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Effects of a structured educational intervention on knowledge and emergency management in patients at risk for anaphylaxis

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Abstract

Background: Structured educational programs for patients at risk for anaphylaxis have not yet been established. Patients and caregivers often lack adequate skills in managing the disease.

Objective: To investigate effects of structured patient education intervention on knowledge, emergency management skills, and psychological parameters in patients with previous

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episodes of anaphylaxis and caregivers of affected children.

Methods: In a multicenter randomized controlled trial, 95 caregivers (11 male, 84 female, mean age 37 years) of affected children and 98 patients (32 male, 66 female, mean age 47.5 years) were randomly assigned to an intervention (IG) or control group (CG). The IG received two 3-hour schooling modules of group education; the CG received standard autoinjector training only. Knowledge of anaphylaxis and emergency management competence in a validated training anaphylaxis situation as main outcome measures as well as secondary psychological parameters were assessed at baseline and 3 months after intervention.

Results: In comparison to controls, the intervention led to significant improvement of knowledge from baseline to 3-months-follow-up (caregivers: IG 3.2/13.2 improvement / baseline versus CG 0.7/12.6; $p < 0.001$; patients: IG 3.9/10.8 versus 1.3/12.6; $p < 0.001$). Moreover, emergency management competence was increased after intervention as compared to controls (caregivers: IG 8.6/11.2 versus CG 1.2/10.8; $p < 0.001$; patients: 7.1/11.0 versus 1.1 / 11.1; $p < 0.001$). Intervention showed significant reduction of caregiver anxiety (-1.9/8.4 versus -0.7/7.5; $p < 0.05$). There were no significant changes in the depression scores.

Conclusion: Structured patient education programs may be beneficial in the management of anaphylaxis by increasing patients' empowerment to prevent and treat the disease.

Key words: anaphylaxis, caregivers, education, emergency management skills, patients

Short title: Educational intervention in patients with anaphylaxis

Authors contributions: KB, SS, KiB, TB, JF, NG, MG, TJ, LK, CK, LL, OP, BP, ER, FR, SS, RS, MW, UG, JR participated in the design and/or execution of the study, JK analysed data, KB, SS drafted the manuscript, all authors were involved in the preparation of the manuscript.

Introduction

Anaphylaxis is a serious allergic reaction, which is rapid in onset and may cause death.^{1, 2} It is a significant public health problem in industrialized countries. The lifetime prevalence has been estimated to be 0.05 – 2%.³ The rate of hospital admissions due to anaphylaxis have increased during the last decade.^{4, 5} Anaphylaxis is a medical emergency and requires immediate discontinuation of exposure to the trigger as well as prompt treatment including intramuscular injection of epinephrine.² Fatal anaphylactic reactions do occur.⁶ The most common triggers for anaphylaxis are foods, insect stings and drugs.^{3, 6, 7} Avoidance of the triggers may be difficult and the recurrence rate of anaphylaxis has been reported to be high (57 episodes/100 patient-years).⁸ In almost all patients with fatal food anaphylaxis, the triggers were identified and the patients knew of their food allergy, but were unable to avoid the allergen.⁹⁻¹¹ Identification of the cause and avoidance, antigen-specific immunotherapy for example for hymenoptera venom allergy, proper therapy of bronchial asthma, as well as effective training in self-treatment are crucial for the management of patients after anaphylaxis.¹²

Patients who have experienced an acute episode of anaphylaxis are prescribed emergency medication, particularly an epinephrine auto-injector and instructions on how to avoid the culprit allergen and how to self-treat anaphylaxis is given to all patients.¹² However, this is often insufficient to achieve an understanding of how to avoid triggers, how to recognize the symptoms, how to differentiate it from anxiety, and why, when and how to inject epinephrine in the future. Compliance with carrying and using epinephrine is generally poor.^{6, 8, 13, 14} Epinephrine prescription does not ensure correct self-application of the medication. Only half of the patients with recurrent anaphylaxis were able to use the epinephrine autoinjector correctly, despite verbal and printed instructions, and practice with a trainer.⁸ The large majority of victims of fatal food anaphylaxis were adolescents or young adults.^{10, 11} Only 10% of college students with food anaphylaxis always carried an epinephrine autoinjector. Relevant factors for this age group may include denial, risk-taking behaviour, and possibly the belief that they are not at risk, having gone a long period without having an allergic reaction. Lack of knowledge and incorrect application of emergency medication by patients and caregivers of children have been identified as major gaps in anaphylaxis management.¹²

Despite the absence of allergic reactions, people at risk of anaphylaxis must continually follow avoidance strategies and be prepared for an emergency; this need for vigilance may

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create a psychological burden with high levels of stress and anxiety for patients and their family members.¹⁵ Patient education may be an option to ensure effective long-term care by promoting patient empowerment. Although the concept of action plans for the management of chronic disorders have been developed, no standardized educational intervention for patients at risk for anaphylaxis has been described in the literature yet.^{12, 16} In order to educate patients in the self-management of the disease, we developed a standardized intervention program and assessed its effect on patient performance and coping with the disease. We have used our collective experience from educational programs for bronchial asthma and atopic eczema and the input from nine consensus conferences to define the content and structure of such a program, including study design and choice of evaluation instruments.^{17, 18} This multicenter randomized controlled study assessing changes from baseline to three months after intervention shows that a structured educational program had a significant effect on patient knowledge, emergency management competence and on coping with the disease in caregivers of 63 children and 67 adults with anaphylaxis.

Methods

Patients

Ten centres with long-term experience in the diagnosis and treatment of anaphylaxis in Germany recruited caregivers of children and adults at risk of anaphylaxis who carried an epinephrine auto-injector. Each centre recruited the following number of caregivers/adults respectively: Berlin Charité:15/15, Bonn: 24/0; Cologne: 8/0, Giessen: 11/4; Osnabrück: 37/0; Freiburg: 0/16, Munich LMU: 0/9, Munich TUM: 0/17, Tübingen: 0/28, Wiesbaden: 0/13). Inclusion criteria included a confirmed diagnosis by an allergist (WAO criteria),² a prescription of an emergency kit, and sufficient German language skills to complete the questionnaires. A total of 98 adults (mean age: 48 years, range: 18 to 78 years) and 95 caregivers (mean age of 37 years, range: 24 to 47) who had children at risk for anaphylaxis (mean age of 5 years, range: 11 months to 14 years) were eligible and agreed to participate in the study. All participants (caregivers and adults) gave written informed consent (Figure 1). The study was approved by the individual Ethics Committees of each participating study center, the main ethics committee approval was given by Fachbereich Humanmedizin of the Justus-Liebig-University Giessen/Germany. After three months, 80 caregivers (n = 44 IG and n = 36 CG) and 96 patients (n = 52 IG and n = 44 CG) finished the study. 15 caregivers (n = 5 IG and 10 CG) and 2 patients (both IG) dropped out. For the analyses values of the lost caregiver and patients were estimated using "last observation carried forward (LOCF)". The differences between the two groups (completer versus non

completer) for baseline values are small and significant only for one variable (Table 1).

Study design

The study was designed as a randomized controlled exploratory intervention study. Randomization was designed and prepared centrally (Inst. of Med. Psychology) and completed by each individual center. All patients and controls had previously received non-standardised training on patient-specific avoidance strategies, recognition of symptoms, and when and how to administer emergency medication at the time of the prescription of the adrenaline autoinjector. The intervention consisted of two three hour sessions given over two consecutive weeks with a median of $n = 6$ (range: 4 – 13) participants. Caregivers of children and adults in the intervention and control groups were informed about evaluation at baseline directly before starting the program and follow-up at three months without encouragement to refresh their skills and knowledge. Control patients were assigned to a waiting list for active intervention with no sham training sessions and no restriction on allergist consultations when needed. They received intervention after the three month assessment. The sample size estimation was based on a medium effect size ($f=0.25$), $\alpha=0.05$ and power = 0.80.

Intervention

The contents and structure of the program were developed based on the consensus of a multidisciplinary group of professionals who met at nine conferences during a 2.5 year period. A manual, specifying the content, didactic methods and media of each session was designed and used in train-the-trainer sessions. In order to ensure that all sessions for study participants would be consistent and of high quality, designated trainers were required to attend a 30 hour train-the-trainer workshop led by the anaphylaxis education and training working group (Arbeitsgemeinschaft Anaphylaxie Training und Edukation, AGATE), which covered the course content and how to educate caregivers and patients. The patient intervention program was standardized to provide age- and theme-centred group training and participants attended two three hour sessions over a two week period. Content for the sessions (listed in Table 2), delivered by a multi-disciplinary team of allergists, psychologists, and dietitians, covered recognition of anaphylaxis, daily strategies such as label reading and food preparation, risk reduction measures, coping with anxiety, and administration of an epinephrine autoinjector. To improve their skills and confidence level, participants were encouraged to practice what they had learned during the first session, including administering an

epinephrine autoinjector using a training device, and to teach others, such as relatives, friends, and teachers, how they could help in an emergency. Trainers of the intervention programme were required to undergo a 30 hours train-the-trainer workshop with special education about how to perform and lead such a patient group and the programme which was developed by the Task Force (AGATE). Previous to the study all trainers who participated in the study were trained by well-experienced trainers of the Task Force to establish an equally qualified intervention for every participating centre.

Outcome measures

The study looked at outcomes based on differences from the start of the study and three month follow-up for primary measures for caregivers' / patients' knowledge about anaphylaxis and their competence level in managing an anaphylactic reaction, during a simulation exercise, as well as secondary measures that observed differences in their ability to cope with anxiety and depression.

Assessment of caregiver and patient knowledge

We graded the practical patient knowledge on anaphylaxis using a multiple choice patient questionnaire designed by the research team with 20 questions covering the acute self-management, which was filled out by each participant (in case of children by the primary caregiver). The number of correctly answered questions up to a maximum total of 20 was summed up and analyzed.

Assessment of caregiver and patient practical emergency management competence

Based on the examination method Objective Structured Clinical Examination (OSCE), an assessment of emergency management competence in a simulated anaphylactic reaction was developed and validated in a pilot study in 56 patients and 7 medical students.¹⁹ In this OSCE, participants (in case of children the primary caring parent) were asked to provide the emergency set of medications and the real autoinjector was replaced by a training device for the test. As a standardised validated model for an anaphylactic emergency in a simulation exercise,¹⁹ the participant was confronted with a theoretical anaphylactic reaction and instructed to tell in-depth what to notice, what to do, which further steps might be necessary while demonstrating the practical use of the self-medication including autoinjector use.

Before and after intervention the skills in different items were rated by the same allergist trainer unblinded to intervention allocation. Correctly mentioned items and correct performances were added up to a maximum total score of 25.

Assessment of anxiety and depression

The German version of the HADS (Hospital Anxiety and Depression Scale) was employed to assess the influence of anaphylaxis on psychological well-being. The HADS is a self-reported instrument widely used in patient in hospital settings.²⁰

Statistical analyses

Statistical analyses were performed using IBM SPSS Statistic (Version 20 for Windows). Analyses of covariance were used to compare differences in outcome variables (3-month-follow-up – baseline) between the two arms (covariate = baseline values of the respective variable). For the analyses values of the non completer caregiver and patients were estimated using “last observation carried forward (LOCF)”. Main outcome measures and psychological parameters were calculated at $\alpha = 0.05$, with f as effect size.

Results

In total, 219 patients were assessed for eligibility to take part in the study. Of these, 193 participants were randomized (Figure 1): 95 caregivers of children, and 98 adults with previous episodes of anaphylaxis (non completer: 15 caregivers and 2 adult patients). The values for the participants who are non completer were estimated by “last observation carried forward (LOCF)”. There were no differences between completer and non completer for the adult patients for the baseline values. For the caregivers there was one significant difference: Caregivers who dropped out were a marginally younger (completer: 37.6 years; non completer: 34.6 years; $p < 0.05$) and were more often women (15 out of 84) than men (0 out of 11) (Table 1). Importantly, there were no changes in the significances of the results for outcome measures, if patients who dropped out would have been excluded (data not shown). In both groups the severity of anaphylaxis did not differ significantly between the intervention and control groups at baseline. Additionally, no statistically significant differences were found between the intervention and control groups for any outcome measure at baseline. The

number of participants with food allergy and non-food allergy (insect venom allergy, drug allergy and mastocytosis/idiopathic anaphylaxis) was comparable between intervention and control arms, respectively (Table 3).

Neither gender, age nor the cause of the allergy has a significant effect on the main outcome variables (results not shown).

Knowledge on anaphylaxis

At baseline the mean score for anaphylaxis knowledge was comparable between the IG and CG for caregivers and slightly different for adults (Table 3). Three months after the educational intervention program, the knowledge had significantly increased for caregivers (IG n = 49, increase baseline to 3-months-follow-up = 3.2; CG n = 45, increase baseline to 3-months-follow-up = 0.7; difference IG minus CG = 2.5 (95% confidence interval = 95%CI = 1.6-3.5, $p < 0.001$)(Table 4). There are similar results for the adult group (IG n = 51 increase baseline to 3-month follow up = 3.9 versus CG n = 44 increase = 1.3; difference IG versus CG = 2.7 (CI = 1.6; 3.8); $p < 0.001$) (Table 4)

Practical emergency management competence

In the simulation exercise subjects had to demonstrate what to tell and to show what has to be done. After three months follow-up the competence improved in both intervention groups but not in the control groups with no education. Caregivers (IG n = 49; difference baseline to 3-month follow-up = 8.7 versus CG n = 44 difference = 1.2; difference IG versus CG = 7.4 (CI = 5.8; 9.0; $p < 0.001$)); Adults (IG n = 52, difference baseline to 3-month follow-up = 7.1 versus CG n = 43, difference = 1.1; difference IG versus CG = 6.0 (CI = 4.6; 7.4; $p < 0.001$))(Table 4).

Anxiety and depression

Participants did not show increased anxiety or depression levels in the HADS-D [18] scales before or after the intervention. Educational intervention led to a significant improvement of anxiety for the caregivers (IG n = 52; difference baseline to 3-month follow-up = -1.9 versus CG n = 44 difference = -0.7; difference IG versus CG = -1.1 (CI = -2.2; -0.11); $p < 0.05$) There were no significant differences between groups in the adult patients in both scales and for

caregivers in the depression scale (Table 4).

Discussion

A patient education program for the management of anaphylaxis is significantly more effective at improving knowledge and practical skills needed to prevent and treat a possible anaphylactic reaction compared to no intervention. In this study over a period of three months, statistically significant benefits were seen in the intervention group on anaphylaxis-relevant knowledge as well as on practical skills on how to manage anaphylaxis in a simulation exercise and to a lesser extent on anxiety of caregivers of affected children. It was important to include a control group into the study, since outcome improvements may also be observed by taking the tests repeatedly and learning even in the absence of any education. In our study, however, the outcome in knowledge and emergency management competence were not at all or only marginally improved in the control group. There was no significant difference in the outcome regarding the different elicitors causing anaphylaxis. We analyzed differences between groups at baseline and found no major imbalances between study and control groups. The effect of education on improvement of disease management compares favourably with the improvement in management achievable without education.

The design of the interventional education program was developed by a multiprofessional German taskforce group on anaphylaxis of the German Society of Allergology and Clinical Immunology (DGAKI) over a period of two years (Table 2). The structure has been adapted from successfully applied patient education programs for atopic eczema (AGNES) and bronchial asthma (AGAS) and includes practical skills, disease management, and psychosocial interventions to reduce especially phobic anxieties about anaphylaxis.^{17, 18} One important aspect of the program is the cooperation between different professions. In order to become a trainer, the applicant has to complete a 30 hour training course. The team for the education program must consist of at least one certified experienced allergist as trainer as well as the required team members for the program, i. e. psychologist and dietician.

Structured educational programs aim to empower patients in self-management of diseases. Whereas such programs are highly effective with diseases such as bronchial asthma and atopic dermatitis, this study is the first one to prove that such an educational patient intervention is also beneficial for patients with anaphylaxis. A strategy that provides patient

and caregiver education can complement the individual counselling of the patient. Such an approach may be appropriate for anaphylaxis in patients who are required to carry an epinephrine autoinjector as the result of experiencing severe episodes of anaphylaxis and/or having a high risk of recurrent reactions.

Although many allergists are familiar with anaphylaxis guidelines, great variations may exist concerning prescription of epinephrine and explaining autoinjector use.²¹ This leads to confusion by the patients about the proper use of emergency medication, especially whether and how to use the epinephrine autoinjector in a specific situation. In several studies, less than half of the patients with recurrent anaphylaxis were able to use their epinephrine autoinjector correctly,^{8,10,22} despite instructions and practice with an autoinjector training device. Moreover, many patients do not carry the emergency medication and/or do not use it when needed.^{10, 11, 13, 23} A structured educational program may overcome these problems and improve compliance.

There are limitations to our study. We did not include long-term effects of the intervention, such as the number of anaphylactic events and the severity of the current anaphylaxis before and after educational intervention. Future studies should incorporate these parameters but will be much more difficult and costly to compose. Regarding the short-term efficacy we have examined knowledge and practical skills only within a simulation exercise. Nevertheless, a significant improvement of the outcome parameters in the intervention group and not in the control group indicates an effect of patient and caregiver education.

In summary, the present study shows that a patient education program can be effective in the empowerment of patients at risk for anaphylaxis. Our standardized 6-hour-educational intervention in two sessions induced significant improvement of anaphylaxis-related knowledge and practical emergency management skills evaluated three month after participation. Further study is required to assess the long-term clinical effects.

Tables and Figures

Table 1. Baseline characteristics for completer and non completer (ns = not significant; nc not calculated because of too few cases in one group)

Caregivers	80 / 84.2	15 / 15.8 %	
Group: Intervention	44 / 89.8%	5 / 10.2%	
Control	36 / 78.3%	10 / 21.7%	ns
Age (years) mean (SD)	37.56 (4.42)	34.57 (4.42)	p < 0.05
Gender: male	11 / 100 %	0 / 0 %	
female	69 / 82.1 %	15 / 17.9 %	ns
Education: low	33 / 78.6 %	9 / 21.4 %	
high	44 / 88.0 %	6 / 12.0 %	ns
Type of allergy: food allergy	73 / 86.9%	11 / 13.1 %	
non food	2 / 66.7 %	1 / 33.3 %	
unknown/ missing	5 / 62.5 %	3 / 37.5 %	ns
Anaphylactic shock: yes	50 / 82.0 %	11 / 18.0 %	
no	29 / 87.9 %	4 / 12.1 %	ns
Comparison baseline values			
Knowledge	13.11 (3.08)	12.13 (3.31)	ns
Emergency management competence	10.83 (4.67)	12.00 (3.61)	ns
Anxiety (HADS)	8.20 (3.99)	6.50 (3.55)	ns
Depression (HADS)	4.31 (3.40)	2.93 (2.27)	ns
Adult patients	96 / 98.0 %	2 / 2%	
Group: Intervention	52 / 96.3 %	2 / 3.7 %	
Control	44 / 100%	0	nc
Age (years) mean (SD)	47.63 (13.24)	43.00 (31.1)	nc
Gender: male	32 / 100 %	0 / 0 %	
female	64 / 97.0 %	2 / 3 %	nc
Education: low	52 / 98.1 %	1 / 1.9 %	
high	42 / 97.7 %	1 / 2.3 %	nc
Type of allergy: food allergy	19 / 100 %	0	
non food	67 / 97.1 %	2 / 2.9 %	
unknown/ missing	10 / 100 %	0	nc
Anaphylactic shock: yes	80 / 98.8 %	1 / 1.2 %	
no	15 / 93.8 %	1 / 6.3 %	nc

Comparison baseline values			
Knowledge	11.63 (3.61)	13.00 (n=1)	nc
Emergency management competence	11.09 (4.29)	8.00 (0.00)	nc
Anxiety (HADS)	5.39 (3.02)	5.50 (3.54)	nc
Depression (HADS)	2.81 (2.67)	1.10 (0.14)	nc

Table 2. Structure and content of education program for caregivers of children and adult patients with anaphylaxis

Day 1			
Session	Topic	Duration	Media
Introduction	Mutual exploration	10-15	Flip-chart, marker, pin board, index cards, nametags
Basics	Expectations and goals	20	Flip-chart, marker, pin board, index cards
Basics	Definition of anaphylaxis, diagnostic, recognizing symptoms and cofactors	20-30	Flip-chart, marker, +/- , pictures, transparencies, overhead projector
Basics	Recognizing and differentiating anxiety	15-20	Flip-chart, marker
Break		10	
Prevention and therapy	General preventive and therapy options	30	Transparencies, overhead projector, or: flip-chart, marker
Emergency	Knowledge of own medication, effects, use	15-20	Patient medication, tags
Emergency management	Presentation of an emergency action plan	15-20	Transparencies, overhead projector, flip-chart, marker emergency ID
Autoinjector	Autoinjector training and demonstration	15	Autoinjector-dummies, autoinjector, +/- transparencies, overhead projector, demo CD
Homework	Handling the autoinjector at home, emergency action plan	10	Autoinjector-dummies
Day 2			
Session	Topic	Duration	Media
Introduction	Summary, check homework	5-15	Flip-chart, marker

Emergency therapy	Emergency action in role plays, ease anxiety, increase competence	45	Mat, blanket, flip-chart, marker, pictures, autoinjector-dummies, medication, phone (real life simulation)
Trigger-related preventive measures	Food (if relevant for specific group)	20	Transparencies, flip-chart, marker
Trigger-related preventive measures	Medication (if relevant for specific group)	10-15	Transparencies, flip-chart, marker
Trigger-related preventive measures	Insect toxin (if relevant for specific group)	20	Transparencies, flip-chart, marker
Trigger-related preventive measures	Latex (if relevant for specific group)	10-15	Transparencies, flip-chart, marker
Break		10	
Everyday strategies	Help with dealing with anaphylaxis on a daily basis	15	Transparencies, flip-chart, emergency ID, medical alert bracelet/tag/pendant, storage, emergency phone, medical documents for air travel
Everyday strategies	Options, strengthen confidence, dealing with anaphylaxis in community	20-30	Transparencies, flip-chart, handout with patient organization addresses, internet resources,
Summary	Feedback	10	Flip-Chart, certificate

Table 3. Baseline characteristics of caregivers of children with previous episodes of anaphylaxis and adult patients where education intervention was performed for anaphylaxis vs. no education (control group)

Caregivers	n = 49	n = 46	
Age (years) mean (SD)	36.33 (4.52)	37.89 (4.61)	ns
Gender: male	6 / 54.5 %	5 / 45.4 %	
female	43 / 51.2 %	41 / 48.8 %	ns
Education: low	22 / 52.4 %	20 / 47.6 %	
high	25 / 50.0 %	25 / 50.0 %	ns
Type of allergy: food allergy	45 / 53.6%	39 / 46.4 %	
non food	2 / 66.7 %	1 / 33.3 %	
unknown/ missing	2 / 25.0 %	6 / 75.0 %	ns
Anaphylactic shock: yes	35 / 57.4%	26 / 42.6 %	
no	14 / 42.4%	19 / 57.6 %	ns

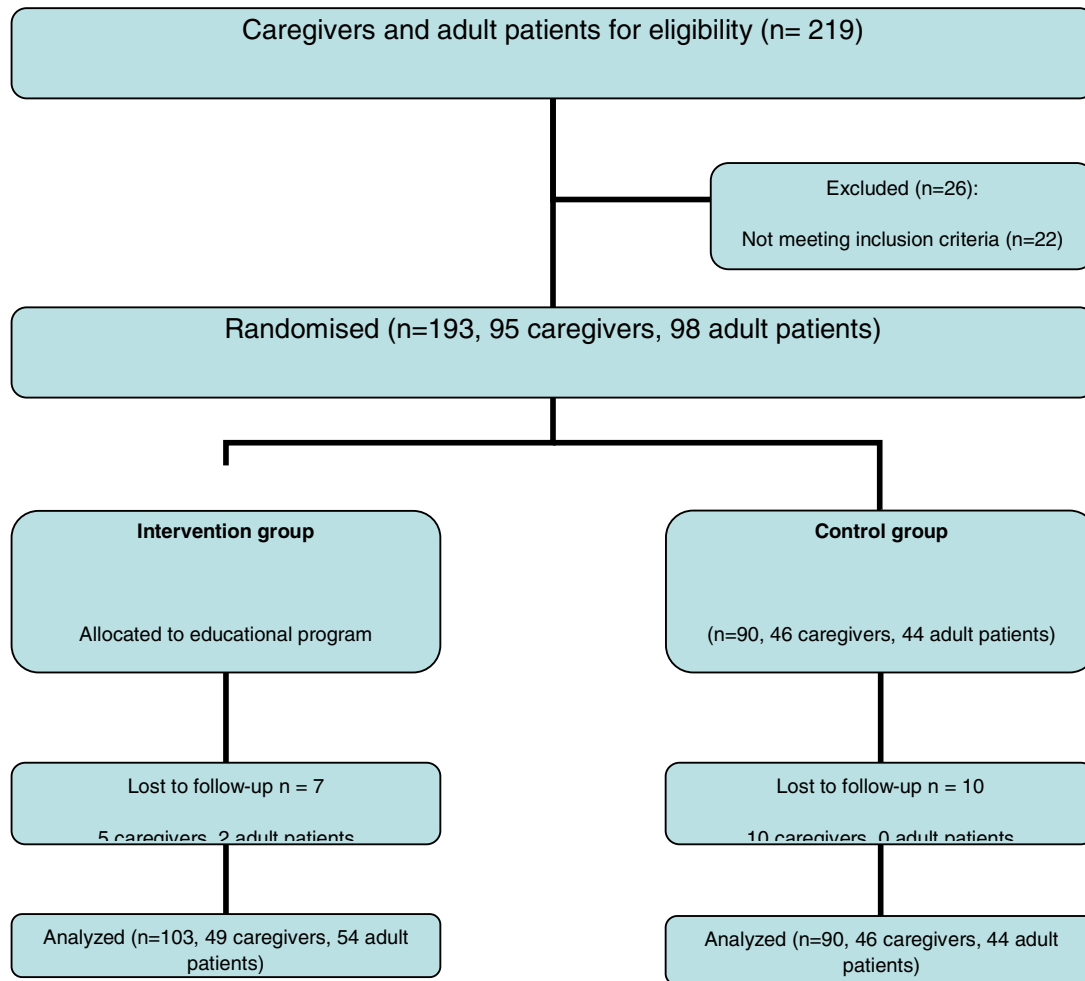
Comparison baseline values			
Knowledge mean (SD)	13.24 (3.03)	12.64 (3.23)	ns
Emergency management competence (SD)	11.18 (4.95)	10.84 (4.03)	ns
Anxiety (HADS) mean (SD)	8.41 (3.98)	7.45 (3.91)	ns
Depression (HADS) mean (SD)	4.55 (3.44)	3.63 (3.07)	ns
Adult patients	n = 54	n = 44	
Age (years) mean (SD)	47.56 (15.56)	47.50 (10.58)	ns
Gender: male	16 / 50.0 %	16 / 50.0 %	
female	38 / 57.6 %	28 / 42.4 %	ns
Education: low	29 / 54.7 %	24 / 45.3 %	
high	23 / 53.5 %	20 / 46.5 %	ns
Type of allergy: food allergy	13 / 68.4%	6 / 31.6 %	
non food	35 / 50.7 %	34 / 49.3 %	
unknown/ missing	6 / 60.0 %	4 / 40.0 %	ns
Anaphylactic shock: yes	47 / 58.0 %	34 / 42.0%	
no	7 / 43.8%	9 / 56.3%	ns
Comparison baseline values			
Knowledge (SD)	10.82 (3.84)	12.61 (3.07)	p < 0.05
Emergency management competence (SD)	10.96 (4.63)	11.09 (3.83)	ns
Anxiety (HADS) (SD)	5.14 (3.18)	5.68 (2.80)	ns
Depression (HADS) (SD)	2.68 (3.02)	2.89 (2.17)	ns

Table 4. Outcome variables, using analyses of covariance (covariate = baseline values) of differences between baseline and 3 months' follow-up for groups receiving an educational program in anaphylaxis and controls (estimated marginal means (95% confidence interval))

	Intervention	Control	Intervention minus Control		
Outcome variables	Estimated marginal means (95% CI) of differences (3 month – baseline)	Estimated marginal means (95% CI) of differences (3 month – baseline)	Estimated marginal means (95% CI) of differences (Intervention – Control)	P value	Effect size f
Caregivers	n = 49	n = 46			
Knowledge (MD=1)	3.16 (2.50; 3.82)	0.65 (-0.04; 1.34)	2.51 (1.55; 3.47)	<0.001	0.55
Emergency management competence (MD=2)	8.57 (7.46; 9.69)	1.20 (0.03; 2.38)	7.37 (5.75; 8.99)	<0.001	0.96
Anxiety (MD=5)	-1.87 (-2.58; -1.15)	-0.74 (-1.46; -0.02)	-1.13 (-2.15; -0.11)	< 0.05	0.23
Depression (MD=4)	-1.21 (-1.83; -0.60)	-0.39 (-1.01; 0.24)	-0.83 (-1.71; 0.05)	0.065	0.20
Adult patients	n =54	n = 44			
Knowledge (MD=3)	3.94 (3.21; 4.68)	1.27 (0.48; 2.06)	2.67 (1.58; 3.77)	<0.001	0.39
Emergency management competence (MD=3)	7.14 (6.17; 8.11)	1.13 (0.07; 2.20)	6.01 (4.57; 7.45)	<0.001	0.89
Anxiety (MD=2)	-0.55 (-1.17; 0.08)	-0.02 (-0.70; 0.66)	-0.52 (-1.45; 0.41)	ns	0.11
Depression (MD=2)	-0.05 (-0.53; 0.44)	0.09 (-0.44; 0.62)	-0.14 (-0.85; 0.58)	ns	0.04

Completer analyses: same results but anxiety not significant for caregiver group

Figure 1. Flow of patients through trial



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