

Distance Education to Improve the Quality of Asthma Treatment in Primary Health Care: Cluster Randomized Clinical Trial - RESPIRANET

Educação a distância para melhorar a qualidade do tratamento da asma na Atenção Primária à Saúde: ensaio clínico randomizado em cluster - RESPIRANET

Educación a distancia para mejorar la calidad del tratamiento del asma en la atención primaria de salud: ensayo clínico aleatorizado grupal - RESPIRANET

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Abstract

Objective: The mere dissemination of standard care recommendations has been insufficient to improve clinical results in patients with asthma. The objective of the present study was to evaluate the clinical effectiveness of a multifaceted asthma distance education for primary care providers. **Methods:** Cluster randomized controlled trial. Full primary care teams were included if they had access to telehealth support and free basic asthma treatment. Before randomization, selected teams indicated asthma patients between 5-45 years old for inclusion. The intervention group received three interactive online sessions, printed educational material, reminders, booklet for patients, and frequent stimulus to use consulting services. The control group received no intervention. Symptom-free days per two weeks was the primary result. Controlled asthma, unscheduled asthma doctor visits, and preventive inhaled corticosteroid use were the secondary results. Six months after intervention, the results were compared with baseline data using generalized estimating equations for repeated measures and clustering effect. Results: Were enrolled 71 primary care teams and 443 individuals. Most patients (60.3%) were female, and 44% were younger than 12 years old. The attendance of interactive sessions by the teams was 50%. The odds ratio (OR) for additional symptom-free day was 1.31 (95%CI 0.61-2.82; p=0.49). For the secondary results, the results were: controlled asthma OR 1.29 (95%CI 0.89-1.87; p=0.18); unscheduled asthma doctor visits OR 0.81 (95%CI 0.60-1.10; p=0.17); and preventive inhaled corticosteroid use OR 1.02 (95%CI 0.71-1.47; p=0.91). **Conclusions:** Multifaceted distance education in asthma care for primary care providers was not effective to improve patients' results. Telemedicine needs to deal with significant obstacles in professional education. ClinicalTrials.gov registry: NCT01595971.

Keywords: Asthma; Education, Distance; Family Practice; Primary Health Care; Telemedicine; Clinical Trial

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Resumo

Objetivo: A mera disseminação de recomendações de cuidados padronizados tem sido insuficiente para melhorar os desfechos clínicos em pacientes com asma. O objetivo do presente estudo foi avaliar a eficácia clínica de uma intervenção educativa multifacetada a distância sobre asma para profissionais da atenção primária à saúde. **Métodos:** Ensaio clínico randomizado por cluster. Equipes completas de atenção primária foram incluídas se tinham acesso a suporte de telessaúde e tratamento básico gratuito para asma. Antes da randomização, as equipes selecionadas indicaram pacientes asmáticos entre 5-45 anos para inclusão. O grupo de intervenção recebeu três sessões online interativas, material educativo impresso, lembretes, folheto para pacientes e estímulos frequentes para o uso de serviços de consultoria. O grupo controle não recebeu intervenção. O desfecho primário foi dias sem sintomas por duas semanas. Asma controlada, consultas médicas não programadas para asma e uso preventivo de corticosteroides inalatórios foram os desfechos secundários. Seis meses após a intervenção, os resultados foram comparados com a linha de base, usando equações de estimativas generalizadas para medidas repetidas e efeito de agrupamento. Resultados: Foram inscritas 71 equipes de atenção primária e 443 indivíduos. A maioria dos pacientes (60,3%) era do sexo feminino e 44% tinha menos de 12 anos de idade. A frequência das equipes nas sessões interativas foi de 50%. O odds ratio (OR) para dias sem sintomas adicionais foi de 1,31 (IC 95% 0,61-2,82; p=0,49). Para os desfechos secundários, os resultados foram: asma controlada 1,29 (IC 95% 0,89-1,87; p=0,18); visitas não programadas de asma ao médico OR 0,81 (IC 95% 0,60-1,10; p=0,17); e uso preventivo de corticosteroides inalatórios OR 1,02 (IC 95% 0,71-1,47; p=0,91). **Conclusões:** Ações multifacetadas de educação a distância em cuidados de asma para profissionais de saúde da atenção primária não foram eficazes para melhorar os resultados nos pacientes. A telemedicina precisa lidar com obstáculos significativos na educação profissional. Registro ClinicalTrials.gov: NCT01595971.

Palavras-chave: Asma; Educação a Distância; Medicina de Família e Comunidade; Atenção Primária à Saúde; Telemedicina; Ensaio Clínico

Resumen

Objetivo: La mera difusión de las recomendaciones de atención estándar ha sido insuficiente para mejorar los resultados clínicos en pacientes con asma. El objetivo del presente estudio fue evaluar la efectividad clínica de una educación multifacética a distancia sobre el asma para los proveedores de atención primaria. **Métodos:** Ensayo controlado aleatorizado por grupos. Se incluyeron equipos completos de atención primaria si tenían acceso a apoyo de telesalud y tratamiento básico gratuito para el asma. Antes de la aleatorización, los equipos seleccionados indicaron pacientes con asma entre 5-45 años de edad para inclusión. El grupo de intervención recibió tres sesiones interactivas en línea, material educativo impreso, recordatorios, folleto para los pacientes y estímulos frecuentes para utilizar los servicios de consultoría. El grupo control no recibió ninguna intervención. El resultado primario fue días sin síntomas por dos semanas. Los resultados secundarios fueron asma controlada, visitas médicas no programadas para el asma y el uso preventivo de corticosteroides inhalados. Seis meses después de la intervención, los resultados se compararon con los datos de referencia utilizando ecuaciones de estimación generalizadas para medidas repetidas y efecto de agrupación. Resultados: Se inscribieron 71 equipos de atención primaria y 443 personas. La mayoría de los pacientes (60,3%) eran mujeres y el 44% eran menores de 12 años. La asistencia a sesiones interactivas por parte de los equipos fue del 50%. La razón de probabilidades (OR) para un día sin síntomas adicional fue de 1.31 (IC del 95%: 0.61 a 2.82; p=0.49). Para los resultados secundarios, los resultados fueron: asma controlada O 1.29 (IC del 95%: 0.89 a 1.87; p=0.18); visitas al médico para el asma no programadas O 0,81 (IC del 95%: 0,60 a 1,10; p=0,17); y el uso preventivo de corticosteroides inhalados OR 1.02 (IC del 95%: 0.71 a 1.47; p=0.91). **Conclusiones:** La educación a distancia multifacética en el cuidado del asma para los proveedores de atención primaria no fue efectiva para mejorar los resultados de los pacientes. La telemedicina debe enfrentar obstáculos significativos en la educación profesional. Registro de ClinicalTrials.gov: NCT01595971.

Palabras clave: Asma; Educación a Distancia; Medicina Familiar y Comunitaria; Atención Primaria de Salud; Telemedicina; Ensayo Clínico

Introduction

Asthma is a highly prevalent chronic disease that affects individuals of all ages, representing an important cause of morbidity and, consequently, direct and indirect healthcare expenditures.¹⁻⁵ The southern region of Brazil, characterized by a humid subtropical climate with well-defined seasons, moderately cold winters and hot summers,⁶ presents the highest prevalence of diagnosis for this condition, estimated at 5.3% of adults.⁷ Among elementary school students, the prevalence of clinical symptoms has been estimated at 23.6%.⁸ Among diagnosed adults, 30 to 43% report having experienced an exacerbation in the previous year and up to 16% live with important physical limitations caused by the disease.⁷ Factors associated with reduced control of asthma symptoms include the underreporting of uncontrolled asthma, underuse of recommended maintenance treatments, and lack of patient information about the disease.⁹

Although standard care procedures for patients with asthma are well established in internationally recognized clinical practice guidelines,¹ the mere dissemination of systematized recommendations has been insufficient to improve the care process or clinical results.¹⁰⁻¹³ Strategies involving organizational changes and educational interventions have been evaluated as potential alternatives to those currently used as part of an effort to improve the care provided to patients with chronic diseases.¹³⁻¹⁸ Reviews of interventions for changing professional practice have demonstrated the positive effects of combined educational strategies on care practices and clinical results.¹⁰⁻¹²

Access to continuing education for health professionals who practice in locations far from training centers can be difficult due to the necessary commuting time. A strategy that can favorably impact this situation is telemedicine, which has gained ground owing to the widespread use of information and communication technologies.¹⁹⁻²¹

In 2010, the *Programa Nacional Telessaúde Brasil Redes* (Networks Brazilian National Telehealth Program) was established to provide assistance to primary care providers in the public health system through synchronous and asynchronous consulting, tele-education and telediagnosis.^{22,23} The objective of the present study was to evaluate the clinical effectiveness of a multifaceted asthma distance education for primary care providers who are members of the Family Health Strategy^{24,25} (Box 1) in Rio Grande do Sul, the southernmost state in Brazil.

Box 1. Family Health Strategy in Brazil.

The Family Health Strategy (FHS) is the structuring model of Primary Care in Brazil since 1994:

- one FHS team is composed of a physician, a nurse, a nurse assistant and at least one community health worker;
- health promotion, preventive and curative care is provided;
- geographically assigned population of 2000 to 3500 people (although often there are assigned populations of 5000 people or more);
- **mainly municipal and federal financing, with variable contribution from some states;**
- great heterogeneity in professional training, quality of care provided and organization of the team work.

Methods

Study design

This was a cluster randomized trial, with health care teams allocated to one of two comparison groups. The intervention group participated in a multifaceted distance education intervention, while the control group received no educational intervention. The Research Ethics Committee of the Hospital de Clínicas de Porto Alegre evaluated and approved this study (no. 10-0245).

Participants

The study sample consisted of health care teams from the Rio Grande do Sul Family Health program that participated in the Brazilian National Telehealth Networks Program in 2010.²² Teams were eligible if they had at least one general practitioner, one nurse, one nurse technician and one community health worker, had the ability to recommend a minimum of ten patients with a diagnosis of asthma, and were located in

a municipality with free of charge inhaled medication for asthma treatment (short-acting bronchodilators and corticosteroids).

The recommended patients were eligible if they were between five and 45 years of age, had medically diagnosed asthma, and had at least one asthma doctor visit or hospitalization in the year prior to the beginning of the study. Individuals with other chronic diseases with pulmonary complications, such as tuberculosis, cancer, and cystic fibrosis, or those with severe mental illness, were excluded.

All patients who agreed to participate in the study gave written express consent.

Randomization and blinding

A researcher with no involvement in the trial and blinded to the primary care providers' identities performed the randomization. Due to the small size of the municipalities, and in order to avoid unblinding the details of the intervention, the health care teams of each municipality were grouped together for randomization so that all health care teams of the same municipality were allocated to the same group. For sample size and analysis purposes, the health care teams were considered the clusters, as this was the level of intervention and greater variability would be expected in the clinical care at the municipality level. The randomization sequence was created using Random Allocation Software (version 2.0) and was stratified by the mean number of patients included per municipality with an 1:1 allocation ratio using random numbers.

Due to the intervention's characteristics, complete blinding of the professionals and researchers involved in the project was impossible. To minimize potential biases, participant selection and baseline data collection were performed prior to randomization. Interviewers with no involvement in other stages of the trial collected the result data. An independent statistician performed the analyses.

Intervention

RESPIRANET is a complex educational intervention focused on asthma and aimed at primary care providers. It was developed in accordance with current clinical practice guidelines for asthma management and adapted to the characteristics of local health services and population.^{1,26,27} Intervention group received printed educational material, reminders, booklet for patients and frequent stimulus to using consulting services, beside the online sessions; the control group had access to consulting services and online materials (not printed), as every physician in the state of Rio Grande do Sul. The protocol did not include an obligatory clinic visit during the study period. More specifically, the intervention contains the following components:

Interactive online sessions

A series of three monthly two-hour videoconferences featuring different modules for professionals at higher (physicians and nurses) and basic levels (nurse technicians and community workers) about the epidemiological aspects, diagnosis, classification and management of asthma. All sessions were performed using the software Adobe® Connect™. The higher-level sessions were conducted by a pulmonologist from a tertiary care hospital in the state capital, while the basic-level sessions were conducted by a family physician. Both are members of our research group. At least one team member should participate for a team to be considered present at each module.

Educational material

Videoconference materials provided in both printed and digital form, along with algorithms and tables for the diagnosis, classification and treatment of asthma, as well as clinical summaries of differential diagnoses of respiratory symptoms.

Reminders

Educational materials with algorithms and tables to be used as a desk calendar and monitoring flow charts to be attached to the medical records.

Educational booklet for patients

Illustrated educational material written in simple language for patients addressing topics such as the concept of asthma, its symptoms, diagnosis and treatment, and the use of inhalers. The health care teams were encouraged to use the booklets as a tool for promoting self-care.

Access to medical specialists

A consulting service was provided by TelessaúdeRS-UFRGS to discuss asthma cases. The health care teams were encouraged to use the service during the online sessions.

Controls

Health care teams in the control group had access to the consulting service provided by TelessaúdeRS-UFRGS and the educational materials available on the project website, but with no encouragement to use them. The respective patients received the usual care provided by the general practitioner.

Results and instruments

Patients recommended for the study received a home visit from an interviewer and were asked to respond to a baseline questionnaire. Six months after the intervention period, the patients received a second home visit to follow-up questionnaire, irrespective of attending to the clinic or not. For participants under 12 years of age, the primary caregiver in the presence of the child answered the questionnaires. All results were auto-referred and were obtained by trained and blinded interviewers.

The primary endpoint was symptom-free days per two weeks, which was obtained by subtracting the number of symptomatic days in the last two weeks from 14. Symptoms included wheezing in the chest, chest tightness, coughing and shortness of breath.

Controlled asthma was a secondary result, defined as: (a) no nocturnal symptoms in the last month; and (b) less than two episodes of diurnal symptoms a week in the last month; and (c) used relief medication up to twice a week in the last month. All other individuals were classified as uncontrolled. Additional secondary results were unscheduled doctor visits, defined as individuals who required urgent treatment for asthma attacks in the last six months; and inhaled corticosteroid therapy, defined as individuals who frequently used inhaled corticosteroids in the last six months, regardless of symptoms, preventive use, or association with long-acting bronchodilators.

Sample size

Sample size calculation was based on the primary endpoint (symptom-free days per two weeks) considering an intra-cluster correlation (at the health care team level) coefficient of 0.01, estimated from a pilot study conducted in the municipality of Pareci Novo (mean symptom-free days per two weeks estimated at 10.15 with a standard deviation of 4.01). To detect an absolute difference of 1.2 day between groups with 80% power and a significance level of 0.05, sample size of 64 clusters (32 per group) was necessary, with an average size of six individuals per cluster (health care team), totaling 384 individuals. Assuming a dropout rate of up to 20%, the final sample was calculated at 78 clusters (39 per group), or 468 individuals.

Statistical analysis

The sample characteristics are presented for all individuals interviewed at baseline and for those with any follow-up. Quantitative variables with symmetric distribution were expressed as mean and standard deviation, while those with asymmetric distribution were expressed as median and first and third quartiles. Categorical variables were expressed as absolute and relative frequencies.

The results were analyzed using generalized estimating equation (GEE) models for repeated measures and clustering effect. Change in intervention effect over time was assessed through the interaction between group and study stage.

The effect of the intervention was estimated through odds ratio (OR) using, respectively, linear regression for the primary result and logistic regression for the secondary results, in univariable and multivariable models adjusted for the propensity score of baseline characteristics.^{28,29} Data were analyzed in SAS Studio version 3.6. Statistical significance was set at 5%, except for group interaction and study stage, for which it was set at 10%.

Research data are available through contact with the authors and can be requested through analysis plan.

Results

All 126 municipalities in Rio Grande do Sul that participated in the Brazilian National Telehealth Networks Program in 2010 were assessed for eligibility. Seventy-five municipalities were excluded because they did not have complete health care teams or did not provide free inhalation treatment for asthma. Of 51 eligible municipalities, 37 agreed to participate (Figure 1). These municipalities included 71 health care teams. Randomization resulted in 34 teams for the intervention group and 37 teams for the control group. The teams recommended 468 individuals with a diagnosis of asthma to enrolment. From 453 individuals who answered the baseline questionnaire, ten were excluded due to age (<5 years or >45 years), remaining 443 individuals at baseline. Sixty-three individuals (14.2%) were excluded from the analyses for not completing the follow-up (Figure 2). The retrospective calculated power for the main result was 68%.

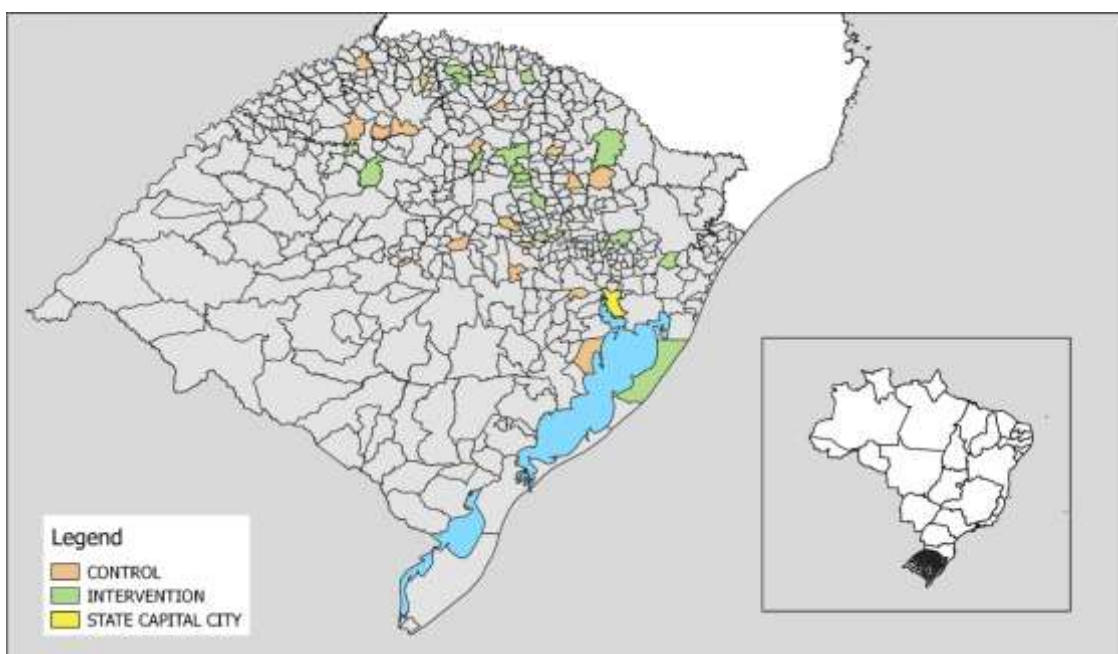


Figure 1. Map of state of Rio Grande do Sul with the capital city and included municipalities according to study group, RESPIRANET, Rio Grande do Sul, 2011.

The sociodemographic and clinical characteristics of patients at baseline, collected from August to November 2010, are presented in Table 1. Despite the randomization, a statistically significant difference was observed in female participants and economic classifications D and E at baseline between followed-up individuals in the comparison groups. A borderline significant difference was also observed for mean years of education among individuals aged 12 years or older. No other characteristics were significantly different.

The total attendance frequency in the interactive sessions was approximately 50%, both for the higher level and basic modules. More high-level professionals attended the inaugural meeting than lower-level professionals (74% vs. 62%, respectively), although this reversed over time (50% vs. 56% for the second session and 26% vs. 32% for the third session).

Between October and December 2011, patients were reevaluated. The majority (84.2%) of patients attended the clinic in the 6 months before the follow-up evaluation. The comparison between of baseline and follow-up results is presented in Table 2 and Figure 3. An increase in mean symptom-free days per two weeks was observed in both groups (+0.68 day in the intervention group and +0.35 day in the group control), as it was an increase in the proportion of patients with controlled asthma (+6.4% in the intervention group and +3.1% in the control group). There was a reduction in the proportion of patients with unscheduled doctor visits due to asthma in the last six months (-29.5% in the intervention group and -23% in the control group), as well as a reduction in the proportion of patients taking preventive inhaled corticosteroids (-12.7% in the intervention group and -10.1% in the control group). Change in intervention effect over time was assessed through group and stage interaction and was not significant for any result ($p > 0.287$) (Table 2).

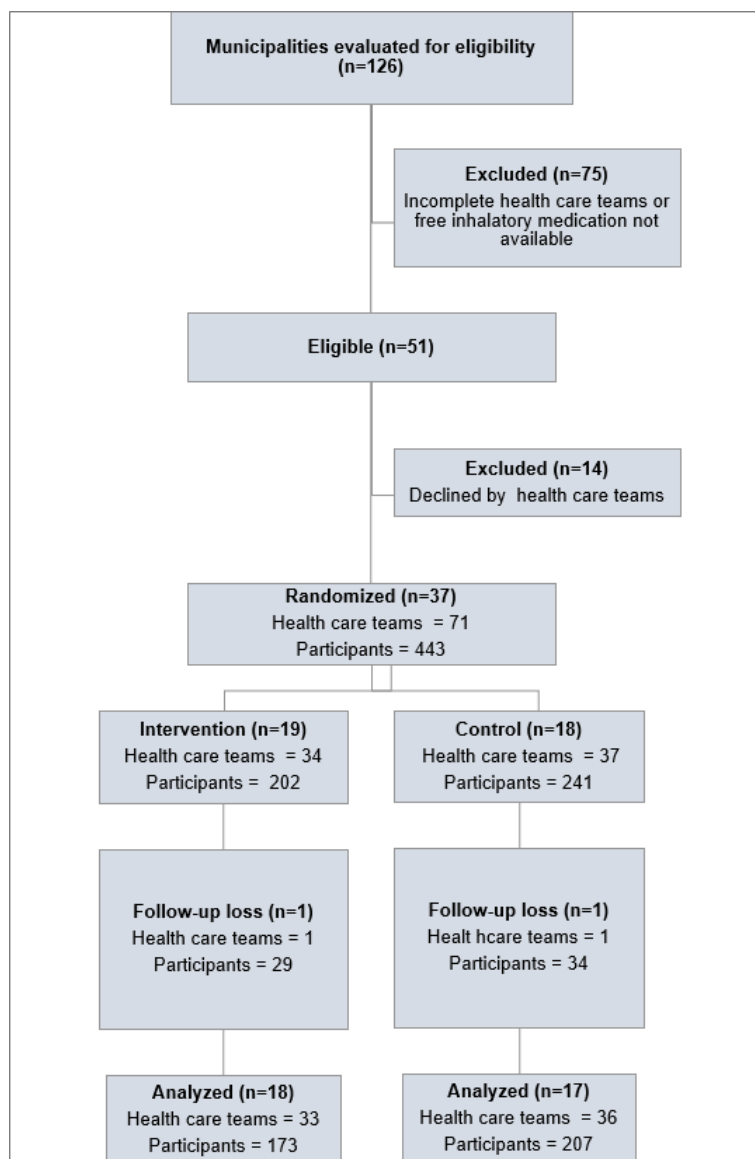


Figure 2. Randomization of health care teams and follow-up, RESPIRANET, Rio Grande do Sul, 2011.

The OR estimates for the intervention group are presented in Table 2. The following OR was found in the univariable analysis: 1.83 (95%CI 0.87-3.85) for additional symptom-free day per two weeks; 1.41 (95%CI 0.99-2.00) for controlled asthma; 0.75 (95%CI 0.55-1.00) for unscheduled doctor visits in the last six months; and 1.01 (95%CI 0.71-1.43) for preventive inhaled corticosteroid use. In the multivariable analysis, adjusted for the propensity score of the sociodemographic characteristics, tobacco exposure and clinical profile, the observed OR were 1.31 (95%CI 0.61-2.82) for additional symptom-free day per two weeks, 1.29 (95%CI 0.89-1.87) for controlled asthma, 0.81 (95%CI 0.60-1.10) for unscheduled doctor visits in the last six months, and 1.02 (95%CI 0.71-1.47) for preventive inhaled corticosteroid use.

Table 1. Patient characteristics at baseline according to allocated group, RESPIRANET, Rio Grande do Sul, 2011

Characteristics	Intervention		Control		Total		p-value*
	All included	Followed up	All included	Followed up	All included	Followed up	
	(n=202)	(n=173)	(n=241)	(n=207)	(n=443)	(n=380)	
Female (%)	103 (51.0)	91 (52.6)	164 (68.1)	145 (70.1)	267 (60.3)	236 (62.1)	< 0.001
Under 12 years old (%)	95 (47.0)	78 (45.1)	100 (41.5)	84 (40.6)	195 (44.0)	162 (42.6)	0.376
Age (mean, sd)							
5 to 11 years old	7.57 (1.99)	7.53 (2.04)	7.72 (2.05)	7.71 (2.07)	7.65 (2.02)	7.62 (2.05)	0.535
12 to 45 years old	25.78	25.89 (10.67)	28.72 (10.23)	28.13 (10.24)	27.45 (10.49)	27.16 (10.47)	0.155
Socio-Economic Classification D and E (ABEP 2013)	25 (12.9)	21 (12.6)	52 (21.8)	43 (21.0)	77 (17.8)	64 (17.2)	0.033
Years of education (mean, sd)**	7.71 (3.28)	7.78 (3.32)	6.91 (3.47)	6.89 (3.44)	7.25 (3.41)	7.28 (3.41)	0.052
Health insurance (%)	34 (17.1)	25 (14.7)	48 (19.9)	37 (17.9)	82 (18.6)	62 (16.5)	0.409
Smoker (%)**							0.516
Current	12 (11.4)	10 (10.8)	20 (14.3)	18 (14.6)	32 (13.0)	28 (13.0)	
Former	10 (9.5)	8 (8.6)	17 (12.1)	14 (11.4)	27 (11.0)	22 (10.2)	
Never	83 (79.1)	75 (80.6)	103 (73.6)	91 (74.0)	186 (75.9)	166 (76.9)	
Passive smoking at home (%)	65 (32.3)	58 (33.7)	94 (39.0)	81 (39.1)	159 (36.0)	139 (36.7)	0.277
Clinic visits in the last year (median; p25, p75)	4 (3,7)	4 (3,7)	5 (3,10)	5 (3,9)	5 (3,8)	5 (3,8)	0.116
Hospitalizations for asthma, lifetime (%)	139 (68.8)	115 (66.5)	161 (66.8)	133 (64.3)	300 (67.7)	248 (65.3)	0.650
Daily use of inhaled medication (%)	100 (49.5)	88 (50.9)	121 (50.2)	104 (50.2)	221 (49.9)	192 (50.5)	0.903
Use of inhaled corticoid (%)	80 (39.6)	71 (41.0)	96 (39.8)	82 (39.6)	176 (39.7)	153 (40.3)	0.778

* Comparison between followed-up groups; Test for proportions based on the χ^2 statistic or Wilcoxon test (age, years of education, clinic visits in the last year).

** Only for patients aged 12 to 45 years. sd: standard deviation, p25: 25th percentile, p75: 75th percentile.

Discussion

This study shows that multifaceted training (involving interactive sessions, materials, reminders and specialist support) was not effective to improve patients' results. Although many strategies were used to improve the efficacy of the intervention, this finding reinforces the difficulties in changing clinical practice.

These study findings may be somewhat frustrating. However, negative trials are instrumental in designing new and better interventions. There is no doubt about the importance of professional development in the healthcare context.³⁰ The possibility of evaluation of formats, characteristics, and ways the effectiveness of these interventions are discussed in the literature. Reviews on this topic point out the limited or even null effects of single interventions.^{10-12,15,30} Current evidence shows that multifaceted, interactive and personalized interventions that consider both the care context and the professional's difficulties represent the gold standard for educational proposals.^{11-13,30,31} Such characteristics are following adult learning theory.^{11,12} One of such effective interventions is ECHO project, that is based in weekly teleconsultations on clinical cases, approaching specialists and primary care physicians in community of learning.³² Our project differs from that, as it was leaner: it had a shorter duration (3 encounters during 3 months), and it was delivered for clinics individually. Patients' cases were not addressed, although physicians could ask for teleconsultations.

Table 2. Clinical outcomes for intervention and control group patients of the Rio Grande do Sul primary health care teams, RESPIRANET, Rio Grande do Sul, 2011.

Outcomes	Group	Stage		Difference	p-value*	Univariable model [§]		Multivariable model [†]	
		Baseline (n=380) mean (sd) or n (%)	Follow-up (n=380) mean (sd) or n (%)			OR (95%CI)	p-value	OR (95%CI)	p-value
Primary									
Symptom-free days	Intervention	9.71 (4.48)	10.39 (4.60)	0.68	0.5656	1.829 (0.869 - 3.850)	0.112	1.312 (0.612 - 2.815)	0.485
	Control	9.28 (4.78)	9.62 (4.76)	0.35					
	Difference	0.44	0.77						
Secondary									
Controlled asthma	Intervention	53 (30.6)	61 (37.0)	(6.4)	0.6583	1.407 (0.989 - 2.003)	0.058	1.287 (0.887 - 1.869)	0.184
	Control	51 (25.0)	55 (28.1)	(3.1)					
	Difference	(5.6)	(8.9)						
Unscheduled doctor visits	Intervention	102 (59.0)	51 (29.5)	(-29.5)	0.2884	0.745 (0.554 - 1.001)	0.051	0.807 (0.595 - 1.095)	0.169
	Control	130 (63.1)	83 (40.1)	(-23)					
	Difference	(-4.1)	(-10.6)						
Preventive inhaled corticosteroid use	Intervention	71 (41.0)	49 (28.3)	(-12.7)	0.6319	1.006 (0.708 - 1.431)	0.972	1.022 (0.709 - 1.474)	0.906
	Control	82 (39.6)	61 (29.5)	(-10.1)					
	Difference	(1.4)	(-1.2)						

* **Obtained in the group* stage interaction with generalized estimation equations for repeated measures and clustering effect.** [§] Unadjusted measure of association
[†] **Measure of association adjusted for propensity score for the predictor variables sex, age, economic classification, schooling, health plan, smoking (active or passive), previous hospitalization for asthma, number of consultations in the last year, and preventive inhaled corticosteroid use at baseline.** An alternative propensity score that did not include the outcome of the investigation as a predictor was used to analyze the secondary outcome 'preventive inhaled corticosteroid use'. sd: standard deviation.

Our results point out that even multifaceted interventions with telemedicine support - a resource that is increasingly present in health systems - still have to deal with significant obstacles to achieving their goals. We tried to overcome this obstacles using simplified online sessions (restricted to 3 encounters), that were interactive and customized to 2 levels of professionals (basic and higher). The remote aspect of this intervention should be emphasized, as we could reach regions distant from state capital city. Therefore, the studied intervention could be adapted to become an even more personalized intervention for each participating health professional.

Additional limitations of our study must be pointed out. The low attendance in the interactive sessions may explain the lack of benefit.³⁰ This limitation was found in studies evaluating similar strategies. The reasons to low attendance are multiple, and include: time pressures, lack of awareness, familiarity or agreement with the guidelines, lack of self-efficacy and result expectancy, complexity of the guidelines and resistance to change from previous practice.³³

The fact that physicians are the prescribers of medication could explain the intervention's lack of effect on inhaled corticosteroid use, while other results, more sensitive to multidisciplinary care (e.g., inhalation

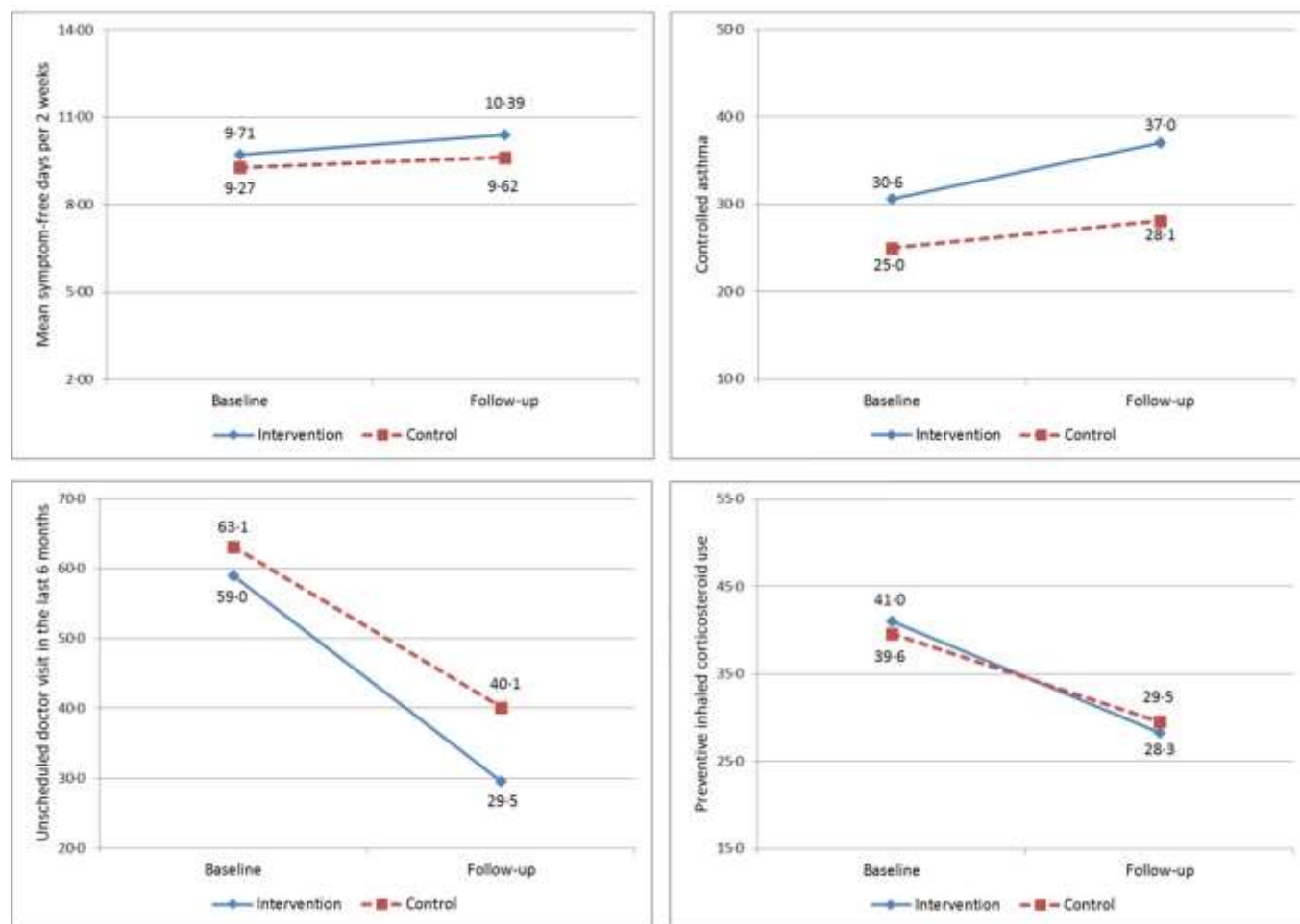


Figure 3. Clinical outcomes for intervention and control group patients of the Rio Grande do Sul primary health care teams at baseline and at the end of follow-up, RESPIRANET, Rio Grande do Sul, 2011.

technique), may have been impacted by the performance of other professionals.³² Due to the multifaceted nature of the intervention, other aspects of the intervention must also have failed to explain the absence of benefit.

We cannot exclude the hypothesis that patients did not benefited from the intervention due to methodological limitations. First, there was no obligatory visit after the educational period. In the one hand this may have decreased the intervention efficacy, in the other hand, we tried to keep the intervention the simplest and 84.2% of the patients attended the clinic in the previous 6 months. Second, the interventions we tested in this trial could be promptly implemented, despite that, changes in clinical practice take time to improve patients' results and our follow-up assessment may have been performed too early.

When assessing the effects of educational interventions, work processes are much more sensitive to improvement than clinical results, considering frequency, latency, and magnitude.¹⁰ We regret we did not evaluated the effects in processes of care (such as prescriptions or educational visits) as this will limit the ability to adapt this intervention to more efficient models.

The number of individuals completing the follow-up was lower than that estimated by the sample calculation, which may have been determinant in the non-significant borderline differences observed for clinical results. The retrospective power analysis confirms the lack of power for the primary result. However, even if the primary result were statistically different, the clinical difference of less than 1 day of symptoms would not be relevant.

Both groups showed improvement in the clinical results blunting the intervention effects. Some factors could be related to the clinical improvement observed in the follow-up. Health care teams themselves recommended the individuals for participation in the trial; this may have produced a sample representative of the worst controlled patients. This factor can increase the importance of the Hawthorne effect and the regression to the mean in the results. It should also be noted that patients were observed at two different times of the year from a climactic point of view. While baseline data collection began in the second half of winter and extended through spring, follow-up data were collected in the second half of spring of the following year, very close to the hottest season. This factor could also explain the reduction of inhaled corticosteroid use in both groups. Thus, the colder season is associated with excessive symptoms, uncontrolled disease, and intercurrent diseases.^{34,35}

It is also worth noting that in October 2010, during baseline data collection, a national program called the 'Popular Pharmacy' was expanded. This public health policy aimed to increase the population's access to specific medications, and from that point, it began to offer inhaled asthma medications (ipratropium, beclomethasone, and salbutamol) free of charge upon presentation of a prescription.³⁶ This event was an unplanned co-intervention.

All listed aspects potentially implicated in clinical improvement were common to both groups and cannot serve as biases for or against the intervention results. The point estimations observed in clinical results, although not statistically significant, indicating a potential benefit of educational interventions. At last, it should be explored if this intervention is effective in different professional and socioeconomic settings and healthcare systems.

Due to the long time lag between study conduction and report (see declaration section), we must inform how RESPIRANET program evolved. TelessaúdeRS-UFRGS believes in systemic solution to highly prevalent problems. With this in mind, this study worked as a concept proof. The frustrating initial results lead to adaptation and expansion of RESPIRANET. After this study, we created (in association with State's Health Council) a Telespirometry program, to provide exams to primary care patients statewide. We also changed our educational focus to a permanent process of review the referrals from primary care to specialized care: clinical protocols were created and frequent teleconsultations between primary care physicians and TelessaúdeRS-UFRGS physicians were performed. These lead to great changes in the care of respiratory diseases, reducing the number of referrals by 70%. Besides that, currently we are conducting two randomized trials on combined education (primary care physicians and patients) based on spirometry results.

Conclusion

Despite using the recommended multifaceted education strategies, the RESPIRANET intervention could not improve clinical results in asthma patients. Improvements should focus on higher attendance, and integrate some of the intervention's resources into daily clinical activities, and the clinical record system, such as reminders and consulting services.¹³

Declarations

The RESPIRANET project began in the state of Rio Grande do Sul in 2011 as a partnership between TelessaúdeRS-UFRGS and the state government. The initiative aimed to help primary care teams become more effective in the management of chronic respiratory diseases through telemedicine. As an initial effort, distance education resources and teleconsultations were explored, at which time the clinical trial described in this article was developed. The project evolved and, in 2013, after seven regional points for spirometry collection were established, it began to offer testing in a decentralized manner throughout the state, with interpreting and reporting produced at a distance by pulmonologists.

The time lag between the completion of data collection and the publication of the results of this clinical trial is due to the irreparable loss of the principal investigator, Karine Margarites Lima. After her death, the data were maintained by LH and EH and later assigned to RR for analysis and publication of the results.

Authors' contributions

EH, KML, RNU, MAFM, and SSM developed the intervention and study protocol, while KML and MAFM contributed to its implementation. KML wrote the first draft of the manuscript, while RR, with the assistance of LH, DVR, and AV, analyzed the data and wrote the second draft of the manuscript. RNU, DVR, MRG, SSM, and EH revised the second draft and produced the final version. RR, MAFM, RNU, LH, DVR, AV, MRG, SSM, and EH read and approved the final version.

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For KML (*in memoriam*), a researcher affiliated with this study, whose charisma, dedication, and hard work for people, medicine and epidemiology warrants our eternal gratitude.

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Conflict of interest

EH coordinated the TelessaúdeRS-UFRGS project until December 2016. The other authors are all project collaborators. The interviewers and researchers who implemented the project were remunerated.

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