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ASSIST Study: Investigation of a digital health solution providing real-time inhaler technique guidance

Submission date 01/06/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/06/2022	**Overall study status** Completed	
Last Edited 27/03/2024	**Condition category** Respiratory	

Plain English Summary

Background and study aims
Most medicines for asthma are given by inhaler so that medicine can directly reach the lungs and work better. However, we know it's difficult to use an inhaler properly and mistakes are often made. Poor inhaler technique has been linked to increased asthma symptoms, hospital admission and the need for more asthma medicines. To be certain patients are using their inhaler correctly, it is necessary for patients to be trained regularly; showing someone once is not enough! However, patients and their health care professionals are busy and opportunities to check and refresh inhaler technique are often limited.

Clip-Tone is a small device fitted to the top of the patients' inhaler which makes a very quiet whistle when used properly. This is used with the Clip-Tone Buddy app which detects the specific sound of the Clip-Tone along with the sound of the inhaler being pressed and provides real time feedback on the screen on how to improve inhaler technique. Together the device and app are known as the Clip-Tone System, CTS.

The study aim is to assess whether a new tool can help people to learn how to use their asthma inhaler better.

Who can participate?
People in England or Wales with asthma aged 16 or above who are regularly prescribed one of the following brands of inhaler and has been using it for at least 1 month:
1. Fostair pMDI (100 mcg Beclometasone/ 6 mcg Formoterol per dose; 200 mcg Beclometasone/ 6mcg Formoterol per dose); Chiesi Ltd
2. Clenil Modulite pMDI (50 mcg, 100 mcg, 200 mcg or 250 mcg Beclometasone per dose); Chiesi Ltd
3. Trimbow pMDI (87 mcg Beclometasone, 5 mcg Formoterol, 9 mcg Glycopyrronium per dose); Chiesi Ltd
4. Seretide Evohaler pMDI (50 mcg Fluticasone/Salmeterol 25 mcg per dose; 125 mcg Fluticasone

/Salmeterol 25 mcg per dose; 250 mcg Fluticasone/ Salmeterol 25 mcg per dose); GSK UK Ltd
5. Flixotide Evohaler pMDI (50 mcg Fluticasone per dose; 125 mcg Fluticasone per dose; 250 mcg Fluticasone per dose); GSK UK Ltd

What does the study involve?
This study will compare the CTS with the usual care asthmatics receive. Once in the study, participants will be allocated to one of the two groups (to receive either usual care or the Clip-Tone System), with an equal chance of being in either group (like tossing a coin). The study will take place remotely via video consultations allowing easy access to the study. The inhaler technique will be assessed in both groups at 1, 3 and 6 months and compared. Asthma symptoms will also be assessed. Participants can keep the CTS at the end of the study and those in the "usual care" group will be given the CTS at the end of the 6-month study period as a "thank-you".

What are the possible benefits and risks of participating?
Benefits:
1. A Greater understanding of correct inhaler use
2. Reinforcement of effective inhaler technique
3. An opportunity to contribute to innovative technology development

Participating in the study is not likely to cause discomfort or expose you to any additional risks.

Participants will continue to use their medication as usual. Those in the intervention group will be asked to use the Clip-Tone system as often as they can when they take their inhaler as prescribed.

Where is the study run from?
The University of Manchester (UK), although visits are able to be held remotely meaning that anyone from England or Wales is able to participate

When is the study starting and how long is it expected to run for?
October 2020 to April 2024

Who is funding the study?
The National Institute for Health and Care Research (UK)

Who is the main contact?
Prof Clare Murray, clare.murray@manchester.ac.uk
Miss Naomi Brooke, Naomi.brooke@manchester.ac.uk

Study website
www.Clin-e-cal.com/Clip-Tone-study

Contact information

Type(s)
Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
312455

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52693, IRAS 312455, Grant codes: NIHR202884

Study information

Scientific Title
Assessment of an electronic system of the impact on inhaler skills and technique

Acronym
ASSIST

Study hypothesis
Participants using the Clip-Tone System will improve inhaler technique scores more than those receiving care as usual.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/05/2022, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8009; gmeast.rec@hra.nhs.uk), ref: 22/NW/0137

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
See additional file

Condition
Asthma

Interventions
Current interventions as of 08/02/2023:
The main aim of the study is to establish whether the use of the Clip-Tone System (CTS) improves and maintains inhaler technique in asthmatic patients over a 6-month period compared with those receiving “usual care” alone. Other aims include:
1. To assess the use of the CTS in asthmatic patients (> 16 years) and its effects on asthma control and unscheduled clinical visits over a period of 6-months
2. To develop an understanding of how patients use CTS in a real-world setting
3. To develop an understanding of what frequency of use of CTS is desirable

The Clip-Tone System technology consists of two parts:
1. Clip-Tone - a small plastic retrofit device available in two variants (developed and manufactured by commercial partner Clement Clarke International; both CE marked, Class I medical devices available on prescription from May 2021)

1.1. Clip-Tone E fits GSK-manufactured Evohalers (Ventolin, Flixotide, Seretide brands)
1.2. Clip-Tone F fits Chiesi-manufactured inhalers (Fostair, Trimbow, Clenil brands)
2. Clip-Tone Buddy app - class I medical device accessory (CE marked), available on Apple and Google app stores.

Both parts of the system are independently protected by patents (granted and pending) - a collaboration agreement is in place clearly delineating background and foreground IP ownership.

We will carry out a randomised controlled study comparing inhaler techniques in those using Clip-Tone System (CTS) with standard care (the “usual care” group) over a 6-month period. Potential recruits will attend an online baseline visit where formal consent to participate will be taken and eligibility criteria checked. The initial inhaler technique will be assessed using a formal inhaler technique score. An asthma control questionnaire will be completed (a validated asthma questionnaire to detect the level of asthma symptom control). Some baseline questions will be asked about their asthma e.g. medication, exacerbations, and HCP involved.

We plan to randomise 126 participants, half to CTS and half to usual care. At the beginning of the study, an online computer programme will be used to generate 150 numbers in random order. At the point of randomisation, the researcher will allocate the next available number to the participant. When this number is an even number the participant will be allocated to the care as usual group. When this number is odd, they will be allocated to the intervention group. Those allocated to the CTS group will have the Clip-Tone posted to them along with a code for the Clip-Tone Buddy App and a short virtual visit will be arranged the following week to ensure the participant knows how to use the device and the features of the app.

Participants will all attend 3 further follow-up visits in 1, 3 and 6 months from the baseline visit. All of the visits will be online remote visits as a default, although those local to the University of Manchester may request a face-to-face visit if preferred. At each visit, the inhaler technique will be assessed using the formal inhaler technique score. An asthma control questionnaire will be completed and a few questions will be asked about asthma healthcare utilisation since the previous visit.

Previous interventions:
The main aim of the study is to establish whether the use of the Clip-Tone System (CTS) improves and maintain inhaler technique in asthmatic patients over a 6-month period compared with those receiving “usual care” alone. Other aims include:
1. To assess the use of the CTS in asthmatic patients (> 16 years) and its effects on asthma control and unscheduled clinical visits over a period of 6-months
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We will carry out a randomised controlled study comparing inhaler technique in those using Clip-Tone System (CTS) with standard care (the “usual care” group) over a 6 month period.

Potential recruits will attend a baseline visit where formal content to participate will be taken and eligibility criteria checked. Initial inhaler technique will be assessed using a formal inhaler technique score. Asthma control questionnaire will be completed (a validated asthma questionnaire to detect level of asthma symptom control). Some baseline questions will be asked about their asthma e.g. medication, exacerbations, HCP involved.

We plan to randomise 126 participants, half to CTS and half to usual care. At the beginning of the study a online computer programme will be used to generate a 150 numbers in a random order. At the point of randomisation the researcher will allocate the next available number to the participant. When this number is an even number the participant will be allocated to the care as usual group. When this number is odd, they will be allocated to the intervention group. Those allocated to the CTS group will have the Clip-Tone posted to them along with a voucher code for the Clip-Tone Buddy App and a short virtual visit will be arranged the following week to ensure the participant knows how to use the device and the features of the app.

Participants will all attend 3 further follow-up visits in 1, 3 and 6 months from the baseline visit. At each inhaler technique will be assessed using the formal inhaler technique score. Asthma control questionnaire will be completed and a few questions will be asked about asthma health care utilisation since the previous visit.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Clip-Tone System

Primary outcome measure
Current primary outcome measure as of 07/02/2024:
Inhaler technique measured using inhalation time at baseline and 6 months and an inhaler technique checklist score (based on UK Inhaler Group standards) at baseline, 1 month, 3 months, and 6 months

Previous primary outcome measure:
Inhaler technique measured using an inhaler technique checklist (based on UK Inhaler Group standards) at baseline, 1 month, 3 months, and 6 months

Secondary outcome measures
1. Asthma control measured using the validated Asthma Control Questionnaire (ACQ) at baseline, 1 month, 3 months, and 6 months.
2. Frequency and pattern of use of the Clip-Tone System measured using usage data within the app at baseline, 1 month, 3 months, and 6 months.
3. Data on unscheduled healthcare visits measured through self-reported questionnaires at baseline, 1 month, 3 months, and 6 months.

Overall study start date

01/10/2020

Overall study end date
30/04/2024

Eligibility

Participant inclusion criteria
1. Provision of signed and dated informed consent
2. Willingness to comply with the study procedures and confirmed availability for the study duration
3. Aged ≥16 years
4. Self-reported asthma diagnosis and currently receiving treatment
5. Regularly prescribed one of the following brands of inhaler and has been using it for at least 1-month prior to enrolment:
5.1. Fostair pMDI (100 mcg Beclometasone/ 6 mcg Formoterol per dose; 200 mcg Beclometasone/ 6mcg Formoterol per dose); Chiesi Ltd
5.2. Clenil Modulite pMDI (50 mcg, 100 mcg, 200 mcg or 250 mcg Beclometasone per dose); Chiesi Ltd
5.3. Trimbow pMDI (87 mcg Beclometasone, 5 mcg Formoterol, 9 mcg Glycopyrronium per dose); Chiesi Ltd
5.4. Seretide Evohaler pMDI (50 mcg Fluticasone/Salmeterol 25 mcg per dose; 125 mcg Fluticasone/Salmeterol 25 mcg per dose; 250 mcg Fluticasone/ Salmeterol 25 mcg per dose); GSK UK Ltd
5.5. Flixotide Evohaler pMDI (50 mcg Fluticasone per dose; 125 mcg Fluticasone per dose; 250 mcg Fluticasone per dose); GSK UK Ltd
6. Access to a smartphone or tablet device and willingness to use it to regularly assess inhaler technique for the study duration

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 126; UK Sample Size: 126

Total final enrolment
126

Participant exclusion criteria
1. Using a spacer to assist with using their inhaler
2. Prescribed oral steroids for asthma in the preceding 1-month

3. Medication is not self-administered
4. Previous treatment for acute asthma in an ICU

Recruitment start date
01/11/2022

Recruitment end date
01/09/2023

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
University of Manchester
School of Biological Sciences
Oxford Road
Manchester
United Kingdom
M13 9PT

Sponsor information

Organisation
University of Manchester

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clinicaltrials@manchester.ac.uk

Sponsor type
University/education

Website

http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study outcomes are intended to be presented at relevant respiratory sector conferences and publication in a peer reviewed journal is planned.

Intention to publish date
31/01/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	15/05/2022	08/06/2022	No	Yes

Protocol file	version 2.0	16/05/2022	04/01/2023	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 4.0	16/01/2024	07/02/2024	No	No
Protocol file	version 5.0	11/03/2024	27/03/2024	No	No