

Preschoolers' and parents' asthma education trial (P²AET)—a randomized controlled study

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Abstract We aimed to evaluate a family-oriented psycho-educational asthma training program for the age group of 2–5 years, involving both parents and children. Children were included after having at least 3 obstructive episodes in their life plus chronic or recurrent wheeze in the 6 months before the start of the study. In the multicenter randomized trial we had (1) a waiting group (WG), (2) an instruction group (IG) trained in a structured way according to the national asthma guideline, and (3) an education group (EG), having a standardized multiprofessional psycho-educational program, according to the national licensed asthma education for the age group of 6–18 years. All were assessed after 6 months. A subgroup analysis was performed on those being on regular inhaled corticosteroids at study entry (74.3%). A total of 338 children were randomized, and 288 (85%) completed the study. In the asthma emergency management, test scores increased most in EG, less in IG, and not in WG. For emergency visits the risk ratio for EG was 0.68 compared to IG: Patients regularly inhaling corticosteroids (74.3%) had an increased risk for emergency visits when having only an instruction (OR 3.99 [1.89–8.40]) or had been waiting (OR 2.5 [1.16–5.37]) when compared to those having an asthma

education. We conclude that in the German health system, the family oriented psycho-educational program provided in a standardized manner by a multiprofessional team is effective also in the age group of 2–5 years. It should be made accessible to each asthmatic child.

Keywords Toddlers · Children · Family oriented · Asthma education · Multiprofessional

Introduction

Asthma education programs for children and adolescents with bronchial asthma and their parents were first developed at the end of the 1980s. An overall effect on asthma morbidity was shown, but many of these programs dealt with groups mixed by age and asthma severity [1, 2]. A more detailed analysis of the impact of psycho-educational interventions is only available for children and adults with severe asthma [3].

In Germany, psycho-educational family-oriented programs were introduced in the 1990s but have so far been evaluated only for families with children aged 6 years or older [4–6]. However, asthma has to be treated also in younger children, where special emphasis has to be laid on the training of their parents. The German working group on asthma education in childhood and adolescence (Arbeitsgemeinschaft Asthmaschulung (AGAS)) developed a program for families of asthmatic children aged 2–5 years (Asthmaschulung für Eltern von Vorschulkindern (ASEV)). The pre–post evaluation of the respective modules showed a significant increase of knowledge of the parents, an improved inhalation technique of the children, and an overall satisfaction of the parents and physicians [5].

However, for the implementation of the ASEV in the asthma management of all children (e.g., to be recommended

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in the national guidelines), evidence of efficacy (e.g., level 1a–2b according to the Oxford Centre for Evidence-based Medicine [7]) is necessary. This evidence is also a prerequisite to provide ASEV as an element of asthma care in the framework of the German Disease Management Program. Therefore, we planned a study to prove efficacy in terms of reduction of emergency visits.

Patients and methods

Setting

This was a multicenter study in places throughout Germany. Twenty-five asthma training centers applied, but only 15 took part eventually (see the list in the [Appendix](#)). The centers had to provide an asthma training team certified by the AGAS [4] to provide the national licensed asthma training program (Asthmaschulung) in the age group of 6 years and older. In addition, there were two half day meetings at the annual national conferences of the AGAS to assure an equal approach in each city. Each group of trainers included a psychologist, a nurse practitioner, and a pediatrician (This pediatrician was not the physician providing the regular care of the participants). Education and instruction took place in groups of 6–8 families.

The centers were all well known to the local pediatricians as they have provided asthma training in the age group of 6 years and older for more than 5 years. The pediatricians were informed about the trial. They asked the parents of the children fulfilling the inclusion criteria to register with the asthma training center. There were no costs for the parents but also no incentives.

Study design

Children from 24 to 60 months of age with an asthma diagnosis made by their pediatricians were eligible (in Germany, more than 95% of the preschool children receive primary care by a pediatrician). They must have had 3 or more episodes of wheeze during their life PLUS recurrent or chronic wheeze in the 6 months before the study started, as documented by their primary health care physician [8, 9]. They were not required to fulfill the stringent asthma index [10].

Parents willing to take part in a randomized clinical trial were registered in their asthma training center. They received an information sheet and had to sign the informed consent form. When a group of at least 18 had been collected, the asthma training center mailed a list of participants' registration numbers to the study coordinator for randomization. Central randomization was performed based on random numbers by the study coordinator and

resulted in three equally large groups of 6–8 families. This procedure guaranteed (1) a balanced distribution of randomized groups by block randomization and (2) concealment of allocation by concurrency. Thereafter all families were evaluated the first time and received the date of education or training (according to the randomization in short time) or re-evaluation/education (after 6 months, if randomized to the waiting group). The families were informed accordingly.

As each participating family received at least one instruction (which is required by the national asthma guideline), the Ethics Committee of the Albert-Ludwigs-Universität Freiburg allowed to perform the trial without a formal informed consent procedure. However, parents had to consent to handle and store their data according to the national and state regulations, and we used the informed consent form, which had been developed according to good clinical practice, when we addressed the ethics committee.

Interventions

The *instruction group* received a structured program according to the requirements of the National German guideline [11]: In one hour's time, a group of 6–8 parents was instructed by the nurse and the pediatrician about the prescribed asthma medication and how to use it. They were also informed about the goals of asthma therapy. They received a written treatment and emergency plan, and had an exercise with their child how to use their inhalation equipments.

The *education group* had their instruction (as above) plus a parents' program in groups of 6–8 families of 3–4 appointments of 9.5 h altogether. This standardized family-oriented psycho-educational asthma training program was taught by an interdisciplinary team (see above); the outcomes regarding knowledge, skills, and competencies were those of the certified program of the AGAS [4]. Along with the group meetings, each family had personalized inhalation training with their child.

Families in either group had a check whether the child's asthma drugs (e.g., type of reliever or controller) were in line with the guideline [11]. If not, the primary care physician was informed by call. Due to the health system regulations in Germany, where the pediatrician in the asthma training team is hampered to adapt asthma therapy by own prescription, families not yet having reached the treatment goals defined by the guideline [11] were asked to see their primary care physician.

Both the instruction and the education group were re-evaluated after 6 months. At this occasion, the families of the instruction group were offered to take part in the education program.

Asthma severity was assessed by the Rosier score [12], and instead of school absence, we asked for absence from

kindergarten. If there was no answer or the answer was “don't know,” the item scored zero.

To learn more about the impact of asthma in the German preschool population, we also asked for the number of nights when parents' sleep was disturbed, and the number of days parents had to be absent from their workplace.

Allergic sensitization was determined by the use of a double screening test, the Pharmacia CAP® fx5 (egg white, milk, fish, wheat, peanut, and soybean) and SX1 (timothy grass, rye, birch, mugwort, house dust mite, cat, dog, and molds).

Outcomes

The main outcomes were the number of emergency visits and the number of hospitalizations, captured by the parents' questionnaire. Secondary outcomes were either related to the adherence to the national asthma guideline (e.g., having a written medication and emergency plan, as indicated in the parents' questionnaire and the competence to act accordingly [see below for the emergency management test]) or the quality of life (disruption of parents' sleep and parents' absence from work due to the asthma of the child). The questionnaire was also used to check the medication (parents were asked to give the trade names of the drug; assignment of drugs to the respective group was done by the study coordinator).

In an Asthma emergency management test, parents were asked to write down by heart, what to notice and what to do, if the child presented with breathing difficulties. The following sequence of items was required (score per item): be considerate (1); stay away from/remove triggers (1); inhale salbutamol (2); wait 10 min for the effect (1) while assisting the child in an easy-to-breathe position (2); and being specifically attentive for the degree of dyspnea [parents' attentiveness] (2); then, if necessary, inhale salbutamol a second time (2); apply the provided systemic corticosteroid (1); and contact your doctor (2), resulting in a maximum score of 14 points. Parents' attentiveness was thought to guide asthma therapy as well as to trigger emergency management. It therefore was included as an important variable in the multivariate model to explain the number of emergency visits.

All questionnaires were anonymized.

A subgroup analysis was planned for those children regularly inhaling corticosteroids at study entry.

Statistics

The final analysis of outcomes at six months was based on actual observations only. No attempt was made to impute for missing values, since subjects with only baseline data were without any information at the time of the assessment.

The trial was analyzed using SAS9. Standard methods were employed for the description of the data. Group comparisons were established by means of Chi-square tests (binary outcomes) and Kruskal–Wallis tests (continuous outcomes). Changes over time were analyzed using McNemar tests (binary outcomes) and Wilcoxon signed rank tests (continuous outcomes).

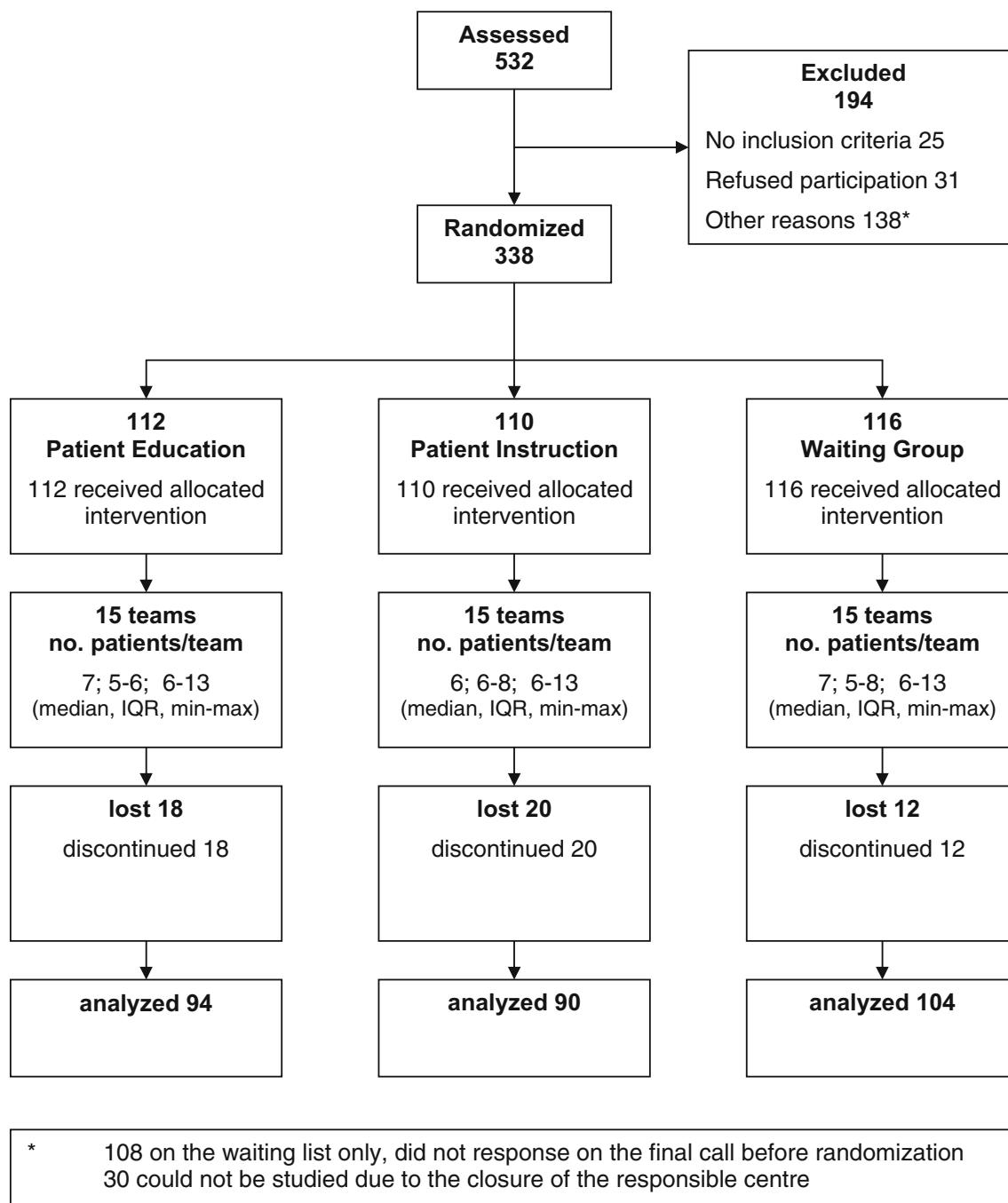
For the main outcomes, data of the whole patient group as well as of the group receiving ICS as a controller at study entry were analyzed. In more detail, the impact of treatment groups on the outcome ‘emergency visit’ was investigated further by means of multivariate logistic regression models. First, prespecified variables besides assigned treatment were entered in the model (parents' attentiveness, having a treatment plan, having an emergency plan, ongoing ICS controller therapy, regular use of SABA, and calling the doctor in case of an emergency). A variable selection strategy was applied (backward elimination), leaving only variables with $p < 0.1$ beside the hypothesis variable (randomized group) in the final model.

Results

Most of the 15 asthma training teams had one group of patients randomized; only two had two, so that 17 groups of patients altogether underwent the study protocol. The patient flow can be seen in Table 1. The patients' characteristics at the time of randomization can be seen in Table 2. The children had a mean age of 3.9 years, 33.7% of them were female. The three intervention groups were also well matched for the prevalence of other atopic diseases (atopic dermatitis 29.5%, hay fever 22.7%), as well as for asthma severity, measured by the adapted Rosier score (mean 8.4) and the ICS controller inhalation in the last 6 months (74.3%). In the same time span, two thirds of them (63.4%) had seen a doctor in an emergency situation; every seventh (14.7%) had been hospitalized during an asthma episode.

The families widely used both electric nozzle nebulizers (68%), e.g., PARI® devices, and metered dose inhalers in combination with spacers (77%). As reliever, they had used SABA by inhalation (75.7%), ICS (10.8%), systemic CS (33.2%), and other drugs (4.5%). As controllers, the children had received ICS (74.3%), inhaled SABA (35.3%), montelukast (19.8%), LABA (16.8%), DNCG (3%), and other drugs (4.5%). There was no mismatch in the medication between the intervention groups.

Families with asthma education reported less emergency visits than those who had only got instructions, and this is also true for the subgroup using regularly ICS at study entry (Table 3). The waiting group had less emergency visits than the instruction group but more hospitalizations (Table 3).

Table 1 Patients

After the intervention there were changes, which can be caused by the intervention, but may as well have happened for other reasons (e.g., having written treatment and emergency plan including medication according to the guideline). But the changes nevertheless have an impact on the successful asthma management, and therefore on the main outcomes. A list of such variables changed after the observation period is given in Table 4.

According to the international and national guidelines, asthma patients must have a written plan on the treatment and especially for the case of emergency. Only one third (38.1%) of our families had such a plan at the beginning of the trial, and they were also not familiar with the action to take in a case of emergency (a mean of 3.8 points out of 14 corresponds to a poor performance in the Asthma emergency management test). Regarding these two prerequisites of a successful asthma

Table 2 Patients' characteristics

	All (338)	Education (112)	Instruction (110)	Waiting (116)
Age (years $\pm$ SD)	3.9 $\pm$ 1.1	3.9 $\pm$ 1.1	3.9 $\pm$ 1.1	3.9 $\pm$ 1.1
Gender (female)	33.7%	29.2%	38.8%	33.3%
Patient atopic dermatitis ^a	29.5%	34%	28.8%	25.5%
Patient hay fever ^a	22.7%	26.2%	20.2%	21.4%
Allergic sensitization (any ^b)	40.0%	39.8%	42.6%	37.8%
Asthma severity (Rosier score; mean $\pm$ SD)	8.4 $\pm$ 4.7	7.8 $\pm$ 4.2	8.5 $\pm$ 4.9	8.8 $\pm$ 4.9
Emergency visit ^c	64.3%	65.8%	66.1%	61.1%
Hospitalization ^d	14.7%	14.5%	16.5%	13.3%
Continuous corticosteroid inhalation ^e	74.3%	79.3%	73.6%	69.9%

^a Doctors' diagnosis, life time prevalence^b Allergens included in the Pharmacia CAP® fx5 and sx1^c One or more in the half year before randomization; mean number was 2.2, with no difference between groups^d Only single hospitalizations^e During the half year before randomisation

therapy, education resulted in a sufficient rate of families having a plan at hand (83%) and also in a significant improvement in the written test (mean score 8.6/14 points). There was an improvement in the instruction group, but not to an acceptable level (64% having a plan; mean score in the test, 6.2/14). No change was seen in the waiting group.

Regarding the medication, at the end of the trial, the educated families had received more drugs in accordance

with the guidelines, than it was the case in the other groups. As changes of medication towards the recommendation of the guidelines occurred also in the waiting group (e.g. the pre/post difference of 1/3 for the misuse of SABA as controller), the difference cannot completely be assigned to the interventions alone. Furthermore we found, that before the intervention, having a written emergency plan at hand was not predictive for the scores of the written test.

Table 3 Effects of intervention on the main outcomes

		All (%)	Education (%)	Instruction (%)	Waiting (%)	Group difference (<i>p</i>)
All patients		(pre 338/post 288)	(pre 112/post 94)	(pre 110/post 90)	(pre 116/post 104)	
Emergency visit	pre ^a	64.3	65.8	66.1	61.1	0.681
	post ^b	43.1*	37.2	54.4	38.5	0.030
Hospitalization ^c	pre	14.7	14.5	16.5	13.3	0.788
	post	6.9**	5.3	8.9	6.7	0.631
Patients on ICS at inclusion		(pre 248/post 214)	(pre 88/post 76)	(pre 81/post 66)	(pre 79/post 72)	
Emergency visit	pre ^d	66.8	64.8	71.3	64.6	0.590
	post ^e	43.5*	30	59.1	43.0	0.003
Hospitalization ^c	pre	16.6	14.8	18.8	16.5	0.786
	post	6.5***	3.9	7.6	8.3	0.514

^a One or more in the half year before randomization; mean number was 2.2, with no difference between groups, for all patients^b One or more in the half year before evaluation; mean visit number after education was 0.8, after instruction 1.3, and 0.8 in the waiting group, respectively ($p=0.032$ for group difference)^c One or more in the half year before randomization/evaluation; only single hospitalizations^d One or more in the half year before randomization; mean visit number in the education group was 2.3, in the instruction group 2.2, and 2.8 in the waiting group, respectively ($p=0.924$ for group difference)^e One or more in the half year before evaluation; mean visit number after education was 0.6, after instruction 1.5, and 0.9 in the waiting group, respectively ($p=0.003$ for group difference)* $p<0.0001$, pre vs. post** $p=0.001$, pre vs. post*** $p=0.0005$, pre vs. post

Table 4 Changes during the observation period

		All (pre 338/post 288)	Education (pre 112/post 94)	Instruction (pre 110/post 90)	Waiting (pre 116/post 104)	Group difference (p)
Medication						
SABA inhalation as emergency medication	Pre	75.4%	75.7%	76.4%	74.3%	0.930
	Post	81.6%	91.5%	82.2%	72.1%	0.002
Oral CS as emergency medication	Pre	33.2%	38.7%	30.9%	30.1%	0.310
	Post	36.1%	44.7%	37.8%	26.9%	0.031
ICS as controller	Pre	74.3%	79.3%	73.6%	69.9%	0.272
	Post	64.2%	71.3%	57.8%	63.5%	0.158
SABA as controller	Pre	35.3%	33.3%	36.4%	36.3%	0.865
	Post	16.3%	9.6%	15.6%	23.1%	0.036
Preparedness to emergency						
Emergency plan in writing at hand	Pre	38.1%	36.9%	39.4%	38.1%	0.928
	Post	61.8%	83%	64%	40.4%	0.001
Asthma emergency management test (points $\pm$ SD)	Pre	3.8 $\pm$ 2.2	3.9 $\pm$ 2.2	3.8 $\pm$ 2.2	3.6 $\pm$ 2.3	0.43
	Post	6.3 $\pm$ 3.7	8.6 $\pm$ 3.3	6.2 $\pm$ 3.4	4.3 $\pm$ 2.9	0.001

However, after the intervention, those having a plan scored 7.4 versus 4.7 (means, $p < 0.001$).

Asthma control is influenced by many factors. In general, a randomized controlled trial is thought to be balanced for all factors beside the intervention. However, as expected we saw factors not directly influenced by instruction/education changing during the trial. Therefore we wanted to control for those factors we could identify by the descriptive statistics, and also those belonging to the same category, which we regarded influential for the number of emergencies more or less independent on instruction/education: ongoing ICS controller treatment, regular use of SABA as reliever, having a treatment plan, having an emergency plan, and parents' attentiveness.

In a first step of a multivariate regression analysis with the outcome “emergency visit,” we could first show that parents' attentiveness, having a treatment plan, and the regular use of SABA as reliever had no significant ($p > 0.2$) influence. In the final model after variable selection (Tables 5 and 6) in the whole study population, having only an instruction was a risk factor for the need of an emergency visit (OR, 2.0) when compared with those families who had asthma education.

In the subgroup with ICS use at study entry, the risk was even higher (OR, 3.99) and was increased also in the waiting group (OR, 2.5). Ongoing ICS controller therapy (mirroring asthma severity) was an independent risk factor for an emergency visit in either population.

Asthma severity as measured by the Rosier score decreased in either group (education pre/post mean: 7.8/5.8, training 8.5/7.4; waiting 8.8/6.6; $p < 0.0001$ for the decrease, and $p = 0.41$ for the comparison of differences). In accordance to this, the asthma impact on family life was diminished by time, less so by the different interventions (Table 7).

Discussion

In this trial, we aimed to evaluate the effect of a standardized family-oriented psycho-educational asthma training program in comparison to the standard basic instruction given to the parents of children with asthma, aged 2–5 years. Families were randomized to either one of these groups or a group waiting for the program. The included patients could be characterized as suffering mild to moderate asthma according to the Rosier score; 75% of them were taking ICS as controller at study entry.

The education program improved knowledge on asthma and skills as—documented by the asthma emergency management test—more effective than instruction alone. The waiting group remained unchanged.

Regarding the main outcomes, the percentage of patients with emergency visit went down in general from the half year before inclusion (64.3%) to the half year before evaluation (43.1%). The effect was significantly greater in the education (65.8% to 37.2%) than in the instruction group (66.1% to 54.4%), a difference that was even more

Table 5 Risk factors for the need of an emergency visit in the 6 months before evaluation. At study entry, 248 patients regularly used inhaled corticosteroids. A complete data set (including the second evaluation) was available from 214 children. For this subset of patients the distribution of the parameters of the final model are given

	Education <i>n</i> =76 (%)	Instruction <i>n</i> =66 (%)	Waiting <i>n</i> =72 (%)
Emergency visit	30.2	59.0	43.0
Emergency plan at hand	84.2	66.6	47.2
Ongoing ICS controller therapy	77.6	69.7	79.1

Table 6 Risk factors for the need of an emergency visit in the 6 months before evaluation. The final model for the all patients and the subgroup on ICS at study entry is given

Final model	Emergency visit during 6 months before evaluation					
	All patients			ICS at study entry		
	Odds ratio	95% C.I.	<i>p</i> value	Odds ratio	95% C.I.	<i>p</i> value
Education group	1	Control		1	Control	
Instruction group	2.20	1.20–4.06	0.0114	3.99	1.89–8.40	0.0003
Waiting group	1.19	0.65–2.16	0.5783	2.50	1.16–5.37	0.0187
ongoing ICS controller therapy	1.84	1.07–3.06	0.0261	2.60	1.25–5.39	0.0102
emergency plan at hand	— ^a			1.80	0.91–3.52	0.0869

^a OR, 1.29; *p*=0.47 in the initial multivariate model

pronounced in the subgroup of children with need of ICS at inclusion (Table 3).

The same could be observed in the numbers of hospitalizations, but not at a significant level.

As educational measures are prone to contamination [13], we sought to control for variables, which could represent contamination by a multivariate analysis: The only independent significant risk factor for an emergency visit was the need for ICS, mirroring asthma severity. Again in the group with need of ICS at inclusion education showed a more pronounced effect on emergency visits in the whole group: the OR for need of an emergency visit in the training versus the education group were 3.99 versus 2.02 (Table 6). This observation is in line with meta-analyses on education in difficult asthma [14] or severe asthma (indicated by a hospitalization) [3] where it was easier to show an effect of education than in asthma in general [2].

In the meta-analysis of Boyd et al. [3], an effect on the number of emergency visits was shown, when combining three studies (two from USA and one from UK) on children recruited after an asthma hospitalization [15–17] in the age group of 1–5 years. However the patients of two of these studies only had a mean age under 6, with a maximum

recruitment age of 9 [15] and 15 [17] years. The setting of the three studies [15–17] were different (primary care, secondary/primary care), as were the measures in the control group (usual care, basic/asthma education, and single intensive asthma education) and those in the intervention group (home visits {6x 1 h} by a nurse, written material plus two instructions {partially home based} by a nurse, and 2 years follow-up by a case-managing nurse). In our study, the instruction group was more or less treated like the control group in those studies, whereas our education group received more hours of psycho-educational program, but with a lower instructor to patient ratio due to the training in groups.

As a single study, only the last one reported a significant effect of the intervention. In the meta-analysis, a significant risk ratio of 0.72 could be calculated for emergency visits, the risk of hospitalization was not found to be diminished [14; analysis 2.1 and 2.2]. In our study, the risk ratio education/instruction was 0.68 for all patients and 0.51 for those using ICS at inclusion. We regarded reporting the risk ratio alone as insufficient even in a randomized study. The background of the study was a rather poor adherence of German pediatricians to the national asthma guideline with e.g., a high rate of misuse of salbutamol as a controller.

Table 7 Effects of intervention on family life

		All (pre 338/post 288)	Education (pre 112/post 94)	Instruction (pre 110/post 90)	Waiting (pre 116/post 90)	Group difference (<i>p</i>)
Disruption of parents sleep (# of nights, mean ± SD) ^a	Pre	15.7±23.1	14.1±20.1	15.7±21.7	17.2±26.9	0.688
	Post	7.3±14.1	4.7±7.4	7.2±9.8	9.8±20.2	0.030
	Difference ^b	−8.6±22.4	−10.2±18.7	−8.6±18.0	−7.1±28.3	0.160
Parents work days lost, mean ± SD) ^a	Pre	7.4±11.2	6.0±7.3	7.2±10.4	8.8±14.6	0.886
	Post	3.3±7.3	2.4±5.0	2.5±4.6	4.9±10.2	0.221
	Difference ^b	−4.1±10.4	−3.3±6.6	−5.0±9.6	−4.2±13.4	0.153

^a In the 6 months before randomisation/evaluation

^b *p* for all pre–post differences <0.001

Fortunately, during the time when the study was conducted, misuse diminished but not in the same amount in either study group. This change happened not only in the education and instruction groups, but also in the waiting group due to the circumstance that the treating physicians may have been taught to prescribe the correct medication also by others beside us (we indeed had to instruct families and doctors during the training according the national asthma guideline). A meta-analysis of disease management programs has shown that good patient education and successful guideline implementation are both needed for a sufficient asthma control [18], and that therefore, they cannot replace each other.

Even after introducing all the variables mirroring possible bias in the calculation, the instruction group had a higher risk of an emergency visit than the education group (OR, 2.02). This holds also true for the subgroup analysis of those children on continuous ICS at inclusion (OR, 3.99); in this subgroup, also the members of the waiting group had a higher risk for an emergency visit (OR, 2.5).

To our surprise, the waiting group did nearly as well as the education group. Coffman et al. [3], when reasoning about the fact that they observed less hospitalizations but an unaffected number of emergency visits as a result of asthma education, made the point of a possible paradoxical effect of education: Those parents might be sensitized by asthma education for breathing difficulties and will seek help in a situation, which would not force the uneducated ones to do so. A closer look on the interventions described in the meta-analysis proved them to be most similar to what was given as an instruction in our study. In a systematic review on the effectiveness of psycho-educational interventions on health outcomes in children with difficult asthma, the authors also found that psycho-education in comparison with standard asthma training reduces the number of hospitalizations [14].

We interpret this bell-shaped curve of the number of emergency visits starting with low numbers in the group on the usual care, with the peak in the instructed/trained patients and a low number in those having received a psycho-educational intervention as follows: standard care means that the child got the diagnosis of asthma and (a pair of) drugs. Of these, salbutamol is the “powerful” drug and used for exacerbation. The perception of asthma is low, and so is the number of visits. Asthma training/instruction means that the basic knowledge of asthma has been taught, and inhalation skills have been learned. Thus, the awareness of asthma is increased, presumably more than the competence to cope with exacerbations. Only the psycho-educational approach eventually empowers the patients and his family to cope with a substantial number of different asthma events adequately.

Apart from asthma training and education, the number of emergency visits in a given population is also highly dependent on asthma severity, the availability and compliance with guidelines by the health care provider, and the socio-economic background.

Weaknesses of the study are those inherent to the study topic: first is the difficulty in diagnosing asthma in this age group. The studies [8–10] defining guideline criteria for asthma in the study age group had a focus on prognosis rather than on patients' need for treatment of the actual condition (bronchial hypersensitivity). Thus, our inclusion criteria followed the guideline for inclusion but were not exclusive if these [10] were not fully met. Reasonably, the use of ICS as controller should start an integrated asthma therapy. Furthermore, as asthma education in Germany is seen as a pedagogic intervention, no direct influence on the asthma medication of the single patient is possible. However, as this will be the health-care reality for several years, the study describes best the role of contemporary asthma education.

Another weakness could be the fact, that education quality is highly dependent on the educating individuals, and especially so in the case of a multicenter study. However, the teams involved in the study must have been certified pediatric asthma training teams for the age group over 5 years. In addition, there were two half day meetings at the annual national conferences of the AG Asthmaschulung to assure an equal approach in each city.

Every measure in health care should be cost-effective. A calculation on this is easy if the measure is as simple as taking a pill, and the medical background is stable, like in a health maintenance system [17], and as it was in Germany, when asthma education was introduced [5, 6]. As a kind of blueprint, the calculation on the health economic impact of the standardized patient training course program on neurodermatitis in Germany could be used [19]. However, the conditions of diagnosing, treating, and health care management of pediatric asthma in Germany now are changing rapidly in only one year's time, with a new national guideline introduced by the end of last year [20] and a new disease management program this year. Thus, it only can be said, that asthma education is effective in improving asthma management and control in the children 2–5 years old.

Two-to-five-year-old children with bronchial hypersensitivity do not outgrow their disease quickly. This German study provides evidence, that in this group of patients, a family-oriented psycho-educational asthma program is superior to the standard instruction of parents. In the first instance, the program should be made accessible to each asthmatic child. Comprehensive recommendations for further research, especially for studies on cost-effectiveness, can be found in the HTA report [14].

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Appendix

Asthmaschulungen für Eltern von Vorschulkindern

The ASEV Study group

Team	City	Members
Der Bunte Kreis	Augsburg	Michael Gerstlauer, MD Cordula Seidl Carmen Fromme
Puste mal	Berlin	Petra Wagner PD Doris Staab, MD
TAK-TIC	Bielefeld	H.-G. Bresser, MD Kerstin Landwehr, MD Katharina Hagemeister
Luftkurs	Osnabrück	R. Szczepanski, MD Sylvia Lindner
Kölner Puste-Pänz Kölner Förderverein für das Allergie- und asthmakranke Kind e.V. AG Kinderasthmaschulung Luftmobil	Köln	Eckhard Korsch, MD Monika Aichele-Hoff
	Versmold	Maria Oberschelp Gisela Friede Gitta Brockmann
Atme los	Wesel	Claudia Suerbaum, MD Irene Groß
Ambulantes Schulungszentrum Würzburg	Würzburg	Doris Götz Ursula Hartung, MD
Asthmaschulungsteam Dr. Heitz	Stuttgart	Manfred Heitz, MD Marion Rokenbauch
Praxis-Luftkurs Neuss	Neuss	Jürgen Funck, MD Kirsten Kolm Franjo Obradovic
Atempause	Bielefeld	Uwe Büsching, MD Joachim Kühn, MD Jutta Redekop Frau Mrozowski
Asthmateam Blasius	Erlangen	Karla Plöger-Trinczek Karin Schellenberger
Asthmaschulung Pustelblume	Fürth	Irena Neustädter, MD
Asthmaschulung "Atemzug"	Hückeswagen	Dieter Bulle, MD
Institut für Disease Management oHG	Essen/ Dortmund	Dirk Straub, MD Hans-Jörg Köhler, MD Frank Neuhaus
Aufwind	Hamburg	Martin Tiedgen, MD

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