

Evaluating an online self-help intervention for parents of children with food allergies

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Abstract

Background: Parents of children with food allergies (CwFA) experience reduced quality of life (QoL) and may have reduced access to in-person interventions in the COVID-19 pandemic. This trial developed and evaluated an online, self-help, information provision website, aimed at improving QoL in parents of CwFA.

Methods: In a single-blinded, randomised controlled trial (RCT), participants were randomised to either receive access to the website or a waiting-list control. At baseline, post-intervention (week 4) and follow-up (week 8), measures of parental food allergy-related QoL, depression, anxiety, stress, intolerance of uncertainty (IU) and self-efficacy were obtained.

Results: A total of 205 participants were randomised; 97% were females, 91% white and 78% educated \geq degree level, with a mean age of 38.95 years (SD = 6.89). 44.9% ($n = 92$) were retained at follow-up. The arms did not significantly differ on any outcome at any time point. For a sub-group of participants above the clinical cut-off for depression at baseline, the intervention may have improved QoL. Participants reported the website content as useful and accessible, but accessed it infrequently. In baseline data, IU and self-efficacy were significantly associated with QoL.

Conclusion: While the COVID-19 pandemic has encouraged greater provision of online interventions, our RCT suggests this particular website is not suitable for this population in general, although future research could examine its efficacy for depressed parents of CwFA, to increase confidence that the sub-group finding was not a Type 1 error. The baseline data suggest IU and self-efficacy remain potential proximal targets for intervention.

KEYWORDS

food allergy, intervention, online, parents, quality of life, self-help, website

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1 | INTRODUCTION

Caring for a child with a food allergy (CwFA) can have a significant, detrimental impact on the carer's mental health and quality of life (QoL).^{1,2} While food allergy-related fatalities are relatively uncommon when anaphylaxis is managed successfully,³ the difficulty in predicting who will experience anaphylaxis, combined with its potentially fatal consequences, can lead to high levels of parental uncertainty and anxiety.⁴ However, there is little research examining whether supporting parents to tolerate the uncertainty around this low-chance, but high-consequence, outcome might lead to improvements in parental anxiety and QoL.

Increasing parental self-efficacy (i.e. parent's 'confidence and belief in [their] ability to carry out certain actions and manage situations')⁵ with respect to their child's food allergy offers another potential means of improving their QoL and reducing anxiety.^{4,5} In principle, self-efficacy can be increased by the provision of credible, understandable information.⁶ However, thus far, research evaluating the effectiveness of information provision interventions on parental self-efficacy, anxiety and QoL, in relation to CwFA, is either absent or of poor quality.^{7,8} Indeed, there is only limited evidence of efficacy for any form of psychosocial intervention addressing the QoL of parents of CwFA and, thus far, study quality has been largely suboptimal.⁷

Therefore, there is a need to develop more efficacious interventions for parents of CwFA and for more robust evaluations of these, with credible, proximal intervention targets being parents' ability to tolerate uncertainty and their self-efficacy with respect to food allergy. In order to maximise the accessibility and minimise the cost of such interventions, examining the efficacy of their delivery via an online, self-help format is also timely,⁹ especially in the light of the evidence from other fields that suggests this can be an effective medium¹⁰ and in the light of the COVID-19 pandemic where remote support is advised for allergic conditions and immune deficiencies.¹¹ The current study developed and evaluated the efficacy of an online, self-help intervention aimed at improving the food allergy-related QoL of parents with CwFA. The intervention targeted IU and allergy-related self-efficacy. The study also examined variables associated with QoL in the baseline data.

2 | METHOD

2.1 | Design

This single-blind, parallel arm randomised controlled trial (RCT) was waitlist controlled, with measures collected via an online survey at baseline (week 0), post-intervention (week 4) and follow-up (week 8). The wait-list arm was subsequently granted access to the intervention, and feedback on the intervention was sought from both arms at 12 weeks. Ethical approval was granted by a university ethics committee, and the trial was pre-registered on *clinicaltrials.gov* (NCT03529747).

Key Message

An online, self-help, information provision website, aimed at improving quality of life in parents and carers of children with food allergies, was ineffective. Future interventions of this sort might benefit from greater tailoring to the needs of the particular parents who are accessing them.

2.2 | Participants

Recruitment occurred online via social media connected with voluntary organisations such as *Allergy UK*, the *Anaphylaxis Campaign*, and *Food Allergy Research and Education*. Participants had to be a parent or caregiver of a child under the age of 18 with a parent-reported food allergy diagnosis, have access to the Internet and be comfortable reading English. All participants provided informed consent.

2.3 | Randomisation

Randomisation was conducted automatically by Qualtrics software with an equal probability of allocation to each arm. Randomisation was not blocked, as the software did not have this functionality at the time the study was run, resulting in unequal group sizes. The researchers could not tell in advance which participants would be allocated to which arm.

2.4 | Measures

The measures, which were collected entirely online using Qualtrics software, without involvement of the research team, were as follows:

2.4.1 | Primary outcome

The primary outcome was food allergy-related QoL measured using the Food Allergy Quality of Life-Parental Burden scale (FAQoL-PB).¹² This 17-item, self-report questionnaire employs a 7-point Likert response scale ranging from one (not troubled) to seven (extremely troubled). The items cover the impact of food allergy on parents' emotions and coping abilities, time, activities and general health.¹³ Total scores range between 17 and 119.

2.4.2 | Secondary outcomes

Symptoms of generalised anxiety disorder were assessed using the 7-item generalised anxiety disorder screener (GAD-7),¹⁴ which produces a total score ranging between 0 and 21. Symptoms of depression were measured by the 8-item Patient Health Questionnaire

(PHQ-8),¹⁵ which produces a total score between 0 and 24. Both the GAD-7 and PHQ-8 use a 4-point Likert response scale, where respondents report the frequency of each symptom over the past 2 weeks, ranging from zero ('not at all') to three ('nearly every day'). Finally, the 10-item version of the Perceived Stress Scale (PSS)¹⁶ was employed to assess participants' levels of perceived stress over the past month. It uses a 5-point Likert response scale, which ranges from 0 ('Never') to 4 ('Very Often') and produces a total score in the range 0 to 40. On all outcomes, higher scores indicated greater impairment.

2.4.3 | Mediators

IU was assessed using the 27-item Intolerance of Uncertainty Scale (IUS).¹⁷ This measures negative beliefs about uncertainty and its perceived consequences, and employs a 5-point Likert response scale, where answers range from one ('Not at all characteristic of me') to five ('Entirely characteristic of me'). Total scores range between 27 and 135, with higher scores indicating higher levels of IU. The other proposed mediator was food allergy self-efficacy, as measured by the 21-item Food Allergy Self-Efficacy Scale for Parents (FASE-P).⁵ This assesses parents' confidence in managing their child's food allergy, with each item rated on a response scale from 0 ('Cannot do at all') to 100 ('Highly certain can do'). The overall mean score ranges between 0 and 100, with lower scores indicating lower self-efficacy.

2.4.4 | Engagement and feedback

Website access data were recorded by Google Analytics, and participant feedback on the intervention was collected by a bespoke, 13-item questionnaire. This comprised a mix of Likert type items (e.g. how much do you agree or disagree with the statement 'web-based support for carers/parents is useful?') and open-ended questions (e.g. 'what aspect(s) of the website did you find the most useful?').

2.5 | Intervention

The intervention comprised a self-help website developed in consultation with existing literature,^{3,8} a medical paediatric allergy specialist (the third author) and focus groups with parents of CwFA. It was intended to (i) increase parents' self-efficacy in relation to caring for a CwFA, through the provision of information about food allergies and their management, and (ii) strengthen parents' ability to tolerate the uncertainty associated with having a CwFA, by providing guidance on ways of managing uncertainty, and associated worry and anxiety, grounded in cognitive-behavioural therapy (CBT) techniques (Table 1). Participants could access the website on any device capable of Web-browsing, at any time. After they had been provided with access, they did not receive prompts.

TABLE 1 Website content summary by page. Further details of the intervention have been published elsewhere²⁵

Website page	Title	Information summary
1	What is an allergy?	A simple definition of an allergy and guidance on how to recognise symptoms of an allergic reaction
2	Food allergy vs. food intolerance	The difference between allergies and intolerances, and how to identify allergens in foods (via label checking)
3	Anaphylaxis	A definition of anaphylaxis, information about how to recognise symptoms and steps to take in the case of an anaphylactic reaction
4	Auto-injectors	Guidelines on correct administration of automatic adrenaline injectors (AAI) that distinguish between instructions from the three main AAI providers (Emerade, Epipen and Jext). Viewers are linked to training videos on the provider websites. This page also has a video recorded by an allergy specialist outlining correct administration
5	Managing anxiety	A simple cognitive-behavioural formulation for stress and worry is presented ('hot cross bun' cycle)
6	The worry diagram	A 'worry tree' is outlined, using allergy-specific worries suggested by parents in the focus group
7	Psychological resources	Signposting to support services (including psychological therapy services) and online self-help information sites. Sources of further allergy information are also included
8–11	Frequently asked questions (FAQs)	FAQs that are based on questions raised by focus group members and commonly reported uncertainties identified in the literature
12	Myth busting	This challenges common myths and misconceptions around food allergy and management plans
13	Top tips for parents of food-allergic children	Tips provided by the focus group, aiming to normalise anxiety and stress related to caring for a CwFA
Additional	Allergy Profile	A completable, individualised allergy profile that can be downloaded, so that caregivers can be aware of symptoms specific to the child they are caring for and also have a convenient means of providing a summary of this to others

Abbreviation: CwFA, child/children with food allergies.

2.6 | Data analysis

An intention-to-treat analysis using SPSS version 24 was employed and, due to deviations from normality, between-group differences in change scores were examined using non-parametric, Mann-Whitney *U* tests. Effect sizes were calculated using Rosenthal's *r* statistic.¹⁸ Associations with quality of life in the baseline data were examined using correlations and multiple regression.

3 | RESULTS

3.1 | Participants and participant flow

The 205 participants who were randomised were largely female (97%), university-educated (78%), identified as white (91.2%), and from the United Kingdom (81%). Regarding their CwFA, their mean age was 8 years old, 41.5% were females, 76% were reported to

TABLE 2 Demographic characteristics of RCT participants

	Both conditions N = 205 Mean (SD)	Intervention group N = 112 Mean (SD)	Control group N = 93 Mean (SD)
Age (years)	38.95 (6.89)	38.96 (6.7)	38.94 (7.14)
	N (%)	N (%)	N (%)
Gender			
Female	199 (97.1%)	109 (97.3%)	90 (96.8%)
Country			
United Kingdom	166 (81.0%)	88 (78.6%)	78 (83.9%)
United States	21 (10.2%)	15 (13.4%)	6 (6.5%)
Europe—other	11 (5.4%)	5 (4.5%)	6 (6.5%)
Other	7 (3.4%)	4 (3.6%)	3 (3.2%)
Ethnicity			
White	187 (91.2%)	102 (91.1%)	85 (91.4%)
Asian	7 (3.4%)	3 (2.7%)	4 (4.3%)
Mixed race	7 (3.4%)	4 (3.6%)	3 (3.2%)
Black	3 (1.5%)	3 (2.7%)	0 (0%)
Missing	1 (0.5%)	0 (0%)	1 (1.1%)
Employment status			
Part-time	73 (35.6%)	35 (31.3%)	38 (40.9%)
Full-time	70 (34.1%)	36 (32.1%)	34 (36.6%)
Homemaker/carer	46 (22.4%)	29 (25.9%)	17 (18.3%)
Self-employed	15 (7.3%)	11 (9.8%)	4 (4.3%)
Unemployed	1 (0.5%)	1 (0.9%)	0 (0%)
Education			
Undergraduate degree	86 (42.0%)	42 (37.5%)	44 (47.3%)
Postgraduate degree	74 (36.1%)	43 (38.4%)	31 (33.3%)
No degree	45 (22.0%)	27 (24.1%)	18 (19.4%)
Current health			
No difficulties	151 (73.7%)	79 (70.5%)	72 (77.4%)
Anxiety	23 (11.2%)	13 (11.6%)	10 (10.8%)
Physical health diagnosis	10 (4.9%)	5 (4.5%)	5 (5.4%)
Complex mental health	5 (2.4%)	5 (4.5%)	0 (0%)
Depression	5 (2.4%)	3 (2.7%)	2 (2.2%)
Missing	11 (5.4%)	7 (6.3%)	4 (4.3%)
Previous psychological support			
No	119 (58.0%)	63 (56.3%)	56 (60.2%)
Yes	78 (38.0%)	45 (40.2%)	33 (35.5%)
Missing	8 (3.9%)	4 (3.6%)	4 (4.3%)

Abbreviation: RCT, randomised controlled trial.

have multiple allergies, and they were diagnosed with an allergy on average at 1.7 years old (Tables 2 and 3). The two arms' scores on the outcome measures at baseline did not significantly differ (all $ps > .05$) (Table 4).

There was substantial participant attrition: of the 205 participants, 103 completed measures at post-intervention (Week 4), and 92 participated at follow-up (Week 8) (Figure 1). However, there were no significant differences in baseline measures and characteristics between those participants who completed post-intervention measures and those who withdrew, and the same applied regarding attrition at follow-up (all $ps > .05$). An analysis using G*Power 3.1 revealed that the achieved sample size for the intention-to-treat

analysis at the post-intervention time point was sufficient to detect a medium effect size ($d = 0.57$) when the power was set to the conventional level of 0.8.

3.2 | Intervention effects

For the primary outcome of parental QoL, baseline to post-intervention change scores did not significantly differ between the intervention and control groups (FAQoL-PB: $U = 1223.500$, $Z = -0.613$, $p = .54$, $r = -.06$). The same was the case for baseline to follow-up change scores (FAQoL-PB: $U = 1040.500$, $Z = -0.102$,

TABLE 3 Demographic characteristics of food-allergic children. In cases where there were missing data, separate sample sizes have been provided. If parents had more than one food-allergic child, data are included for their oldest child

	Both conditions N = 205	Intervention group n = 112	Control group n = 93
	Mean (SD)	Mean (SD)	Mean (SD)
Child age (years)	8.08 (4.74), N = 108	7.36 (4.87), n = 52	8.75 (4.55), n = 56
Age at diagnosis (years)	1.7 (2.15)	1.6 (2.08)	1.8 (2.23)
	N (%)	N (%)	N (%)
Gender			
Female	85 (41.5%)	49 (43.8%)	36 (38.7%)
Multiple allergies	156 (76.1%)	93 (83.0%)	63 (67.7%)
Allergen			
Peanut	134 (65.4%)	81 (72.3%)	53 (57.0%)
Tree nut	122 (59.5%)	75 (67.0%)	47 (50.5%)
Milk	86 (42.0%)	50 (44.6%)	36 (38.7%)
Egg	94 (45.9%)	55 (49.1%)	39 (41.9%)
Sesame	40 (19.5%)	25 (22.3%)	15 (16.1%)
Soya	30 (14.6%)	20 (17.9%)	10 (10.8%)
Wheat	20 (9.8%)	13 (11.6%)	7 (7.5%)
Fish	19 (9.3%)	12 (10.7%)	7 (7.5%)
Shellfish	8 (3.9%)	6 (5.4%)	2 (2.2%)
Comorbid diagnoses			
Asthma	110 (53.7%)	61 (54.5%)	49 (52.7%)
Eczema	138 (67.3%)	78 (69.6%)	60 (64.5%)
Hay fever	86 (42.0%)	49 (43.8%)	37 (39.8%)
Medication			
Antihistamines	193 (94.1%)	108 (96.4%)	85 (91.4%)
Auto-injector (AAI)	181 (88.3%)	99 (88.4%)	82 (88.2%)
Anaphylaxis			
AAI Training	153 (74.6%)	85 (75.9%)	68 (73.1%)
Administered AAI	49 (23.9%)	30 (26.8%)	19 (20.4%)
Administered AAI from carer	23 (11.2%)	13 (11.6%)	10 (10.8%)
Child attended hospital for reaction	126 (61.5%)	70 (62.5%)	56 (60.2%)
Anaphylactic reaction	105 (51.2%)	59 (52.7%)	46 (49.5%)
Management plan	172 (83.9%)	92 (82.1%)	80 (86.0%)

$p = .919$, $r = -.01$). Similarly, baseline to post-intervention change scores did not differ significantly between arms on any of the secondary measures (PHQ-8: $U = 1285.500$, $Z = -0.204$, $p = .838$, $r = -0.02$; GAD-7: $U = 1303.000$, $Z = -0.087$, $p = .931$, $r = -.01$; PSS: $U = 1310.500$, $Z = -0.037$, $p = .971$, $r = .00$). Nor did the groups significantly differ on the secondary measures' baseline to follow-up change scores (PHQ-8: $U = 807.500$, $Z = -1.940$, $p = .052$, $r = -.20$; GAD-7: $U = 929.000$, $Z = -0.983$, $p = .326$, $r = -.10$; PSS: $U = 933.500$, $Z = -0.942$, $p = .346$, $r = -.10$) (Table 4).

3.3 | Mediators

Given that there were no significant intervention effects, mediation analysis was not justified. Furthermore, baseline to post-intervention change scores did not significantly differ between arms for either of the purported mediators (IUS: $U = 1282.000$, $Z = -0.040$, $p = .968$, $r = .00$; FASE-P: $U = 1121.000$, $Z = 1.454$, $p = .146$, $r = -.14$), and the same was true for their baseline to follow-up change scores (IUS: $U = 811.500$, $Z = -1.733$, $p = .083$, $r = -.18$; FASE-P: $U = 969.500$, $Z = -0.657$, $p = .511$, $r = -.07$).

3.4 | Sub-group analyses

Given the absence of overall intervention effects and the possibility that the intervention may have been effective only for participants experiencing greater difficulties at baseline, *post hoc* exploratory analyses were conducted. For baseline depression and anxiety, sub-groups of participants in the clinical range were constructed using validated cut-offs.^{15,19} For QoL and perceived stress, as such cut-offs do not exist, the median was employed. Sub-groups were also constructed for CwFAs, and for those who had received a diagnosis within the last three years. For participants who were above the threshold for clinical depression at baseline, the intervention did have a significant, beneficial effect on the primary outcome (Table 5). Amongst this sub-group, the intervention participants saw an improvement in mean FAQoL-PB score from 96.7 (SD = 12.6) to 83.2 (SD = 23.3), in comparison with the control group where the mean FAQoL-PB score barely altered (pre-mean = 96.5; SD = 11.9; post-mean = 96.3; SD = 7.2). However, this analysis was not pre-specified, and when the Bonferroni correction for multiple comparisons was applied, significance was not sustained.

3.5 | Engagement and adherence

Google Analytics recorded 108 hits on the website, with an average duration of 2.65 min (SD = 5.85; minimum 0.00; maximum 28.10 min). Thirty-five participants completed the feedback questionnaire. Broadly, respondents commented that the

TABLE 4 Descriptive statistics for intention-to-treat analysis at each time point

	Baseline (week 0)			Post-intervention (week 4)			Follow-up (week 8)					
	Treatment (n = 112)			Control (n = 93)			Treatment (n = 43)			Control (n = 49)		
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
FAQoL-PB (/119)	84.16 (19.06)	86.00 (26.75)	85.44 (19.34)	90.00 (30.00)	78.32 (19.11)	79.00 (30.00)	80.55 (20.30)	82.00 (29.75)	72.77 (21.21)	72.00 (37.00)	79.39 (18.89)	83.00 (27.50)
PHQ-8 (/24)	4.96 (4.93)	4.00 (6.00)	4.44 (4.15)	4.00 (6.00)	5.45 (5.20)	3.00 (7.00)	5.34 (4.86)	4.00 (7.50)	4.74 (4.76)	4.00 (7.00)	6.29 (5.52)	5.00 (6.00)
GAD-7 (/21)	5.70 (4.93)	5.00 (6.00)	6.02 (5.43)	5.00 (8.50)	5.55 (5.52)	4.00 (7.00)	6.43 (5.83)	5.00 (7.00)	4.40 (4.69)	4.00 (7.00)	7.35 (6.16)	6.00 (9.50)
PSS (/40)	17.50 (7.25)	17.50 (8.50)	17.17 (6.62)	18.00 (8.50)	16.87 (8.02)	16.00 (10.00)	17.48 (7.24)	18.50 (9.50)	15.77 (7.68)	16.00 (9.00)	18.22 (7.70)	20.00 (11.50)
FASE-P (/100)	71.48 (13.98)	72.38 (20.81)	72.26 (13.55)	73.24 (19.93)	71.42 (13.70)	72.33 (21.73)	70.86 (13.27)	69.52 (20.23)	72.42 (17.42)	75.05 (27.67)	72.61 (12.61)	71.14 (21.93)
IUS (/135)	63.05 (22.07)	61.00 (24.75)	65.03 (21.54)	63.00 (33.50)	62.65 (23.10)	58.00 (36.50)	67.29 (22.88)	68.00 (37.50)	63.29 (24.37)	60.50 (42.75)	67.29 (23.60)	67.00 (39.00)

Abbreviations: FAQoL-PB, Food Allergy Quality of Life - Parental Burden scale; FASE-P, Food Allergy Self-Efficacy Scale for Parents; GAD-7, Generalised Anxiety Disorder 7-item screener; IUS, Intolerance of Uncertainty Scale; PHQ-8, Patient Health Questionnaire 8-item version; PSS, 10-item version of the Perceived Stress Scale.

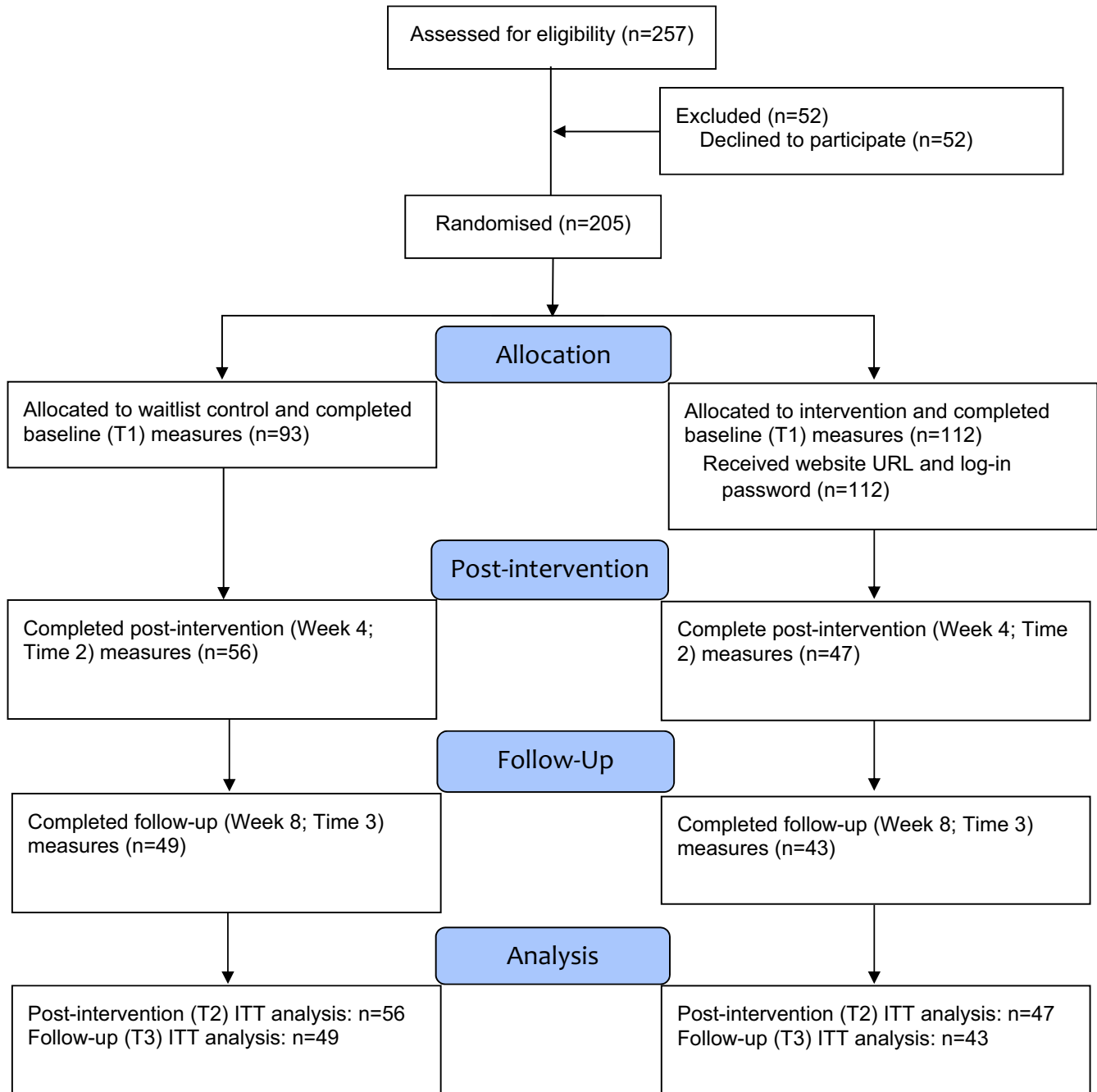


FIGURE 1 CONSORT diagram identifying flow of participants through the RCT

Web-based support was useful, but reported adherence to the website was low: 27 participants (77%) stated that they either 'strongly agreed' or 'agreed' that Web-based support for parents was useful; 21 (60%) stated that they visited the website less than once a month; and six (17%) reported that they had never visited the website.

3.6 | Adverse events

No adverse effects of the intervention were reported.

3.7 | Baseline relationships with QoL

At baseline, parental QoL was significantly correlated with all the other outcome and mediator variables in the expected directions ($p < .001$). A multiple regression, with QoL as the dependent variable, revealed that the two candidate mediating variables, namely IU and food-related self-efficacy, explained 28.3% of the variance in QoL ($F(2, 202) = 41.17, p < .001$) and that each made a significant contribution to this (IUS: $\beta = 0.20, t(202) = 3.76, p < .001$; FASE-P: $\beta = -0.59, t(202) = 6.85, p < .001$; recall that higher FAQoL-PB scores indicate lower QoL).

TABLE 5 An analysis of baseline to post-intervention treatment effects for sub-groups of participants experiencing greater baseline difficulty

Sub-group	N	Quality of Life (FAQoL-PB)		Depression (PHQ-8)		Anxiety (GAD-7)		Stress (PSS)	
		Intervention vs. control	p-value	Intervention vs. control	p-value	Intervention vs. control	p-value	Intervention vs. control	p-value
Quality of life									
High FAQoL-PB (Score ≥ 88)	48	U = 233.5, Z = -0.974	.330	U = 265.5, Z = -0.305	.760	U = 279.0, Z = -0.021	.983	U = 242.5, Z = -0.787	.431
Depression									
PHQ-8 ≥ 10	15	U = 9.5, Z = -2.068	.036*	U = 26.5, Z = -0.059	.953	U = 26.0, Z = -0.119	.905	U = 24.0, Z = -0.355	.722
Anxiety									
GAD-7 ≥ 10	21	U = 34.5, Z = -0.819	.424	U = 33.0, Z = -0.937	.381	U = 34.5, Z = -0.822	.424	U = 43.0, Z = -0.156	.910
Perceived stress									
High PSS (Score ≥ 18)	45	U = 208.5, Z = -0.801	.423	U = 227, Z = -0.372	.710	U = 220.5, Z = -0.523	.601	U = 216.0, Z = -0.627	.530
Multiple allergies									
Allergy ≥ 2	78	U = 711.5, Z = -0.485	.627	U = 710.5, Z = -0.502	.616	U = 684.5, Z = -0.766	.444	U = 653, Z = -1.073	.283
Time since diagnosis									
≤ 3 years	20	U = 33.0, Z = -1.255	.230	U = 48.0, Z = -0.118	.941	U = 43.5, Z = -0.467	.656	U = 46.5, Z = -0.229	.824

Abbreviations: FAQoL-PB, Food Allergy Quality of Life -Parental Burden scale; GAD-7, Generalised Anxiety Disorder 7-item screener; PHQ-8, Patient Health Questionnaire 8-item version; PSS, 10-item version of the Perceived Stress Scale.

* $p < .05$.

4 | DISCUSSION

This is the first RCT of an online, self-help intervention for parents of CwFA. The new intervention comprised a Web-based informational resource for parents that aimed to improve their food allergy-related QoL and reduce their psychological distress, through targeting their self-efficacy and IU. Contrary to expectations, neither the primary outcome (change from baseline in food allergy-related QoL) nor the secondary outcomes differed between groups at the post-intervention or follow-up time points. Similarly, change in the purported mediating variables, namely IU and food allergy-related self-efficacy, did not significantly differ between arms. Furthermore, although the sub-group of participants whose depression scores were in the clinical range did show significantly improved QoL, this failed to survive a correction for statistical multiple comparisons and hence needs to be replicated, either using appropriate inclusion criteria and screening or stratification, before it can be considered a robust finding. Therefore, while the COVID-19 pandemic has encouraged greater provision of online interventions,^{20,21} the use of this website is not currently indicated.

Potential contributors to the failure to observe any robust intervention effects are the high degree of attrition between randomisation and post-intervention, and the fact that both Google Analytics and participants' self-reports suggest that, even for those participants who remained, the use of the website was relatively low. Thus, the website may have been insufficiently engaging for the participants and/or they may have struggled to prioritise it amongst other activities. This is consistent with studies that suggest Web-based and self-help interventions are prone to high attrition rates.^{9,22} Human contact, such as telephone calls, can aid retention,^{9,23} so it may be that future Web-based interventions for parents of CwFA would benefit from being guided.

In addition, given that the needs of parents of CwFA change over time and are dependent on context,²⁴ it is possible that the content of the website was not a good fit for the current sample, despite having been developed in consultation with parents of CwFA. It is worth noting that the study's sample had substantial experience with food allergy, with the CwFA having received their allergy diagnosis 6.4 years previously, on average. Therefore, future similar interventions may benefit from being more closely tailored to the needs of the parent group in question or having adaptable content that is tailored to the user.

In the baseline data, lower IU and higher food-related self-efficacy were associated with greater parental QoL. Therefore, these variables remain potentially useful targets for future interventions for parents with CwFA. That said, until an intervention is trialled that successfully impacts these variables in this population, we cannot be certain whether their relationship with parental quality of life is a causal one.

Aside from the shortcomings of the intervention detailed above, the study had the following limitations. First, the final sample was composed of primarily well-educated, Caucasian women who had parented a CwFA for some years, limiting generalisation beyond this

population. Second, partly because of the high level of attrition, the study was powered to detect a medium but not a small effect, raising the possibility of a Type 2 error. Third, as is usual with psychosocial interventions, due to the difficulty of concealing the nature of such interventions from participants, the RCT was single rather than double blind. Fourth, the associations in the baseline data may have been inflated by shared method variance, as all the variables were measured by self-report. Therefore, in addition to the previously mentioned improvements to the intervention, future trials would benefit from recruiting a larger, more diverse, clinical, and representative sample and from employing additional means of outcome measurement.

In conclusion, in this first RCT of a Web-based, self-help intervention for parents of CwFA, no robust, significant, intervention effects were observed. This may have been because of high attrition rates and lack of engagement with the intervention. Future research could seek to improve engagement through greater tailoring to the needs of the parent group in question and through the use of prompts.

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CONFLICT OF INTEREST

The authors declare there are no conflicts of interest in relation to this work.

AUTHOR CONTRIBUTIONS

Naomi Sugunasingha: Conceptualization (equal); Data curation (lead); Formal analysis (lead); Investigation (lead); Methodology (equal); Project administration (lead); Resources (lead); Software (lead); Validation (lead); Visualization (lead); Writing – original draft (lead); Writing – review & editing (supporting). **Fergal W. Jones:** Conceptualization (equal); Data curation (supporting); Formal analysis (supporting); Investigation (supporting); Methodology (equal); Project administration (supporting); Resources (supporting); Software (supporting); Supervision (equal); Validation (supporting); Visualization (supporting); Writing – original draft (supporting); Writing – review & editing (equal). **George du Toit:** Conceptualization (supporting); Methodology (supporting); Resources (supporting); Supervision (supporting); Writing – review & editing (supporting). **Christina J. Jones:** Conceptualization (equal); Data curation (supporting); Formal analysis (supporting); Investigation (supporting); Methodology (equal); Project administration (supporting); Resources (supporting); Software (supporting); Supervision (equal); Validation (supporting); Visualization (supporting); Writing – original draft (supporting); Writing – review & editing (equal).

PEER REVIEW

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DATA AVAILABILITY STATEMENT

Anonymised data are available to suitably qualified researchers on request to the corresponding author.

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