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

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

# Plain English summary of protocol

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

# **Contact information**

Type(s)

Principal investigator

Contact name

Prof Clare Murray

**ORCID ID** 

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### Contact details

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## Type(s)

**Public** 

#### Contact name

Miss Naomi Brooke

## **ORCID ID**

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

312455

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

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 objectives**

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

## Study type(s)

**Treatment** 

## Health condition(s) or problem(s) studied

**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 asthmatic 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 asthmatic control and unscheduled clinical visits over a period of 6-months
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### The Clip-Tone System technology consists of two parts:

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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.

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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(s)

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

# Key secondary outcome(s))

- 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.

# Completion date

30/04/2024

# **Eligibility**

## Key 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

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

16 years

## Sex

Αll

## Total final enrolment

126

## Key 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

### Date of first enrolment

01/11/2022

## Date of final enrolment

01/09/2023

# Locations

## Countries of recruitment

United Kingdom

England

# Study participating centre University of Manchester School of Biological Sciences

Oxford Road Manchester United Kingdom M13 9PT

# Sponsor information

## Organisation

University of Manchester

### **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**

# 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? |
|-------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| HRA research summary          |                               |              | 28/06/2023 | No             | No              |
| Participant information sheet | version 2                     | 15/05/2022   | 08/06/2022 | No             | Yes             |
| Participant information sheet | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| Protocol file                 | version 2.0                   | 16/05/2022   | 04/01/2023 | 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              |
| Study website                 | Study website                 | 11/11/2025   | 11/11/2025 | No             | Yes             |