FEDERAL UNIVERSITY OF PARAIBA

HEALTH SCIENCE CENTER

PHISIOTERAPY DEPARTMENT

DEAN OF RESEARCH

RESEARCH PROJECT

IMPACT OF EDUCATIONAL INTERVENTION PROTOCOL ON THE LEVEL OF KNOWLEDGE, CLINICAL CONTROL AND LUNG FUNCTION OF PEOPLE WITH ASTHMA: RANDOMIZED CONTROLLED CLINICAL TRIAL.

JOÃO PESSOA
2025

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Impact of educational intervention protocol on the level of knowledge, clinical control and lung function of people with asthma: randomized controlled clinical trial.

Research project submitted to the UFPB Pro-Rectory for Research, Notice 01/2024-Vigência2024/2025- PIBIC, PIBIC-AF, PIBITI, PIVIC, PIVITI

Proposer: Prof Dra. Renata R. Tomaz Barbosa

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2025/03/04

Title: Impact of educational intervention protocol on the level of knowledge, clinical control and lung function of people with asthma: randomized controlled clinical trial.

Keywords: Heath Education, Asthma, Spirometry, Respiratory Tract Disease.

Abstract

Objective: To evaluate the effects of a proposed educational intervention on people with asthma attending the Pulmonary Function Clinic in the city of João Pessoa -PB. **Method:** randomized controlled clinical trial, conducted in accordance with CONSORT recommendations. People with asthma will participate in the study, from the Pulmonary Function Clinic of the Department of Physiotherapy at UFPB. Study participants will be allocated into two groups (experimental and control). Individuals allocated to the control group will receive standard follow-up according to the clinic routine. Patients allocated to the experimental group will undergo an educational intervention BUNDLE, prepared in accordance with the recommendations of the Global Initiative for Asthma-GINA (2024). Spirometry date, knowledge about asthma and correct control over inhalation therapy by the Angeline's questionaire, clinical control of the disease using the Asthma Control Test (ACT) and Children Asthma Control Test (C-ACT) questionnaire, number of asthma attacks, amount of medication used, hospitalizations and visit. to the emergency room in the last 4 weeks will be assessed. Assessments will be carried out at the first contact (baseline) and four weeks after the first contact. **Statistical analysis**: Qualitative variables will be described in absolute and relative frequencies. For quantitative variables, normality will initially be tested using the Kolmogorov-Smirnov test, and the data will be described according to their distribution. The paired t test, or non-parametric test, Wilcoxon, will be used to compare the values obtained pre and post intervention. The relationship between the number of correct answers and the categorical variables will be evaluated using the Student's t test or ANOVA, according to the number of variable categories. A multiple linear regression analysis (Stepwise method) will be carried out between the independent variables, to assess which are capable of determining the variation in the number of correct answers (retention and knowledge about asthma and inhalation therapy). For each outcome, the covariates that presented $p < 0.20$ in the bivariate analysis will be used in the regression. Variables with $p < 0.05$ will be considered and retained in the final model. A significance level or p-value < 0.05 and 95% confidence intervals will be used for all

tests. **Expected results:** This study aims to contribute to a better understanding of the effectiveness of educational intervention strategies in people with asthma. From this perspective, the results of this research may help in the future to identify barriers and facilitators associated with the retention and adherence of users' knowledge about asthma, aiming to serve as a precursor in the development of health education strategies for other chronic respiratory pathologies.

INTRODUCTION

Asthma is a chronic inflammatory disease characterized by hyperresponsiveness of the lower airways and variable airflow limitation. It is clinically manifested by recurrent episodes of wheezing, dyspnea, chest tightness and coughing, and results from an interaction between genetics, environmental exposure and other specific factors that lead to the development and maintenance of symptoms. [1, 2]

According to the *Global Initiative for Asthma* - GINA (2024), asthma affects around 300 million people worldwide and, due to its high frequency in children, it is suggested that there will be an increase in the overall prevalence of this disease in the coming years.[1, 3–5]

Epidemiological data show that asthma is the fourth leading cause of hospitalizations in the Brazilian Unified Health System (SUS) [3, 4] and, due to its high prevalence and comorbidity, it should be considered a public health problem, requiring the implementation of effective measures to control it [5, 6].

The Brazilian Ministry of Health highlights the importance of health promotion for people with chronic respiratory diseases, including asthma, with considerable positive repercussions on the management of the disease. Among these strategies, health education is considered a useful, effective and recommended resource for controlling chronic respiratory diseases, with a significant influence on reducing morbidity rates and increasing quality of life. [7]

Health education strategies have been considered essential for asthma control, as they promote knowledge, increase the ability to identify aggravating and triggering factors, and improve adherence to treatment. [7, 8]

Brazilian researchers have observed the existence of barriers to the

participation of users in asthma education programs, with emphasis on the lack of infrastructure, especially human resources, and difficulty in maintaining patient follow-up.[8] It should also be noted that the greater number of structural barriers, such as lack of time, financial resources, the fact of living far away and the need for frequent returns to the health service reduces the possibility of a patient participating in a health education program.[8–10]

Angelini et al (2009), observed the effectiveness of a health education protocol in the knowledge, management and clinical control of asthma in adult individuals treated at an outpatient clinic of a reference center for asthma treatment in the city of São Paulo. However, out of a cohort of 164 individuals evaluated, only 51 patients returned to be re-evaluated over a 12-month period.[8]

In the current literature, no studies have been identified that analyze the effectiveness of health education protocols applicable to pulmonary rehabilitation services. To this end, we hypothesized that health education strategies offered in rehabilitation services could reduce barriers to participation and increase effectiveness in the management of the disease. The aim of this study is to evaluate the effects of a proposed educational intervention for people with asthma attending the Pulmonary Function Clinic in the city of João Pessoa -PB

1.2 Objectives

1.2.1 General Objectives

To evaluate the effects of a proposed educational intervention for people with asthma attending the Pulmonary Function Clinic in the city of João Pessoa -PB

1.2.2 Specific Objectives

- Evaluate the effects of an educational intervention protocol on asthma knowledge and the correct use of inhalation therapy.
- Identify the factors associated with knowledge and retention of information about asthma.
- Evaluate the effects of educational interventions on clinical asthma control, number of hospitalizations and emergency room visits in the last four months.

- Evaluate the effects of an educational intervention protocol on the pulmonary function of people with asthma.

2. METHODS

2.1 Ethical Aspects

The project was submitted for consideration by the Research Ethics Committee (CEP) in accordance with Resolution 466/12 of the National Health Council, obtaining a favorable opinion under number 6.968.418. Before beginning the implementation of this protocol, the study will be registered with ClinicalTrials.gov (*the U.S. National Health Service Institute).*

Participation in the study will be on a voluntary basis, with orientation about the experiment and the signing of a Free and Informed Consent Form - TCLE.

Individuals will be informed that participation in the study is not compulsory, that there will be no financial costs and that they will remain anonymous in relation to the data collected. They will also be free to refuse to participate or to withdraw their consent at any stage of the study without penalty or reprisals.

In the event of any changes in the alignment of the protocol or in the development of the project, participants will be formally informed via the telephone contact previously provided.

2.2 Trial design

This is a randomized controlled clinical trial conducted in accordance with the recommendations of the CONSORT guideline.[11]

2.3 Population

The population of this study will consist of people with a clinical diagnosis of asthma made by a medical professional, considering the following criteria: (i) presence of respiratory symptoms, such as wheezing, shortness of breath, chest tightness and cough, which vary with time and intensity, together with (ii) variable limitation of expiratory airflow. Asthma control and severity will be assessed following

the recommendations of GINA (2024).[1]

2.4 Sampling and Allocation Process

The sample will be made up of patients attending the Pulmonary Function Clinic of the Physiotherapy Department at UFPB. The pulmonary function outpatient clinic is a university extension project offering free care to the community, run by the Cardiorespiratory Physiotherapy Research Laboratory - LAFIPCARE of the UFPB Physiotherapy Department.

This study will be conducted according to the following design: One researcher (researcher 1) will be responsible for the confidentiality of the allocation. One researcher (researcher 2) will be responsible for randomization. A third researcher (researcher 3) will apply the educational intervention protocol and a fourth researcher will carry out the statistical analysis.

The allocation will be concealed using sealed, opaque envelopes, numbered consecutively. Each participant will be represented by a numerical code determined by researcher 1.

Individuals will be recruited non-probabilistically and randomly assigned to one of two groups (experimental or control) via the website www.randomization.com.

Due to the nature of the intervention, only the researchers responsible for each stage of the study will be blinded in the development of this research.

2.5 Sample calculation

For sample size calculation, the main outcome considered was the clinical control of asthma (ACT/c-ACT), with the following statistical parameters: a significance level of 5%, a power of 80%, and a minimally important clinical difference of +3 points, totaling a sample of 28 individuals, with 14 in each group.

2.6 Inclusion Criteria

The study will include people with a clinical diagnosis of asthma [3], assisted

by the Pulmonary Function Clinic, who have ventilatory dysfunction assessed by spirometry.

2.7 Exclusion criteria

The study will exclude users who are obese, undergoing treatment with systemic corticosteroids; have undergone previous chest surgery; and are unable to perform any of the proposed assessment steps.

2.8 Selection of Participants

Recruitment

The sample will be made up of people with a clinical diagnosis of asthma, assisted by the Pulmonary Function Clinic of the Physiotherapy Department of UFPB, who meet the eligibility criteria.

2.9 Measuring instruments and procedures

A standardized assessment form will be used to collect personal, sociodemographic and anthropometric data. The questionnaire proposed by Angelini et al.(2009) [8] will be used to assess knowledge about asthma and correct mastery of inhalation therapy (Appendix 1). The number of correct answers will be counted to quantify asthma knowledge.

Clinical control of the disease will be assessed using the Asthma Control Test (ACT) questionnaire (Appendix 2) and C-ACT. Participants will also be assessed on the number of asthma attacks, the amount of medication used, hospitalizations and emergency room visit in the last 4 weeks. Evaluations will be carried out at the first contact (baseline) and four weeks after the first contact.

The study participants will be allocated into two groups. The individuals allocated to the control group will receive standard follow-up according to the clinic's routine. Patients allocated to the experimental group will undergo a BUNDLE educational intervention, designed in accordance with the recommendations of the Global Initiative for Asthma - GINA (2024) [1], as shown in Table 1.

***Asthma Control Test* (ACT)**

The ACT will be used to assess the clinical control of asthma. It is a simple instrument, with adequate validity and reproducibility (cronbach's alpha: 0.93), easy to apply, consisting of five questions referring to the last four weeks, among which there are five possible answers, with each answer corresponding to a score.The higher the score, the greater the asthma control[13].

Childhood Asthma Clinical Control Test - (c-ACT)

The Children's Asthma Clinical Control Test (c-ACT) is one of the most clinically used instruments for assessing asthma control in children up to 11 years old. It is a simple questionnaire, easy to apply, with adequate validity and reproducibility (Cronbach's alpha: 0.677), translated and validated for Brazilian children by Oliveira et al., (2016). [14]

The questionnaire stands out for containing items considered fundamental standards for assessing asthma control at the outpatient level, and can be applied in primary and observational research. It is an instrument made up of seven short-answer questions, the first four of which are answered by the child being assessed and ask about their own perception of their current asthma control, restrictions on their activities and sleep disturbances during the night. To answer these questions, the children must choose one of four children's faces that represent emotions on a scale from sad to happy. [14]

The remaining three questions are answered by a parent or legal guardian and ask about the child's respiratory symptoms (asthma symptoms during the day, wheezing episodes and night waking) in relation to the period prior to 4 weeks. At the end of the questions, the assessed child is given a score, with a cut-off point below 19 being considered indicative of uncontrolled asthma. [14]

Pulmonary Function Evaluation - Spirometry

Spirometry is considered the classic test for assessing lung function, widely recommended and applicable in care practice. This project will initially use the

SPIROSTIK, Geratherm® spirometer. This instrument follows the recommendations imposed by the Brazilian Society of Pneumology, the American Thoracic Society and the European Respiratory Society. [15]

A mouthpiece and a bactericidal filter will be attached to the device, which will be exchanged between each participant. In order to prevent air escaping, all measurements will be carried out with the patient wearing a nose clip and they will be instructed to clamp the mouthpiece with their teeth and adjust their lips around it properly.

The evaluators will receive prior training and will be wearing all the personal protective equipment necessary to prevent contact with fluids or aerosols in order to minimize risks, such as contamination with COVID-19. Spirometry measurements will be carried out following the protocol of the American Thoracic Society and the European Respiratory Society. [16, 17]

Patients with obstructive ventilatory dysfunction, with a reduction in the predicted values of FEV1 and FEV1/FVC, will be submitted to a bronchodilator test (Salbultamol /Aerolin ® 100 µg, 4 jets at an interval of 30 seconds each, sustained to total lung capacity -CPT- for 10 seconds between each inspiration). A new pulmonary function test will be carried out 15 minutes after administration of the drug.

During the test, patients will remain seated, wearing the nose clip and with their head in a neutral position. To perform the test, the patient will be asked to inhale deeply as far as possible, take a minimum pause (1-2 seconds) and then blow out with maximum effort and continue with maximum exhalation until the end of the test.

The maneuvers will be carried out according to the following protocol: 1) maximum inspiration before the start of the test; 2) minimum pause (1-2 seconds); 3) expiration with maximum effort; 4) maximum inspiration; 5) absence of artifacts, such as coughing in the first second, leakage, obstruction of the mouthpiece, Valsalva maneuver, closure of the glottis, hesitation during the maneuver, new inspiration during the maneuver.

Patients should have a volume-time curve that shows no change in volume greater than/equal to 0.025 l during the last second (plateau); a satisfactory test duration (six seconds); and to ensure that the forced expiratory volume in the first second (FEV1) will be performed in a curve with maximum effort, the back-extrapolated volume should be 5% of the forced vital capacity (FVC) or 0.150l, whichever is greater.

A minimum of 3 and a maximum of 8 maneuvers will be performed to obtain 3 acceptable maneuvers (using the criteria mentioned above) and with a maximum difference of 0.150L (for FVC values above 1 liter) or 0.1L (for FVC values below 1 liter) between the two largest maneuvers, with the largest measurements from the two tests being chosen. 11 One minute's rest will be given between each maneuver and the flow-volume and volume-time curves will be analyzed for each maximum effort. Among the acceptable and reproducible curves, the values of FEV1, FVC, Tiffeneau index (FEV1/FVC) and peak expiratory flow (PEF) will be selected, which can be taken from different curves and the value of forced expiratory flow between 25% and 75% of FVC (FEF25-75%), selected from the curve with the highest sum between FVC and FEV1.

BUNDLE of Educational Intervention

Bundles are defined as a set of interventions or clinical actions that, when carried out reliably, can improve patient outcomes. The British Thoracic Society (BTS) has observed that the implementation of bundles within asthma patient care has reduced the number of hospitalizations due to exacerbation of the disease.[18]

The educational intervention bundle was drawn up in accordance with the recommendations of GINA (2024) [1], and will cover topics on the etiopathogenesis and pathophysiology of asthma, inhaler treatment, precipitating factors for crises, self-management skills, environmental control, as well as the importance of drawing up a written therapeutic plan and regular medical follow-up (Chart 1).

The educational intervention will be offered as a group activity and will be conducted in a single meeting, lasting approximately sixty minutes. Users will attend a standardized dialogical lecture using audiovisual resources, where they will have the opportunity to discuss and answer any questions related to the topics covered. At the end of the intervention, participants will receive a booklet containing all the points covered in the intervention, as well as a diary to record the amount of medication used, visits to the emergency room and asthma-related hospitalizations. This approach will provide a comprehensive view of the effectiveness of the intervention and the participants' commitment to the protocol.

Chart 1. BUNDLE of Educational Intervention

Content	Activity objectives
1. Etiopathogenesis and Pathophysiology of Asthma	1. Present the structures and functions related to the respiratory system. Report on the functional importance of this system, as well as identifying the alterations and symptoms present in individuals with asthma;
2. Inhaler treatment	2. Identification of the drugs commonly used in the treatment of asthma, as well as the route of administration; Simulated practical activity on how to use the pressurized nebulizer, emphasizing the importance of the spacer;
3. Precipitation factors for crises and self-management skills	3. Recognize the factors that trigger bronchospasm attacks and the onset of symptoms related to asthma attacks;
4. Strategies for environmental control	4. Know the environmental control strategies needed to prevent asthma attacks;
5. Written therapeutic plan	5. Learn about the need for access to a written, completed, guided and individualized therapeutic plan. The importance of the therapeutic plan in the management of treatment, symptom control and guidance on what to do in the event of an exacerbation.
6. Periodic medical follow-up	6. Learn about the need for regular medical monitoring and pulmonary function tests.

RISKS AND BENEFITS

This study presents minimal foreseeable risks. Among the possible risks, we would highlight the possibility of some kind of embarrassment during the sociodemographic questionnaires, and if this occurs, the individuals will be informed that their answers are not obligatory. During the pulmonary function tests, patients may experience mild symptoms of dizziness or shortness of breath. If this occurs, the tests will be suspended immediately.

2.9 Benefits

Participants in the study will receive specialized assessments that will enable more assertive multidisciplinary follow-up, allowing for greater agility and appropriate therapeutic management. In addition, the study aims to contribute to a better understanding of the effectiveness of educational intervention strategies for people with asthma, which could help in the future to identify barriers and facilitators associated

with knowledge retention and adherence and to develop health education strategies for other chronic respiratory diseases. Furthermore, this study will be available to society and could serve as a basis for future clinical trials. The researcher in charge will have access to the set of duly organized and processed data generated by the project.

2.10 Statistics analysis

The data will be analyzed using the Statistical Package for the Social Sciences (SPSS) software, version 23.0 (SPSS, Chicago, IL, USA). Initially, the normality of the data will be tested using the Kolmogorov-Smirnov test. If a parametric distribution is observed, the data will be described using the mean and standard deviation. Variables with a non-parametric distribution will be presented as medians and interquartile ranges. Categorical variables will be described as relative and absolute frequencies.

The paired t-test or its non-parametric counterpart, Wilcoxon, will be used to compare the values obtained before and after the intervention, relating to (i) the number of correct answers about asthma knowledge and inhaler medication, (ii) emergency room visits, (iii) the number of hospitalizations, (iv) clinical asthma control (ACT/c-ACT).

Retention of information about knowledge of asthma and inhalation therapy will be analyzed using the number of correct answers obtained from the questionnaire at the end of the educational intervention at each visit. The relationship between the number of correct answers and the categorical variables will be assessed using Student's t-test or ANOVA, depending on the number of categories of the variables.

Then, a multiple linear regression analysis (Stepwise method) will be carried out between the independent variables to assess which are capable of determining the variation in the number of correct answers (retention and knowledge of asthma and inhalation therapy). For each outcome, the covariates with $p < 0.20$ in the bivariate analysis will be used in the regression. Variables with $p < 0.05$ will be considered and retained in the final model.

Variables with missing values of less than 20% will be analyzed by intention to treat. 24 To assess the magnitude of the effect in the group (pre- vs. post-intervention) and between the groups (experimental vs. control) in the post-intervention

period, the Effect Size (ES) will be calculated using Cohen's method, applying the ratio between the mean difference between the groups and the pooled standard deviation. The reference values for defining the TE will be: small = 0.21-0.49; medium = 0.50-0.79; high = >0.80. 25 The percentage change (Δ%) will be expressed as the difference between the mean values obtained pre- and post-intervention, in percentage form relative to the pre-intervention mean. A significance level or p-value <0.05 and 95% confidence intervals will be used for all tests.

3. MAIN CONTRIBUTIONS AND PERSPECTIVES OF THE STUDY

The recommendations for asthma management and control state that educational interventions are associated with better knowledge and control of the disease, resulting in lower hospitalization rates and lower public health costs.[3] Despite these recommendations, there are few references in the current literature regarding protocols for educational interventions for people with chronic respiratory diseases.

This study aims to contribute to a better understanding of the effectiveness of educational intervention strategies for people with asthma. From this perspective, the results of this research may in future help to identify barriers and facilitators associated with retaining and adhering to users' knowledge about asthma, with a view to serving as a precursor in the development of health education strategies for other chronic respiratory pathologies.

In this perspective, this study aims to corroborate the process of generalist, humanist, critical and reflective academic training, based on local aspects with important contributions to society. This study aims to stimulate partnerships between the Physiotherapy Department of the Federal University of Paraíba and other departments, institutions and other social actors, with a view to expanding knowledge and physiotherapeutic practices in the area of respiratory and cardiovascular physiotherapy based on scientific evidence.

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TIMETABLE

ACTIVITIES	2024					2025					
	JUN/ JUL	AGO/ SET	OUT	NOV	DEZ	FEV/ MAR	ABR /MA I	JUN/ JUL	AGO	SET	OUT
Creation and consolidation of a research group with undergraduate students and collaborations with other teachers											
Updating the Theoretical Framework											
Project submission to Plataforma Brasil											
Training and methodological discussion with team members											
Patient recruitment											
Application of the educational intervention protocol											
Data analysis											
Presentation of partial data - writing scientific articles with cross-sectional data.											
Writing scientific articles											
Presentation of papers at national and international congresses and journals											
Activity report											

APPENDICES

APPENDICE 1- Questionnaire to assess asthma knowledge and mastery of inhaler technique

Assessment of clinical improvement

How many times have you had to go to the emergency in the last month because of asthma?
0 ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) more than 4 times ( )
How many days have you had to take a corticosteroid tablet in the last month, e.g. Meticorten/Prednisone?
0 ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) more than 4 times ( )
How many times have you been unable to go to work or school or do your homework because of asthma in the last month?
0 ( ) 1 ( ) 2 ( ) 3 ( ) 4 ( ) more than 4 times ( )

Pathophysiology and environmental control

What do you think is wrong with the lung?
Asthma ( ) Bronchitis ( ) Both ( )
What is asthma to you?
( ) I do not know
( ) is a contagious disease
( ) is a disease you can catch from contact with a cat
( ) is an inflammation of the bronchi
( ) is an infection in the bronchi

What is bronchospasm, when you wheeze or feel tightness in your chest?
( ) is do not know
( ) closing the air path in the bronchi
( ) clogged lungs
( ) dirt in the lungs
( ) lung infection
Do you think someone could die from asthma?
Yes ( ) No ( )

Check what could cause a person to have an asthma attack:

cigarette smoke ( ) animal hair ( )
cleaning product ( ) weather change ( )
strong perfume/smell ( ) dust and/or pollution ( )
mold/smell ( ) pregnancy ( )
food ( ) emotion/rage/sadness ( )
menstruation ( ) laughter ( )
flu/cold ( ) medicine ( ) physical exertion ( )

Mark on the line how important it is to take care of the place where you live so that you don't have any more asthma attacks. (As if you were going to give a score from 0 to 10,

by ticking a box on the line). 0 _____ 10

Treatment and inhalation technique
What are bronchodilators used for in asthma?
( ) I don't know
( ) it's a medication to open up the bronchi
( ) it's a medication to improve inflammation
( ) is a medication that speeds up the heart
What are corticosteroids used for in asthma?
( ) I don't know
( ) it's a medication to make the crisis go away
( ) it's a medication to treat inflammation
( ) it's a medication that makes you swollen
Do you think that corticosteroids:
( ) can make you dependent
( ) can be bad for your heart
( ) should be used when an asthma attack starts
( ) should be used to prevent asthma attacks
Do you know how to use your spray and/or powder medication?
Yes ( ) No ( )

CHECK THE USE OF THE MEDICATION (the patient is asked to demonstrate how they normally use two doses of the medication with placebo devices; the educator checks and marks what they have done, following the list below).

With spacer ( )
Take the cap off the pump ( )
Fit the spacer ( )
Shake the pump ( )
Releases all the air before putting the pump in the mouth ( )
Fires a jet from the pump ( )
Pulls the medicine out slowly with the mouth open ( )
Holds breath after pulling the medicine ( )
Counts to 10 and then releases the air ( )
Waits a minute to shoot another jet (**)**

Without spacer ( )
Take the cap off the pump ( )
Shake the pump ( )
Leave space between the pump and the mouth ( )
Release all the air before putting the pump in the mouth ( )
Shoots a jet from the pump ( )
Pulls the medicine out slowly with your mouth open ( )
Holds breath after pulling the medicine ( )
Counts to 10 and then releases the air ( )
Waits a minute to shoot another jet ( )

APPENDICE 2. Asthma Control Test - ACT

					SCORE
1. In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or at home?					
All of the time **[1]**	Most of the time **[2]**	Some of the time **[3]**	A little of the time **[4]**	None of the time **[5]**	.....
2. During the past 4 weeks, how often have you had shortness of breath?					
More than Once a day **[1]**	Once a day **[2]**	3 to 6 times a week **[3]**	Once or twice a week **[4]**	Not at all **[5]**	.....
3. During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?					
4 or more nights a week **[1]**	2 to 3 nights a week **[2]**	Once a week **[3]**	Once or twice **[4]**	Not at all **[5]**	.....
4. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?					
3 or more times per day **[1]**	1 or 2 times per day **[2]**	2 or 3 times per week **[3]**	Once a week or less **[4]**	Not at all **[5]**	.....
5. How would you rate your asthma control during the past 4 weeks?					
Not Controlled at All **[1]**	Poorly Controlled **[2]**	Somewhat Controlled **[3]**	Well Controlled **[4]**	Completely Controlled **[5]**	.....

If your score is 19 or less, your asthma symptoms may not be as well controlled as they could be. No matter what your score is, share the results with your healthcare provider.

TOTAL: .....

FEDERAL UNIVERSITY OF PARAIBA-UFPB
HEALTH SCIENCE CENTER
PHYSIOTERAPY CENTER

INFORMED CONSENT FORM – TCLE

(Resolution of nº. 466/2012)

Dear Sir or Madam,

This research project is entitled "Impact of an educational intervention protocol on the level of knowledge, clinical control and pulmonary function of people with asthma: a randomized controlled clinical trial". This project is being carried out by students of Physiotherapy at the Federal University of Paraíba, for the purposes of study and preparation of academic work under the guidance of Professor Dr. Renata Ramos Tomaz Barbosa, Professor Dr. Maria do Socorro Nunes Gadelha and Professor Dr. Tatiana Onofre.

The aim of this project is to optimize therapeutic strategies and resources for adults and children with chronic respiratory diseases. It also aims to increase clinical control, reduce the risk of exacerbations and hospitalizations, and enable targeting and access to pulmonary rehabilitation services, with a view to promoting comprehensive and resolutive care. The participation of volunteers will be essential, as the information collected will be analyzed and may result in the development of measures to prevent respiratory diseases. We ask for your cooperation in filling in an assessment form containing questions about living conditions, the level of education of caregivers and economic issues, and a physiotherapy assessment based on the information in the medical records. We request your authorization to present the results of this study at health events and to publish in a national and/or international scientific journal. The data relating to identification will not be published, preserving the privacy of the volunteers, where there will be no type of exposure for the user of the system and their guardians. When the results are published, your name will be kept strictly confidential. We would like to inform you that this study poses no risk to the health of any of the participants. This study presents minimal foreseeable risks. Among the possible risks, we highlight the possibility of some kind of embarrassment during the application of the sociodemographic questionnaires, and if this occurs, the individuals will be informed that their answers are not obligatory. During lung function tests, patients may experience mild symptoms of dizziness or shortness of breath. If this occurs, the tests will be suspended immediately.

We would like to clarify that your participation is voluntary and therefore you are not obliged to provide the information and/or collaborate with the activities requested by the researcher. If you decide not to take part in the study, or decide to withdraw from it at any time, you will not suffer any harm, nor will there be any changes to the care you have been receiving at the institution.

INFORMED CONSENT FORM: Considering that I have been informed of the objectives and relevance of the proposed study, how I will participate, the procedures and risks arising from this project, I declare my consent to participate in the research, as well as agreeing that the data obtained in the investigation will be used for scientific purposes (dissemination at events and publications). I am aware that I will receive one copy of this document.

By signing at the end of this document, YOU, voluntarily, as a PARTICIPANT of the research, express your free and informed consent to take part in this study and declare that you are sufficiently informed, in a clear and objective manner, about this investigation. And you will receive a copy of this Informed Consent Form (ICF), signed by the Researcher in Charge.

João Pessoa, ____ de_____ de _____

_____

Signature, in full, of the Research Participant

Prof Dra Renata R. Tomaz

Signature, in full, of the researcher responsible for the research.

WATER MARK

The researchers will be at your disposal for any clarification you may deem necessary at any stage of the research.

Contact Information:

- Principal and Other Members of the Research Team:

Supervisor: Profa Dra Renata R. Tomaz Barbosa
E-mail: renatatomazf@gmail.com // Phone: (83) 9935-1535 Branch: 3217183
Physiotherapy Department/CCS/UFPB

- Research Ethics Committee Adress and Contact Information (CEP)/CCS/UFPB. Research Ethics Committee (CEP) Health Science Center (1º floor) of Federal University of Paraíba Campus I – Cidade Universitária / CEP: 58.051-900 – João Pessoa-PB Phone: +55 (83) 3216-7791 // *E-mail:* comitedeetica@ccs.ufpb.br Opening Hours: 07h to 12h and 13h to 16h. Homepage: http://www.ccs.ufpb.br/eticaccsufpb