Assessment of Asthma Management in Children Over 6 Years of Age and Their Caregivers: Implications for the Implementation of the SMART Strategy in Pediatrics

Protocol Version and Date: Version: 1 – Date: 14/05/2025

Protocol Code: IIBSP-EMA-2025-05

Short Title: Asthma Management in Children

Sponsor: Institut de Recerca de l'Hospital de la Santa Creu i Sant Pau – IIB Sant Pau c/ Sant Quintí, 77-79 08041 Barcelona Tel: +34 93 556 56 17 Fax: +34 93 553 78 12

Principal Investigator: Victòria Morón Faura. Pediatric Pulmonology MSc Nurse, Hospital de la Santa Creu i Sant Pau. c/ Sant Antoni Maria Claret, 167. 08025 Barcelona. Tel: +34 647 026 964 E-mail: vmoron@santpau.cat

1. Justification

Asthma is the most common chronic inflammatory disease in children, affecting quality of life and having a significant impact on the individual, their environment, and society. In Spain, its prevalence is 10.4% among schoolchildren aged 6–7 years and 15.2% among adolescents aged 13–14 years, most of whom will reach adulthood requiring some form of treatment to control asthma.

This study seeks to evaluate the effectiveness of an educational intervention in the management of asthma exacerbations, by assessing the competence of children with asthma and their caregivers in inhalation technique, the control of exacerbations, and the degree of therapeutic adherence, as well as by analyzing the appropriate implementation of action protocols during crisis situations.

1.2. Research Questions

Do children and adolescents have adequate knowledge about asthma management and inhaler technique? Do children and adolescents improve asthma management after a brief educational intervention?

1.3. Hypothesis

A brief nursing educational intervention on asthma management and inhaler technique will improve knowledge and correct use of inhaled treatment in pediatric asthma patients by more than 50%, with an increase of over 50% in the proper execution of inhaler technique.

2. OBJECTIVES:

2.1. Main Objective:

Quantify the change in the level of knowledge about asthma management and the correct execution of inhaler technique in pediatric asthma patients (or their caregivers) after receiving a brief nursing educational intervention, expressed as a percentage of improvement from the pre-test. An increase of more than 50% in both dimensions is expected.

2.2. Secondary Objectives:

- Evaluate the percentage of subjects who move from "incorrect technique" to "correct technique" according to InTeQ (39) after the intervention, identifying the critical steps that improve the most.
- Measure the change in the Likert scale of autonomy (0 = dependent to 4 = fully autonomous) and calculate the proportion of participants who move to the "visual supervision" or "autonomous" level.
- Compare the average ACQ score pre- and post-intervention, and calculate the percentage of children who move from poorly/partially controlled (≥ 1.0) to well controlled (< 1.0).

- Determine the increase in the proportion of participants who correctly identify at least 3 of the 5 exacerbation signs/symptoms (persistent cough, wheezing, dyspnea, chest tightness, tachypnea) after the education.
- Analyze the variation in the number of rescue puffs administered in the last week, measuring the average reduction and the percentage of subjects who reduce by at least one puff per week.
- Evaluate the change in the total score of the Inhaler Adherence Test (TAI) pre- and post-intervention, and classify the proportion of patients who improve their adherence category (from poor/intermediate to good).
- Identify and compare the frequency of each non-adherence pattern (erratic, deliberate, unconscious) before and after the intervention, to detect which one decreases the most after the educational program.

3. MATERIAL AND METHODS:

3.1. Study Design

Quasi-experimental study with a pre-test/post-test design in a single cohort. There is no randomization or parallel control group; all participants receive the nursing educational intervention, and their results before and after are compared.

3.2. Study Population. Inclusion and Exclusion Criteria

All patients in follow-up at the pediatric allergy and pulmonology clinic with a diagnosis of asthma who use inhalers as prescribed treatment, between September 1, 2025, and February 28, 2026, will be invited to participate consecutively and/or their primary caregivers.

Pediatric Population (patients): Patients in follow-up at the pediatric allergy and pulmonology clinic.

Inclusion Criteria:

1. Age between 6 and 17 years.
2. Clinical diagnosis of asthma and at least 6 months of follow-up in our center's pediatric allergy and pulmonology clinic.
3. Prescribed treatment with corticosteroid inhalers with or without LABA for at least 6 months.

Exclusion Criteria:

1. Language barriers (lack of Spanish comprehension).
2. Occasional/occasional use of inhalers (not on a regular schedule).
3. Significant active or passive smoking.
4. Significant immunocompromise (immunosuppression, oncological disease, transplant).

Caregiver Population
Inclusion Criteria:

1. First-degree relationship with the patient or living together for > 50% of the time.
2. Ability to understand and respond to the questionnaire.

Exclusion Criteria:

1. Language barriers or cognitive difficulties preventing understanding/responding. Justification in "Ethical Aspects".

3.3. Definition of Variables and Instruments
Main Variables (dependent):

- Level of knowledge about asthma management: total pre/post score on an ad hoc questionnaire.
- Correct inhaler technique: categorized by InTeQ as "correct" (0 errors) vs. "incorrect" (≥1 error).

Secondary Variables:

- Degree of autonomy (Likert scale 0–4).
- Asthma control (ACQ, average of 5 items): (≤ 0.75) well controlled, (0.75 - 1.50) partially controlled, (>1.50) poorly controlled.
- Number of rescue puffs in the last week.
- Adherence (TAI total, 10 items): good (≥50), intermediate (46–49), poor (<45).
- Non-adherence pattern (erratic, deliberate, unconscious).
- Recognition of exacerbations (identification of ≥3 of 5 symptoms).

The main variable will be the level of knowledge about asthma management in children and the primary caregiver. This will be measured through five variables: inhaler technique and autonomy in its use, asthma control, adherence to inhaler treatment, recognition of exacerbations, and use of rescue inhalers.

Sociodemographic data collected will include: relationship with the patient if they are not the one completing the questionnaire, education level of the accompanying parent/patient, patient age, and patient sex.

For the qualitative variable "inhaler technique," the InTeQ questionnaire, validated for pediatrics, will be used to assess the use of pressurized inhalers according to guidelines, with 5 critical items, to which the item "shake the device" was added for those using pMDI. The 5 critical steps evaluated are: exhale completely before, close lips tightly, inhale deeply, hold breath afterward, exhale slowly, applicable to both pressurized devices with a chamber and

dry powder devices. The item "device activation" was removed as it is inherent to the procedure and to facilitate its applicability. Patients with no errors will be included in the "correct technique" group, and those with one or more errors will be included in the "incorrect technique" group. The ad hoc questionnaire will ask about the degree of autonomy in performing the process, measured with a Likert scale with 5 items rated from 0 to 4: “completely dependent,” “needs help in more than one point of the technique,” “needs help in one point of the technique,” “only visual supervision,” or “completely autonomous.”

Asthma control will be measured through the Asthma Control Questionnaire (ACQ), in its ACQ version, which has been validated for use in pediatrics, specifically for children over 5 years old. It consists of 5 questions about symptoms, with 7 possible responses, and the total ACQ score is calculated by averaging the responses to the 5 questions, yielding a score between 0 and 6, where: 0 indicates complete asthma control (no symptoms), and 6 represents very poor asthma control (severe symptoms). Average scores under 0.75 indicate adequate asthma control, according to GEMA 5.4 criteria: no symptoms, no nocturnal awakenings, need for rescue medication only once a week or less, and no daily life limitations. Scores above 1.5 indicate poor asthma control.

To measure the variable "number of puffs administered during a crisis," questions from the ad hoc questionnaire will be used to assess the number of rescue inhalations taken during a crisis and those administered in the last week.

To identify the pattern of unconscious adherence non-compliance, the only specific questionnaire for measuring inhaler adherence, called the Inhaler Adherence Test (TAI), will be used. It is validated only for those over 18 years old, although validation in pediatrics is currently underway. It consists of 10 items to be completed by the patient/caregiver if identifying low adherence is desired, and 2 additional items to be filled out by the healthcare professional, which are specific to determine unconscious non-compliance patterns. The patterns of non-adherence identified are: erratic (medication forgetting), deliberate (lack of will to follow the schedule), or unconscious (lack of knowledge about the schedule or technique).

Exacerbations will be measured with items described by the Spanish Society of Pediatric Pulmonology (SENP), including the presence of the following symptoms:

- Persistent cough
- Wheezing sounds during breathing
- Difficulty breathing or speaking
- Chest pain or tightness
- Rapid breathing, frequent breaths

The presence and recognition of these symptoms will be collected through the ad hoc questionnaire, which will include closed questions with binary, multiple, or Likert-type

responses. The ad hoc questionnaire will conclude with a question assessing confidence in the use of the chamber in different types of situations.

3.4. Expected Sample Size

The sample required to estimate an increase of ≥50% in knowledge and technique, with a 95% confidence level (Z = 1.96), expected proportion $p = 0.5$ (maximum variance), and margin of error $d = 0.05$, was calculated using the formula $n = Z^2 p(1–p)/d^2 = (1.96^2 \cdot 0.5 \cdot 0.5)/0.05^2 = 384.16 \approx 385$ *participants*. Accounting for an anticipated 10% attrition rate, the adjusted sample size is 385 / (1–0.10) ≈ 428 participants.

3.5. Methodology. Sources of Information

Visit 0 (Screening): At the screening visit, patients and caregivers will be informed about the study objectives and procedures. Eligibility will be assessed through an interview and review of the medical record, applying inclusion and exclusion criteria. Upon confirmation of eligibility, written informed consent will be obtained. Basic sociodemographic variables (age, sex, educational attainment of the parent/caregiver and the child) and relevant clinical history will be collected.

The screening visit may coincide with the baseline visit (V1), during which the initial assessment (pre-test) and the educational intervention will be conducted, provided the following conditions are met:

- The participant must have signed the informed consent form before undergoing any study-specific procedure, including completion of the pre-test questionnaire.
- During the same visit, inclusion criteria will be confirmed and exclusion criteria ruled out.
- Only participants who have successfully completed the screening process and signed informed consent will be considered enrolled in the study.

Visit 1 (Baseline): At the baseline visit, prior to the educational intervention, inhalation technique will be evaluated using the InTeQ checklist, and the level of autonomy will be assessed using a Likert scale (0–4). In accordance with the validated Asthma Control Questionnaire (ACQ) (40), participants aged ≥11 years will be invited to complete the instrument to assess asthma control, while for children ≤10 years, it will be completed by the caregiver or, if necessary, by the nurse. To ensure consistency, the Test of Adherence to Inhalers (TAI) and an ad hoc questionnaire designed to assess knowledge of exacerbation management and inhaled therapy will also be administered. These will be self-completed by participants ≥11 years, or by the caregiver (with or without assistance) for younger children. In addition, pulmonary function tests (PFTs) will be performed according to standard clinical practice protocols.

Visit 2 (6 months post-intervention): Participants will be scheduled six months after the intervention to repeat the evaluation. The InTeQ, autonomy scale, ACQ, TAI, and ad hoc

questionnaire will be administered again. In addition, pulmonary function tests (PFTs) will be performed as deemed necessary by the pulmonologist. Finally, pre- and post-intervention results will be compared to analyze changes in knowledge, inhalation technique, asthma control, adherence, and recognition of exacerbations.

3.6. Data Management and Analysis

To ensure the protection of participants' privacy and compliance with current data protection regulations, the data collected in this study will be pseudonymized prior to analysis. Personally identifiable information will be replaced with a unique alphanumeric code assigned to each participant. This code will not allow direct identification of the subject without access to a correspondence key, which will be securely stored and protected by the principal investigator.

Pseudonymized data will be used for all statistical analyses and publications, and under no circumstances will information that enables direct or indirect identification of participants be included.

The dataset will be stored in an Excel file located on the secure server of the Hospital de la Santa Creu i Sant Pau (HSCSP). Access will be restricted through unique credentials for authorized investigators, ensuring confidentiality and compliance with data protection regulations (GDPR). After import from Excel, the data will undergo a cleaning and quality control process (detection of outliers, duplicate records, and range checks).

The principal investigator will be responsible for creating the study database.

A descriptive analysis will be performed using absolute frequencies and percentages for qualitative variables; mean and standard deviation for normally distributed quantitative variables; and median and interquartile range for non-normally distributed quantitative variables. Subsequently, a bivariate analysis will be conducted using the Chi-square test, Fisher's exact test, Student's *t* test for independent samples, or the Mann–Whitney *U* test, as appropriate. To evaluate patient-related factors associated with adherence to inhaled therapy, a multivariable logistic regression model will be constructed including variables that showed a significant association in the bivariate analysis, in order to identify independently associated factors.

3.7. Limitations of the Study Design, Information Sources, and Analytical Methods

The limitations of this study may lie in the lack of awareness among patients/caregivers regarding the treatment they should be receiving. Although the use of primary sources (data collected directly from patients and caregivers) provides information closely aligned with the real-world context, it introduces the risk of recall bias and social desirability bias.

One limitation of this study is the exclusion of patients with significant language barriers. This decision may have introduced a selection bias. The exclusion of these patients (although minimal) may have led to an overestimation of the effectiveness or comprehension of the treatment observed in the sample. We acknowledge this limitation and consider it necessary to

develop, in future studies, specific strategies to enable broader and more equitable inclusion of these vulnerable groups.

The TAI questionnaire will be used, which, although still undergoing validation for the pediatric population, is widely applied in clinical practice and regarded as an optimal instrument.

The sample may not be representative due to the lack of randomization. For this reason, it was decided to include all patients consecutively to obtain a broader view of the study population. The quasi-experimental design without a randomized control group limits the ability to establish strong causal inferences.

This study will be conducted in a single center, which may limit the generalizability of the findings to other contexts or settings. Furthermore, the lack of variability could restrict the applicability of the results. Conducting the study in multiple centers would be valuable and clinically relevant to increase sample diversity and allow greater generalization of the findings to the overall population.

4. ETHICAL CONSIDERATIONS

Benefit–Risk Assessment of the Research

The proposed educational intervention entails a favorable balance between benefits and risks. Benefits include the potential improvement in knowledge of asthma management, correction of inhalation technique, increased adherence, and early recognition of exacerbations, which may translate into better clinical control and reduced hospitalizations. Risks are minimal, primarily associated with the time required of participants for visits and questionnaires, and the potential cognitive fatigue from responding to multiple instruments. No invasive procedures or interference with routine clinical practice are anticipated. Data confidentiality and informed consent ensure respect for participants' autonomy and protection.

Ethical Considerations Regarding Participant Information and Informed Consent

The study will be conducted in strict accordance with international ethical guidelines for medical research in humans. The investigator will be responsible for ensuring that the study complies with the principles set out in the Declaration of Helsinki.

Before the study begins, the Ethics Committee of Hospital de la Santa Creu i Sant Pau must approve the study protocol, the information sheet to be provided to participants, and the informed consent form to be used.

The Ethics Committee will be informed of any subsequent amendments to the protocol, and its opinion will be sought if a new evaluation of the ethical aspects of the study is required.

The investigator is responsible for obtaining informed consent from the patient. No patient may participate in any study-specific procedure before providing consent, or, when the patient is unable to consent due to their clinical condition, before consent is obtained from their legal guardian/family member.

Prior to enrolling any participant and before obtaining informed consent, the investigator or a

designated delegate will explain to the potential participant or their legal guardian/family member the study objectives, methods, potential risks, and any possible inconveniences. The explanation regarding the nature, scope, and possible consequences of the study will be provided in language that is easily understandable.

In this study, it was considered necessary to exclude patients with significant language barriers that would prevent adequate understanding of study procedures and objectives. This decision is grounded in ethical principles.
From the principle of autonomy, obtaining informed consent requires full comprehension on the part of the participant. In cases where substantial language barriers exist, and where sufficient resources (e.g., interpreters or cultural mediators) and time to ensure adequate and safe understanding are not available, consent could be defective, thereby compromising the ethical validity of participation. From the principles of beneficence and non-maleficence, this could also undermine the quality of the intervention and patient safety.
Regarding the principle of justice, although we acknowledge that these patients constitute a potentially vulnerable group who may benefit significantly from the intervention, their proportion within the sample is very small, and under current circumstances, it is not feasible to guarantee equal participation conditions without jeopardizing the methodological and ethical integrity of the study. Nevertheless, supportive measures have been implemented outside the study protocol to address the needs of these patients through the use of adapted graphic materials and individualized care, underscoring the research team's commitment to their well-being.

This exclusion is therefore considered an ethically necessary measure given real-world resource constraints and will be appropriately reported as a study limitation in the results and subsequent publications.

Potential participants or their legal guardians/family members must be given sufficient time to consider their decision to participate and the opportunity to ask questions. After this explanation, and before enrollment, informed consent must be properly documented by the signature of the participant or their legal guardian/family member.

Given that access to medical records for purposes other than clinical care requires the patient's explicit consent, patients currently under follow-up at the hospital will be asked to provide consent for access to the medical record data necessary for the study. Accordingly, the Participant Information Sheet / Informed Consent Form will be submitted to the Ethics Committee for review.