

mySinusitisCoach: patient empowerment in chronic rhinosinusitis using mobile technology*

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Abstract

Mobile health technology is emerging to take a prominent position in the management of chronic diseases. These technologies aim at enhancing patient empowerment via education and self-management. To date, of all the different apps available for patients with sinus disease, none were developed by medical experts dealing with chronic rhinosinusitis (CRS). The European Forum for Research and Education in Allergy and Airway diseases (EUFOREA) has undertaken a multi-stakeholder approach for designing, developing and implementing a tool to support CRS patients in monitoring their symptoms and to provide patients with a digital support platform containing reliable medical information about their disease and treatment options. mySinusitisCoach has been developed by medical experts dealing with CRS in close collaboration with patients, primary care physicians and community pharmacists, meeting the needs of both patients and health care providers. From a research perspective, the generation of real life data will help to validate clinical studies, patient stratification and improve understanding of the socio-economic impact of CRS, thereby paving the way for better treatment strategies.

Key words: chronic airway disease, rhinosinusitis, mobile application, education, self-management

Introduction

Chronic rhinosinusitis (CRS) affects 11% of the European population and is associated with a significant socio-economic burden ^(1,2). CRS with and without nasal polyps are the main constituent disease entities with each having different pathophysiological mechanisms or endotypes underlying the disease ⁽³⁾. Evidence-based treatment guidelines (EPOS) provide guidance to physicians for the management of CRS aiming at achieving or maintaining clinical control ⁽⁴⁾. The cornerstone of CRS treatment is prolonged anti-inflammatory treatment in combination with Functional Endoscopic Sinus Surgery (FESS) in case of failure of medical treatment. Despite currently available treatment modalities for CRS, including sinus surgery, up to 40% of patients still suffer from uncontrolled disease ⁽⁵⁾. Few studies so far have evaluated the burden of uncontrolled CRS in real life using the EPOS criteria for CRS disease control ^(5,6). Uncontrolled upper airway disease might be attributed to disease-, treatment-, diagnosis- and patient-related factors ⁽⁷⁾. The relative importance of these factors still needs to be determined but it has been suggested that active participation

of patients in the management of their disease may reduce the burden of uncontrolled disease through better adherence and personalized care ^(8,9). Mobile health technology has the potential to increase patient participation via self-management and education. Recently, education and personalized messages were identified in market research by app developers as most effective in changing patient behavior and are easy to implement ⁽¹⁰⁾. More challenging, but still having a high impact are app features that improve the communication with the healthcare provider ⁽¹⁰⁾. The success of future mobile (m)Health tools likely depends on the inclusion of those features that are lacking in most currently available apps for chronic upper airway diseases. For example, MASK-rhinitis is a pioneering project allowing allergic rhinitis patients to track their nasal, ocular or lung symptoms and share it with their health care provider ^(11,12). First results demonstrated its utility to phenotype patients with allergic rhinitis (AR) and to evaluate the impact of allergic rhinitis on work productivity ^(13,14). Recently, the use of a visual analogue scale (VAS) on smartphone screens was validated to assess AR control ⁽¹⁵⁾. Follow-up studies are needed to demonstrate its utility in

improving disease control and adherence to treatment by the use of the app. Currently, different mobile apps related to sinus disease are available but none were developed by medical experts dealing with CRS. EUFOREA started a program to increase patient participation and empowerment in CRS, encouraging them to become active players in the integrated care pathway⁽¹⁶⁾. This approach fully matches the concept of precision medicine, for which participation of the patient is one of the 4 key pillars^(9,17). mySinusitisCoach has been developed in collaboration with the EUFOREA network of Rhinology experts, and different national and international bodies representing patients, primary care physicians, pharmacists and the eHealth community. This manuscript describes the developmental process, the different functionalities and the expected benefits of the app. We here aim to inform the Rhinology community about the unique approach used to design, develop and implement the app, which might serve as a state-of-the-art example for other projects.

Identifying the needs in CRS management

The needs of patients with CRS vary depending on the phase of their disease severity, experience and geographical distribution. It is assumed that patients with upper airway symptoms rely on self-medication and/or over-the-counter treatment to deal with the first symptoms of rhinosinusitis. Early detection of CRS is warranted to avoid delay in presentation to the primary care physician or ENT specialist. An integrated approach aligning different health care providers dealing with CRS is needed to deliver a uniform message to the patient⁽⁹⁾. While newly diagnosed patients need reliable information about their disease and treatment options, patients with established or uncontrolled disease also require closer follow-up of their symptoms and disease control. Additionally, patients undergoing surgery will benefit from intensified monitoring of their symptoms. From the research perspective, there is a need to validate findings from clinical studies with real life data to guarantee applicability at the population level⁽¹⁸⁾.

Implementation of supported self-management into clinical practice in CRS

Treatment algorithms have been developed and presented in EPOS guidelines⁽⁴⁾. From the patient's perspective, poor adherence to treatment, incorrect use of treatment and limited knowledge about CRS and the treatment options might hamper their path to maintain or achieve optimal disease control^(19–21). A blended health care approach is needed where the patient is well informed about the treatment options by the physician, in accordance with the guidelines, allowing the patient to understand the rationale of a treatment decision. Mobile health tools are aimed at supporting this process and allow disease monitoring over time, which contributes to supported self-management of the disease.

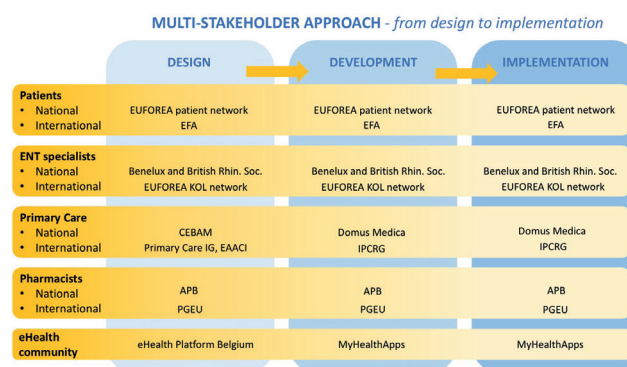


Figure 1. Multi-stakeholder approach from design to implementation.

EFA: European Federation of Allergy and Airways Diseases Patients' Associations, CEBAM: Belgian Centre for Evidence-Based Medicine, Domus Medica: Belgian Association of Primary Care Physicians, EAACI: European Academy of Allergy and Clinical Immunology, IPCRG: International Primary Care Group, APB: Association of Pharmacists in Belgium, PGEU: Pharmaceutical Group of the European Union.

Development of mySinusitisCoach: a multi-stakeholder approach from design to implementation

EUFOREA aimed at consulting all relevant stakeholders early on during the process of design and development of mySinusitisCoach. Patient-focused group meetings were organized in different countries throughout Europe to identify the patients' needs and their perspective on new developments in the field of mobile health technology. In addition, national as well as international representatives of patient organizations (EFA), associations of primary care physicians (Domus Medica, IPCRG), associations of community pharmacists (Association of Pharmacists in Belgium or APB and Pharmaceutical Group of the EU or PGEU) and E-Health community have provided feedback on design and development of mySinusitisCoach (Figure 1). This approach creates a unique European platform for dissemination of mySinusitisCoach and for implementation into clinical practice.

mySinusitisCoach: availability and data protection

The system has been initially deployed in three countries (Belgium, The Netherlands and United Kingdom) and is available in two languages (Dutch and English). The app can be downloaded for free from the app stores (for iPhone: App Store, for smartphones that run on Android: Google Play). mySinusitisCoach has been registered as a class I medical device. Data aggregated in an anonymized way through mySinusitisCoach are stored on a private, secured server (ISO 27001 certified) for '15 years. A penetration test for the backend website of mySinusitisCoach is scheduled for 2018. Geolocalized data is only stored after explicit consent by the app user. The data are owned by EUFOREA. The Terms of Use allow the use of anonymized data for research purposes.

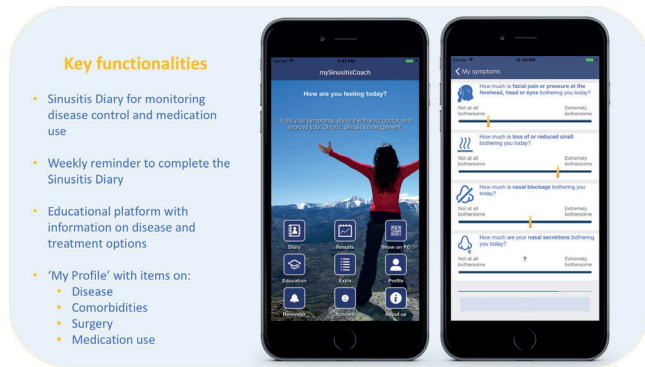


Figure 2. Key functionalities of mySinusitisCoach.

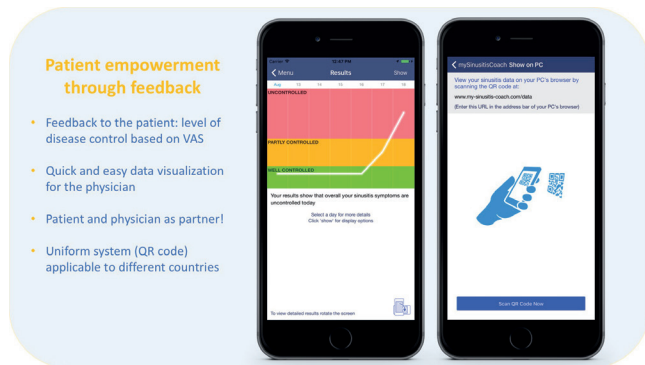


Figure 3. Patient empowerment through feedback to the patient and the physician.

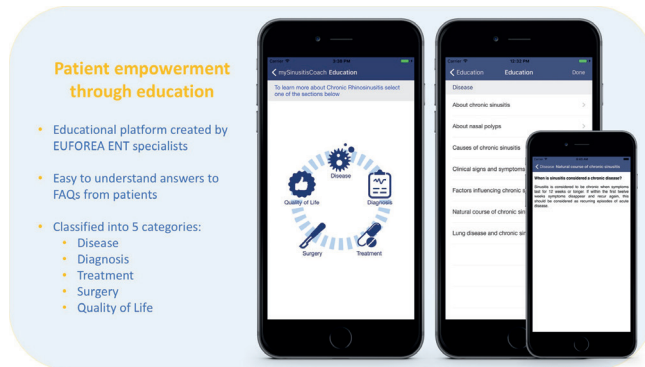


Figure 4. Patient empowerment via patient education.

Monitoring disease control

Profile of the patient

Demographic characteristics (year of birth, gender, country, language, smoking status), presence of co-morbidities (AR, asthma, COPD), disease-related factors (duration of symptoms, presence of nasal polyps, previous surgery) are recorded in the 'Profile' menu by the patient themselves. Country-specific medication lists for nasal, lung or eye symptoms are available from the 'Profile' menu and allow patients to indicate their medication use, for which compliance can be recorded after filling the Diary.

Table 1. Sinusitis Diary questions.

VAS for	Question
Global sinusitis symptoms	How much are your global sinusitis symptoms bothering you today?
Facial pain or headache	How much is facial pain or pressure at the forehead, head or eyes bothering you today?
Smell impairment	How much is loss of or reduced smell bothering you today?
Nasal Blockage	How much is nasal blockage bothering you today?
Nasal secretions	How much are your nasal secretions bothering you today?
Post-nasal drip	How much are nasal secretions dripping into the throat bothering you today?
Lower airway symptoms	How much is shortness of breath or wheezing bothering you today?
Impact on sleep quality	How much are your sinusitis symptoms affecting your sleep quality?
Impact on work and daily life	How much are your sinusitis symptoms affecting your work or daily activities today?

Sinusitis Diary

The Sinusitis Diary is a simple tool to monitor rhinosinusitis symptoms and their impact on lower airway symptoms, sleep quality and work or daily life. This tool relies on a visual analogue scale, allowing the patient to score how bothersome a particular symptom is for him/her on a particular day. A similar system has been used and validated in the past to monitor allergy symptoms^(15,22). The questions of the Sinusitis Diary are listed in Table 1. Questions with a previous VAS \leq 2 (e.g. result of the day before) were dropped from the Diary for 1 week to avoid an overload of questions that might be irrelevant for the patient at that time.

In addition to rhinosinusitis symptoms, medication use is recorded as a last item of the Diary. A weekly reminder to complete the Diary is activated in the app. This can be switched off/on and the time point can be chosen according to the patients' preference.

Feedback to the patient

Upon completion of the Sinusitis Diary, the patient receives feedback about the level of control of his/her global rhinosinusitis symptoms: well controlled (VAS \leq 2), partly controlled (VAS $>$ 2 and VAS \leq 5), uncontrolled (VAS $>$ 5)⁽⁵⁾. The results of the specific symptoms over time are visualized when rotating the screen of the mobile device into landscape mode. A patient who has uncontrolled disease for a prolonged time receives the following notifications:

- After 1 week: 'Your rhinosinusitis symptoms are uncontrolled. Did you properly rinse your nose with saline?'

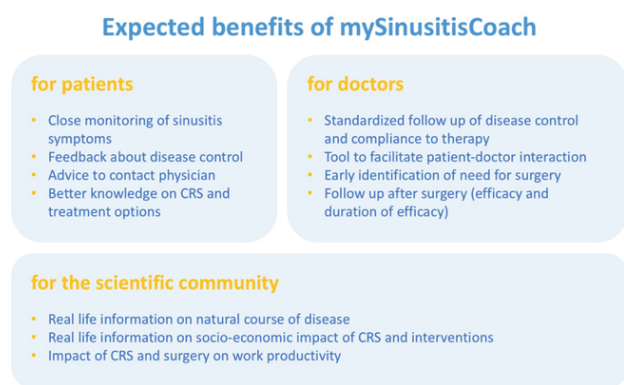


Figure 5. Expected benefits of mySinusitiscoach for the different stakeholders.

- After 2 weeks: 'Your rhinosinusitis symptoms are uncontrolled for 1 week. Did you properly take your medication?'
- After 3 weeks: 'Your sinusitis symptoms are uncontrolled for 2 weeks. Uncontrolled sinus disease is seen in 40% of patients with chronic rhinosinusitis who were prescribed nasal sprays and have had sinus surgery. The reasons for that might be due to exposure to air pollution or allergens, other airway diseases, medication that is inefficiently reducing the ongoing inflammation or not taking adequately your medication.'
- After 4 weeks: 'Your rhinosinusitis symptoms are uncontrolled for 4 weeks. You may consider visiting your GP or ENT doctor to discuss your symptoms and check your treatment.'

Feedback to the physician

During patient consultation, the data on the level of disease control, VAS of specific symptoms and use of medication can be visualized on any PC with internet connection. The link 'www.my-sinusitis-coach.com/data' contains a QR code that can be scanned by the patient with his/her smartphone. At that time, the patient authorizes visualization of his/her data on the PC. Scanning allows the physician to identify the specific patient, to evaluate disease control and medication use; and discuss this information with the patient to determine or adapt CRS treatment for the following period.

Measuring quality of life

SNOT-22 questionnaire

The SinoNasal Outcome Test (SNOT)-22 questionnaire is widely used and validated to assess quality of life in CRS patients, to evaluate treatment effectiveness or to identify patients eligible for sinus surgery⁽²³⁻²⁶⁾. This questionnaire has been included in the app as an optional questionnaire to complete monthly.

EQ-5D-5L questionnaire

The EuroQoL-5Dimension-5Level (EQ-5D-5L) generic question-

naire is used to assess the general health-related quality of life of chronically ill patients⁽²⁷⁾. Five specific dimensions of the patients' health are scored: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Such generic questionnaire allows comparison of the patients' overall health across different medical conditions. Similar to the SNOT-22 questionnaire, the EQ-5D-5L questionnaire has been included in the app as an optional questionnaire to complete monthly.

Patient support through reliable education

Patients are in need of information about their disease and treatment options. Their needs may vary depending on their phase in the disease journey but often the internet is their primary source of information (unpublished data). This information might however be biased or unreliable. Consequently, EUFOREA has created a support platform for patients with upper airway disease with both online educational material as well as the educational platform available from mySinusitisCoach. EUFOREA key opinion leaders (KOLs) have collected frequently asked questions from their patients and answered them in short and easy to understand language. The questions and answers (Q&A) have been checked to match the health literacy of the average patient by a panel of primary care physicians for each country. The Q&A were classified into 5 topics (disease, diagnosis, treatment, surgery and quality of life) to facilitate the search for the patients.

Expected benefits for the different stakeholders

For the patient

This tool was developed in collaboration with patients to ensure acceptability and use over a prolonged period of time by a large group of patients. Feedback by the European patient organization (EFA) was obtained at different time points and the app was tested with patients during the development phase. Close monitoring of the patients' rhinosinusitis symptoms, feedback about disease control and advice to contact their treating physician may lead to increased awareness of the patients about their disease, thereby contributing to better compliance with their therapy. The educational platform may lead to better knowledge about CRS and available treatment options allowing active participation of patients in the management of their disease.

For the healthcare professional

Longitudinal information about disease control and adherence to therapy will be available for the doctor. This information may help to decide upon the best treatment strategy and facilitate the patient-doctor interaction⁽²⁸⁾. The educational platform may aid the doctor in providing information on treatment options to the patient or allow referral to the platform which might be time saving. In addition this tool could identify those patients who are in need of more extensive medical or surgical treatment⁽²⁹⁾.

In the post-operative setting it may facilitate the follow-up of the surgical intervention as well as duration of effect.

For the scientific community

Currently, guidelines and care pathways are developed based on clinical studies that are performed in highly selected patient populations, for valid scientific reasons, however this does not validate the extrapolation of results achieved into the general population⁽³⁰⁾. mySinusitisCoach will provide real life data on the natural course of disease, socio-economic impact of CRS and outcomes of medical as well as surgical interventions. In addition, it allows the evaluation of the impact of CRS on lower

airway symptoms, sleep quality and work productivity.

Authorship contribution

SS, BP, JB, CB, WJF and PWH developed mySinusitisCoach, wrote the manuscript and reviewed the manuscript.

Others: provided feedback on design, development and implementation of the app during brainstorming sessions; and reviewed the manuscript.

Conflict of interest

No conflict of interest.

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