



HAL
open science

Standard patient training versus Vik-Asthme chatbot-guided training: ‘AsthmaTrain’ – a protocol for a randomised controlled trial for patients with asthma

Carey Meredith Suehs, Isabelle Vachier, David Galeazzi, François Vaast, Fanny Cardon, Nicolas Molinari, Arnaud Bourdin

► To cite this version:

Carey Meredith Suehs, Isabelle Vachier, David Galeazzi, François Vaast, Fanny Cardon, et al.. Standard patient training versus Vik-Asthme chatbot-guided training: ‘AsthmaTrain’ – a protocol for a randomised controlled trial for patients with asthma. *BMJ Open*, 2023, 13 (2), pp.e067039. 10.1136/bmjopen-2022-067039 . hal-04001698

HAL Id: hal-04001698



<https://hal.science/hal-04001698>

Submitted on 24 Feb 2023

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L’archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d’enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

BMJ Open Standard patient training versus Vik-Asthme chatbot-guided training: 'AsthmaTrain' – a protocol for a randomised controlled trial for patients with asthma

Carey Meredith Suehs ^{1,2}, Isabelle Vachier,^{1,3} David Galeazzi,² François Vaast,¹ Fanny Cardon,⁴ Nicolas Molinari,^{2,5} Arnaud Bourdin ^{1,6}

To cite: Suehs CM, Vachier I, Galeazzi D, *et al*. Standard patient training versus Vik-Asthme chatbot-guided training: 'AsthmaTrain' – a protocol for a randomised controlled trial for patients with asthma. *BMJ Open* 2023;**13**:e067039. doi:10.1136/bmjopen-2022-067039

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-067039>).

Received 29 July 2022

Accepted 10 February 2023



© Author(s) (or their employer(s)) 2023. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to

Dr Carey Meredith Suehs; careysuehs@protonmail.com

ABSTRACT

Introduction Therapeutic education for patients with asthma has been shown to reduce asthma morbidity. The high availability of smart phones provides the opportunity to furnish patient training via specifically designed chatbot applications. The goal of this protocol is to perform a first pilot comparison of traditional face to face versus chatbot-guided patient therapeutic education programmes for patients with asthma. **Methods and analysis** Eighty adult patients with a physician-confirmed diagnosis of asthma will be enrolled in a two-parallel-arm, randomised (1:1) controlled pilot trial. A single-Zelen consent procedure is deployed to first enrol all participants in the comparator arm, that is, the standard patient therapeutic education programme at the University Hospitals of Montpellier, France. This means of patient therapeutic education is based on reoccurring interviews and discussion with qualified nursing staff as per usual care. Following baseline data acquisition, randomisation will be performed. Those patients randomised to the comparator arm will not be informed of the second arm. Those patients randomised to the experimental arm will be proposed access to a specifically designed chatbot (Vik-Asthme) as the second tested means of patient training (refusals continue with standard training, though analysed as intention to treat). The primary outcome is change in the total Asthma Quality of Life Questionnaire score at the end of follow-up (6 months). Secondary outcomes cover asthma control, spirometry, general health status, programme adherence and burden for medical staff, exacerbations and medical resource use (medications, consults, emergency visits, hospitalisation and intensive care).

Ethics and dissemination This study ('AsthmaTrain' protocol version 4–20220330) has been approved by the Committee for the Protection of Persons Ile-de-France VII on 28 March 2022 (reference number 21.03617.000059). Enrolment began on 24 May 2022. Results will be published in international peer-reviewed journals.

Trial registration number NCT05248126.

INTRODUCTION

Despite persistent symptoms and exacerbations, many patients with asthma do not perceive their level of disease as serious or

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A high-quality methodology using a randomised clinical trial design optimises the level of evidence when comparing two means of patient education.
- ⇒ A single-Zelen consent procedure limits resentful demoralisation effects.
- ⇒ The nature of patient education interventions restricts opportunities for blinding, though some blinding may occur as a byproduct of the single Zelen consent procedure.
- ⇒ A limitation of this study is its single-centre nature.
- ⇒ This pilot study will provide a first comparison of patient education options, valuable information for building personalisation hypotheses and the required data for constructing optimally powered, multicentre confirmatory studies.

lacking control¹ and their levels of knowledge concerning their disease remain poor. Poor adherence to treatment and to other aspects of disease management are thought to be strongly implicated in the poor level of asthma control in the general population, contributing to rates as high as 50% of observed exacerbations.² Like many other chronic diseases, patient education is an important part of asthma management.^{3–5} Patient education programmes that include symptom monitoring, recognising/responding to worsening asthma (eg, via an action plan), and regular review of control, treatment and skills (inhaler technique) by healthcare professionals greatly reduce asthma morbidity in both adults and children (GINA (Global Initiative for Asthma) Evidence level 'A').⁶

In an increasingly 'connected' world, the means of accomplishing patient education via multimedia interventions is becoming more accepted. Patients often show interest



in using technology for home monitoring^{7 8} or asthma education purposes.^{9 10} Web-based telemonitoring with home spirometry has been demonstrated as effective and accessible to persons with no computer background.^{7 8} Even a simple automatic telephone messaging system can improve how patients with asthma perceive the control of their disease.¹¹

Internet-based telemonitoring or interactive multimedia support have been demonstrated as superior to traditional specialist-guided or generalist-guided usual care in terms of asthma control or symptoms,^{12–15} lung function,^{12 13} symptom or assessment reporting,^{14 16} symptom-free days,^{13 17} inhaler technique,¹⁶ the use of corticosteroids¹⁷ and the number of emergency department visits.¹⁷ The ORs for a clinically significant improvement in the Asthma Quality of Life Questionnaire score (AQLQ) (ie, a change of >0.5) in an internet-based monitoring randomised against usual care or a specialist-monitored group was 2.00 (95% CI 1.38 to 3.04)¹³ or 2.21 (95% CI 1.09 to 4.47),¹² respectively.

In general, asthma knowledge correlates with less rescue medicine use¹⁷ and fewer urgent consults.¹⁷ However, much of our knowledge on how internet-based or multimedia interventions might benefit asthmatic populations is based on paediatric populations^{11–15 18 19} and remains to be confirmed for adults. In addition, not all internet-based asthma education or monitoring interventions have similar performances, and some show little advantage or only short-term advantages compared with usual care.²⁰ Effects on health-resource utilisation remain unclear.¹⁵ The onset of smartphone usage has provided new opportunities for managing patients outside the walls of healthcare facilities. Within this context, the overall goal of the ‘AsthmaTrain’ study is to perform a first, small pilot study comparing a new French-language chat-bot guided asthma patient education programme (the ‘Vik-Asthme’ application) with the classic, authority-approved patient education programme at the University Hospitals of Montpellier, Montpellier, France.

Study objectives

The primary objective of ‘AsthmaTrain’ is to compare a population of adult patients with asthma and participating in a standard patient education programme with a similar population participating in Vik-Asthme-guided education programme in terms of overall scores on the AQLQ.^{21 22} Secondly, the two study arms will also be compared in terms of the following: (1) the subdomains of the AQLQ score, (2) clinical variables including lung function, asthma control and exacerbation rates, (3) general health status via the Euroqol 5-domain 5-level questionnaire (EQ-5D-5L^{23 24}), (4) programme adherence (as well as burden for the medical team and (5) major categories of direct health resource consumption. Finally, because education intervention success may depend on patient-specific characteristics, an ancillary study will compare the following baseline traits between the 50% best intervention responders in either arm: (1)

the big five personality traits (via the Big Five Inventory (BFI) questionnaire^{25 26}), (2) anxiety and depression (via the Hospital Anxiety and Depression questionnaire (HADS)^{27 28}) and (3) coping mechanisms (via the Ways of Coping Checklist (WCC) questionnaire²⁹).

METHODS

Study design

This prospective, parallel-arm, randomised (1:1), controlled, pilot trial with a single-Zelen consent procedure (where consent in the experimental arm occurs postrandomisation)^{30 31} will compare changes in quality of life, asthma control, lung function and health resource consumption between one group of patients with asthma participating in a classic treatment education programme (the ‘standard education’ arm) with a similar, second group of patients participating in a novel, chatbot-guided treatment education programme (the ‘Vik-Asthme’ arm) (figure 1). In our single Zelen design, all patients will initially consent for the standard patient education programme prior to randomisation (consent 1). At this point, they are not informed about the ‘Vik-Asthme’ arm of the study. Randomisation (with stratification according to month of enrolment and initial asthma severity) is then discretely carried out, and those patients allocated to the ‘Vik-Asthme’ arm are proposed to perform their patient education programme via the chatbot. A second round of patient information and consent (consent 2) ensues for these patients in the ‘Vik-Asthme’ arm only. Patients allocated to the standard education arm are not informed about the existence of the chatbot, thus avoiding resentful demoralisation effects.³² Patients in the ‘Vik-Asthme’ arm who refuse the chatbot continue with the standard education programme despite their allocation to the Vik-Asthme arm.

Study presentation and enrolment will take place during routine visits and the Montpellier University Hospital, Montpellier, France. Interested, eligible patients will be provided with educational materials (either standard education written materials or the Vik-Asthme application) and instructed on how to participate in their respective educational programmes. The patients will then be monitored via monthly telephone calls and a final study visit at 6 months post-inclusion (figure 1).

Population

This study takes place at the Montpellier University Hospital located in Montpellier, France. Enrolment started on 24 May 2022 and the completion of inclusions is expected prior to 24 November 2023. The study centre is a government-funded university hospital that, as a result of the single-payer health insurance system in vigour in France, should include patients spanning a large range of socioeconomic and urban-versus-rural categories. The study population corresponds to adult patients with a physician-confirmed diagnosis of asthma (see eligibility criteria provided in table 1).

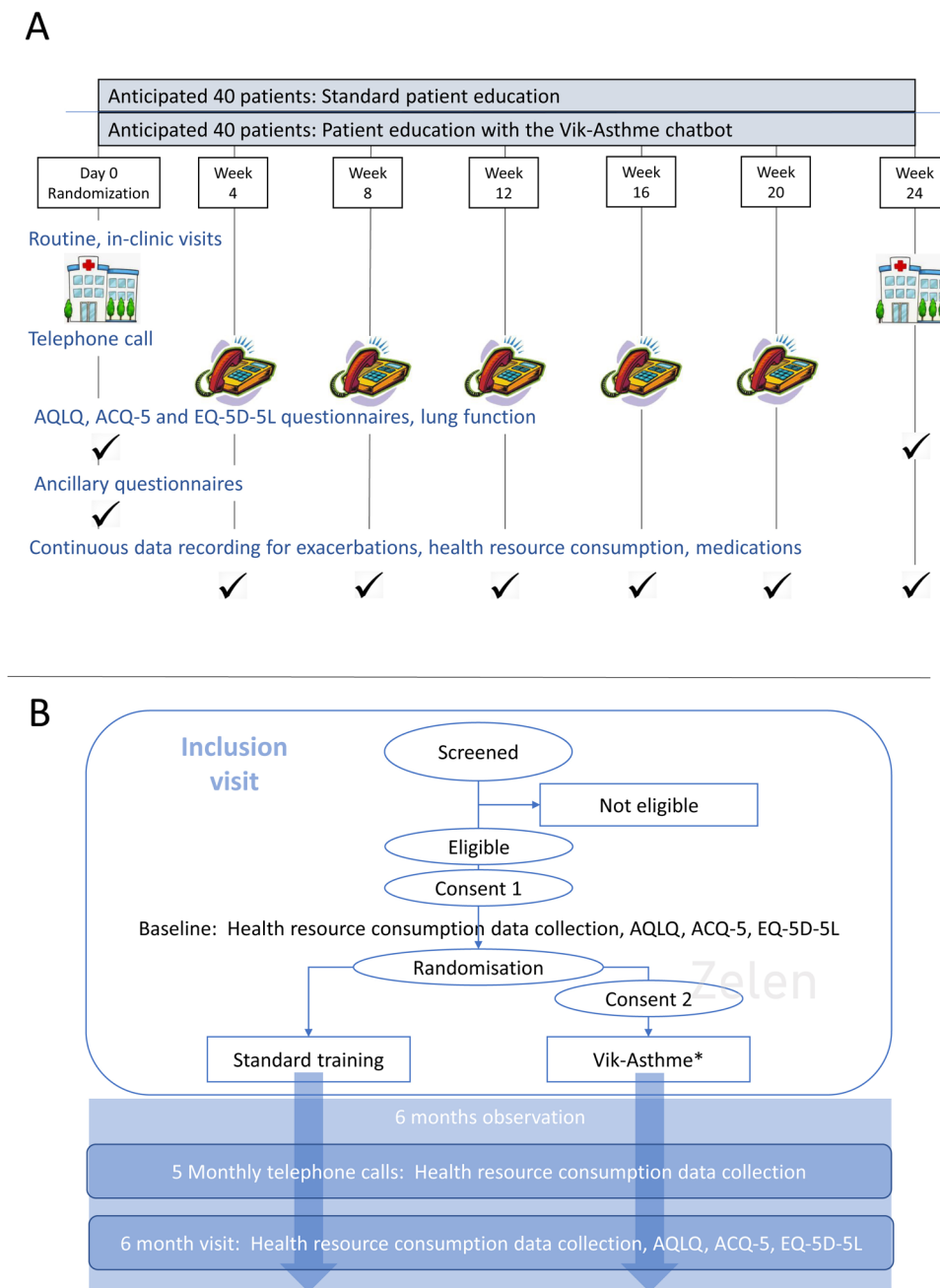


Figure 1 Graphic presentation of the general AsthmaTrain study design (A) and the anticipated study flow chart (B). *Patients randomised to the ‘Vik-Asthme’ arm who refuse the chatbot intervention will proceed with standard training according to a single Zelen design. Analysis will respect the randomisation arm (intention to treat).

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Interventions

Experimental intervention

The experimental intervention consists in providing the patient with access to a specific version of the ‘Vik-Asthme’ chat bot for the duration of the study. Should the patient be unable to use or refuse to use the chatbot, the reasons for refusal will be documented and the patient

will proceed with the comparator intervention (see ‘Comparator intervention’).

‘Vik-Asthme’ is a virtual assistant available to the public as an application typically downloaded to one’s personal mobile phone. The specific educational content of the version of ‘Vik-Asthme’ used for this study was developed via collaboration between Wefight, the company developing and marketing the ‘Vik’ series of chatbots for medical applications (<https://wefight.co/fr>), and the general pulmonology team at the University Hospitals of Montpellier, Montpellier, France (under the supervision of Pr Arnaud Bourdin).

Table 1 Patient eligibility criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> ▶ Minimum age: 18 ▶ Physician-confirmed diagnosis of asthma 	<ul style="list-style-type: none"> ▶ Protected populations according to the French Public Health Code Articles L1121-6,8* ▶ The subject has already participated in this study ▶ Subject unable to comply with trial procedures/visits† ▶ Potential for interference from another study‡ ▶ Non-beneficiary of the French single-payer national medical insurance system ▶ Lack of informed consent ▶ Patients already using the Vik-Asthme application in their daily lives or having already followed a therapeutic education programme

*For example, pregnant, parturient or lactating women, prisoners, adults under guardianship or otherwise unable to consent.

†For example, the subject is unavailable for the required visits, or has a language barrier that prevents study comprehension.

‡The patient is participating in another study that may affect the results of this study (or has done so in the month preceding inclusion), or the study is in an exclusion period stipulated by another study.

The same multidisciplinary team (asthma nurse, physiologist, psychologist, smoking-cessation nurse and social worker) in charge of classic therapeutic training (see 'Comparator intervention') helped develop specific content for the experimental chatbot corresponding to the following chapters: disease understanding (including how to recognise symptoms and exacerbations), medication mechanism of action, personalised medication handling (with links to video demonstrations), psychological aspects and support, sports/physical activity and physiotherapy, knowledge about smoking harms and how to access smoking cessation support, social help including occupational aspects and finally management of indoor/outdoor aeroallergens. In addition to patient education via the chatbot content, the 'Vik-Asthme' chatbot includes programming (based on rules established by the scientific committee and the most frequent patient requests observed on a previous version of the chatbot) that can deploy various alerts to designated medical staff. Alerts are summarised via 'green-orange-red' presentations to a specific dashboard visualised by nursing staff each morning at the hospital. An orange-level alert will trigger an email to see if the patient is experiencing asthma worsening and help manage a potential episode. A red-level alert will result in a phone call and potentially an un-scheduled visit to the department. This alert system was tested prior to study initiation to ensure feasibility and effectiveness.

In a short, face-to-face interview between nurse and patient, the nurse will assist the patient in downloading the chatbot and verifying data continuity with the hospital's information system. The chatbot is designed to not require further patient training. During this session, the chatbot settings will be personalised according to the shared educational diagnosis.

During the inclusion and follow-up periods required by this protocol, all further development of the chatbot, with the exception of essential debugging, will cease.

Comparator intervention

The comparator intervention is the usual therapeutic training for patients (*éducation thérapeutique des patients*:

ETP) cursus currently used in the General Pulmonology unit at the Arnaud De Villeneuve Hospital, Montpellier, France and approved by the French Regional Health Authority for the Occitanie Region (Agence Régionale de Santé Occitanie). This starts with a shared educational assessment involving the patient-caregiver dyad. Through discussion, the dyad establishes questions, milestones and priorities. The latter can include (but is not restricted to) treatment management (during maintenance phases, exacerbations and emergency situations), how treatments are taken (particularly the handling of inhaled devices, symptom perception and tracking, environmental management (indoor and professional environments), allergen management, vaccinations, smoking (and assistance with quitting), physical activity, rehabilitation of a hyperventilation syndrome if required, and psychological support for issues such as the patient's entourage, perceived support or social difficulties. A personalised written action plan is drafted for each patient and updated in-line with routine consults and further ETP sessions.

ETP sessions are organised during consultations and as often as necessary as determined by the patient-caregiver dyad and associated tools/goals. Multiple means of communication can be implemented (face-to-face interviews, email, telephone, teleconsultations, etc).

A typical ETP session consists in a 15–30 min interview performed by qualified nursing staff and can result in feedback to the doctor concerning patient adherence or problems with current treatment. Patient training sessions may be specified by a physician, or spontaneously initiated by a nurse (but systematically implemented at the initiation of this protocol). The face-to-face ETP interview between nurse and patient takes place in a calm, secluded area where the patient and nurse can speak in private and build a trusting relationship. During the course of the conversation, the nurse will reinforce any messages highlighted by the physician and provide a lay definition for asthma. The patient's treatment will be discussed, with emphasis on the context underlying the treatment, the treatment goals and why the treatment

and adherence are important. The nurse also presents different inhaler types to the patient and uses an appropriate placebo inhaler to demonstrate correct inhaler technique to the patient. Inhaler technique is reinforced by a mock inhaler-technique activity performed by the patient (while coached by the nurse). Handling-skills are assessed, potentially changing to preferred device. Other therapeutic areas can be covered: smoking cessation, allergen avoidance, trigger avoidance, occupational adaptations, physiotherapy requirement, lifestyle adaptation, etc. Email and phone numbers are provided to patients

who may contact the department in case of asthma worsening.

Outcomes

A summary of the outcomes chosen for the Asthma-Train protocol is given in table 2. In order to gain a first idea of how the 'ETP' and 'Vik-Asthme' interventions might impact patients over a 6-month period, we chose as our primary outcome the change in the total score for the AQLQ.^{21 22} This score is easy to obtain (self-questionnaire) and correlates with asthma control.

Table 2 The study outcome list, including patient-specific measures, how they are to be aggregated and for which time frames, and the associated general statistical analysis type

Patient-specific measure	Analysis metric and time frame	Analysis type
Asthma Quality of Life Questionnaire (AQLQ) ^{21 22}	Primary outcome: Change in the total AQLQ score from baseline to 6 months	CC
	The change in the 'symptoms' domain of the AQLQ from baseline to 6 months	
	The change in the 'activity limitation' domain of the AQLQ from baseline to 6 months	
	The change in the 'emotional function' domain of the AQLQ from baseline to 6 months	
	The change in the 'environmental exposure' domain of the AQLQ from baseline to 6 months	
Asthma Control Questionnaire 5 (ACQ-5) ^{21 22 40-42}	Change in the ACQ-5 score from baseline to 6 months	
Forced expiratory volume in 1 s (FEV1, % predicted) †	Change in FEV1 % predicted values from baseline to 6 months†	
Forced vital capacity (FVC, % predicted) †	Change in FVC % predicted values from baseline to 6 months†	
FEV1/FVC (% L/L) †	Change in FEV1/FVC ratios from baseline to 6 months†	
The Euroquol 5-Domain 5-Level (EQ-5D-5L) questionnaire ^{23 24}	Change in the EQ-5D-5L index value‡ from baseline to 6 months	
Programme adherence	Percentage of patients participating in the 6-month visit	CC
	For the experimental arm only, weeks of chatbot usage	Descriptive
Burden for medical staff	Cumulative number of emails to/from the patient from baseline to 6 months	CC
	Cumulative number of telephone calls to/from the patient from baseline to 6 months	
A list of medications taken (with beginning and end dates and dosages)	The cumulative dose for target medications§ from baseline to 6 months	
	Accumulating daily doses for target medications§ from baseline to 6 months.	REA
A list of medical consults (with dates)	The cumulative number of target consults¶ occurring between baseline and 6 months	CC
	Accumulating numbers of target consults¶ from baseline to 6 months	REA
A list of unexpected/emergency medical consults (with dates)	The cumulative number of unexpected/emergency consults occurring between baseline and 6 months	CC
	Accumulating numbers of unexpected/emergency consults from baseline to 6 months	REA
A list of hospitalisation episodes (with beginning and end dates)	The cumulative no of days of hospitalisation (in relation to asthma) occurring between baseline and 6 months	CC
	Accumulating numbers of days of hospitalisation (in relation to asthma) occurring between baseline and 6 months	REA
A list of intensive care episodes (with beginning and end dates)	The cumulative number of days of intensive care (in relation to asthma) occurring between baseline and 6 months	CC
	Accumulating numbers of days of intensive care (in relation to asthma) occurring between baseline and 6 months	REA
A list of exacerbation episodes** (with beginning and end dates)	The cumulative no of days of exacerbation occurring between baseline and 6 months	CC
	Accumulating numbers of days of exacerbation occurring between baseline and 6 months	REA

*See the assessments section for a description of the instruments used in this protocol.

†Prebronchodilator and postbronchodilator values.

‡Determined using the valuation set for France.⁴³

§Short-acting β antagonists, long-acting β antagonists, short-acting muscarinic antagonists, long-acting muscarinic antagonists, corticosteroids (inhaled, oral and nasal groups).

¶Generalists, specialists, nursing, other.

**With severity level as defined by the Global Initiative for Asthma (GINA).

CC, comparison of central tendency (eg, t-tests, Mann-Whitney tests as appropriate); REA, recurrent event analysis.

Additionally, the individual AQLQ subdomains will be evaluated as secondary outcomes. As a complement to the disease-specific AQLQ, a general health-status tool (the EQ-5D-5L)^{23 24} will also be evaluated.

The study participants will also be asked to fill out a simple diary throughout the study. This diary will simply list the treatments taken by each patient, as well as symptoms, exacerbations, medical consults, hospitalisations and intensive care stays that may occur during follow-up. The data will be used to generate prespecified metrics as presented in [table 2](#).

Describing the baseline population

In addition to outcomes, additional data will be recorded at baseline to help characterise the population. These include age, sex, body mass index, respiratory rate and peak expiratory flow (L/min). The patient's education and work level will be characterised by the highest educational level achieved and socioprofessional category. Substance usage will be characterised by smoking (never, former, current, pack years), alcohol consumption and consumption of other substances (cannabis, opiates, amphetamines, cocaine, other (with open description)).

The patient's asthma history and severity will be described using the month and year of first asthma symptoms and initial asthma diagnosis, global initiative for asthma (GINA) level of severity, premenstrual asthma and the maximum methacholine dose from previous methacholine testing. If performed during routine care, the fraction exhaled nitric oxide (FENO; ppb) will be recorded. The highest known blood eosinophil count for the patient will be recovered, as well as the results for the most recent skin prick test. A list of comorbidities will also be recorded for each patient.

Finally, prior experience with patient therapeutic education (and specifically for asthma) will be indicated, as well as psychometric characteristics (via the questionnaires BFI, HADS, WCC for an ancillary study).

Sample size and recruitment potential

There are currently no data available that would help describe expected outcome results in the targeted study populations. For this reason, the sample size of this pilot trial is set at 30 patients per arm. To allow for missing data (taking into account potential for loss to follow-up and its consequences for a small sample size), the number is increased to 40 patients per arm and 80 patients overall. This sample size is sufficient for demonstrating a significant difference between the 2 arms for the primary outcome (quantitative AQLQ score) of 1 point with a common SD of 1.5 points, a 1:1 sampling ratio, a type-I error rate set at 5% and power at 84%.

Under an exhaustive, consecutive recruitment scenario based on recent patient lists at the Montpellier University Hospitals, the latter corresponds to a theoretical recruitment period of about 4 months. However, to allow for the potential of pandemic conditions to disrupt research, the inclusion period was set at 18 months.

Achieving recruitment goals

To facilitate recruitment, an information letter will be provided to all patients by welcome-desk staff as patients come in for consults during the inclusion period. This letter will request that incoming patients with asthma indicate their interest for participating in a therapeutic education research project.

Logistics/visits

An overview of the time frames for study visits, interventions and assessments is provided in [table 3](#).

The inclusion visit

Inclusions will occur during routine visits. The study will be orally presented to the patient (by study investigators or their delegates), along with a first information letter, and eligibility criteria will be verified. The patient, if interested, orally consents to an observational study evaluating a patient therapeutic education intervention (consent 1). Should the patient decline participation, the reason is noted (and later tabulated for the study flowchart). The investigator (or delegated staff) then enrolls the patient for the study using the web-based electronic case report form (eCRF) application specifically created for the study. In-line with [table 3](#), baseline data are collected, and spirometry is performed (according to American Thoracic Society / European Respiratory Society (ATS/ERS) guidelines³³). If FENO is performed during routine care, the latter results are also recorded. The patient diary is initiated by study staff in collaboration with the patient. The patient is carefully instructed on its use and the importance of complete data for study results.

Following baseline data collection, the investigator (or delegated staff) uses the eCRF to perform randomisation. For patients randomised to the standard ETP arm, no further information is given, and the patient proceeds to standard ETP training. For patients randomised to the 'Vik-Asthme' arm, a second round of oral and written (information letter 2) information is presented to the patient. The patient, if interested, then provides oral consent for a study evaluating a chat-bot-guided patient education intervention (consent 2). These patients then proceed with 'Vik-Asthme' initiation/training. Patients not interested in the Vik-Asthme application can refuse it; these patients will proceed to ETP training as initially proposed. The patient's choice (and reasons for refusal when they exist) is recorded on the eCRF. All patients leave this visit with a calendar of planned telephone interviews and the end-of-study visit, as well as the health resource use diary that he/she fills out during the study.

Telephone calls

Monthly telephone calls are made to the patient in line with [table 3](#). The purpose of these calls is to promote protocol adherence and to recover data concerning exacerbations, health resource utilisation and medications. The patients are reminded to keep filling out their diary.

Table 3 Time frames for a given patient with associated events/interventions/assessments

Visits	Vinc	Tel 1*	Tel 2*	Tel 3*	Tel 4*	Tel 5*	Veos
Day or week in the study	D0	D28 W4	D56 W8	D84 W12	D112 W16	D140 W20	D168 W24
Leeway		±3D	±3D	±3D	±3D	±3D	+14D
Enrolment							
Verification of eligibility criteria	●						
Information letter and consent 1	●						
Randomisation	●						
Information letter and consent 2 ('Vik-Asthme' arm only)	●						
Interventions							
Deployment of the standard education programme	●						
Deployment of the 'Vik-Asthme' application*	●*						
Evaluations							
Baseline demographics and psychometric data (including questionnaires BFI, HADS, WCC)	●*						
Questionnaires AQLQ and EQ-5D-5L	●*						●*
Questionnaire ACQ-5	●						●
Lung function: spirometry	●						●
Data recovery on exacerbations, health resource use and medications		●*	●*	●*	●*	●*	●*

*Elements specific to the protocol and not part of routine care.
 ACQ-5, Asthma Control Questionnaire 5; AQLQ, Asthma Quality of Life Questionnaire; BFI, Big Five Inventory; D, day; EQ-5D-5L, Euroqol 5-domain 5-level questionnaire; HADS, Hospital Anxiety and Depression; Tel, telephone call; Veos, the end-of-study visit; Vinc, the inclusion visit; W, week; WCC, Ways of Coping Checklist.

End-of-study visit

The end-of-study visit will occur during a routine visit 6 months after inclusion. During this visit, the AQLQ, ACQ-5 and EQ-5D-5L questionnaires are administered and spirometry is performed. If FENO assessment is performed during routine care, these results are also recorded. The patient's diary is reviewed and recovered.

Finally, the patient is asked to respond to an end-of-study question: How often have you used the Vik-Asthme chatbot over the past 6 months? (Never; Every day, Twice a week, Once a week, Twice a month, once a month or less). If the patient does not know what the Vik-Asthme chatbot is, the correct response is 'never'.

Data concerning the number of emails and telephone calls addressed to the patient are recovered.

Allocation and blinding

Randomisation will be managed by the Clinical Research and Epidemiology Unit (CREU) at the University Hospitals of Montpellier, France with ENNOV CLINICAL software. The randomisation will be centralised and available online. Access to allocation modules will be restricted to designated personnel. Patient enrolment and allocation will be carried out by the participating investigators via the eCRF. Randomisation is carried out following enrolment and data collection for baseline assessments. Stratification will take into account the month of enrolment (September, October, February and March (typical exacerbation months) vs other months), and initial disease severity (GINA steps 1-2-3 vs 4-5).

This protocol aims to compare two different ways of engaging with the patient and teaching. The notion of blinding per se is not adapted to this protocol, which is carried out, for all practical purposes, in an 'open' fashion. Nevertheless, the Zelen randomisation procedure, which aims to maintain the comparator arm ignorant of the existence of the experimental arm in order to avoid 'resentful demoralisation' effects,³² may also result in a partial blinding effect.

Data collection and management

Data entry is performed as close to real-time as possible using an eCRF developed by the CREU using ENNOV Clinical-ClinSight software. A paper version of the eCRF is also available to facilitate data collection under field conditions or if internet services are down. All eCRF fields should be addressed and missing data must be justified and communicated by the study clinical research technician to the site principal investigator immediately when discovered.

Data quality control starts at data entry via the eCRF, whose fields are parameterised to avoid impossible or highly improbable values. In addition, the Data Manager at the CREU will implement additional computerised tests to ensure the completeness, consistency and reliability of data according to standard data management plans at the University Hospitals of Montpellier. eCRF access is restricted to appropriate study staff via an online password system.



Statistics

Statistical analysis will be performed by the CREU and described in a detailed statistical analysis plan (maintained by the CREU) before data extraction and unblinding. Any deviations from the SAP, reasons for such deviations and all alternative or additional statistical analyses that may be done, will be described in the final report.

The level of significance is set at $p < 0.05$ (bilateral). For secondary/exploratory outcomes, the p value (bilateral) will take into account multiple comparisons³⁴ using false discovery rate corrections. Safety parameters will remain uncorrected to avoid ruling out a safety concern. Missing data due to loss to follow-up or participant withdrawal are expected to be few and imputation will not be used. The primary outcome will be analysed using complete cases. Data tables will indicate variation in sample size. The following paragraphs are designed to give an overview of the techniques to be used (also see [table 2](#) for general guidance) but are not a substitute for the complete SAP.

Analytical populations

The safety population will include all patients who were provided access to the Vik-Asthme chatbot, the intention-to-treat (ITT) population all patients included in the protocol, according to randomisation, and the per-protocol (PP) population all patients included in the ITT for whom no major protocol deviations were found. In this study, we anticipate analysing only the ITT and safety populations. However, should refusal of continuing consent be unbalanced between arms, or there is a need for sensitivity analysis, we will also perform analyses on the PP population.

Descriptive statistics

Normally distributed quantitative variables will be summarised as means \pm SD, or otherwise as medians (IQR). Qualitative variables will be presented as numbers (percentages).

Comparisons of central tendency, including the primary outcome

Quantitative variables will be compared between groups using t -tests or Mann-Whitney tests in accordance with variable distributions and sample sizes. Qualitative data will be compared between groups using χ^2 or Fischer's exact tests, as appropriate.

Recurrent event analyses

The time-related accumulation of events (eg, mg of medication per day, or days of hospitalisation) within each group will be estimated using the Nelson non-parametric method for estimating the mean cumulative function (MCF). Graphically, the population mean curve is a step function with many small steps, one for each event in the population. MCF graphs (with Nelson's 95% CI) for each randomisation group will be generated, as well as the MCF difference between the two. The approximate day when the MCF curves begin to separate will be determined according to when the 95% CIs of the MCF difference curve no longer includes zero.^{35–39}

Ancillary analysis

The general goal of the ancillary analysis is to explore the hypothesis that different types of education strategy might be appropriate for different types of people. To explore this possibility, patients will be divided into responders and non-responders (\geq or $<$ median improvement in AQLQ scores or a measure of medication adherence) in either arm, and the baseline characteristics compared between arms for responders and again for non-responders. In the same spirit, strategy response will be modelled as an interaction between study arm and patient baseline profile. This is an exploratory study; p values will not be corrected and will be described as exploratory.

Monitoring and auditing

Given the low level of risk associated with this protocol, a data safety and monitoring board and interim analyses are not foreseen.

Sponsor clinical research associates will perform monitoring visits (at a rhythm determined by inclusions). At this time, the following visit times are planned: study initiation, 50% inclusions, 100% inclusions and end of follow-up. Monitoring visits will cover consent procedures, primary endpoint data quality and protocol adherence. Each will be documented by a written report.

The adverse events/incidents related to patient usual care will be declared by any health professional to the various circuits of sanitary vigilance applicable to each product or practice concerned in conformity with the regulations in force.

Auditing can occur at any time in-line with sponsor quality procedures. In case of audit, investigators will permit direct access to all study documents, accountability records, medical records, and source data.

DISCUSSION

The results of this protocol will provide data crucial for a first comparison between a classic patient education programme for asthma and its chatbot-guided analogue. The single Zelen randomisation with stratification on season and initial disease severity is designed to result in comparable populations with as little contamination between arms as feasible, while optimising the level of evidence generated. However, there are certain limitations to this protocol that deserve consideration. First, this is a single centre study, and larger confirmatory studies will be required to generalise to diverse centres across France, or in languages other than French. There is also an evident selection bias related to patient motivation due to the fact that therapeutic education is not mandatory, and patient willingness-to-participate will shape the overall study population. Additionally, patients unwilling or unable to use a smart phone will obviously not be able to access the chatbot, and this is likely to occur among the elderly. However, this should not affect the comparability of arms, and such bias is inherent to any voluntary education programme. It is also impossible for

a chatbot to replace the coaching provided by an experienced nurse, especially as concerns inhaler technique. The chatbot can provide informational videos describing proper technique, and potentially increase adherence via reminders, but correction of poorly practised technique would be difficult. Finally, though a single-Zelen consent procedure limits resentful demoralisation effects, the possibility for patients in the experimental arm to choose the comparator programme is likely to underestimate the PP effect of the chatbot, rendering the conclusions of the study conservative in nature. Comparing two means of patient education also corresponds to a situational context where blinding is difficult, though the Zelen design creates blinding potential. Despite these limitations, the awaited results of this study will provide a first comparison of patient education options, valuable information for building personalisation hypotheses, and the required data for constructing optimally powered, multi-centre confirmatory studies.

ETHICS AND DISSEMINATION

Confidentiality

In the eCRF and analysis databases, the patients will be identified via study-specific numbers. The patient's initials and sex are used in order to assist identification during the study and may appear on the eCRF or associated paper support. No other identifying information may be so used.

Seeking research approval

This research will be carried out in accordance with French law, Good Clinical Practice and the Declaration of Helsinki. This study was approved by a randomly chosen independent ethics committee (Committee de Protection de Persons Ile-de-France VII) on 20 January 2022 (reference number 21.03617.000059). Future protocol modifications, if any, must be approved by the study steering committee (AB (director), NM (methodologist), CMS (scientist)), the assigned ethics committee and transmitted to all participating investigators. Ethics committee documentation will be addressed to the French National Agency for Medicines and Health Products Safety (ANSM).

Steering Committee

The steering committee is responsible for study conduct and maintaining key study documents (information materials (see online supplemental file 1), eCRF paper form, data sharing plan) up to date and available to the public at <https://osf.io/u972h/>.

Data access

The study dataset is the property of the sponsor (University Hospitals of Montpellier, 191 Avenue du Doyen Gaston Giraud, F-34295 Montpellier, France) and will be made available to the steering committee and participating investigators. Aggregated study results will be

published in a peer reviewed journal. Authorship will be attributed according to the criteria stipulated by the International Committee of Medical Journal Editors. In accordance with French regulations, study participants will be provided with results on request. Members of the public may request the data set from the study director following publication of the results.

Author affiliations

¹Department of Respiratory Diseases, Univ Montpellier, CHU Montpellier, Montpellier, France

²Department of Medical Information, Univ Montpellier, CHU Montpellier, Montpellier, France

³Medicine Biology Mediterranee, Department of Respiratory Diseases and Addictology, Arnaud de Villeneuve Hospital, CHRU Montpellier, Montpellier, France

⁴Department of Research and Innovation, CHU Montpellier, Montpellier, France

⁵IMAG, CNRS, Univ Montpellier, CHU Montpellier, Montpellier, France

⁶PhyMedExp, CNRS, INSERM, Univ Montpellier, CHU Montpellier, Montpellier, France

Twitter Carey Meredith Suehs @SuehsCarey

Contributors CMS wrote the first draft of the AsthmaTrain protocol and related sections of grants. Further intellectual input and corrections were made by AB, IV and NM. DG designed the case report form and further refined protocol content. FV provided expertise on classic therapeutic education procedures. FC provided expertise on regulatory and monitoring aspects.

Funding Financial support for this study was provided by a competitive call for tender organised by the Occitanie Region of France (2019/2021 READYNOV grant 'ASMAH') and collectively awarded to the study sponsor and Wefight (CA Center, Bat C, 621 Rue Georges Méliès, 34000 Montpellier, France), the developer of the Vik-Asthme chatbot.

Disclaimer The study sponsor and funders were not involved in, and will not be involved in study design, analysis or interpretation of data, or publication decisions.

Competing interests IV, DG, FC and FV report no competing interests. CMS reports grants and personal fees from Astra Zeneca, grants from GSK, outside the submitted work. NM reports personal fees from Astra Zeneca, grants from GSK, outside the submitted work. AB reports grants, personal fees, non-financial support and other from GSK, grants, personal fees, non-financial support and other from Astra Zeneca, grants, personal fees, non-financial support and other from Boeringher Ingelheim, personal fees, non-financial support and other from Novartis, personal fees, non-financial support and other from Chiesi Farma, non-financial support and other from Teva, personal fees, non-financial support and other from Sanofi Regeneron, grants, personal fees, non-financial support and other from Actelion/Jansen, other from United Therapeutics, other from Pulsar, personal fees, non-financial support and other from Roche, outside the submitted work.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iDs

Carey Meredith Suehs <http://orcid.org/0000-0002-2175-3496>

REFERENCES

- 1 Price D, Fletcher M, van der Molen T. Asthma control and management in 8,000 European patients: the recognise asthma and link to symptoms and experience (realise) survey. *NPJ Prim Care Respir Med* 2014;24:14009.
- 2 Williams LK, Peterson EL, Wells K, et al. Quantifying the proportion of severe asthma exacerbations attributable to inhaled corticosteroid nonadherence. *J Allergy Clin Immunol* 2011;128:1185–1191.
- 3 Cabana MD, Slish KK, Evans D, et al. Impact of physician asthma care education on patient outcomes. *Health Educ Behav* 2014;41:509–17.
- 4 Felix SN, Agondi RC, Aun MV, et al. Clinical, functional and inflammatory evaluation in asthmatic patients after a simple short-term educational program: a randomized trial. *Sci Rep* 2021;11:18267.
- 5 Schuermans D, Hanon S, Wauters I, et al. Impact of a single 10 min education session on asthma control as measured by act. *Respir Med* 2018;143:14–7.
- 6 Global Initiative for Asthma. Global strategy for asthma management and prevention; 2020. Available: <https://ginasthma.org> [Accessed 20 Sep 2020].
- 7 Finkelstein J, Cabrera MR, Hripcsak G. Internet-based home asthma telemonitoring: can patients handle the technology? *Chest* 2000;117:148–55.
- 8 Finkelstein J, Hripcsak G, Cabrera MR. Patients' acceptance of internet-based home asthma telemonitoring. *Proc AMIA Symp* 1998:336–40.
- 9 Rhee H, Wyatt TH, Wenzel JA. Adolescents with asthma: learning needs and Internet use assessment. *Respir Care* 2006;51:1441–9.
- 10 Letourneau N, Stewart M, Masuda JR, et al. Impact of online support for youth with asthma and allergies: pilot study. *J Pediatr Nurs* 2012;27:65–73.
- 11 Lv Y, Zhao H, Liang Z, et al. A mobile phone short message service improves perceived control of asthma: a randomized controlled trial. *Telemed J E Health* 2012;18:420–6.
- 12 Rasmussen LM, Phanareth K, Nolte H, et al. Internet-based monitoring of asthma: a long-term, randomized clinical study of 300 asthmatic subjects. *J Allergy Clin Immunol* 2005;115:1137–42.
- 13 van der Meer V, Bakker MJ, van den Hout WB, et al. Internet-based self-management plus education compared with usual care in asthma: a randomized trial. *Ann Intern Med* 2009;151:110–20.
- 14 Araújo L, Jacinto T, Moreira A, et al. Clinical efficacy of web-based versus standard asthma self-management. *J Investig Allergol Clin Immunol* 2012;22:28–34.
- 15 Pool AC, Kraschewski JL, Poger JM, et al. Impact of online patient reminders to improve asthma care: a randomized controlled trial. *PLoS One* 2017;12:e0170447.
- 16 Chan DS, Callahan CW, Hatch-Pigott VB, et al. Internet-based home monitoring and education of children with asthma is comparable to ideal office-based care: results of a 1-year asthma in-home monitoring trial. *Pediatrics* 2007;119:569–78.
- 17 Krishna S, Francisco BD, Balas EA, et al. Internet-enabled interactive multimedia asthma education program: a randomized trial. *Pediatrics* 2003;111:503–10.
- 18 Wise M, Gustafson DH, Sorkness CA, et al. Internet telehealth for pediatric asthma case management: integrating computerized and case manager features for tailoring a web-based asthma education program. *Health Promot Pract* 2007;8:282–91.
- 19 Kadariya D, Venkataramanan R, Yip HY, et al. KBot: knowledge-enabled personalized chatbot for asthma self-management. *Proc Int Conf Smart Comput SMARTCOMP* 2019;2019:138–43.
- 20 Rikkers-Mutsaerts ERVM, Winters AE, Bakker MJ, et al. Internet-based self-management compared with usual care in adolescents with asthma: a randomized controlled trial. *Pediatr Pulmonol* 2012;47:1170–9.
- 21 Juniper EF, Guyatt GH, Epstein RS, et al. Evaluation of impairment of health related quality of life in asthma: development of a questionnaire for use in clinical trials. *Thorax* 1992;47:76–83.
- 22 Juniper EF, Guyatt GH, Ferrie PJ, et al. Measuring quality of life in asthma. *Am Rev Respir Dis* 1993;147:832–8.
- 23 Essink-Bot ML, Stouthard ME, Bonsel GJ. Generalizability of valuations on health states collected with the euroqolc-questionnaire. *Health Econ* 1993;2:237–46.
- 24 van Agt HM, Essink-Bot ML, Krabbe PF, et al. Test-retest reliability of health state valuations collected with the euroqol questionnaire. *Soc Sci Med* 1994;39:1537–44.
- 25 Plaisant O, Srivastava S, Mendelsohn GA, et al. Relations entre Le big five inventory Français et Le Manuel diagnostique des troubles mentaux dans un échantillon clinique Français. *Annales Médico-Psychologiques, Revue Psychiatrique* 2005;163:161–7.
- 26 Plaisant O, Courtois R, Réveillère C, et al. Validation PAR analyse factorielle Du big five inventory Français (BFI-fr). analyse convergente avec Le NEO-PI-R. *Annales Médico-Psychologiques, Revue Psychiatrique* 2010;168:97–106.
- 27 Lépine JP, Godchau M, Brun P, et al. Evaluation de l'anxiété et de la dépression chez des patients hospitalisés dans un service de médecine interne. *Ann Med Psychol (Paris)* 1985;143:175–89.
- 28 Untas A, Aguirrezabal M, Chauveau P, et al. Anxiété et dépression en hémodialyse: validation de l'ospital anxiety and depression scale (HADS). *Néphrologie & Thérapeutique* 2009;5:193–200.
- 29 Bruchon-Schweitzer M, Cousson F, Quintard B, et al. French adaptation of the ways of coping checklist. *Percept Mot Skills* 1996;83:104–6.
- 30 Zelen M. A new design for randomized clinical trials. *N Engl J Med* 1979;300:1242–5.
- 31 Campbell R, Peters T, Grant C, et al. Adapting the randomized consent (zelen) design for trials of behavioural interventions for chronic disease: feasibility study. *J Health Serv Res Policy* 2005;10:220–5.
- 32 Adamson J, Cockayne S, Puffer S, et al. Review of randomised trials using the post-randomised consent (zelen's) design. *Contemp Clin Trials* 2006;27:305–19.
- 33 Graham BL, Steenbruggen I, Miller MR, et al. Standardization of spirometry 2019 update. an official american thoracic society and european respiratory society technical statement. *Am J Respir Crit Care Med* 2019;200:e70–88.
- 34 Harrington D, D'Agostino RB Sr, Gatsonis C, et al. New guidelines for statistical reporting in the Journal *N Engl J Med* 2019;381:285–6.
- 35 Nelson W. Confidence limits for recurrence data—applied to cost or number of product repairs. *Technometrics* 1995;37:147–57.
- 36 Nelson WB. *Recurrent events data analysis for product repairs, disease recurrences, and other applications*. SIAM, 2003.
- 37 Yan J, Fine JP. Analysis of episodic data with application to recurrent pulmonary exacerbations in cystic fibrosis patients. *J Am Stat Assoc* 2008;103:498–510.
- 38 Siddiqui O. Statistical methods to analyze adverse events data of randomized clinical trials. *J Biopharm Stat* 2009;19:889–99.
- 39 Barker C. Exploratory method for summarizing concomitant medication data -- the mean cumulative function. *Pharm Stat* 2010;9:331–6.
- 40 Juniper EF, Guyatt GH, Willan A, et al. Determining a minimal important change in a disease-specific quality of life questionnaire. *J Clin Epidemiol* 1994;47:81–7.
- 41 Juniper EF, Bousquet J, Abetz L, et al. Identifying “ well-controlled ” and “ not well-controlled ” asthma using the asthma control questionnaire. *Respir Med* 2006;100:616–21.
- 42 Juniper EF, Svensson K, Mörk A-C, et al. Measurement properties and interpretation of three shortened versions of the asthma control questionnaire. *Respir Med* 2005;99:553–8.
- 43 Andrade LF, Ludwig K, Goni JMR, et al. A French value set for the EQ-5D-5L. *Pharmacoeconomics* 2020;38:413–25.

Standard patient training versus Vik-Asthme chatbot guided training: 'AsthmaTrain', a protocol for a randomized controlled trial for patients with asthma

Carey Suehs, Isabelle Vachier, David Galeazzi, François Vaast, Fanny Cardon, Nicolas Molinari, Arnaud Bourdin

Supplementary materials

Informed consent materials*

* The following materials were current at the time of submission. Please see the study repository (<https://osf.io/u972h/>) to ensure up-to-date information.



AsthmaTrain

Version n° 4.0 du 14/03/2022

LETRE D'INFORMATION ET RECUEIL DE CONSENTEMENT

EDUCATION THERAPEUTIQUE DES PATIENTS ASTHMATIQUES : EVOLUTION DE LA QUALITE DE VIE

ASTHMA TRAIN – RECHMPL21_0423

Promoteur de la recherche : CHU de Montpellier

Investigateur coordonnateur : Pr Arnaud BOURDIN

Madame, Monsieur,

Votre médecin vous propose de participer à une recherche dont le CHU de Montpellier est le promoteur.

Votre participation est entièrement volontaire. Si vous ne désirez pas prendre part à cette recherche, vous continuerez à bénéficier de la meilleure prise en charge médicale possible, conformément aux connaissances actuelles.

Avant de prendre une décision, il est important que vous lisiez attentivement ces pages qui vous apporteront les informations nécessaires concernant les différents aspects de cette recherche. Vous disposez d'un délai de réflexion avant de donner votre consentement au médecin. N'hésitez pas à poser toutes les questions que vous jugerez utiles à votre médecin.

PRESENTATION DE LA RECHERCHE

Gérer son asthme n'est pas toujours évident. De nombreux patients manquent d'informations sur la nature de l'asthme, la technique d'inhalation appropriée, l'importance d'un traitement régulier ou le moment où demander de l'aide. Améliorer et personnaliser l'éducation thérapeutique des patients asthmatiques peut donc améliorer plusieurs aspects de la maladie.

Dans ce contexte, nous demandons actuellement aux patients asthmatiques de participer à une étude axée sur l'éducation des patients et les changements subséquents dans la qualité de vie (et d'autres aspects importants de l'asthme) sur une période de six mois.

OBJECTIF DE LA RECHERCHE

L'objectif général de cette étude est d'évaluer l'évolution de la qualité de vie associée à l'asthme à la suite d'un programme d'éducation thérapeutique du patient. Dans le même temps, nous évaluerons également les changements dans la fonction pulmonaire, le contrôle de l'asthme et la consommation de ressources de santé. Nous explorerons également comment les réponses à l'éducation thérapeutique diffèrent entre les patients selon leurs réponses à plusieurs questionnaires (sur la personnalité, anxiété, réponse aux stress).

METHODOLOGIE DE LA RECHERCHE

AsthmaTrain est une étude se déroulant uniquement sur le centre de Montpellier. Il est prévu d'inclure 80 patients. Chaque patient sera suivi sur une période de 6 mois.

Si vous acceptez de participer, vous bénéficierez d'un programme d'éducation thérapeutique labellisé par l'Agence Régionale de Santé pour les patients asthmatiques.

DEROULEMENT DE LA RECHERCHE

Cette étude comporte deux visites à l'hôpital : une au début de l'étude et la seconde à la fin de l'étude six mois plus tard. Ces deux visites auront lieu en même temps que des visites de routines nécessaires pour la prise en charge de votre asthme et le programme d'éducation thérapeutique (qui peut varier en fonction des besoins de chaque patient(e)). Ces deux visites sont séparées par 5 appels téléphoniques (mensuels).



AsthmaTrain
Version n° 3.0 du 19/01/2022

Lors de la première visite, vous serez informé de l'étude et invité à donner votre consentement. Votre fonction pulmonaire sera évaluée et vous serez invité à remplir plusieurs questionnaires pendant les temps d'attente. Vous aurez également un entretien avec une infirmière. Cet entretien a pour objectif de proposer un programme d'éducation thérapeutique spécifique à votre situation et vos besoins. Suite à ce premier entretien, vous serez informé de l'utilisation d'un journal du patient. Vous serez tenu de remplir votre journal tout au long des six mois de suivi.

Le personnel de l'étude vous contactera tous les mois pour vous rappeler de remplir votre journal et pour vous aider à récupérer les données.

Enfin, la visite de fin d'étude est assez similaire à la première : votre fonction pulmonaire sera évaluée, et il vous sera demandé de remplir plusieurs questionnaires. Votre journal sera récupéré à ce moment.

Un aperçu des visites est fourni dans le tableau suivant.

Visites	V1	Tel 1*	Tel 2*	Tel 3*	Tel 4*	Tel 5*	V2
Jour ou Semaine	J1	S4	S8	S12	S16	S20	S24
Vérification des critères d'inclusion	X*						
Lettre d'information et recueil du consentement	X*						
Programme d'éducation thérapeutique				X			
Données démographiques et questionnaires (BFI, HADS, WCC)	X*						
Questionnaires AQLQ et EQ-5D-5L	X*						X*
Questionnaire ACQ-5	X						X
Fonction pulmonaire : spirométrie	X						X
Récupération des données sur les exacerbations, les RDV médicaux et les traitements pris	X*	X*	X*	X*	X*	X*	X*

*Examens spécifiques à la recherche (non prévus dans le soin courant)

LES BENEFICES ATTENDUS

Dans cette étude, vous recevrez une éducation thérapeutique adaptée aux patients asthmatiques. Cette information est susceptible d'améliorer votre compréhension de la maladie et ce que vous devez faire pour la gérer. En plus d'être plus étroitement surveillé du fait de votre participation à une recherche scientifique, votre participation et les données générées par cette étude peuvent également contribuer à la compréhension de la maladie et de l'impact d'une bonne information sur la qualité de vie des patients comme vous.

LES INCONVENIENTS POSSIBLES

En sus de la prise en charge habituelle, il vous sera demandé de remplir des questionnaires et un carnet patient. Les risques associés à cette étude ne diffèrent donc pas des soins habituels. Du fait du faible niveau de risque associé à cette étude, il n'est pas attendu d'événements indésirables.

Votre participation sincère à cette étude est cruciale pour son succès. Cela signifie participer aux deux visites et remplir plusieurs questionnaires au début et à la fin de l'étude. Il vous sera également demandé de remplir un carnet patient détaillant vos prises de traitements et de symptômes tout au long de l'étude et de participer aux appels téléphoniques mensuels.

LES MODALITES DE PRISE EN CHARGE LIE AU PROJET DE RECHERCHE

La participation à cette recherche n'engendrera aucun frais supplémentaire par rapport à ceux que vous auriez pour le suivi habituel de cette maladie. Tous les soins médicaux relevant de votre suivi médical habituel ou non requis par le protocole de cette recherche continuent d'être pris en charge selon la procédure habituelle.



AsthmaTrain

Version n° 3.0 du 19/01/2022

Vous ne recevrez aucune contrepartie financière, directe ou indirecte, pour votre participation à la recherche ou pour votre participation à toute recherche optionnelle ou pour l'utilisation de vos échantillons biologiques.

En participant à ce projet de recherche, vous ne pouvez pas participer simultanément à une autre recherche interventionnelle.

RECUEIL ET TRAITEMENT DES DONNEES

Dans le cadre de la recherche à laquelle le *CHU de Montpellier* vous propose de participer, un traitement informatique de vos données personnelles va être mis en œuvre pour permettre d'analyser les résultats de la recherche au regard de l'objectif de cette dernière qui vous a été présenté. De plus, les données concernant les événements de vigilance seront conservées, analysées et transmises, le cas échéant, conformément à la réglementation.

Le responsable de ce traitement est le CHU de Montpellier (39, avenue Charles Flahault – 34295 MONTPELLIER Cedex 5).

Le médecin investigateur et tout autre personnel du projet de recherche sont tenus au secret professionnel et sous la responsabilité du médecin s'occupant de votre traitement recueillent des données personnelles, notamment de santé, vous concernant. Le médecin et autre personnel du projet de recherche recueillent des informations à votre sujet, sur votre santé, sur votre participation dans le projet. Ces informations, appelées « Informations personnelles », sont consignées sur les formulaires, appelés cahiers d'observations, fournis par le promoteur, ou dans la base de données de vigilance concernant les événements indésirables. Seules les informations strictement nécessaires au traitement et à la finalité de la recherche sont collectées sur une base de données sécurisée puis conservées à l'issue de la recherche, sous la responsabilité du Pr Arnaud BOURDIN pendant 15 ans. Afin d'assurer la confidentialité de vos informations personnelles, ni votre nom, ni aucune autre information qui permet de vous identifier directement ne sont saisis sur le cahier d'observation ou dans tout autre dossier que le médecin investigateur du projet de recherche fournit au promoteur de la recherche ou aux personnes ou sociétés agissant pour son compte, en France.

Ces données sont identifiées par un code (*numéro d'inclusion et initiales*). Le code est utilisé pour que le médecin du projet de recherche puisse vous identifier si nécessaire.

Ces données, sous cette forme qui assure leur confidentialité, peuvent être transmises également aux Autorités de Santé, ou aux personnes mandatées par le promoteur.

Conformément aux dispositions de la loi, modifiée, relative à l'informatique, aux fichiers et aux libertés (loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés) et au règlement général sur la protection des données (règlement UE 2016/679), vous disposez d'un droit d'accès, de rectification, d'effacement ou de limitation des informations collectées vous concernant dans le cadre de ce traitement.

Dans certains cas, vous pouvez également vous opposer à ce que certains types de traitement des données soient réalisés. Vous disposez également d'un droit d'opposition à la transmission des données couvertes par le secret professionnel susceptibles d'être utilisées dans le cadre de cette recherche et d'être traitées.

Vous pouvez également accéder directement ou par l'intermédiaire du médecin de votre choix à l'ensemble de vos données médicales en application des dispositions de l'article L1111-7 du code de la santé publique.

Si vous devez vous retirer, les données recueillies avant votre retrait peuvent encore être traitées avec les autres données recueillies dans le cadre du projet de recherche, si leur effacement compromet la réalisation des objectifs du projet ou la sécurité des autres participants (notamment les données des événements de vigilance).



AsthmaTrain
Version n° 3.0 du 19/01/2022

Vos droits cités ci-dessus s'exercent auprès du médecin qui vous suit dans le cadre de la recherche et qui connaît votre identité. Le promoteur répondra à vos demandes dans la mesure du possible conformément à ses autres obligations légales et réglementaires et lorsque la loi l'exige.

Si vous avez d'autres questions au sujet du recueil, de l'utilisation des informations personnelles ou des droits associés à ces informations, vous pouvez contacter le Délégué à la Protection des Données du CHU de Montpellier (mail : dpo@chu-montpellier.fr) ou le médecin investigateur de l'étude, Pr Arnaud BOURDIN.

Si malgré les mesures mises en place par le promoteur, vous estimez que vos droits ne sont pas respectés, vous pouvez déposer une plainte auprès de l'autorité de surveillance de la protection des données compétente en France, la Commission Nationale de l'Informatique et des Libertés (CNIL).

Si le responsable de traitement souhaite effectuer un traitement ultérieur des données à caractère personnel vous concernant pour une finalité autre que celle pour laquelle ces données à caractère personnel ont été collectées, vous serez informé(e) au préalable quant à cette autre finalité, à la durée de conservation des données, et toute autre information pertinente permettant de garantir un traitement équitable et transparent.

ASPECTS LEGAUX

Votre médecin doit vous fournir toutes les explications nécessaires concernant cette recherche. Si vous souhaitez vous en retirer du projet de recherche à quelque moment que ce soit, et quel que soit le motif, vous continuerez à bénéficier du suivi médical et cela n'affectera en rien la surveillance future.

Conformément à la réglementation, vous devez être bénéficiaire d'un régime de protection sociale pour participer à une recherche impliquant la personne humaine.

Conformément à l'article L.1111-6 du Code de la Santé Publique, vous pouvez désigner une personne de confiance qui peut être un parent, un proche ou votre médecin traitant et qui sera consultée au cas où vous seriez hors d'état d'exprimer votre volonté et de recevoir l'information nécessaire à cette fin. Elle rend compte de votre volonté. Son témoignage prévaut sur tout autre témoignage. Cette désignation est faite par écrit et cosignée par la personne désignée. Elle est révisable et révocable à tout moment.

Si vous le souhaitez, votre personne de confiance peut vous accompagner dans vos démarches et assister aux entretiens médicaux afin de vous aider dans vos décisions.

Conformément aux Bonnes Pratiques Cliniques (ICH E6, CPMP/ICH/135/95) et à la loi n°2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine :

- cette recherche a obtenu un avis favorable du Comité de Protection des Personnes Ile de France VII. Le rôle du CPP est d'assurer la protection des droits des personnes participant à une recherche, notamment en s'assurant que tout projet de recherche mené en France, respecte diverses mesures (médicales, éthiques et juridiques). Ce comité est totalement indépendant du médecin en charge de la recherche ainsi que du promoteur.

- Cette recherche est conforme à la méthodologie de référence mise en place par la Commission Nationale de l'Informatique et des Libertés (CNIL), et permet d'assurer la sécurité et la confidentialité des données personnelles collectées pendant cette recherche.

- le promoteur de cette recherche, le CHU de Montpellier (39, avenue Charles Flahault – 34295 MONTPELLIER Cedex 5), a souscrit une assurance de responsabilité civile auprès de le Sham (contrat n° 165763).

- le promoteur assume l'indemnisation des conséquences dommageables de la recherche impliquant la personne humaine pour la personne qui s'y prête et celle de ses ayants droit, sauf preuve à sa charge que le dommage n'est pas imputable à sa faute ou à celle de tout intervenant sans que puisse être opposé le fait d'un tiers ou le retrait volontaire de la personne qui avait initialement consenti à se prêter à la recherche



AsthmaTrain

Version n° 3.0 du 19/01/2022

(l'article L1121-10). Lorsque la responsabilité du promoteur n'est pas engagée, les victimes peuvent être indemnisées dans les conditions prévues à l'article L. 1142-3.

Informations en cours de recherche

Cette lettre d'information décrit les connaissances actuelles sur la recherche au moment où il est signé. Vous serez informé(e), par écrit, en temps voulu, de toute nouvelle information découverte au cours de la recherche, afin de vous permettre de décider si vous souhaitez continuer de participer ou non à cette recherche. Dans ce cas, vous devrez donner de nouveau votre consentement.

Résultats de la recherche

- lorsque cette recherche sera terminée, vous serez tenu informé personnellement des résultats globaux par votre médecin dès que ceux-ci seront disponibles, si vous le souhaitez.

Après avoir lu cette note d'information, n'hésitez pas à poser toutes les questions que vous désirez au médecin investigateur.

Après un délai de réflexion, si vous acceptez de participer à cette recherche, votre médecin recueillera votre consentement oral. Un exemplaire du présent document vous sera remis.

En vous remerciant par avance pour votre participation à cette étude



AsthmaTrain

Version n° 3.0 du 14/03/2022

LETTRÉ D'INFORMATION ET RECUEIL DE CONSENTEMENT Groupe Vik**EDUCATION THERAPEUTIQUE DES PATIENTS ASTHMATIQUES : EVOLUTION DE LA QUALITE DE VIE****ASTHMATRIN – RECHMPL21_0423**

Promoteur de la recherche : CHU de Montpellier

Investigateur coordonnateur : Pr Arnaud BOURDIN

Madame, Monsieur,

Vous avez accepté de participer à la recherche AsthmaTrain et nous vous en remercions. Dans le cadre de cette étude, vous avez été tiré au sort pour bénéficier d'une application nommée Vik Asthme – CHU de Montpellier. Cette application a été adaptée et développée spécifiquement par le département de Pneumo-allergologie du CHU de Montpellier en partenariat avec l'entreprise « Wefight ». Cette application pour smart phone fait partie des outils spécifiques d'éducation thérapeutique, et elle est mise à disposition pour un sous-groupe de patients dans cette étude ; vous faites partie de ce sous-groupe.

L'option d'utiliser l'application Vik Asthme – « CHU de Montpellier » est entièrement volontaire. Si vous ne désirez ou ne pouvez pas utiliser l'application Vik Asthme, votre programme d'éducation thérapeutique comportera comme à l'habitude des entretiens avec différents médecins et paramédicaux dédiés, comme habituellement proposé et comme initialement annoncé dans votre première lettre d'information.

Avant de prendre une décision, il est important que vous lisiez attentivement ces pages qui vous apporteront les informations complémentaires nécessaires concernant les différents aspects de cette recherche. Vous disposez d'un délai de réflexion avant de donner votre consentement au médecin. N'hésitez pas à poser toutes les questions que vous jugerez utiles à votre médecin.

PRESENTATION DE LA RECHERCHE

L'étude compare ceux qui vont utiliser l'application « Vik Asthme - CHU de Montpellier », qui est un « chat-bot » supposé rendre l'éducation thérapeutique et la gestion de la maladie plus dynamique, à ceux qui ne vont pas l'utiliser, sur 6 mois.

Si vous acceptez d'utiliser l'application Vik-Asthme - CHU de Montpellier, il est important que vous essayiez de la garder secrète. Cela aidera à ne pas influencer les autres patients et personnel participant à cette étude.

OBJECTIF DE LA RECHERCHE

Les objectifs restent ceux déjà précisés dans la première note d'information :

L'objectif général de cette étude est d'évaluer l'évolution de la qualité de vie associée à l'asthme à la suite d'un programme d'éducation thérapeutique du patient. Dans le même temps, nous évaluerons également les changements dans la fonction pulmonaire, le contrôle de l'asthme et la consommation de ressources de santé. Nous explorerons également comment les réponses à l'éducation thérapeutique diffèrent entre les patients selon leurs réponses à plusieurs questionnaires (sur la personnalité, anxiété, réponse aux stress).

METHODOLOGIE DE LA RECHERCHE

AsthmaTrain est une étude se déroulant uniquement sur le centre de Montpellier. Il est prévu d'inclure 80 patients. Chaque patient sera suivi sur une période de 6 mois.

Un tirage au sort désignera 40 patients qui pourront bénéficier de l'application Vik Asthme - CHU de Montpellier. Vous faites partie de ces 40 patients.

DEROULEMENT DE LA RECHERCHE

Le déroulé de l'étude est quasiment identique à celui présenté sur la précédente lettre d'information. Les éléments supplémentaires ont été ajoutés dans le tableau en gras.



AsthmaTrain
Version n° 3.0 du 14/03/2022

Visites	V1	Tel 1*	Tel 2*	Tel 3*	Tel 4*	Tel 5*	V2
Jour ou Semaine	J1	S4	S8	S12	S16	S20	S24
Vérification des critères d'inclusion	X*						
Lettre d'information et recueil du consentement	X*						
Tirage au sort	X*						
Lettre d'information et recueil du consentement Vik ¹	X*						
Début de l'utilisation de l'application Vik Asthme ¹	X*						
Données démographiques et psychométriques (incluant les questionnaires BFI, HADS, WCC)	X*						
Questionnaires AQLQ et EQ-5D-5L	X*						X*
Questionnaire ACQ-5	X						X
Fonction pulmonaire : spirométrie	X						X
Récupération des données sur les exacerbations, les RDV médicaux et les traitements pris	X*	X*	X*	X*	X*	X*	X*

*Examens spécifiques à la recherche (non prévus dans le soin courant)

¹ Uniquement pour les patients tirés au sort dans le bras Vik Asthme

LES BENEFICES ATTENDUS

Il se peut qu'un programme d'éducation thérapeutique amélioré par une application smart phone donne des résultats différents de ceux des programmes traditionnels. Mais, cette idée est controversée et peu étudiée dans l'asthme. Pour être clair, nous ne possédons pas actuellement les données nécessaires pour bien comparer les stratégies d'éducation thérapeutiques entre elles, et c'est une des raisons pour laquelle cette recherche a été élaborée. Dans tous les cas, vous allez recevoir un programme d'éducation thérapeutique, et cette bonne information vise à améliorer votre compréhension et votre vécu de la maladie et ce que vous pouvez faire pour la gérer. En plus d'être plus étroitement surveillés du fait de votre participation à une recherche scientifique, votre participation et les données générées par cette étude peuvent également contribuer à une meilleure compréhension de la maladie et de l'impact d'une bonne information sur la qualité de vie des patients.

LES INCONVENIENTS POSSIBLES

Les inconvénients possibles sont inchangés par rapport à la première note d'information :

En sus de la prise en charge habituelle, vous allez recevoir une éducation thérapeutique spécifique, et il vous sera demandé de remplir des questionnaires et un carnet patient. Les risques associés à cette étude ne diffèrent donc pas des soins habituels. Du fait du faible niveau de risque associé à cette étude, il n'est pas attendu d'événements indésirables.

Votre participation sincère à cette étude est cruciale pour son succès. Cela signifie participer aux deux visites et remplir plusieurs questionnaires au début et à la fin de l'étude. Il vous sera également demandé de remplir un carnet patient détaillant vos prises de traitements et de symptômes tout au long de l'étude et de participer aux appels téléphoniques mensuels.

LES EVENTUELLES ALTERNATIVES MEDICALES

Si vous refusez d'utiliser l'application Vik Asthme - CHU de Montpellier, vous bénéficierez du programme habituel d'éducation thérapeutique pour le patient du CHU de Montpellier, comme expliqué dans la première note d'information.

AUTRES DISPOSITIONS REGLEMENTAIRES

L'ensemble des éléments indiqués sur la note d'information générale de l'étude sont valables si vous participez à l'étude dans le bras application Vik Asthme.

Après avoir lu cette note d'information, n'hésitez pas à poser toutes les questions que vous désirez au médecin investigateur.

Après un délai de réflexion, si vous acceptez de participer au bras Vik Asthme, votre médecin recueillera votre consentement oral. Un exemplaire du présent document vous sera remis.