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A research study to explore the impact of GP support via text messages to patients with asthma and/or chronic obstructive pulmonary disease

Submission date
05/08/2022

Recruitment status
No longer recruiting

Registration date
09/08/2022

Overall study status
Completed

Last Edited
24/11/2023

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Asthma and chronic obstructive pulmonary disease (COPD) are lung conditions that affect a considerable proportion of the UK population, and non-adherence to medication may prevent optimal patient outcomes. It is estimated that only about 50% of medications for chronic disease are taken as prescribed, and adherence for asthma and COPD medication may be even lower than this. Research suggests that text message interventions can help improve adherence to medication in patients.
Drawing on this research, Accurx (a software company that enables NHS healthcare teams and patients to communicate) has developed a 6-month series of text messages which aims to improve medication adherence and symptom control in patients with asthma and COPD.
This study aims to investigate whether a series of supportive text messages sent to patients with asthma and/or COPD from their GP practice can improve medication adherence and symptom control.

Who can participate?
A number of GP practices across England will invite their eligible patients to sign up to take part in the study. Eligible patients must be over 18 years of age, have a diagnosis of either asthma or COPD, have been prescribed a preventer inhaler, have a mobile phone and be able to receive and read SMS messages.

What does the study involve?
A number of GP practices (around 150) will invite their eligible patients with asthma and/or COPD to take part in the study. Patients who sign up (participants) will read an information sheet and sign a consent form. All participants will then be randomly allocated to one of two groups: a control group or an intervention group. All participants in both groups will continue to receive their usual care from their GP practice, but participants in the intervention group will also receive a series of supportive text messages from their GP practice over a 6 month period. The text messages will provide reminders to patients to take their medication and information

and support on why it's important to take it.
All patients, regardless of whether they are in the control group or the intervention group, will also be asked to complete a survey at baseline (week 1), midpoint (week 13) and endline (week 26). These surveys will ask patients about their medication adherence and their symptom control, as well as a few questions on which NHS services they have used over the few months. At the end of the study, the research team will look at the survey data as well as data on participants' prescription requests, to understand whether these text messages had any impact on medication adherence and symptom control.

What are the possible benefits and risks of participating?
There are no major risks associated with participating in this study. It is a light-touch behavioural intervention and participants can opt-out at any stage if they would prefer not to receive any further text messages. The primary benefit of participating is the opportunity to contribute to what researchers know about how GP practices can support patients with asthma and/or COPD.

Where is the study run from?
Accurx (UK)

When is the study starting and how long is it expected to run for?
April 2022 to November 2023

Who is funding the study?
Accurx (UK)

Who is the main contact?
Victoria Fussey, tori@accurx.com

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316452

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 316452

Study information

Scientific Title
A randomised controlled trial to evaluate the impact of supportive text messages from GP practices on self-reported symptoms and inhaler adherence in patients with asthma and/or chronic obstructive pulmonary disease who have been prescribed a preventer (daily) inhaler

Study objectives
A 6-month series of supportive text messages sent to patients with asthma and/or chronic obstructive pulmonary disease (COPD) from their GP practice improves medication adherence and symptom control

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/12/2022, North West - Liverpool Central Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 2071048016; liverpoolcentral.rec@hra.nhs.uk), ref: 22/NW/0332

Study design
Multicentre non-blinded prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Asthma, chronic obstructive pulmonary disease (COPD)

Interventions
This trial will be a 6-month prospective, randomised controlled trial in which the study population is randomly allocated (1:1) to an intervention or control group. The trial is multicentre and is non-blind. All patients in both groups will continue to receive their usual care for the duration of the study. Randomisation will be at the individual level. Participants will be randomly allocated as per a computer-generated randomisation list using a random number generator as part of the Microsoft .NET framework.

This is a behavioural intervention. The intervention will consist of a series of supportive text messages to patients from their GP practice over a 6 month period. The messages will vary in frequency from 2 or 3 in the first weeks of the trial to only 1 or 2 a month in the final months of the trial. The content of the messages will vary; some will contain information about how to use a preventer inhaler, some will emphasise the importance of using it, and some will provide simple reminders to patients to take their inhaler.

All participants will continue to receive their usual care throughout the duration of the study; the text message intervention with be in addition to their usual care.

Intervention Type
Behavioural

Primary outcome measure
Medication adherence measured using the MARS-5 Questionnaire from baseline (week 1) to midpoint (week 13) and endpoint (week 26)

Secondary outcome measures
1. Symptom control measured using the Asthma Control Test from baseline (week 1) to midpoint (week 13) and endpoint (week 26). (for asthma patients)
2. Symptom control measured using the COPD Assessment Test from baseline (week 1) to midpoint (week 13) and endpoint (week 26) (for COPD patients and patients with both asthma and COPD)
3. Days between consecutive preventer inhaler prescription requests measured using medical record data from baseline (week 1) to midpoint (week 13) and endpoint (week 26)
4. Differences in the number of emergency admissions between the intervention and control groups measured using bespoke survey questions over the 26-week trial period
5. Differences in the utilisation of NHS resources between the intervention and control groups measured using bespoke survey questions over the 26-week trial period

Overall study start date
01/04/2022

Completion date
01/11/2023

Eligibility

Key inclusion criteria
1. Willing and able to provide informed consent and comply with the study instructions
2. Male and females age 18 years or older
3. Confirmed diagnosis of asthma and/or COPD as recorded in the patient's GP medical record
4. Currently prescribed a preventer inhaler
5. Access to a mobile phone
6. Ability to check text messages on phone
7. Ability to read

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
4000

Key exclusion criteria

1. Inability to understand the study procedures
2. Inability or reluctance to provide responses to the study questionnaires
3. Inability to receive and respond to text messages

Date of first enrolment
06/03/2023

Date of final enrolment
17/03/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
87 GP practices across England are participating in this trial
United Kingdom
EC2A 3LT

Sponsor information

Organisation
Accurx

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Accurx

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact journal.

Intention to publish date
01/05/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as we did not seek participant agreement to do so.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 2	22/11/2022	16/10/2023	No	No
Basic results		24/11/2023	24/11/2023	No	No