identified a lack of validated measures pre-existing in the literature. They created an ad-hoc questionnaire based on bibliographic review and expert opinion. The questionnaire consisted of 40 items, and all items were explicitly addressed in the intervention/educational programme. (*) 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) The study retained 174/184 (94%) across both workshops. (*)	
13) Danchin et al. (2016)	Single-group pre-test post-test design (Quantitative descriptive study)	A) YES. Authors aimed to develop a training programme for community-based general paediatricians to increase acceptable support for families waiting for specialist input. B) YES. Collected data are appropriate to address the question posed by researchers. 3.1) Paediatricians were recruited from a paediatric research network, and had expressed an interest in allergy research (with no prior experience in management). They were all experienced clinicians with an 18.2 years of experience since qualification. Family participants were recruited from the hospital's pre-existing waiting list. Individuals were excluded children over the age of 7, those with multiple (>3 allergies) and diagnosed anaphylaxis and previous specialist input. As the study used an opportunistic sampling method, they were unable to minimise sampling bias. Some demographic characteristics were recorded, but no information on ethnic or racial diversity was reported. 3.2) Paediatrician participants completed a pretraining survey at baseline and 3 months post training, and allergy knowledge was assessed with an established research survey. Families also completed measures at baseline and follow up, and outcomes were measured using validated anxiety and depression questionnaires. Authors also calculated socio-economic status using an index calculator. (*) 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) All families completed baseline measures, and 82% returned the follow up survey. All clinicians returned both measures.	*
14) Boyle et al. (2017)	Randomised Control Trial (Quantitative randomised control trial)	A) YES. Authors reported the results from a prospective RCT for a brief CBT intervention in mothers of food-allergic children aiming to reduce state anxiety. B) YES. Collected data is appropriate to answer the questions posed by researchers.	****

		2.1) Yes, authors identify that randomisation occurred in computer generated blocks of 4, stratified by maternal state. Randomisation was completed by an independent statistician. (*) 2.2) Researchers were unable to blind clinicians, participants or outcome assessors. They attempted to increase validity of the self-reported outcome data by also collected an objective measure of stress (salivary samples). (*) 2.3) 83% of participants contributed to all of the measures at one year (165/200) (*) 2.4) Drop-out was low, reported at 17% at one year. (*)	
15) Ruiz-Baques, et al. (2018)	Single-group pre-test post-test design (Quantitative descriptive study)	A) Authors aimed to develop an educational programme aimed at parents of food-allergic children and evaluate the effectiveness of said programme. B) Data were appropriate to address the question posed by the researchers. 3.1) Authors did not report the applied inclusion and exclusion criteria for the study, and recruited participants by encouraging them to pre-register to take part in the educational programme and complete pre-test questionnaires. The sample was 75% mothers, 15% fathers and 10% caregivers and all were recruited from Spain. Authors did not report any other demographic characteristics of participants, so it is unclear how representative the sample is. 3.2) Educational materials were developed with the support of researchers and allergy specialists. The authors on the lack of specific validated measures, so assessed outcomes using an ad-hoc questionnaire based on a literature review and of the opinions of allergy specialists. The 40 item questionnaire was designed to evaluate food allergy knowledge and assess the impact of the online programme. (*) 3.3) The study did not include a control or comparison group, greatly limiting authors' ability to make any claims of causality. 3.4) 130/207 individuals completed the educational intervention and completed measures pre- and post-test (63%). (*)	**

Supplementary file 3: Completed Cochrane Risk of Bias Tool for Randomised Control Trials[18]

Study details

Reference	Boyle, R. J., Umasunthar, T., Smith, J. G., Hanna, H., Procktor, A., Phillips, K., ... & Vickers, B. (2017). A brief psychological intervention for mothers of children with food allergy can change risk perception and reduce anxiety: Outcomes of a randomized controlled trial. *Clinical & Experimental Allergy*, *47*(10), 1309-1317. **https://doi.org/10.1111/cea.12981**

Study design

- ☒ Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias	Maternal Anxiety, stress, quality of life and risk perception
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table 2

Is the review team's aim for this result…?

- ☒ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☒ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☒ Journal article(s) with results of the trial

☐	Trial protocol
☐	Statistical analysis plan (SAP)
☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

614

615**Domain 1: Risk of bias arising from the randomization process**

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	Yes, allocation sequence was random. Authors identify that randomisation occurred in computer generated blocks of 4, stratified by maternal state trait anxiety. Randomisation was completed by an independent statistician.	Y
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		Y
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Groups were similar at baseline.	N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias arising from the randomization process?		

616

617Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	It was not possible to blind participants, clinicians or outcome assessors to treatment allocation.	Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?		N
2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?		NA
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Appropriate statistical analyses were used.	Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA

Risk-of-bias judgement	Some risk of bias exists, as authors were not able to blind participants or clinicians to treatment groups. However, the study attempted to increase validity of the results by collecting complementary objective measures of anxiety (salivary samples).	Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		

618

619 Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	It was not possible to blind participants, clinicians or outcome assessors to treatment allocation.	Y
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were important co-interventions balanced across intervention groups?		NA
2.4. Could failures in implementing the intervention have affected the outcome?	Implementation of the intervention was successful for most of the participants.	N
2.5. Did study participants adhere to the assigned intervention regimen?		PY
2.6. If N/PN/NI to 2.3 or 2.5 or Y/ PY/NI to 2.4: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

620

621Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		Y
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		NA
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	Authors identify reasons for missing data	PN
3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?	N=80 in experimental group, 9 lost to follow up, 3 withdrew (bereavement, time pressure) N=85 in control group, 4 lost to follow up, 1 withdrew	PN
3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to missing outcome data?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

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624 Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?		N
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?		PN
4.3 <u>If N/PN/NI to 4.1 and 4.2</u>: Were outcome assessors aware of the intervention received by study participants ?		Y
4.4 <u>If Y/PY/NI to 4.3</u>: Could assessment of the outcome have been influenced by knowledge of intervention received?	Although additional objective measures were also collected (salivary responses) for the primary outcome (anxiety).	PY
4.5 <u>If Y/PY/NI to 4.4</u>: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		PN
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

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627 Domain 5: Risk of bias in selection of the reported result

Signalling questions **5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?**	**Description**	**Response options** NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		N
5.3 ... multiple analyses of the data?		N
Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to selection of the reported result?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

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Overall risk of bias

Risk-of-bias judgement	The study suffers from some methodological concerns which may have resulted in biased results- namely the inability to blind participants, experimenters and outcome assessors. Additionally, outcome measures are primarily self-report measures, and an additional source for data (saliva) was only sought for one of the outcome measures. However, authors have attempted to reduce bias where possible, and have reported processes appropriately.	Low/Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

Study details

Reference	Baptist, A. P., Dever, S. I., Greenhawt, M. J., Polmear-Swendris, N., McMorris, M. S., & Clark, N. M. (2012). A self-regulation intervention can improve quality of life for families with food allergy. Journal of Allergy and Clinical Immunology, 130(1), 263-265. DOI: https://doi.org/10.1016/j.jaci.2012.03.029

Study design

- ☒ Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

Specify which outcome is being assessed for risk of bias	Food allergy quality of life, self-efficacy
Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.	Table E5-E6

Is the review team's aim for this result…?

- ☒ to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- ☒ to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

Which of the following sources were <u>obtained</u> to help inform the risk-of-bias assessment? (tick as many as apply)

- ☒ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)

☐	Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
☐	Company-owned trial registry record (e.g. GSK Clinical Study Register record)
☐	“Grey literature” (e.g. unpublished thesis)
☐	Conference abstract(s) about the trial
☐	Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
☐	Research ethics application
☐	Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
☐	Personal communication with trialist
☐	Personal communication with the sponsor

649**Domain 1: Risk of bias arising from the randomization process**

Signalling questions	Description	Response options
1.1 Was the allocation sequence random?	No information about the randomisation process was reported.	PY
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Some differences are observed related to ethnicity however this is not commented on.	PY
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

650

651 Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?	Authors indicate that the study is blind, but provides no further details. It would not have been possible to blind intervention facilitators to the control vs treatment.	PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?		PN
2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?		NA
2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?		NA
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		Y
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA

Risk-of-bias judgement		Low
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

652

653 Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Description	Response options
2.1. Were participants aware of their assigned intervention during the trial?		PN
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y
2.3. If Y/PY/NI to 2.1 or 2.2: Were important co-interventions balanced across intervention groups?		NA
2.4. Could failures in implementing the intervention have affected the outcome?		PN
2.5. Did study participants adhere to the assigned intervention regimen?	Authors do not report on adherence	NI
2.6. If N/PN/NI to 2.3 or 2.5 or Y/ PY/NI to 2.4: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NI
Risk-of-bias judgement		Low /Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

654

655Domain 3: Missing outcome data

Signalling questions	Description	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		NI
3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data?		N
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?		NI
3.4 If Y/PY/NI to 3.3: Do the proportions of missing outcome data differ between intervention groups?		NI
3.5 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?		NI
Risk-of-bias judgement	As authors did not report on missing data it is difficult to ascertain risk of bias in this domain.	Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

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658 Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Description	Response options
4.1 Was the method of measuring the outcome inappropriate?	However one of the measures (self-efficacy) was measured using an unvalidated questionnaire devised by authors.	PY
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups ?		PN
4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants ?	Outcomes were self-report.	Y
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		PN
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA
Risk-of-bias judgement		Low /Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

659

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661 Domain 5: Risk of bias in selection of the reported result

Signalling questions	Description	Response options
5.1 Was the trial analysed in accordance with a pre-specified plan that was finalized before unblinded outcome data were available for analysis ?		NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		NI
5.3 ... multiple analyses of the data?		NI
Risk-of-bias judgement		Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

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663

664Overall risk of bias

Risk-of-bias judgement	The study has some methodological issues, and often fails to report processes which decreases the confidence in reported results.	Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

665Y=Yes; N=No; PY=Probably yes; PY=Probably no; NI=No information
666
667

668Not for review: PRISMA checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5-6, supp file 1
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	5
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6, supp file 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6, table 1
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6, table 1
Risk of bias in individual	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was	6, supp file

studies		done at the study or outcome level), and how this information is to be used in any data synthesis.	2 and 3
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	6, table 1
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6

669 **1.**
670 **2.** Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	6, supp file 3
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	7, figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6, table 1
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	7, supp files 2 and 3
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	7-10, table 1
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	7, supp files 2 and 3
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	10-11
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of	11-12

		identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	1

671

672*From:* Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): 673e1000097. doi:10.1371/journal.pmed1000097 For more information, visit: **www.prisma-statement.org**.