Telemonitoring for Asthma and COPD through voice analysis; the TACTICAS study

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The goal of the TACTICAS study is to evaluate if acoustic speech characteristics in patients with asthma or COPD correlate with daily dyspnoea symptoms.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON56112

Source
ToetsingOnline

Brief title
TACTICAS

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Astra Zeneca,AstraZeneca en Boehringer Ingelheim,Boehringer Ingelheim

Intervention

Keyword: astma, COPD, eHealth

Outcome measures

Primary outcome

Primary objective

To derive a digital fingerprint of dyspnoea in asthma and COPD by combining speech analysis as well as features extracted from spoken dialogue with daily dyspnoea measurement as gold standard.

Endpoints for primary objective:

Voice analysis: syllables per breath group during standardized free language

self-report

Daily Dyspnoea burden: E-RS score

Secondary outcome

1. To investigate if the digital dyspnoea fingerprint correlates with asthma and COPD severity

Voice analysis: syllables per breath group and other acoustic speech measurements

Disease severity: FEV1 (COPD and asthma), exacerbation burden in the previous year

2. To investigate if the digital dyspnoea fingerprint in asthma and COPD correlates with quality of life.

Voice analysis: syllables per breath group and others acoustic speech

measurements

QoL: CAT (COPD), ACT (asthma)

3. To investigate if the digital dyspnoea fingerprint in asthma and COPD correlates with physical activity.

Voice analysis: syllables per breath group and other acoustic speech measurements

Physical activity: daily step count, 24-h heart rate, VAS score during physical activity

4. To investigate if the digital dyspnoea fingerprint in asthma and COPD correlates with exacerbation occurrence.

Voice analysis: syllables per breath group and other acoustic speech measurements

Exacerbations: EXACT Score

5. To develop a patient interface consisting of a chatbot smartphone application plus wearable to objectively measure symptoms in an ecological momentary assessment. N/A

6. To develop a clinician dashboard that provides meaningful insight into the generated longitudinal patient data.

7. To test feasibility and evaluate the system in a real-world outpatient care

scenario with COPD and Asthma patients.

Study description

Background summary

Telemonitoring (TM) and Mobile health technologies (mHealth) are modernizing medicine.(1) They have the potential to deliver personalized care at home by empowering patients to make healthy decisions.(1) Moreover, they can be used to refine diagnostic processes, tailor treatment choices, improve condition monitoring for actionable outcomes, such as early signs of relapse, and develop new intervention models. TM and mHealth is increasingly deployed in many health care sectors. (2)
Digital phenotyping is the moment-by-moment, in situ quantification of the individual-level phenotype using data from personal digital devices. Through artificial intelligence model-based learning it is possible to derive a digital phenotype or fingerprint from a subject by exploiting the potential of data that are automatically generated and aggregated by smartphones, wearables and other connected devices to measure (or offer robust proxies for) human behavior and function in both health and disease. Today, these data streams include sensor measurements, activity logs and user-generated content.
Despite the potential of TM and mHealth for improving health care services, evidence is contradictory in patients with respiratory diseases, mainly asthma and COPD.(3) There is some evidence that TM might reduce hospitalisation rates in COPD.(4) On the other hand, a recent meta-analysis showed no effect of TM in supporting self-management in patients with asthma or COPD.(2) Moreover, TM was not able to reduce the exacerbation rate in COPD patients, which is an important treatment goal in this population.(5,6)
Symptom relief is another important treatment goal in patients with asthma and COPD. Dyspnoea is the hallmark symptom in both diseases. Dyspnoea as a symptom is traditionally monitored and evaluated via questionnaires, such as the visual analogue score (VAS) or the mMRC scores.(7) Recently, the E-RS score has been advocated by an American Thoracic Society (ATS) taskforce to monitor daily dyspnoea symptoms.(8) For remote monitoring and assessment, the effort or discomfort of breathing should ideally be captured via automatically generated data that are derived from personal devices, rather than questionnaires which take patients* time and effort. Mobile health technologies now offer the possibility to analyse voice. In a pilot study in patients with COPD, it was shown that several acoustic speech characteristics, such as number of inhalations per syllable, differed in patients with COPD compared to healthy controls.(9) Moreover, during an exacerbation this was even more pronounced.(9)
We hypothesize that the quantification of the individual voice of patients with asthma and COPD is a way to capture and digitalise the respiratory discomfort experienced by these patients on a daily basis. Therefore, the main goal of the

present pilot study is to investigate correlates in voice analysis that associate with symptoms in patients with asthma and COPD. This will be done by using a commercially available mHealth application platform (Zana Technologies GmbH). Moreover, we will relate these acoustic speech characteristics in voice to disease severity, quality of life, physical activity and exacerbation rate.

Study objective

The goal of the TACTICAS study is to evaluate if acoustic speech characteristics in patients with asthma or COPD correlate with daily dyspnoea symptoms.

Study design

The TACTICAS study will be a prospective, single-center observational cohort study in adult patients with asthma or COPD attending the university hospital outpatient clinic of the MUMC+ in the Netherlands. The total duration of the study will be 74 weeks. All patients will have an evaluation of the asthma or COPD as part of their routine care at the start and at the end of the study. After informed consent, patients will receive support and instructions how to use the Health watch and the mobile app. During the study, patients will be prompted through a voice dialogue interface on the smartphone three times a day (once at rest in the morning, once during exercise e.g. while taking a break and once at the end of the day) to perform the follow speech tasks: (1) Maximum phonation time (vowel ah) and (2) Free language self-report (e.g. *how are you feeling today*). Moreover, patients will fill in their daily dyspnoea symptoms at the end of the day (E-RS). Quality of life questionnaire will be administered monthly (either CAT or ACT). Passive markers will be collected throughout the day whilst wearing the Healthwatch: Activity patterns, Heart rate, SpO2, exercise walking distance and walking time.

Study burden and risks

Because of the observational nature of the study, the present study poses no risk to patients and burden is only limited to time investment to perform the measurements. Burden consists of: (1) daily interaction via mobile telephone to perform a two-minute speech task (three times a day) and to fil in one questionnaire (at the end of the day), (2) monthly interaction via mobile telephone to fill in one questionnaire about quality of life, (3) continuous recording of vital signs while wearing a smartwatch

Contacts

Public

Universiteit Maastricht

Minderbroedersberg 4-6
Maastricht 6211 LK
NL
Scientific
Universiteit Maastricht

Minderbroedersberg 4-6
Maastricht 6211 LK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 18 years or older
- Physician diagnosed asthma or COPD:
- Willingness and demonstration of ability to use a smartphone and fitness watch and to allow remote monitoring of vital signs.
- Able to understand, read and write Dutch language

Exclusion criteria

- Exacerbation of asthma or COPD within 8 weeks of inclusion into the study
- Chronic respiratory insufficiency, defined as a resting pO2 < 8.0 kPa or pCO2 > 6.5 kPa, measured at sea level
- Co-morbidities that interfere with the registration or interpretation of symptoms, physical activity or quality of life, such as severe heart failure, interstitial lung diseases, or neuromuscular disorders.
- Persons who are dependent on others for activities of daily living.

- Persons who use a wheelchair or walker.
- Active malignancy.
- Expected life-expectancy less than 1 year.
- Investigator*s uncertainty about the willingness or ability of the patient to comply with the protocol requirements.
- Participation in another study involving (non)-investigational products.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-01-2022
Enrollment:	74
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	19-12-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL76219.068.20
Other	NL9360