

Effectiveness of a multicomponent digital lifestyle-change intervention versus usual care for improving health-related quality of life in adolescents with asthma (CLiQ-Asthma): protocol for a multicentre, parallel-group, superiority randomised controlled trial

Document date: 6 October 2026

Authors:

Marta Ferrón Carbonell (MF); Department of Physiotherapy, Universitat Internacional de Catalunya (UIC Barcelona), Spain

Fernanda Salazar Pérez (FS); Department of Physiotherapy, UIC Barcelona, Spain

Marta Amor Barbosa (MA); Department of Physiotherapy, UIC Barcelona, Spain

Monique Messagi Sartor (MM); Department of Physiotherapy, UIC Barcelona, Spain

Ivet Bayés Marín (IB); Department of Medicine, Faculty of Medicine and Health Sciences, UIC Barcelona, Spain

Verónica Sanz Santiago (VS); Paediatrics, Hospital Universitario Niño Jesús, Madrid, Spain

Inés de Mir Messa (IM); Paediatrics, Hospital Universitari Vall d'Hebron, Barcelona, Spain

Olaia Sardón Prado (OS); Paediatrics, Universidad del País Vasco / Hospital Universitario de Donostia, Spain

Mirella Gaboli (MG); Paediatrics, Hospital Universitario Virgen del Rocío, Sevilla, Spain

Ana Lucía González Torres (AG); Paediatrics, Complejo Hospitalario Universitario de A Coruña, Spain

Carlos Martín de Vicente (CM); Paediatrics, Hospital Universitario Miguel Servet, Zaragoza, Spain

Silvia Castillo Corullón (SC); Paediatric Pulmonology, Hospital Clínico Universitario de Valencia, Spain

David Blanco De Tena-Dávila (DB); Department of Physiotherapy, UIC Barcelona, Spain

Márcio Vinícius Fagundes Donadio (MD); Department of Physiotherapy, UIC Barcelona, Spain

Corresponding author: Márcio Vinícius Fagundes Donadio (MD); Department of Physiotherapy, UIC Barcelona, Spain

Abstract

Introduction: Adolescents with asthma may experience reduced health-related quality of life (HRQoL) despite receiving guideline-based clinical care. Movement behaviours (physical activity, sedentary behaviour, and sleep), asthma control, and psychosocial factors are interrelated and potentially modifiable, yet most interventions target them in isolation. CLiQ-Asthma evaluates a multicomponent, digital behaviour-change programme designed to improve HRQoL by supporting adherence to 24-hour movement behaviour recommendations, asthma self-management, and psychosocial well-being. We hypothesise that, compared with usual care, the intervention will improve HRQoL in asthmatic adolescents with reduced HRQoL.

Methods and analysis: This multicentre, parallel-group, superiority randomised controlled trial will enrol 96 adolescents aged 13-17 years with a confirmed diagnosis of asthma (any GINA severity) and reduced HRQoL, recruited from the observational phase of CLiQ-Asthma across seven Spanish referral hospitals; adolescents without access to a compatible mobile device are excluded. Participants will be randomised 1:1 to a 12-week intervention or usual care using computer-generated allocation stratified by sex and asthma severity, managed through a secure electronic system. The intervention comprises an individual motivational interview, personalised movement-behaviour goals monitored with a smartwatch, nine 45-minute online small-group educational sessions, and tailored reminders and feedback; the control group receives usual care. The primary outcome is change in PedsQL Asthma Module total score from baseline to 12 weeks (post-intervention), with maintenance of effects assessed at the 3-month follow-up. Secondary outcomes include asthma control, movement behaviours, and psychosocial factors, assessed post-intervention and at follow-up. The sample size (96; 48 per group) was calculated to detect a between-group difference of 16.93 points in HRQoL (SD 15.27; Seid et al., 2010), with $\alpha=0.05$, 80% power and 20% attrition, and doubled to allow balanced sex-based comparisons. This is a single-blind trial: outcome assessors are blinded to allocation, whereas participants and intervention providers cannot be blinded given the nature of the intervention. The primary analysis will use linear mixed-effects models for repeated measures, with time, group, and their interaction as fixed effects and participant as a random effect. Sex and asthma severity will be included as covariates. The group-by-time interaction will be used to estimate between-group differences in change in the primary outcome from baseline to post-intervention and to assess the maintenance of effects at the 3-month follow-up.

Ethics and dissemination: The study will be conducted in accordance with the Declaration of Helsinki, Good Clinical Practice, the EU General Data Protection Regulation, and applicable Spanish legislation. The study protocol was approved by the Research Ethics Committees (CEIm) of all participating centres. Informed consent from a parent or legal guardian and adolescent assent will be obtained before enrolment. Findings will be disseminated through peer-reviewed publications, scientific conferences, and return sessions with participating centres, patients, and families.

Strengths and limitations of this study

- This is the first multicentre randomised controlled trial to evaluate a multicomponent digital intervention that jointly targets movement behaviours, asthma self-management, and psychosocial well-being to improve health-related quality of life in adolescents with asthma.
- Recruitment across seven Spanish referral hospitals, together with stratified randomisation by sex and asthma severity, enhances the generalisability of the findings and enables prespecified analysis of sex and severity as moderators.
- The intervention is grounded in established behaviour-change theory (Transtheoretical Model and Self-Determination Theory) and combines wearable-based monitoring with structured educational and motivational support.

- Outcomes are assessed at post-intervention and at 3-month follow-up, allowing evaluation of both the immediate effect and its maintenance over time; the intention-to-treat analysis minimises the impact of attrition.
- Blinding of participants and intervention providers is not feasible given the behavioural nature of the intervention; outcome assessor blinding reduces detection bias, although the self-reported primary outcome remains susceptible to expectation effects.

Keywords

asthma; adolescents; non-pharmacological intervention; lifestyle; physical activity; quality of life; remote monitoring; health promotion; behaviour change; sleep; sedentary behaviour; randomised controlled trial

Introduction

Background and rationale {9a, 9b}

Asthma is a chronic, heterogeneous disease and a major global health problem, as it is one of the leading causes of disability in children and adolescents (1,2). In Spain, the Global Asthma Network reported a rising prevalence of asthma symptoms among adolescents, reaching 15.3%, with sex differences (1,3). Despite effective pharmacological treatment and consolidated guidelines (GINA internationally, GEMA nationally) (4), suboptimal health-related quality of life (HRQoL) persists among adolescents with asthma (5,6), indicating that clinical control alone is not always sufficient, particularly during adolescence, a key period for consolidating the health behaviours that shape long-term outcomes (7,8).

Several modifiable factors influence HRQoL. Movement behaviours (MB) encompass physical activity (PA), sedentary behaviour (SB), and sleep duration (SD) within an integrated 24-hour framework. Most Spanish adolescents do not meet these recommendations (9), and reduced PA has been described in adolescents with asthma, particularly in those with moderate-to-severe or uncontrolled disease (10). PA is associated with better lung function, asthma control, and HRQoL (11), whereas excessive SB and inadequate SD relate to worse well-being, more symptoms, and poorer HRQoL (12,13). Asthma control is bidirectionally linked to MB and is itself a key determinant of HRQoL, particularly in girls (5). Achieving good control in adolescence remains challenging, and its barriers and facilitators are related mainly to psychosocial factors (7).

Psychosocial factors, including perceived stress, self-efficacy, executive functioning, social support, and anxiety and depressive symptoms, act as barriers or facilitators of self-management and behaviour change, and relate bidirectionally to asthma control, MB, and HRQoL (14,15,16). Although these factors and movement behaviours have been studied individually, their combined influence on HRQoL in adolescents with asthma remains unclear, and to date no randomised trial has evaluated a multicomponent intervention jointly targeting movement behaviours, asthma self-management, and psychosocial well-being to improve HRQoL in this population. This reinforces the need for multidomain interventions rather than approaches targeting each factor in isolation.

Consistent with this, clinical guidelines (GINA and GEMA 5.5) recommend complementing pharmacological treatment with non-pharmacological, education-based interventions and telehealth resources to support self-management (4,17). Accordingly, the proposed intervention, grounded in the Transtheoretical Model (18) and Self-Determination Theory (19), integrates individualised goal-setting monitored with a smartwatch, online small-group educational sessions, and motivational strategies to improve HRQoL by jointly supporting MB adherence, asthma self-management, and psychosocial well-being. As a behavioural, non-pharmacological programme delivered remotely, it is expected to carry minimal risk.

This trial constitutes the second phase of the CLiQ-Asthma project. The first, observational phase characterised HRQoL, movement behaviours, and psychosocial factors in adolescents with asthma; from this phase, eligible adolescents are identified and invited to the trial.

Choice of comparator {9b}: The comparator is usual care, defined as standard medical management delivered through the participating hospitals' routine clinical pathways, without the additional intervention. Usual care was chosen because it represents the current standard of care that all adolescents with asthma receive irrespective of trial participation, providing the ethically appropriate and clinically relevant reference for testing whether the intervention adds benefit as a complement to guideline-based treatment.

Objectives {10}

The primary objective of this randomised controlled superiority trial is to assess the effect of a 12-week, remote, multicomponent behaviour-change intervention, compared with usual care, on health-related quality of life (PedsQL-Asthma) in Spanish adolescents aged 13-17 years with asthma and lower health-related quality of life, from baseline to 3 months (post-intervention), with a further assessment at 3-month follow-up to evaluate sustainability of effects.

Secondary objectives are to assess the effect of the intervention, at the same time points, on asthma control, management of psychosocial factors, and adherence to movement behaviour guidelines. An additional objective is to explore whether sex and asthma severity moderate the effect of the intervention on these outcomes.

Methods and analysis

Patient and public involvement {11}

During protocol development, a small group of potential end-users, informally pilot-tested the data-collection forms and assessment procedures, and their feedback informed minor refinements. No patients or members of the public were involved in the design or conduct of this trial. Dissemination of trial results to adolescents, families, and the wider community is planned in collaboration with patient associations.

Trial design and setting {12, 13}

This is a multicentre, two-arm, parallel-group, superiority randomised controlled trial with individual randomisation and a 1:1 allocation ratio to the intervention or usual care group.

Participants are recruited from outpatient paediatric pulmonology/allergy clinics in the 7 Spanish public hospitals that contributed to the CLiQ-Asthma observational phase: Hospital Infantil Universitario Niño Jesús (Madrid), Hospital Universitario Virgen del Rocío (Andalucía), Hospital Universitario Donostia (Euskadi), Hospital Universitario Miguel Servet (Zaragoza), Hospital Universitario Vall d'Hebron (Barcelona), Hospital Clínico de Valencia, and Complejo Hospitalario Universitario de A Coruña. The trial is coordinated remotely by Universitat Internacional de Catalunya (Barcelona).

Eligibility criteria {14a, 14b}

Participants must meet the following inclusion criteria: (1) aged 13-17 years; (2) physician-diagnosed asthma of any severity, confirmed according to GINA 2024 criteria, with no exacerbations in the 3 weeks prior to enrolment; (3) stable asthma follow-up and treatment with a minimum of two visits at a participating hospital; (4) fluency in Spanish; (5) no physical limitations preventing participation in physical activity; (6) health-related quality of life below the clinical threshold (PedsQL-Asthma <80), as assessed in the observational phase of the study; and (7) possession of a compatible mobile device.

Exclusion criteria are: (1) medical, psychiatric, or cognitive conditions, or medication unrelated to asthma, with the potential to influence movement behaviours, psychosocial factors, or health-related quality of life; and (2) current participation in another research study.

Eligibility criteria {14b}: No formal eligibility criteria were established for participating sites. Hospitals were selected using a purposive sampling strategy based on: (1) geographic representativeness across Spain's autonomous communities, to capture variability in climate, urbanisation, and sociocultural context; and (2) public hospital status, to ensure a socioeconomically heterogeneous sample. Within these criteria, sites were identified through the research team's professional networks. The responsible clinician at each hospital was a paediatrician or paediatric pulmonologist/allergist with prior involvement in competitive research projects, and with clinical access to a paediatric asthma population meeting the trial's target profile.

Intervention and comparator {15a, 15b, 15c, 15d}

Intervention group

The experimental arm is CLiQ-Asthma intervention, a 12-week, remote, multicomponent behaviour-change programme grounded in the Transtheoretical Model (TTM) and Self-Determination Theory (SDT). It targets movement behaviours, asthma control, and psychosocial factors, aiming to improve health-related quality of life through better asthma self-management, management of psychosocial factors, and adherence to at least two of the three movement behaviour guidelines: (1) ≥ 60 min/day of moderate-to-vigorous physical activity or ≥ 9701 steps/day; (2) ≤ 2 h/day of recreational screen time; and (3) 8-10 h/night of sleep. Its active ingredients are the theoretical mechanisms of change: supporting autonomous motivation (SDT) and matching goals to each participant's readiness to change (TTM) to promote sustained behaviour change.

The programme uses a wrist-worn smartwatch for continuous 24-h monitoring of physical activity, steps, and sleep, and a mobile app through which participants review their personalised goals, log daily progress, and receive personalised feedback and reminders. Structured educational session guides support delivery of the group sessions.

The study manual, educational session guides, motivational interview guide, and goal-setting materials will be openly deposited in Zenodo (<https://zenodo.org/>) under a CC-BY license.

The programme comprises three components:

(1) *Individualised goal-setting programme.* Before the intervention begins, each participant completes a structured individual motivational interview to explore current physical activity, sedentary behaviour, sleep, asthma perceptions, and psychosocial factors, identify their TTM stage of change, and co-design a personalised plan with the interventionist. SMART goals are set at two levels: monthly meso-goals and weekly micro-goals, progressing gradually according to the participant's readiness (e.g., a participant in precontemplation begins with smaller, incremental changes). Adherence to movement behaviours is continuously monitored via the smartwatch, worn throughout the 12-week intervention, and through participants' daily self-logging of goal completion in the app, providing objective data for dynamic adjustment of goals.

(2) *Online group educational sessions.* Nine remote, interactive 45-minute sessions delivered in small groups (3-4 participants) stratified by age and asthma severity. An initial weekly phase (6 sessions, weeks 1-6) covers core content (QoL, movement behaviours, asthma self-management, and psychosocial aspects), followed by a consolidation phase of 3 biweekly sessions focused on maintenance and sustainability of behaviour changes. The session methodology is adapted to developmental stage: for the younger group (13-15 years) it is more facilitator-led and gamified (e.g., gamified quizzes, structured activities, peer challenges), whereas for the older group (16-17 years) it

is more debate-based, emphasising group reflection, case discussion, and critical thinking. Across both formats, sessions are designed to foster peer support and group cohesion.

(3) *Motivational and follow-up strategies.* Digital reminders and personalised feedback, delivered through the mobile app and reinforced during the educational sessions, to sustain participation, adherence, and retention throughout the programme.

The intervention is delivered entirely remotely by a single interventionist across all participants and sites, to ensure standardisation and minimise inter-provider variability; no formal eligibility criteria were established for the role. A clinical psychologist supports the development of the educational and psychosocial materials. The motivational interview and goal-setting are conducted individually, whereas the educational sessions are delivered in the small age- and severity-stratified groups described above.

Throughout the programme, participants in the intervention arm continue to receive usual care delivered by their treating clinicians in accordance with standard clinical guidelines for asthma management in adolescents, which are primarily based on pharmacological treatment, together with their routine clinical follow-up.

Comparator group

The control arm receives usual care alone, as defined above. Usual care is not standardised or altered by the trial and reflects real-world clinical practice, which may vary across participants and sites. Participants in the intervention arm receive this same usual care in addition to the CLiQ-Asthma intervention. Asthma medication (type, dose, and changes) will be recorded in both arms throughout the trial and considered in the analysis.

Criteria for discontinuing or modifying the allocated intervention

The intervention may be temporarily paused during an asthma exacerbation or other clinical incident, and resumed once the participant has recovered. Individual goals are adjusted continuously as an intrinsic part of the intervention, based on smartwatch data and participant feedback. Participants may withdraw or reduce their participation at any time, without affecting their usual clinical care. Any pause, suspension, modification, or withdrawal, together with its reason and timing, is documented in the facilitator log.

Strategies to improve adherence and monitor fidelity

Participant adherence. Adherence and retention of participants are promoted through flexible scheduling, small groups, personalised goals, digital reminders, continuous contact, technical support, and a participation certificate.

Provider fidelity. Delivery of the intervention as specified in the protocol is supported by a standardised operational manual and by the use of a single interventionist across all sites.

Monitoring. Process indicators of adherence and fidelity are recorded throughout the intervention: session attendance and reasons for absence, weekly goal attainment, smartwatch wear consistency, and goal adjustments made in response to feedback, complemented post-intervention by retention/dropout and global participation indicators (e.g., % of sessions attended, % of weeks with goals met, % of valid smartwatch days). Implementation fidelity is monitored through a structured facilitator log, and acceptability of the programme and motivational interview through brief items on perceived clarity, usefulness, and relevance. Drawing on these indicators, participants will be classified for the per-protocol sensitivity analysis as having received the intervention as planned if they (i) attend at least 6 of the 9 educational sessions and (ii) provide valid smartwatch data (≥ 5 valid days per week, each with ≥ 20 h of wear) for at least 70% of the intervention weeks.

Concomitant care

All routine asthma care, rescue medication, changes in controller treatment, urgent care, and other clinically indicated services are permitted. The intervention team does not instruct participants to alter medication. Co-interventions that directly target the same movement behaviours or provide structured asthma self-management training are recorded. Participation in another interventional study likely to affect trial outcomes is not permitted.

Outcomes {16} and Data Collection Methods {25a, 25b}

All outcomes are assessed at baseline (T1), post-intervention (T2) and 3-month follow-up (T3), using instruments validated and available in Spanish. Outcomes were selected for their clinical relevance, responsiveness, and validated measurement in this population, and include patient-reported outcomes to reflect adolescents' own perspectives on their health.

The primary endpoint is PedsQL-Asthma module total scores at baseline (T1), post-intervention (T2), and T3 assessing sustainability of effects. The PedsQL-Asthma module (Seid et al., 2010) is a self-reported, validated instrument for HRQoL in paediatric asthma, available and validated in Spanish (Cronbach's $\alpha = 0.84$, ICC = 0.47). Items are scored and linearly transformed to a 0-100 total score, with higher scores indicating better HRQoL; it is analysed as a continuous variable. HRQoL was chosen as the primary outcome because it is the patient-reported construct most central to the intervention's aim and reflects adolescents' own perspective on the impact of asthma on their daily lives.

The secondary endpoints share the same analysis metric and summary measure as the primary. They comprise:

- Asthma Control Test (ACT) score (Nathan et al., 2004).
- Adherence to the 24-hour movement guidelines (Tremblay et al., 2016), measured as the number of guidelines met (0-3), defined by three components: physical activity (≥ 60 min/day of moderate-to-vigorous activity, or ≥ 9701 steps/day) and sleep duration (8-10 h/night), both from smartwatch data (valid record ≥ 5 days with ≥ 20 h/day); and recreational screen time (≤ 2 h/day; assessed with the Youth Leisure-Time Sedentary Behaviour Questionnaire [YLTSBQ] screen-time module, Cabanas-Sánchez et al., 2018).
- Adolescent Asthma Self-Efficacy Questionnaire (AASEQ) score (Holley et al., 2019).
- Multidimensional Scale of Perceived Social Support (MSPSS) score (Trejos-Herrera et al., 2018).
- Adolescent Stress Questionnaire-Spanish version (ASQ-S) score (Lima et al., 2017).
- Hospital Anxiety and Depression Scale (HADS) score (Licari et al., 2022).

Score ranges, direction of interpretation, and psychometric properties for all instruments are summarised in Table 1.

Table 1. Outcome measures (Phase II)

Outcome	Instrument	Score range	Interpretation	Psychometric properties (Spanish)
HRQoL (primary)	PedsQL-Asthma module	0-100	Higher = better HRQoL	$\alpha = 0.84$; ICC = 0.47
Asthma control	Asthma Control Test (ACT)	5-25	Higher = better control (≥ 21 controlled; 19-20 partly controlled; ≤ 18 uncontrolled)	$\alpha = 0.80$; ICC = 0.75

Movement - behaviour guideline adherence	Adherence to the 24-h movement guidelines	0-3	Higher = more guidelines met	Composite outcome
• Physical Activity	Smartwatch	-	≥60 min/day of moderate-to-vigorous activity or ≥9701 steps/day	Device-based; valid record ≥5 days with ≥20 h/day
• Sedentary Behaviour	YLTSBQ, screen-time module	-	≤2 h/day	ICC = 0.75; r = 0.36
• Sleep Duration	Smartwatch	-	8-10 h/night	Device-based; valid record ≥5 days with ≥20 h/day
Asthma self-efficacy	AASEQ (20 items, 0-3 Likert)	0-60	Higher = greater perceived self-efficacy	$\alpha = 0.78-0.91$; ICC = 0.82
Perceived social support	MSPSS (12 items, 1-7 Likert)	12-84	Higher = greater perceived social support	$\alpha \geq 0.85$; ICC ≥ 0.70
Perceived stress	ASQ-S (10 subscales)	56-280	Higher = greater perceived stress	$\alpha \geq 0.80$; ICC ≥ 0.70
Anxiety & depressive symptoms	HADS (14 items, 0-3 Likert)	0-21 per subscale	Higher = greater symptom severity	$\alpha \geq 0.80$

Three complementary clinical indicators are additionally assessed as secondary outcomes: the number of asthma exacerbations, the number of emergency room (ER) visits, and changes in asthma medication, all obtained from clinical records. The number of exacerbations and the number of ER visits are each recorded as count variables (number of events per participant). Changes in asthma medication are recorded as a nominal categorical variable (step-up, step-down, or no change). All three are assessed over the trial period at baseline (T1), post-intervention (T2), and 3-month follow-up (T3). These indicators reflect asthma morbidity and disease control, complementing the ACT and the trial's patient-reported outcomes .

In addition to the trial outcomes, the following variables are collected: lung function by spirometry (FEV1, FVC, FEV1/FVC, FEF25-75%) and anthropometry (height, weight, BMI), measured by clinical staff; executive functioning (inhibition, working memory, and cognitive flexibility), assessed with the Spanish version of the CogniFit Cognitive Assessment Battery (CAB; Caamaño-Navarrete et al., 2025); sociodemographic and environmental factors (age, sex, socioeconomic level, family structure, parental education, first language, and climate/urbanisation); dietary habits (KIDMED; Mariscal-Arcas et al., 2009); substance use (alcohol, tobacco, or drugs; Tarekegn et al., 2022); and academic performance (average grades in mathematics, physical education, first language, and a foreign language; Adelantado-Renau et al., 2023).

Outcomes and other study variables are collected through three modes, all captures centrally in Research Electronic Data Capture (REDCap™).

Patient-reported data. Are collected through remote electronic questionnaires answered via REDCap using standardised forms with built-in validation rules.

Device-based data. Movement behaviour data are recorded continuously (24 h/day) by the smartwatch during the evaluation windows at T1, T2, and T3 in both groups (valid record: ≥ 5 days with ≥ 20 h/day), exported in tabular formats, and integrated into REDCap with full traceability. A brief familiarisation period precedes device-based assessment to reduce the novelty effect.

Clinician-collected data. Clinical staff record anthropometry and lung function by spirometry at scheduled hospital visits.

Data quality

To promote data quality, a common operational protocol unifies recruitment, assessment, and intervention delivery across sites, applying homogeneous criteria while allowing individualised adaptation. Site teams receive initial training and periodic updates to ensure consistent application of assessment procedures. Data capture is centralised and standardised through REDCap, ensuring traceability and cross-site comparability, and complemented by a monitoring circuit for data-incident resolution and protocol-compliance verification. When inconsistencies or protocol deviations are detected, they are reviewed with the site manager, including additional training, data audit, and, where appropriate, repeat assessments or record correction. For device-based measurement, calibration and verification procedures and predefined valid-data criteria are established, with replacement devices and technical support to minimise data loss. Data collection forms are managed in REDCap and are available from the corresponding author on reasonable request. The instruments used are previously validated in Spanish, so no additional pilot testing of the data collection forms was performed. However, the forms were informally pilot-tested by potential end-users, whose feedback informed minor refinements.

Participant retention

Participant retention in the assessment schedule and complete follow-up are promoted through several strategies aimed at preventing missing outcome data. Study staff at each site remain accessible to participants throughout the trial, and assessments are scheduled flexibly to fit participants' availability and, whenever possible, to coincide with pre-existing clinical appointments, with questionnaires completed remotely. A planned contact calendar with reminders precedes each evaluation window (T1, T2, T3), supported by active follow-up and technical support for questionnaire completion and smartwatch use. Adherence to the assessment schedule is monitored continuously so that difficulties are detected early and individualised measures (rescheduling, additional reminders, or technical support) can be applied to recover data before they are lost. If loss to follow-up exceeds that anticipated, follow-up efforts are reinforced and additional recruitment is activated within the planned period to preserve the sample size.

Non-adherence to the intervention (e.g., low session attendance, insufficient smartwatch wear or no completion of goals) does not by itself lead to cessation of data collection. Participants who deviate from or discontinue the intervention remain in the trial and continue to be assessed on all outcomes at T2 and T3, under the same assessment schedule as fully adherent participants and whenever they consent. For participants who formally withdraw from the trial, no further data are collected from the date of withdrawal. The reasons for non-adherence (e.g., discontinuation of the intervention owing to harms or clinical incidents, lack of efficacy, demotivation, or other participant reasons) and for non-retention (e.g., withdrawal from the trial or loss to follow-up) are recorded systematically in the facilitator log and considered in the interpretation of results.

Harms {17}

Given the non-pharmacological, remote, behavioural nature of the intervention, harms are defined narrowly as asthma exacerbations or other clinical incidents occurring during the intervention or follow-up period, and are assessed non-systematically (passive surveillance). No harms are anticipated to be directly caused by the intervention itself.

Incidents are identified either spontaneously, when a participant or family reports feeling unwell to the study team or their clinician, or through the participant's routine clinical follow-up at the hospital, throughout the 12-week intervention and the follow-up period up to T3. The participant's clinician evaluates, manages, and grades severity according to standard clinical criteria for asthma exacerbations. No specific blinding procedure applies to this assessment.

Exacerbations, which are also counted as a secondary outcome, are classified by the treating clinician as manageable within continued participation or as requiring temporary suspension of the intervention, in which case the programme is paused and resumed once the participant has recovered, with the event, management, and timing documented in the facilitator log. Clinical incidents are communicated directly to the medical team responsible for the participant's routine asthma follow-up.

Participant timeline {18}

The expected timeline spans from screening through a 3-month follow-up, structured into three trial periods: enrolment (screening and baseline assessment, T1), post-randomisation (12-week intervention or usual care, with post-intervention assessment at T2), and close-out (follow-up assessment at T3, 3 months post-intervention) (Figure 1).

Figure 1. Diagram of the schedule of enrollment, interventions, and assessments.

	Trial period					
	Enrolment		Post-randomisation			Close-out
Timepoint	Screening	T1 (baseline)	Weeks 1–6	Weeks 7–12	T2 (week 12)	T3 (3 months post-int.)
Enrolment						
Eligibility screening	X					
Informed consent (parent/guardian) and assent (adolescent)	X					
Randomisation (1:1, stratified by sex and asthma severity)		X				
Intervention or comparator						
Individual motivational interview and goal-setting (intervention arm)		X				
Weekly educational sessions 1–6 (intervention arm)			X			
Biweekly educational sessions 7–9 (intervention arm)				X		
Smartwatch monitoring and app feedback/reminders (intervention arm)			→			
Usual care (both arms)			→			
Assessments						
Sociodemographic data		X				
Clinical data (anthropometry, body composition, spirometry)		X				
Patient-reported outcomes (PedsQL-Asthma, ACT, AASEQ, MSPSS, ASQ-S, HADS, YLTSBQ)		X			X	X
Movement-behaviour monitoring (smartwatch evaluation window)		X			X	X
Process and fidelity indicators (intervention arm)			→			
Harms surveillance			→			

→ indicates continuous delivery or monitoring rather than a discrete visit.

Sample size {19}

The sample size calculation is based on the primary outcome, health-related quality of life measured using the Pediatric Quality of Life Inventory Asthma Module (PedsQL-Asthma). No secondary outcome was used to determine the sample size.

Based on Seid et al. (2010), a minimum detectable between-group difference of 16.93 points and a common standard deviation of 15.27 points are assumed. With a two-sided significance level of $\alpha = 0.05$, 80% statistical power ($\beta = 0.20$), a 1:1 allocation ratio, and an anticipated dropout rate of 20%, 32 participants are required, with 16 participants per group.

To account for potential variability between participants, a more conservative scenario is considered, assuming a higher common standard deviation of 18 points or a smaller between-group difference of 14 points. Under these assumptions, the required sample size is increased to 48 participants, with 24 participants per group.

To enable comparisons by sex, the sample size is doubled, resulting in a final target sample of 96 participants: 48 in the intervention group and 48 in the usual-care control group, with an equal distribution by sex.

The sample size calculation was performed using R software and the `pwr.t.test` function from the `pwr` package.

Recruitment {20}

Eligible adolescents identified during the observational phase are invited to participate before baseline assessment and randomisation. Adequate enrollment will be supported by the multicentre design, which provides access to a large and geographically diverse population of adolescents with asthma. Participant burden will be reduced by conducting questionnaires, study contacts, the intervention, and most follow-up procedures remotely, using flexible scheduling and coordinating clinical assessments with routine hospital appointments whenever possible.

Recruitment progress will be monitored centrally by Universitat Internacional de Catalunya and reviewed with the participating centres periodically. The number of participants screened, eligible, invited, enrolled, and randomised will be monitored by centre. If recruitment is slower than expected, corrective measures will include reinforcing recruitment at individual sites, redistributing recruitment targets towards centres with greater capacity, and extending the recruitment period if necessary.

Randomisation: sequence generation, allocation concealment mechanism, and implementation {21a, 21b, 22, 23}

A biostatistician from the research team, not involved in participant recruitment, intervention delivery, or outcome assessment, developed the computerised randomisation system in R. Participants will be allocated 1:1 to the intervention or usual-care group. Restricted randomisation using permuted blocks will be stratified by sex (female or male) and asthma severity (mild, moderate, or severe). Allocation is managed through a secure, purpose-built application developed in R (a Shiny app) that conceals the sequence: after baseline assessment, the study coordinator enters the participant's coded identifier and stratification variables, and the system reveals only the allocation of the participant currently being randomised, without access to the underlying sequence or future assignments.

The study coordinator will communicate the allocation to the participant and coordinate intervention delivery. The allocation record will be exported as a CSV file and securely stored in REDCap with access restricted to authorised research personnel.

Blinding {24a, 24b, 24c}

Trial participants and the interventionist will not be blinded to treatment assignment because the intervention is clearly distinguishable from usual care. Recruiters and outcome assessors are blinded to group allocation, as well as the data analysts.

At T1, clinical measurements and REDCap assessments will be completed before randomisation. At T2 and T3, the primary and several secondary outcomes are self-reported by participants aware of their allocation, so these outcomes cannot be blinded. Smartwatch-derived outcomes will be collected objectively.

Data management {26}

Trial data will be collected and managed centrally using REDCap. Patient-reported outcomes will be entered directly by participants through standardised electronic forms. Clinical data collected by healthcare professionals will also be entered directly into standardised REDCap forms. Smartwatch-derived data will be exported in tabular format from the digital monitoring platform and integrated into REDCap with full traceability.

Each participant will be automatically assigned a unique alphanumeric study code by REDCap. Files containing direct personal identifiers will be stored separately from the research dataset and will only be accessible to the principal investigator and authorised data-management personnel. Only pseudonymised data will be used for statistical analysis.

Data quality will be promoted through standardised REDCap forms, consistency checks, documented data-processing procedures, and central monitoring by the coordinating team. Records will be reviewed for completeness and inconsistencies before the analysis dataset is generated. REDCap will maintain traceability of data entry and subsequent modifications.

Access to REDCap will be controlled according to user roles. Authorised personnel at each participating hospital will be able to enter and verify data from their centre, while the coordinating team at UIC Barcelona will have access for central monitoring and quality control. Data will be stored in secure institutional REDCap and UIC Barcelona systems, with controlled access and institutional backups following the 3-2-1 backup rule.

Study data will be retained for five years after completion of the study and will subsequently be securely destroyed or anonymised in accordance with applicable legislation and institutional procedures.

Statistical methods {27a, 27b, 27c, 27d}

Descriptive analyses

All statistical analyses will be performed using R version 4.5.0 and appropriate statistical packages (e.g., lme4). Baseline characteristics will be summarised by treatment group using frequencies and percentages for categorical variables, means and standard deviations for normally distributed continuous variables, and medians and interquartile ranges for non-normally distributed variables. Statistical significance is set at a two-sided α of 0.05, and 95% confidence intervals are reported for all effect estimates.

Primary outcome analyses

The analysis will follow the intention-to-treat principle, including all randomised participants and analysing them according to their randomised group, regardless of adherence to the intervention. Two analysis populations are defined: the intention-to-treat population, comprising all randomised participants analysed in their allocated group; and the per-protocol population, comprising those who meet the prespecified adherence criteria (attendance at ≥ 6 of 9 educational sessions and valid smartwatch data for $\geq 70\%$ of intervention weeks). The intention-to-treat analysis is the primary analysis. No interim analyses are planned.

The primary outcome, HRQoL PedsQL-Asthma total score, will be analysed using a linear mixed-effects model for repeated measures. Time will be treated as a categorical variable. The model will include time (T1, T2, and T3), treatment group, and the time-by-group interaction as fixed effects. A participant-level random effect will be included to account for the intra-individual correlation between repeated measurements. Sex and baseline asthma severity will also be included as prespecified fixed-effect covariates. These covariates have been chosen because they are used to stratify randomisation

and may influence health-related quality of life and response to the intervention. Model parameters will be estimated using maximum likelihood.

The intervention effects will be estimated using the adjusted time-by-group interaction contrasts between T1 and T2 and between T1 and T3. The T1-T2 contrast will estimate the intervention effect at the end of the intervention, and the T1-T3 contrast will evaluate the sustainability of the intervention effect three months after completion of the intervention. Both effects will be reported as adjusted between-group differences in PedsQL-Asthma scores, with confidence intervals as specified.

Secondary outcome analyses

Continuous secondary outcomes (ACT, smartwatch-derived movement behaviour measures, and psychosocial scale scores) will be analysed using linear mixed-effects models equivalent to that used for the primary outcome.

Binary secondary outcomes, including adherence to each individual movement behaviour guideline, will be analysed using mixed-effects logistic regression models. Overall adherence to the movement behaviour guidelines, classified as meeting zero, one, two, or three recommendations, will be analysed using an ordinal logistic mixed-effects model. Intervention effects at T2 and T3 will be reported as adjusted odds ratios with 95% confidence intervals and two-sided p-values.

The number of emergency room visits will be analysed using mixed-effects negative binomial regression. Changes in asthma medication (step-up, step-down, or no change) will be analysed using mixed-effects multinomial logistic regression, with no change as the reference category. Both models will include treatment group, time, treatment-by-time interaction, sex, and baseline asthma severity as fixed effects and a participant-level random effect. Intervention effects at T2 and T3 will be reported as adjusted incidence rate ratios or odds ratios, respectively, with 95% confidence intervals and two-sided p-values.

Model assumptions

Model assumptions will be assessed using residual diagnostics and graphical methods, including assessment of residual distributions, homoscedasticity, and influential observations for continuous outcomes. The proportional odds assumption will be assessed for ordinal logistic models. If important departures from model assumptions are identified, appropriate transformations or alternative statistical models will be considered.

Missing data

Missing outcome data will not be imputed. Mixed-effects models will use all available outcome data under the assumption that data are missing at random. The extent and patterns of missing data will be assessed.

Multiplicity and subgroup analyses

No adjustment for multiplicity will be applied. No subgroup analyses are planned.

Moderation analysis

The potential moderating effects of sex and baseline asthma severity on the intervention effects for both the primary and secondary outcomes will be explored by including treatment-by-time-by-sex and treatment-by-time-by-asthma-severity interaction terms in the corresponding mixed-effects models.

Sensitivity analysis

A per-protocol sensitivity analysis will repeat the primary analysis restricted to the per-protocol population. This analysis will assess the robustness of the primary findings to adherence to the intervention and study procedures.

Harms analysis

Asthma exacerbations and other clinical incidents occurring during the 12-week intervention and follow-up period will be summarised descriptively by treatment group. Moreover, for each treatment group, the number and proportion of participants experiencing at least one asthma exacerbation or clinical incident, and the total number of events, will be summarised using frequencies and percentages. No formal between-group hypothesis testing is planned because harms will be identified through passive surveillance, as the number of events is expected to be low.

This protocol incorporates the statistical analysis plan and, as the analysis is described in sufficient detail to meet the guidelines for the content of SAPs for clinical trials (Gamble et al., 2017), a separate SAP document is therefore not provided.

Data monitoring committee {28a, 28b}

No formal Data Monitoring Committee is planned for this trial, as its a short duration and minimal expected risk, non-pharmacological, remote, and behavioural intervention, without invasive procedures. Safety oversight is instead provided through routine clinical management of exacerbations by each participant's referring clinician (see Harms, {17}) and through the coordination meetings between the coordinating team and hospitals referents.

Trial monitoring {29}

Trial conduct is monitored centrally and remotely by the coordinating team at UIC Barcelona, using a risk-based approach. Monitoring covers eligibility, informed consent, protocol adherence, and data completeness and accuracy in REDCap, and is integrated into the coordination meetings with hospital referents; sites with inconsistencies or atypical patterns receive closer review. Monitoring is performed by the coordinating research team and is therefore not independent from the investigators, as the trial has minimal-risk and non-pharmacological nature.

Ethics and dissemination

Research ethics approval {30}

The protocol, participant information sheets, and consent/assent forms have been approved by the Research Ethics Committees for Medicinal Products (CEIm) of each participating hospital, under Spanish Royal Decree 1090/2015 and Law 14/2007 on Biomedical Research:

Site	Committee	Reference	Date

H. Infantil U. Niño Jesús (Madrid)	CEIm HUNJ - <i>reference (single) opinion</i>	R-0065/25 (Acta 10/25)	30 Sep 2025
H. U. Virgen del Rocío (Seville)	CEI HH.UU. Virgen Macarena-Virgen del Rocío accepted study initiation under the single binding opinion	SICEIA-2025-003482 (Acta 12/2025)	16 Dec 2025
H. U. Donostia (San Sebastián)	CEIm de Euskadi	PI2025197 (Acta 24/2025)	17 Dec 2025
H. U. Miguel Servet (Zaragoza)	Institutional authorisation (Medical Directorate) under the single binding opinion	-	26 Jan 2026
H. U. Vall d'Hebron (Barcelona)	CEIm HUVH	PR(AMI)449/2025 (Session 710)	27 Feb 2026
H. Clínico U. Valencia	CEIm HCUV	2026/099 (Acta 459)	30 Apr 2026
CHU A Coruña	-	Approval pending	-

The study has received a favourable ethical approval from the CEIm of Hospital Infantil Universitario Niño Jesús (Madrid), which has been provided to the participating centres as the prior ethical assessment of this multicentre project. Additional local ethical and/or institutional procedures have been completed as required by each participating centre. The Andalusian centre acknowledged the study without issuing an additional ethical opinion, while the Zaragoza hospital obtained the corresponding institutional authorisation from its Medical Directorate. No participant will be enrolled at CHU A Coruña until the required ethical and institutional authorisations have been obtained. Any relevant amendments to the approved protocol will be submitted to the appropriate Research Ethics Committee for review and approval before implementation.

Dissemination policy {8}

Results will be disseminated at three levels, regardless of whether findings are positive, negative, or inconclusive: **(1) Scientific.** Peer-reviewed publications and presentations at national and international paediatrics and respiratory medicine. Summary results will be posted on ClinicalTrials.gov within two years of completion. Reporting will follow CONSORT guidelines. **(2) Clinical.** Return of results to each participating hospital via clinical sessions and create resources for clinicians and managers to support uptake into guidelines and care protocols. **(3) Participants and public.** Participants and families will receive a plain-language summary in Spanish; no individual results will be exposed. Accessible materials co-created with adolescents will be disseminated through patient organisations and workshops for adolescents, families, and schools.

Approval and timeframe. Manuscripts and abstracts will be drafted by a writing group led by the coordinating centre, sent to all hospital referents for review within a defined comment period, and approved by the principal investigator before submission. Any unresolved disagreement will be settled by the principal investigator. The primary results manuscript, based on the post-intervention assessment (T2), will be prepared once T2 data collection is complete and the corresponding database is locked, with submission targeted within 6 months and the 3-month follow-up (T3) results will be reported subsequently.

Authorship. The criteria for authorship recommended by the International Committee of Medical Journal Editors (ICMJE) will be followed and it is not intended to employ professional writers.

Protocol amendments {31}

Protocol modifications will be agreed by the principal investigator, who holds final decision-making authority, and issued as a new protocol version with a unique number and date. Substantial amendments, such as those affecting participant safety or the trial's scientific validity, or ethical conduct, will be submitted to the reference CEIm (H. Infantil U. Niño Jesús), notified to the other participating CEIm, and implemented only after favourable opinion; once approved, they will also be reflected in an updated ClinicalTrials.gov record. The non-substantial amendments will be reported in the annual follow-up report.

Consent or assent {32a, 32b}

Informed consent will be obtained by the hospital referents. Consent will be sought during a routine clinical visit, before any study-related procedure. Eligible adolescents and their parents or legal guardians will receive a verbal explanation of the study and the corresponding participant information sheet, with sufficient time to read it, ask questions, and consult others before deciding. Two separate documents are used for each phase: one addressed to the adolescent (aged 13-17 years) in age-appropriate language and one to the parent or legal guardian (ANNEX 1). Written assent from the adolescent and written consent from the parent or legal guardian are both required for participation. Participants are informed that participation is voluntary, that they may withdraw at any time without any effect on their usual clinical care, and each signatory receives a copy of the signed document. No adults lacking decisional capacity will be enrolled.

No additional consent provisions are applicable as no biological specimens will be collected or stored, and no ancillary studies are planned.

Confidentiality {33}

Participant data will be pseudonymised at collection using a unique alphanumeric code generated by REDCap. Identifying fields are flagged as identifiers and are not visible or exportable, and access is restricted to the authorised staff. Data from all centres are held in a single institutional REDCap environment on secure servers, with role-based access control, audit trails, encryption, and 3-2-1 backups, with reinforced measures given that the data are health data from minors. Data exported for analysis are pseudonymised and no external recipients and no international transfers are foreseen. Data ownership rests with UIC Barcelona as sponsor and coordinating centre. Processing complies with Regulation (EU) 2016/679 and Spanish Organic Law 3/2018. Study data will be retained for five years after completion, and only anonymised data will be published or deposited.

Ancillary and post-trial care {34}

Participants remain under the usual care of their paediatric pulmonology team throughout the trial and their participation does not replace or alter their standard asthma management. Any exacerbation or clinical incident is referred to the treating clinician, and the intervention can be paused or stopped. No additional ancillary care is provided, as the intervention is non-pharmacological and non-invasive and runs alongside the participant's routine clinical follow-up.

There are no post-trial provisions beyond return to usual care, since the programme is time-limited and not a treatment that requires continuation. Participants will keep the educational materials, but will return the smartwatches at the end of the intervention. Given the minimal-risk nature of the trial, there is no specific compensation scheme for trial-related harm, and participants receive no payment for taking part.

Protocol and data sharing {5, 6}

The protocol is deposited in clinicaltrials.gov.

Following publication of the primary results, an anonymised individual participant dataset, together with a data dictionary, README file, and the statistical analysis code, will be deposited in the in Zenodo (<https://zenodo.org/>) under a CC-BY license, in line with FAIR principles. Deposit is conditional on a prior assessment of re-identification risk. If robust anonymisation cannot be guaranteed, aggregate data or controlled access will be used instead.

Funding and conflicts of interest {7a, 7b}

The trial is supported by direct monetary support from a research grant from the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR), 2026 call, Investigador Novel category (reference inv271_2025, €13.000). The funder has no role in the design of the study, data collection, analysis, interpretation, or in the decision to submit results for publication. No other monetary or indirect support has been received.

The investigators declare that they have no financial or non-financial conflicts of interest.

Authors' contributions

Contributors: MF, DB, and MD conceived and designed the study. MD is the Principal Investigator and, with DB, oversees project administration. DB, with MF, developed the statistical methodology and the sample-size calculation. MF drafted the original protocol and coordinated its development. MF, FS, MA, MM, IB and MD developed the methodology and designed the intervention components (movement behaviours, asthma management, executive functioning, stress-coping and self-efficacy, and psychosocial support). MF, FS, MA, MM and MD contributed the exercise, physical-activity, and respiratory-physiotherapy content. IB contributed the psychological intervention content. VS, IM, OS, MG, AG, CM, and SC are the lead clinicians (paediatricians and paediatric pulmonologists) at the participating hospitals and contributed to the clinical eligibility criteria, recruitment strategy, and site-level feasibility. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

AI-based tools were used solely to assist with language editing and improve the readability of the English text. All content was conceived, verified, and approved by the authors, who take full responsibility for it.

Acknowledgements

The authors thank the adolescents who pilot-tested the study materials and data-collection forms during the preparatory phase.

All individuals named have given their consent to be acknowledged.

References

1. Bercedo Sanz A, et al; Grupo GAN España. Prevalence and temporal evolution of asthma symptoms in Spain. Global Asthma Network (GAN) study. *An Pediatr (Engl Ed)*. 2022;97(3):161-171.
2. Asher MI, et al; Global Asthma Network Phase I Study Group. Worldwide trends in the burden of asthma symptoms in school-aged children: Global Asthma Network Phase I cross-sectional study. *Lancet*. 2021;398(10311):1569-1580.
3. Shah R, Newcomb DC. Sex bias in asthma prevalence and pathogenesis. *Front Immunol*. 2018;9:2997.
4. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention. 2024.
5. Valero-Moreno S, et al. Quality of life in patients with asthma: medical indicators and psychological variables. *J Pediatr Nurs*. 2023;69:e136-e144.
6. Plaza-González S, et al. Psychological and sociocultural determinants in childhood asthma disease: impact on quality of life. *Int J Environ Res Public Health*. 2022;19(5):2652.
7. Holley S, et al. Barriers and facilitators to asthma self-management in adolescents: a systematic review of qualitative and quantitative studies. *Pediatr Pulmonol*. 2017;52(4):430-442.
8. Sawyer SM, et al. The age of adolescence. *Lancet Child Adolesc Health*. 2018;2(3):223-228.
9. Tapia-Serrano MA, et al. Adherence to 24-Hour Movement Guidelines among Spanish adolescents: differences between boys and girls. *Children (Basel)*. 2021;8(2):95.
10. Vasconcello-Castillo L, et al. Levels of physical activity in children and adolescents with asthma: a systematic review and meta-analysis. *Pediatr Pulmonol*. 2021;56(6):1307-1323.
11. Ma Q, et al. Effects of aerobic exercise-based pulmonary rehabilitation on quality of life in pediatric asthma: a systematic review and meta-analysis. *Heart Lung*. 2025;69:11-30.
12. Rota AP, et al. Screen time engagement is increased in urban children with asthma. *Clin Pediatr (Phila)*. 2017;56(11):1048-1053.
13. Meltzer LJ, et al. Impact of sleep opportunity on asthma outcomes in adolescents. *Sleep Med*. 2020;65:134-141.
14. Kong S, et al. The association between vigorous physical activity and stress in adolescents with asthma. *Int J Environ Res Public Health*. 2021;18(7):3467.
15. Li L, et al. Screen time and depression risk: a meta-analysis of cohort studies. *Front Psychiatry*. 2022;13:1058572.
16. Laird Y, et al. The role of social support on physical activity behaviour in adolescent girls: a systematic review and meta-analysis. *Int J Behav Nutr Phys Act*. 2016;13(1):79.
17. Guía Española para el Manejo del Asma (GEMA 5.5). Madrid; 2025.
18. Hashemzadeh M, et al. Transtheoretical model of health behavioral change: a systematic review. *Iran J Nurs Midwifery Res*. 2019;24(2):83-90.
19. Patrick H, et al. Self-determination theory: its application to health behavior and complementarity with motivational interviewing. *Int J Behav Nutr Phys Act*. 2012;9(1):18.

ANNEX 1. INFORMATION SHEET AND INFORMED CONSENT

Introduction

We are writing to inform you about a research study in which your child is invited to take part. The study has been approved by a Research Ethics Committee for Medicinal Products. Specifically, we are proposing that your child take part in the second phase of the CLiQ-Asthma study, which is aimed only at adolescents who have already taken part in the previous phase.

Our intention is that you receive correct and sufficient information so that you can decide whether or not to take part in this study. To this end, please read this information sheet carefully and we will clarify any questions you may have.

You may also consult anyone you consider appropriate.

Voluntary participation and right to withdraw consent:

You should know that your child's participation in this study is voluntary and that you may decide not to take part, or change your decision and withdraw consent at any time, without this affecting your relationship with your doctor or causing any detriment to your child's treatment.

Purpose of the study

This study is being carried out to assess whether an intervention programme based on healthy lifestyle habits, asthma management and psychosocial support can improve health-related quality of life in adolescents with asthma. Asthma is a chronic disease that can affect not only physical health but also emotional and social well-being. We therefore aim to offer tools that help adolescents improve their overall well-being.

Objectives:

This second phase aims to evaluate the effectiveness of implementing a 3-month multidisciplinary and multidimensional intervention designed to improve the quality of life of adolescents with asthma. The programme combines three main strategies: first, each adolescent will set individual goals tailored to their needs together with a designated professional, and these will be monitored with the help of a smartwatch; second, they will take part in online educational sessions in small groups, supported by professionals; and third, they will receive motivational support, with reminders and messages to help them stay committed to the programme. The intervention aims to improve asthma control, movement behaviours (physical activity, sedentary behaviour and sleep) and certain key emotional factors such as self-efficacy and stress management.

In addition, the study aims to better understand how and why these strategies help adolescents improve their well-being, cope better with asthma and maintain healthy habits in their daily lives.

Benefits:

Taking part in this study does not guarantee a direct benefit for your child, especially if they are in the control group. However, everyone who takes part is valuable in improving scientific knowledge about how adolescents live with asthma and which strategies can help improve their quality of life. If your child is allocated to the intervention group, they will receive personalised support for three months, with strategies aimed at improving their lifestyle, asthma control and emotional well-being. This support will include the use of a smartwatch to monitor daily habits, online group educational sessions, and motivational tools that will help them get to know themselves better and learn to look after themselves more independently.

Even if your child is in the control group, their participation will make a very important contribution to advancing knowledge about asthma in adolescents. The data collected may help to update clinical guidelines, design new public health programmes and create educational materials tailored to the real needs of this population. The results of the study will be shared at scientific conferences, in medical publications and through patient association networks, so that this knowledge has a useful, applicable and lasting impact.

Study procedures

If you decide that your child will take part in this phase of the study, the first step will be random allocation to determine whether they will be in the intervention group or the control group. Allocation is in a 1:1 ratio, meaning that all participants have the same probability (one in two) of being in either group. It will also be carried out in a secure and balanced way, taking into account both sex and asthma severity, so that all participants have the same chance of being in either group.

If your child is allocated to the intervention group, they will take part for 12 weeks in a personalised programme designed to increase their adherence to recommendations on physical activity levels, time spent in sedentary behaviour and hours of sleep. At the start, they will be given a smartwatch to wear daily, which will automatically record their physical activity, the time they spend at rest and their hours of sleep. In addition, they will have an individual motivational interview with a member of the team, in which they will jointly identify their personal needs, barriers and realistic goals aimed at improving their health-related quality of life.

During these weeks, your child will also take part in a programme of online educational sessions, in small groups made up of other adolescents with similar characteristics. The first six sessions will be held weekly and the next three every two weeks, making a total of nine sessions of about 45 minutes each. These sessions will be remote, practical and participatory, and will address topics such as asthma management, stress, motivation, self-esteem and healthy habits. Sharing experiences and mutual support among the participating adolescents will also be encouraged. Sessions will be scheduled according to your child's availability.

Throughout the intervention, personalised weekly goals will be set and reminders, follow-up messages and motivational resources will be sent. At the end of the programme, an assessment similar to the baseline assessment will be carried out and, three months later, a further assessment will be conducted to check whether the effects have been maintained. If your child completes the programme, they will receive a certificate of participation in recognition of their commitment.

If your child is allocated to the control group, they will not take part in the programme but will continue to receive their usual medical care, without any changes. They will also be assessed at the same time points as the intervention group, which will make it possible to compare results between the two groups and better understand the effectiveness of the intervention.

In addition, the study includes a voluntary qualitative evaluation component, which aims to better understand the experience of adolescents and their families. As part of this, some participants may be invited to take part in a brief individual interview to share their views on the programme and how they experienced it. Likewise, some parents or carers may be invited to take part in online discussion groups (also voluntary), in which their perceptions of the experience of supporting their child during the study, and any improvements they consider useful, will be gathered.

Both the interviews and the discussion groups will be audio-recorded only. Taking part in this part of the study is entirely optional and will not affect the intervention or the adolescent's participation in the study.

The whole process will be led by a multidisciplinary team of physiotherapists, psychologists and paediatric asthma specialists, who will be available to answer questions and provide ongoing support. Your child's participation will be entirely voluntary, their data will be treated confidentially and their usual medical care will not be affected at any time. In addition, they may leave the study if they wish, without having to give any explanation.

Discomfort and possible risks arising from participation in the study:

Taking part in this study poses no risks to your child's health and does not involve any medical procedures that might be uncomfortable. All planned activities form part of the study intervention and include completing questionnaires, attending online sessions and wearing a smartwatch during the day.

At times, staying motivated or meeting certain goals may require a little effort from your child. Wearing the watch may also feel somewhat uncomfortable at first, or your child may feel less inclined to attend a session. These situations are normal, and the study team will be available to support your child and offer any help they need, without pressure.

If at any time your child experiences physical or emotional discomfort, they can report it to the research team or to the responsible medical staff. The situation will be assessed on an individual basis, always seeking what is best for their well-being.

Our aim is for your child to feel supported, respected and cared for throughout the process. Taking part in this study should not interfere with their daily life or cause discomfort, but rather offer them a positive experience tailored to their needs and circumstances.

Personal data protection:

The centre will ensure that the confidentiality of the personal data collected during the study is maintained, in compliance with both national and European data protection laws.

Additional information on the minor's consent:

Please note that your child will be given an information sheet and informed consent form adapted to their level of understanding, which they will be asked to sign. Both you and your child must sign the informed consent form before taking part in the study, in accordance with current regulations on studies involving minors.

Informed consent form

Study title: Changing habits to improve quality of life in adolescents with asthma (CLiQ-Asthma): influence of asthma control and severity, lifestyle, psychosocial factors and sex differences.

I, _____ (***patient's full name***) _____

I have read the information sheet I have been given.

I have been able to ask questions about the study.

I have spoken with: (***name of investigator***).

I understand that my participation is voluntary.

I understand that I may withdraw from the study:

1. Whenever I wish
2. Without having to give any explanation
3. Without this affecting my medical care

I freely give my consent to take part in the study, and I confirm that I have read **Appendix 1** and agree with its contents.

I agree that the doctors responsible for this study may contact me in the future, if deemed appropriate, to add new data to those already collected: Yes___ No___

Participant's signature

Date: ____/____/____

Investigator's signature

Date: ____/____/____

Signature of relative/representative (*if applicable*)

Date: ____/____/____

I wish to be informed of any information arising from the research that may be relevant to my health or that of my relatives: Yes___ No___

Contact telephone or email:

Participant's signature

Date: ____/____/____

Investigator's signature

Date: ____/____/____

Signature of relative/representative (*if applicable*)

Date: ____/____/____

SECTION FOR REFUSAL OR WITHDRAWAL OF INFORMED CONSENT (SIGNATURE OF THE PATIENT AND/OR RELATIVE/REPRESENTATIVE)

I, ...or the relative/representative (*if applicable*) of the patient (patient's name) refuse/withdraw consent to participate in the study signed above.

This withdrawal of informed consent means that, from the date on which it is signed, no further medical data may be collected, without prejudice to the retention of data resulting from research carried out prior to that date.

Date of refusal/withdrawal.....

Signature:

Introduction

We are inviting you to take part in a research study to better understand how asthma affects adolescents like you. The study has already been approved by a Research Ethics Committee for Medicinal Products, which makes sure that everything is done properly and safely. This is the continuation of the study you have already taken part in.

We want you to fully understand what the study involves before you decide whether you want to take part. That is why we explain clearly here what you will do if you take part. If you have any questions, you can ask the doctor or talk about it with your parents or anyone you like.

Voluntary participation and right to withdraw consent:

Taking part in this study is completely voluntary. You decide whether or not you want to do it. You can also change your mind and stop taking part at any time, without this affecting your treatment or how you are cared for at the hospital.

Purpose of the study

Asthma is a condition that can have a big impact on day-to-day life, not only physically but also emotionally and socially. In this second part of the study, we want to find out whether a personalised programme can help improve the quality of life of adolescents with asthma like you. The programme focuses on aspects that we know make a difference, such as movement behaviours (physical activity levels, screen time and hours of sleep), asthma control and some important emotional factors such as stress and self-confidence.

Objectives:

Our aim is to see whether this three-month programme, which combines smartwatch monitoring, online group educational sessions and motivational support, can help you improve your quality of life by building healthier habits, learning strategies to feel better and having more tools to manage your asthma in daily life. We also want to see whether results differ by sex or asthma severity, so that we can better adapt to the needs of each adolescent.

We also want to better understand how and why these strategies help you improve your well-being, cope better with asthma and keep up healthy habits in your daily lives.

Benefits:

Taking part in this study does not mean that your health will improve straight away, but it can help you get to know your body, your habits and how asthma affects your day-to-day life better. If you are in the intervention group, you will receive personalised support for three months. You will have a smartwatch to help you keep track of your movement and rest habits, you will take part in online

sessions with other adolescents and you will learn useful strategies to feel better, both physically and emotionally.

In addition, everything you share (confidentially) will help other adolescents with asthma in the future. Thanks to your participation, we will be able to improve medical care, create more useful programmes and design materials adapted to young people like you. Even if you are not in the intervention group, you will still be an essential part of the study. Your experience counts, a lot.

Study procedures

If you decide to take part in this second part of the study, the first thing we will do is randomly allocate you to one of two groups: the intervention group or the control group. This is done so that everyone has the same chance of being in either group, and it takes into account both whether you are a boy or a girl and how severe your asthma is. This allocation is secure and does not depend on you or the medical team.

If you are in the intervention group, you will take part for three months in a personalised programme designed to help you improve your daily habits and your quality of life. We will give you a smartwatch to wear every day, which will automatically record your physical activity, your sleep and the time you spend at rest. At the start, you will have an individual interview with a member of the team to talk about how you are feeling, what difficulties you have and what personal goals you would like to achieve.

You will also take part in online sessions with other adolescents similar to you. The first six sessions will be weekly and the next three every two weeks. In total, you will attend nine sessions of about 45 minutes each, which will be practical, participatory and focused on topics such as asthma management, stress, self-esteem, motivation and healthy habits. During the programme you will also receive supportive messages and reminders, and together we will adjust your goals to suit your pace.

When the programme ends, an assessment similar to the one at the start will be repeated to see how you have progressed. Then, three months later, we will carry out a final review to check whether the changes have been maintained over time. If you complete the programme, we will give you a certificate of participation in recognition of your effort.

Alongside this, during the study we may invite you (if you wish) to take part in an individual interview to find out your opinion of the programme and your personal experience. These interviews are voluntary, are not part of the main programme and do not affect your participation or your results. Only audio will be recorded (no video) so that we can analyse your experience during the programme.

If you are in the control group, you will not do the programme, but you will continue with your usual medical follow-up and will still take part in the study assessments. Your participation is very important, because it will allow us to compare results between the two groups and find out whether the programme really works. The whole process is designed so that you feel comfortable,

respected and supported, and you can always count on the research team to answer your questions or help you with whatever you need.

Discomfort and possible risks arising from your participation in the study:

Taking part in this study poses no risk to your health. You will not have to undergo any medical tests or procedures that might be uncomfortable. We will ask you to wear a smartwatch during the day, answer some questionnaires and attend online sessions, all designed to suit you as well as possible.

At times, you may find it a bit hard to keep up, stay motivated or meet some of the goals you set yourself. Wearing the watch may also feel a bit strange at first, or some days you may not feel like joining the sessions. That is completely normal, and the team will always be there to support you, without putting pressure on you.

If you feel unwell during the study, whether physically or emotionally, you can tell us at any time. We will talk with you and together we will find the best way to help you, always thinking about what is best for you. We want you to feel comfortable, supported and free to decide at all times.

Personal data protection:

The data collected about you during the study will be treated confidentially. This means that no one outside the study team will be able to know that they are yours. Everything will be done in compliance with the laws that protect your privacy, both in Spain and in Europe.

Additional information on consent:

Although your parents or guardians must give their permission, you also have the right to decide whether you want to take part. This information sheet has been adapted to your age so that you can fully understand what the study involves. If you decide to take part, you will be asked to sign an informed consent form. This confirms that you have understood the information and that you agree to take part voluntarily. If at any time you change your mind, you can stop taking part without it affecting you.

Informed consent form for adolescents over 12 years of age

Study title: Changing habits to improve quality of life in adolescents with asthma (CLiQ-Asthma): influence of asthma control and severity, lifestyle, psychosocial factors and sex differences.

I, _____ (*patient's full name*) _____

In the presence of my parents or legal representatives: (*Full name of father, mother or legal representative*)

I have read the information sheet I have been given.

I have been able to ask questions about the study.

I have spoken with: (*name of investigator*).

I understand that my participation is voluntary.

I understand that I may withdraw from the study:

1. Whenever I wish
2. Without having to give any explanation
3. Without this affecting my medical care

I freely give my consent to take part in the study.

I agree that the doctors responsible for this study may contact me in the future, if deemed appropriate, to add new data to those already collected: Yes ___ No ___

Participant's signature
signature

Parent's/guardian's signature

Investigator's

Date: ____/____/____

Date: ____/____/____

Date: ____/____/____