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Telemonitoring in Asthma Control: A Randomized Controlled Trial

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Keywords: home-monitoring, exacerbation, asthma control test (ACT), peak expiratory flow (PEF), communication technologies

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Abstract

Objective. Telemonitoring seems to be a useful tool for patients' management. The aim of our project was to test the applicability and potential effects of a 12-months telemonitoring of patients with asthma supported by information and communication technologies.

Methods. We included 100 patients with asthma followed in the outpatient pulmonary clinic in a randomized controlled clinical trial. The patients' data was collected by study questionnaires and lung function tests at the inclusion and at the end of interventional period. In the interventional group asthma control test (ACT) and peak expiratory flow measurements (PEF) were stimulated to be regularly reported by Short Message Service (SMS). As a response to reported values, the patients automatically received a preformed text or a call from a study nurse in case of detected predefined critical values.

Results. The compliance of reporting PEF and ACT values was higher than 80% in 96% of patients. Although we did not detect significant differences in ACT score improvement between the two study groups, we found more prominent improvement of ACT score in the subgroup of patients with two or more exacerbations prior to inclusion in the interventional group, compared to the control group. 40 (78%) patients in the interventional group listed at least one positive effect of telemonitoring on management of asthma.

Conclusions. The developed program for home-monitoring of patients with asthma was applicable and offered the patients support in managing their disease. Further studies with more selected patients are needed to confirm its usefulness in improving asthma control.

Keywords: home-monitoring, exacerbation, asthma control test (ACT), peak expiratory flow (PEF), communication technologies

Introduction

Asthma is a common chronic respiratory disease with an estimated prevalence from 2% to 12% in adults (1). Its chronic inflammatory course can be interrupted by acute exacerbations, which apart from worsening the patients' quality of life significantly influence the economic burden. In addition to decreasing the patient's efficacy and causing lost working days, these symptoms are also reasons for emergency department visits and hospitalizations and can even be fatal, especially in cases of inappropriately treated uncontrolled asthma (2,3).

The key factor in asthma control, apart from recognizing the right diagnosis and choosing proper medications, is achieving optimal patient cooperation. The patient's awareness of potential threatening exacerbations and adherence to medication regimens is unfortunately still far from optimal at all severity levels of asthma. Important consequences of suboptimal adherence are poor asthma control, increased mortality and hospitalization rates, decreased quality of life and reduced lung function (4,5).

Effective asthma management can be reached with developing the partnership between the patient and medical personnel, where good communication and proper patient education are crucial (6,7). Apart from knowledge of the disease, the patient needs to be responsible, continuously take the prescribed drugs and monitor the symptoms and peak expiratory flow (PEF), which can warn them of asthma exacerbation (AE) and indicate adaptation of treatment (8,9). Self-management of asthma reduces asthma-related hospitalizations, emergency department visits, missed work/school days and nocturnal waking by one-third to two-thirds (9).

Home telemonitoring enables integrated self-management by providing ongoing monitoring and feedback combined with two-way communication and exchange of information between the patient and medical team (10).

It has positive effects on patients' behaviours and attitudes, and this approach allows the patients to actively participate in the process of care, improves their feeling of security and leads to empowerment in different chronic diseases (11). It also allows identification of early signs of deterioration in patient health and control of acute exacerbation (12).

The purpose of our project was to test the influence of 12 months of continuous home-monitoring of patients with asthma supported by information and communication technologies (ICT) on asthma control. Second, we were interested to what extent telemonitoring can reduce the exacerbation rate and severity, and how supportive can it be in asthma management.

Methods

This single-centre prospective randomized controlled clinical study was conducted from November 2014 through October 2015 at the University Clinic of Pulmonary and Allergic Diseases Golnik, Slovenia. The trial was in accordance with the Helsinki Declaration and was approved by the Republic of Slovenia National Medical Ethics Committee (NMEC, No. 91/10/13).

Patients

We included 100 patients with asthma, aged 18-75, who had a follow-up visit between March and June 2014 in the outpatient department of the university pulmonary clinic, fulfilled the inclusion criteria and agreed with participation in the study by providing written informed consent. All patients were educated in guided self-management and were taught to use a written asthma action plan. Apart from the confirmed diagnosis of asthma (positive methacholine or bronchodilator test), the additional inclusion criteria were at least one asthma exacerbation in the past year with a need for intensification of inhaled corticosteroids or use of systemic corticosteroids, or one of the following symptoms in a stable phase of the disease: daytime or night-time symptoms more than twice a week, use of short-acting bronchodilators more than twice a week, and activity limitation due to asthma. Seven patients (four in the intervention and three in the control group) were treated regularly with stable doses of systemic corticosteroid and omalizumab for more than one year prior to inclusion. We excluded individuals who had an uncertain diagnosis of asthma, experienced asthma exacerbations or had unstable doses of systemic steroids in the last four weeks prior to inclusion, had no access to a mobile phone or had difficulties with using a Short Message Service (SMS) system.

After inclusion in the study, patients were automatically randomized to the intervention or control group in a ratio 1:1 by a computer program.

Outcomes and data collection

The primary outcome was the change in asthma control in one-year study period. The secondary outcomes were the changes between baseline and the endpoint number of exacerbations per patient per year and lung function values. We also assessed subjective effects of programme on asthma symptoms and management.

The patients' data was collected upon inclusion in the study and at the end of a 12-month interventional period by validated test for asthma control assumption - Asthma Control Test (ACT, GlaxoSmithKline), two additional questionnaires and pulmonary function tests (lung volumes, peak expiratory flow (PEF) and exhaled nitric oxide (eNO)).

Additional questionnaires were designed to obtain subjective data about patients' knowledge about asthma and AE treatment, compliance with prescribed ICS medication, subjective perception of symptoms, frequency of acute exacerbations in the year prior to study inclusion and during the study year, and their evaluation of potential programme influence on their asthma management, symptoms, or AE. The latter questionnaires were created by our study group and filled in by the patients at the initiation and at the end of the study year.

Our hypothesis was that telemonitoring would improve asthma control more than conventional asthma treatment. We further expected positive and supportive subjective influences of the programme, resulting in better adherence, lower AE rate, and less symptoms.

Acute exacerbation was defined as an increase in asthma symptoms (shortness of breath, chest tightness, cough, night symptoms, limited activity because of increased symptoms or

wheezing) and a progressive decrease in PEF values or higher PEF variability (support of written self-management plan). AE was detected by the patients and reported at the end of the study. Additionally, a decrease in ACT score and PEF values below the critical values were also detected by the Web-based application in the intervention group.

Software support and interventions

In the scope of the project, we developed a Web-based application for patients with asthma. The solution enabled efficient management of clinical and semantic interoperability, which serve as predispositions of contemporary health care information systems. Clinical data modelling was based on OpenEHR methodology, and BPMN 2.0 was used for process modelling. Due to the use of the OpenEHR platform, the program was ready to connect to the national central patient data registry (CRPP), which was legally established in June 2015.

All patients in the intervention group had access to both SMS and web reporting. They were given instructions and a password for using a web application. They entered their data via SMS or through the web; we did not detect the method of sending the data. Participants received a reminder via an automated SMS to send in PEF values once per week and ACT scores once per month, and the reminder also appeared in the internet application. The data were entered as two-digit (ACT) or three-digit (PEF) numbers.

If the values were not entered or sent within 48 hours, an additional reminder was sent to the patients. The patients were further instructed to measure the PEF values daily and enter the unscheduled PEF values in the system whenever they detected a decrease in PEF (especially during AE). The system also detected unscheduled values.

In the case of detecting preliminary defined critical values for PEF (<80% of best value) and ACT (<20 points), the automatic alarm notice was sent by the application to the study nurse,

who checked the application three times daily on working days. The study nurse conducted follow-up calls to determine possible reasons for decreased values. In the case of need, the patient's pulmonologist was included to advise the patient by phone or arrange a follow-up visit. The study patients were enrolled and treated by three pulmonologists and two study nurses.

The control group did not have access to the web service and did not receive SMS reminders. All patients in interventional and control groups continued with their ongoing asthma care from their pulmonologist, had regular appointments every 3 to 6 months, and were instructed to measure PEF daily and ACT monthly.

Statistical analysis

All statistical analyses were performed in R statistical software (R Core Team, 2017). Quantitative data are represented as medians and interquartile ranges or means and standard deviations, as appropriate (normality of the distribution was evaluated using the Shapiro-Wilk test, and the assumption of normality was rejected if $p < 0.05$). Qualitative data are represented as sample proportions. The data were compared at different time points using a Wilcoxon signed-rank test or a paired t-test, and the groups (test vs. control) were compared to each other using the Mann-Whitney U test or unpaired t-test, as appropriate. A McNemar test was performed to compare the pre- and post-interventional portions of patients with well controlled asthma ($ACT > 20$). To evaluate the independent effect of participation in the test group on ACT differences (ACT after inclusion – ACT before inclusion), we performed logistic regression analysis with ACT difference as the outcome variable and variables with a possible impact on ACT difference as predictors (ACT before inclusion, study group (test vs. control)).

Results

Of 100 patients with asthma who were enrolled in the study, 51 patients were randomized in the interventional group, and 49 in the control group. All 100 patients were included in “intention to treat” (ITT) analysis. The study was completed by 49 (96.1%) of the participants in the interventional group and 49 participants (100%) in the control group. One patient left the study two months after the inclusion because she was diagnosed with kidney cancer. The other patient, who was on omalizumab treatment (with regular visits at pulmonologist) and had frequent critical PEF values, stopped sending values after 6 months, because of frequent alarms and interventions (Figure 1).

Patient characteristics at baseline are shown in Table 1 and are similar in both groups, except a significantly higher exacerbation rate in the year prior to inclusion in the interventional group ($p < 0.05$). Patients considered themselves highly educated (subjective evaluation on scale from 1 to 10; median (interquartile range-IQR)) about asthma management 8 (7-10), AE treatment 8 (7-10) and inhalation technique 9 (8-10).

The compliance of reporting PEF and ACT values through a 12-month period was good and was higher than 80% in 49 of 51 patients, the majority of patients (88%) reported their values, with compliance of more than 90%.

Total amount of contacts required due to values being below our critical value was on average 2-4 per week (4-8% of patient). The highest frequency of check-up calls was in the week of reported ACT values.

Asthma control measured by ACT

We detected a statistically but not clinically significant increase in the ACT score in post-study values (median with IQR) in the interventional group 20 (17-24) and the control group 22 (19-25), compared with pre-study values in both groups; 18 (12-23) in the interventional group and 21 (16-24) in the control group (Table 2). The clinically minimal important difference of 3 points was reached in 17 (33.3%) patients in the interventional group and 15 (30.6%) patients in the control group.

When we selected only the patients who experienced two or more exacerbations prior to study inclusion (higher AE rate), we could detect a higher and statistically significant increase in ACT after 12 months of telemonitoring in the intervention group, in contrast to non-significant increase in the control group (Table 2). After adjusting for the baseline ACT score in repeated measures regression analysis, the trend of higher ACT score after 12 months with regard to test group persisted (coefficient for the test group was 1.27), however it lost its statistical significance. Ten of twenty-four (41.7%) high-AE-rate patients in the interventional group and four of eighteen (22.2%) in the control group reached a clinically minimal important difference in ACT score of 3 points. The number of patients with controlled asthma according to ACT (>20 pt), significantly increased in the interventional group, at the end of a study, in comparison to control group, where the number did not change significantly (Table 2).

Evaluation of the programme effects

Forty patients (78.4%) reported at least one of the listed positive subjective effects of telemonitoring on management of asthma, and 41 (80.4%) were interested to continue the programme. Twenty-eight (54.9%) patients thought the programme resulted in a reduction in

asthma symptoms, 22 (43.1%) reported faster detection and treatment of exacerbations, 15 (29.4%) patients better self-control and 8 (15.7%) better control of medicine supply (Figure 2). Additionally, 4 (7.8%) patients reported higher sense of safety. Although 12 (23.5%) patients stated that the programme improved their adherence, we did not notice an additional increase in the mean reported adherence rate in the study year, which was already high at baseline (80.4%).

Acute exacerbations of asthma and lung function parameters

In the year prior to the study initiation, 48 (94.1%) patients in the interventional group experienced at least one mild to moderate asthma exacerbation, compared to 35 (71.4%) patients in the control group, with a median (IQR) exacerbation number per year 1.0 (1-4) in the intervention and 1.0 (0-2) in the control group ($p<0.05$). Two or more AE were reported in 24 (49.0%) patients in the interventional and in 18 (36.7%) patients in the control group.

During the study year, the number of patients experiencing exacerbation decreased in both groups to 25 (47.1%) in the interventional group and to 24 (49.0%) in the control group. We detected a significant decline in exacerbation number per year in both groups (Table 2). Even though, there was a trend toward higher decrease in AE rate in the intervention group with median and IQR of 1.0 (0-2) compared to control group with median 0 (0-1), the difference in AE decrease between the groups was not significant (Figure 3). Additionally, 7 (13.7%) patients in intervention group reported shorter duration of AE.

The subjective reported rate of AE correlated to the frequency of critical PEF values recorded by Web application, with $r = 0.65$, $p=0.001$, and to critical ACT values, with $r=0.5$, $p=0.001$.

There were no hospitalisations during the study and eleven patients required a three to five day course of oral corticosteroids (five in the intervention and six in the control group). In the

year prior to the study, there were also no hospitalisations; seven patients in interventional and nine in control group required a short course of oral corticosteroids.

We detected a higher increase in PEF, FEV1 and VC values in the interventional group than in the control group, but it did not reach statistical significance. There were no significant differences in changes between pre- and post-study values of eNO in both groups (Table 2).

Discussion

The results of this study confirmed the applicability of the developed home-monitoring programme for patients with asthma.

Asthma is a chronic disease in which patients play a crucial role in their treatment. Previous studies demonstrated that patients can control their disease better if they self-monitor their symptoms and PEF, follow a written action plan and attend regular control visits (13). Our internet and mobile application was developed to be simple and did not demand additional knowledge. It stimulated patients to monitor their disease regularly and gave them an overview of their PEF and ACT values. The majority of our patients (98.0%) completed the 12-month study period. Patients reported ACT and PEF values regularly; the reporting compliance was more than 80% in 96% of patients and over 90% in 45 (88%) patients.

In the scope of self-management of asthma, different telecommunication-based systems have been developed and tested. Our study, which included regular stimulated home monitoring of asthma and medical feedback, detected a statistically significant increase in ACT after 12 months in both the interventional and control group, but failed to confirm a significant improvement in ACT score change in the interventional group compared to the control group,

which was our primary outcome. Improvement in ACT score in the control group could be explained by the effect of more activated and engaged participants in the study. It has already been shown that patients who were included in the study were more likely to engage in positive health behaviours and to adhere more closely to prescribed medical regimens and self-care guidelines. Text-messaging interventions (e.g., reminders, feedback on treatment success) can enhance self-efficacy, and support mechanisms may influence health behaviour and enhance self-management of chronic illnesses(14,15).

Perhaps a reason for negative results was in the selection of patients. Our patients were highly educated about management of asthma, majority attended asthma school, followed a written action plan and were highly engaged, which could have an effect on primary outcome. Previous study, which showed the positive effects of home monitoring, and an increase in asthma control, quality of life, lung function, and airway responsiveness, included mainly less committed patients from general practices. Patients in the control group did not receive any asthma educational session as patients in the interventional group, which magnified the difference in asthma related knowledge (16). Similar findings were reported by another study that included three study groups (telecommunication, control and traditional group that was instructed to follow their written plan). They could detect superiority of telecommunication group only when comparing with the control, but not traditional group (17). The conclusion could be that telemonitoring does not benefit much well educated patients with controlled asthma who already follow their written action plan.

Among negative studies, two meta-analyses failed to prove the difference in asthma symptoms score changes between telemonitoring and standard care, but the included studies differed in duration of the interventions (3 to 12 months), used technologies, interventions and outcome measurements. This extreme heterogeneity makes a comparison of different studies and a synthesis of the results very difficult (18,19).

Stratifying the patients according to the pre-study AE rate enabled us to recognize the patients who might benefit from telemonitoring the most. We detected statistically significant increase in ACT after 12 months of intervention among the patients with two or more exacerbations (high AE) prior to study inclusion in the intervention group, which was not the case for high AE control group. Even though the significance was lost after using regression analysis, the trend of higher ACT score after 12 months with regard to test group persisted. Additionally, the number of patients with well controlled asthma (ACT >20) significantly increased after 12 months of telemonitoring in high AE intervention group. Although the number was small, a higher proportion of patients in the interventional group experienced a clinically important difference in ACT score at the end of the 12-month interventional period: 10 (41.7%) vs. 4 (22.2%) in the control group. These positive effects could be explained by faster detection of exacerbation and adjustment of therapy, better compliance and positive influence of continuous care management. Detected differences between the small groups need further investigation with larger and more homogeneous study groups.

Telemonitoring of PEF and asthma symptoms provides an acceptable sensitivity and specificity for the detection of exacerbations of asthma (20). In our study events with critical PEF values correlated to the rates of reported rate of AE by patients. We detected statistically important decline in mild to moderate exacerbations in both groups. At the beginning, the interventional group had a higher rate of exacerbations per year, and at the end of the study, the rate significantly decreased and did not differ between the groups anymore. Seven patients reported milder and shorter AE in the study period compared to the year prior the study. Still, we could not detect significantly higher decrease of AE in the intervention group. One meta-analysis showed that telemonitoring significantly reduces the number of exacerbations requiring hospital admission in adults, but most of the previous studies failed to prove reduction of asthma exacerbations (17,18,21–23).

As previously suggested, telemonitoring has influence on patient's health behaviour and asthma self-management, which was also detected in our study. The developed programme offered regular feedback information and treatment advice from medical staff, especially in exacerbations, when they were most vulnerable. According to the results of the pre-formed evaluation questionnaires, majority of patients stated at least one of the positive subjective effects of the program. They reported fewer symptoms, faster recognition and treatment of AE, milder and shorter AE, improved self-control of asthma and/or higher sense of safety as a result of the programme intervention. Overall, patients were satisfied with the tested programme, and 41 (80.4%) of them wanted to continue with home monitoring in the future. Although 23.4% of the patients reported better adherence, we could not find any significant influence of the programme on cumulated patient's adherence reported in the questionnaires, which was already high (80.4%) at baseline. High adherence was probably a result of the fact that these patients were treated in the tertiary centre and were highly stimulated and educated for asthma treatment by their pulmonologists and trained nurses (educational data shown in Table 1).

The application also offers a structured graphical overview of the patient's regular PEF/ACT values during the time, which could be a useful tool for continuous patients monitoring in studies testing new treatment approaches.

Even though telemonitoring has an additional value to a standard care, there are also potential disadvantages of telecommunication. One of them is a risk of inaccurate data input leading to an inappropriate action. We minimized the risk by a phone call to the patient to verify the accuracy of the sent data before giving the advice and possible further action. The patients had an e-mail address and mobile phone number of a study nurse and were encouraged to contact her directly in the case of health or programme problems.

A limitation of our study was a small sample size, which was determined by limited resources. The programme was co-dependent on study nurse; since two nurses were responsible for check-up calls and also had their regular clinical work, the number of patients that were enrolled, was reduced to the capabilities of research staff. With 51 patients, two study nurses did not find the check-up calls demanding or time consuming. Secondly, perhaps more appropriate analysis of ACT, which reflects a situation in the last four weeks, would be the 12-month median of ACT, which probably more reliably indicates asthma control throughout the year. However, the calculated medians of ACT values in our patients were in most patients similar to the last reported ACT value, and we had no data about values of ACT in pre-intervention year and in the controls to compare. Even though most of the patients were satisfied with designed programme, there was a deficiency, which was probably a reason for not finishing the trial in one patient. Our critical values for ACT were set up below 20 points and PEF values below 80% of best value, which was too optimistic for patients with uncontrolled asthma. Constant alarm notifications led to dropping out in one patient treated with omalizumab.

Conclusions

This study has shown that the developed mobile and internet programme for home monitoring of patients with asthma was applicable and offered patient support in managing their disease. Even though, we did not detect clinically important increase in ACT score, or significant decrease of AE rate, there was a trend of a higher increase in ACT among the subgroup of patients with a high AE rate in the interventional group. Further investigations with more selected patients who could benefit most from regular home-monitoring are needed. Moreover, the application could be a useful tool for continuous patient monitoring in studies testing new treatment approaches.

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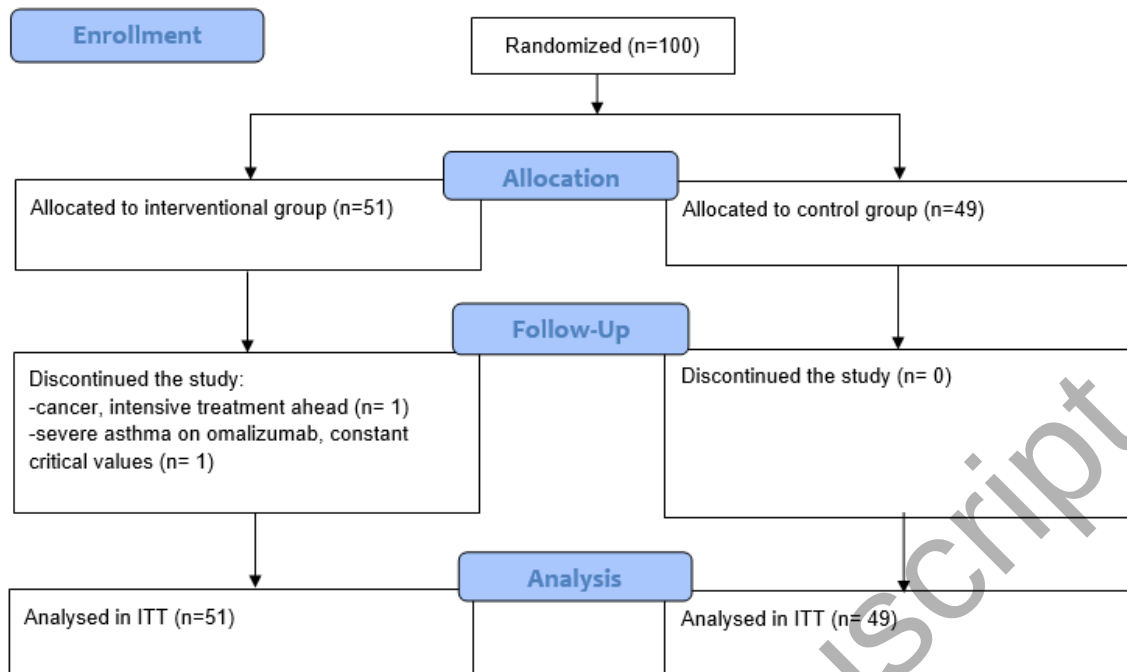


Figure 1: Trial profile

GROUP	INTERVENTION N=51	CONTROL N=49	p value
Gender (N/%)			
Male	24 (47%)	24 (49%)	NS
Female	27 (53%)	25 (51%)	NS
Age (years)	45 (39-61)	53 (40-60)	NS
Smoking (N/%)			
smokers	7 (14%)	6 (12%)	NS
ex-smokers	13 (25%)	18 (37%)	NS
non-smokers	31 (61%)	25 (51%)	NS
BMI (kg/m2)	27 (23-31)	27 (23-31)	NS
Atopy (N/%)	33 (65%)	32 (65%)	NS
Age at diagnosis (years)	34 (20-48)	37 (24-47.5)	NS
Therapy (N/%)			
ICS	13 (25%)	13 (26%)	NS
ICS+LABA	37 (73%)	35 (71%)	NS
AE in last year (No)	1 (1-4)	1 (0-2)	p<0.05
Subjective evaluation of education of			
- Asthma management	9 (8-10)	9.5 (8-10)	NS
- Inhalation technic	8 (7-9)	9 (7-10)	NS
- AE treatment	8 (7-10)	8 (7-10)	NS

Note: BMI-body mass index, ICS-inhaled corticosteroids, LABA-long acting beta agonist

Table 1 Patients' characteristics of intervention and control group given as number of patients/percentages or medians/interquartile ranges

GROUP Pre/post- study	ALL PATIENTS				PTS WITH 2 OR MORE AE			
	INTERVENTION (n=51)		CONTROL (n=49)		INTERVENTION (n=24)		CONTROL (n=18)	
	pre	post	pre	post	pre	post	pre	post
ACT (points)	18 (12-23)	20 (17-24)	21 (16-24)	22 (19-25)	16 (11-19.5)	20 (14-22)	20.5 (15-23)	20.5 (14.3-25)
		p<0.05		p<0.05		p=0.05		p=NS
ACT <20p No(%)	30 (58.8%)	20 (39.2%)	23 (46.9%)	16 (32.7%)	18 (75.0%)	11 (45.8%)	8 (44.4%)	9 (50%)
		p<0.05		p=NS		p<0.05		p=NS
VC (%)	99 (86-111.5)	99 (87-111)	102 (89-112)	100 (92-109)	96 (84.8-108.3)	102 (87-111)	96 (85-107)	93 (77-103)
		p=NS		p=NS		p=NS		p=NS
FEV1 (%)	82.5 (73-96.3)	88 (77.5-92.3)	81 (71-96)	85 (70-96)	82 (75-94)	89 (77.5-96)	73 (55-88)	75 (60.8-93.8)
		p=NS		p=NS		p=NS		p=NS
TI (%)	68.5 (56-74.3)	66.5 (60-73)	62 (56-71)	64 (59-73)	67.5 (59.3-73.5)	68.5 (59.8-73.8)	61 (55-75)	63.5 59-72.3)
		p=NS		p=NS		p=NS		p=NS
eNO (ppb)	54 (30-96)	48.5 (27.3-100)	47 (32-91)	48 (30-94.5)	38 (22-81)	58 (38-100)	45 (34-95.5)	61 (42-95)
		p=NS		p=NS		p=NS		p=NS
PEF (L/min)	430 (320-570)	460 (380-610)	490 (400-555)	460 (310-475)	410 (320-535)	480 (400-555)	448 (398-505)	340 (280-460)
		p=NS		p=NS		p=NS		p=NS
AE in last year (No)	1 (1-4)	1 (0-2)	1 (0-2)	0 (0-1)	4 (2.3-4)	1 (0-3.5)	3 (2-4)	1 (1-1.8)
		p<0.01		p<0.01		p<0.01		p<0.01

Note: ACT-Asthma Control Test, VC-vital capacity, FEV1-forced expiratory volume, TI-Tiffeneau index (FEV1/FVC), eNO-exhaled nitric oxide, PEF-peak expiratory flow, AE-acute exacerbation.

Table 2: Pre- and post-study pulmonary function parameters, ACT and AE rate given as medians/interquartile ranges and numbers/percentages.

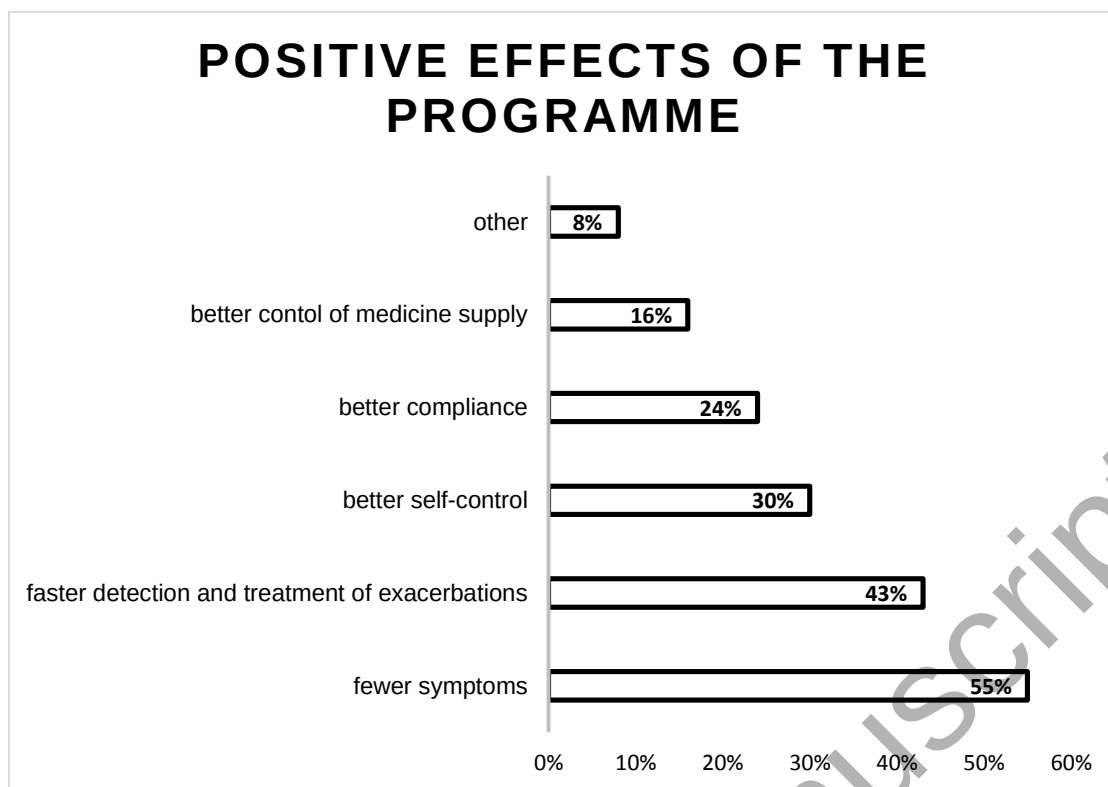
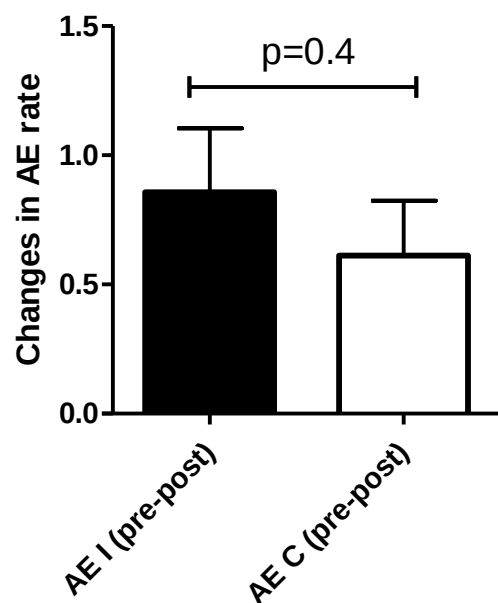


Figure 2: Subjective positive effects of the program on asthma control



*AE I- asthma exacerbation intervention group, AE C- asthma exacerbation control group. (Change in AE rate=AE number per year prior to study inclusion – AE number per year during study year)

Figure 3: Difference in asthma exacerbation rate pre- and post-study in interventional and control group