ASSIST Study:

ASsessment of an electronic System of the Impact on Inhaler Skills and Technique

Participant Information Sheet (PIS)

You are being invited to take part in a research study to investigate a new, digital tool that is designed to help guide people in using their inhaler. We are trying to find out if this tool can help people improve their inhaler technique which in turn may help their asthma. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read it.

About the research

- **Who will conduct the research?**

The research is being carried out at the University of Manchester. The Chief Investigator is Professor Clare Murray, a professor of respiratory medicine at the University of Manchester and Consultant at Manchester University NHS Foundation Trust.

The research is a collaboration with the University and Clin-e-cal Ltd. Clin-e-cal is a company started at the University which has developed the app that is being investigated in this study.

- **What is the purpose of the research?**

It is actually quite difficult to use an inhaler properly and many people who use inhalers for their asthma make mistakes. This can mean that the full dose is not reaching the lungs and people may not be treated as well as they can be or may experience more side effects from the medicine. It is recommended that training on how to use inhalers is given regularly but this may not happen as often as needed.

We would like to test a new tool which has been designed to help guide people to take their inhaler effectively. The tool has two parts - a little device which fits on the inhaler (a Clip-Tone) and a mobile phone app (Clip-Tone Buddy). The Clip-Tone makes a quiet gentle whistling sound when you use your inhaler and inhale at the right speed/strength. The Clip-Tone Buddy app listens for this sound and the sound of the inhaler canister being pressed. Together these are called the Clip-Tone system.

It is simple to use, and patients can use it to guide the use of their inhaler every time they take it. The app can also be used to help remind patients when to take their inhaler and keep a record of when it has been used. We would like to see if people using the Clip-Tone system make fewer mistakes with their inhaler than those who are not using it. This in turn, might lead to people have better control of their asthma and fewer symptoms and side effects.

- **Why have I been invited to take part?**

You have been approached because you may have indicated you would be willing to take part in research related to your asthma and/or your doctor may have identified you as being potentially suitable to take part and given you some information. That is because you are currently prescribed one of the inhalers below and you don't currently use a spacer with your inhaler. We are hoping over 100 people will take part in this study.

Inhaler list

Fostair pMDI All doses	Clenil Modulite pMDI All doses	Trimbow pMDI	Seretide Evohaler pMDI All doses
 Fostair 100 mcg / dose / 6 mcg / dose inhaler	 Clenil Modulite 50 inhaler	 Trimbow 87 mcg / dose / 5 mcg / dose / 9 mcg / dose inhaler	 Seretide 50 Evohaler
 Fostair 200 mcg / dose / 6 mcg / dose inhaler	 Clenil Modulite 100 inhaler		 Seretide 125 Evohaler

	 Clenil Modulite 200 inhaler		 Seretide 250 Evohaler
	 Clenil Modulite 250 inhaler		

- **Will the outcomes of the research be published?**

The findings from the research will be written up in a study report and details of this will be sent to you. We will also hope to publish the findings in academic journals and conference presentations. It may also be used on websites or social media sites. Any publication will not contain any information that will be able to identify any individual.

We will also ask for your permission to use direct quotations, in any research outputs. We will not identify you personally in these quotes.

- **Who has reviewed the research project?**

This study has received Health Research Association (HRA) and NHS ethics approval from xxxx Ethics Committee. (Ethics reference: **xxxxx)**.

In designing this study, we have considered patient opinions on the frequency and nature of participant visits.

- **Who is funding the research project?**

This research has been funded through a grant awarded to the University of Manchester and Clin-e-cal Ltd by the UK Department of Health, National Institute of Health Research (NIHR). The grant was awarded after a competitive process which included peer review.

What would my involvement be?

- **What would I be asked to do if I took part?**

We expect that this research will be able to be conducted through remote video appointments. If you prefer a face-to-face appointment, please let us know and we will accommodate that.

Consent

It is important that you are fully informed about the study before they agree to take part, so please read this leaflet carefully. If you are interested in taking part in the study, we will make an appointment with you to give you an opportunity to ask any questions you have. We will go through the details of the study with you and then formally ask for your consent to take part. This will be recorded and kept with the study records, and we will send you a copy of this consent form. If you need some additional time to consider the information or talk to family or friends, we can make another appointment to complete the consent process.

Study visits

The study will last for 6-months and during that time we will ask you to attend 4 visits. These can all take place virtually (via video-link) or face-to-face. The first visit (baseline – V1) will take slightly longer than the others as we will go through the consent with you. There will be another 3 visits, after 1-month (V2), after 3-months (V3) and the final visit after 6-months (V4). We expect that each of the study visits will take up to 30-minutes. At any point you can ask to withdraw from the study should you so wish.

Baseline visit (V1)

This will take place at the same visit as your consent to take part is taken, once that has been done. The purpose of this visit is to gather some additional information. This will include some questions about you, your asthma and your medication. We will also ask you to demonstrate to us how you use your inhaler. With your consent, we will take a video recording of you taking your inhaler. This is so that your inhaler technique can be independently scored by an expert who has no other role in the study and does not know any information about you. If you do not wish to be video recorded it is possible to opt-out of this part whilst still participating in the research study.

After we have gathered this information, we will randomly allocate you to either using the 'Clip-Tone system' or just to carry on as you would do normally (the 'care as usual' group). You have an equal chance of being allocated to either group.

If you are in the "care as usual" group we would ask that you continue your usual habits, attending medical appointments as before and taking your inhaler as usual.

If you are in the "Clip-Tone system" group, we will send you a Clip-Tone device and some information on how to access the app. We will also make another short appointment once you have received it to make sure you know how to fit it to your inhaler and how to use the app. We will ask you to keep the Clip-Tone on your inhaler and use the app as often as possible. Otherwise, we want you to continue with your usual asthma care, seeing your doctor or asthma nurse as requested.

Visits at 1 and 3 months (V2 and V3)

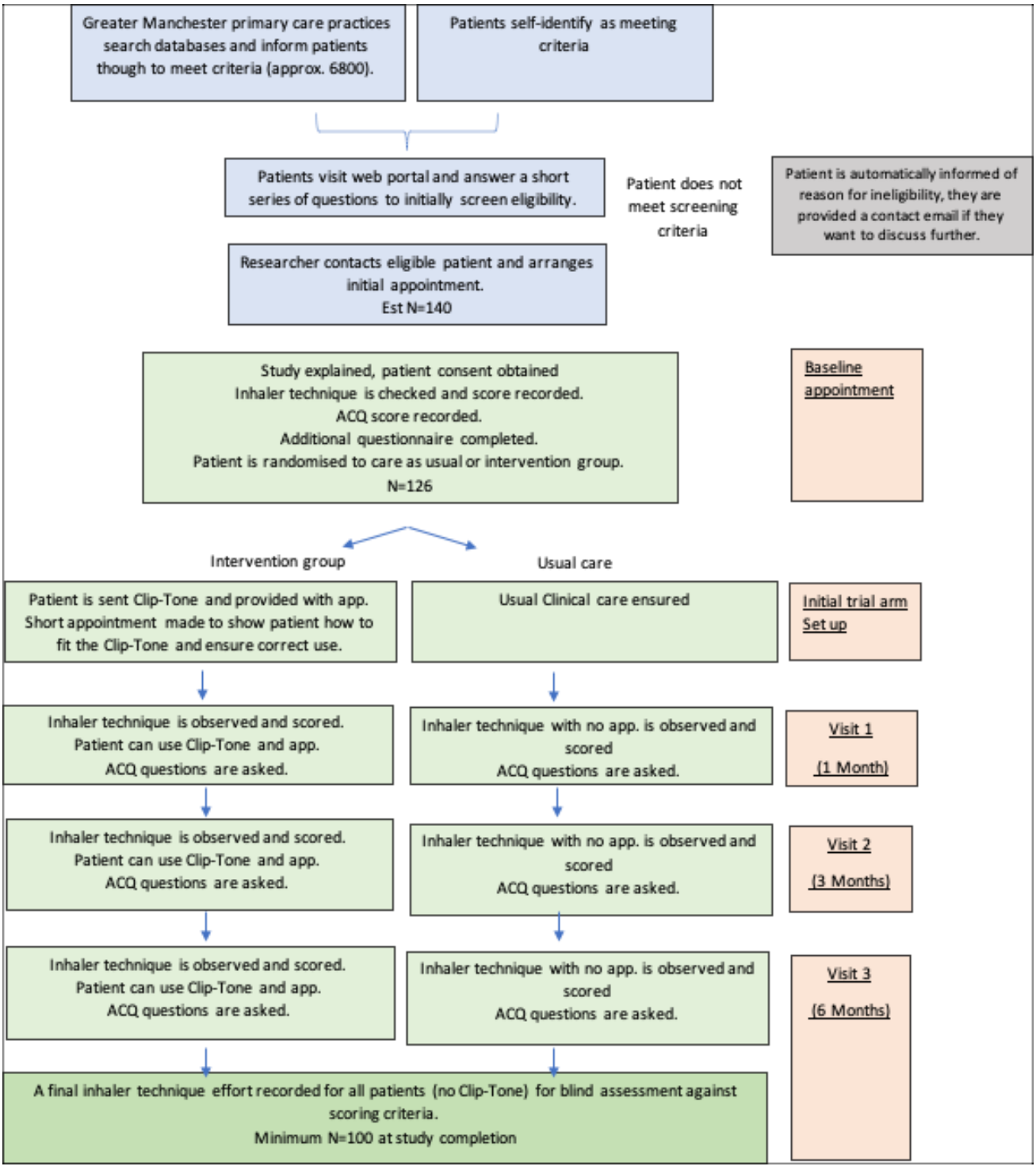
At these visits, we will ask you to demonstrate your inhaler technique. Like the baseline visit, this will be observed by the researcher, but this time will not be recorded. We will also ask you a few questions about your current and recent asthma symptoms.

If you are in the "Clip-Tone system" group, we will ask you to send screenshots of the inhaler tracker which will allow us to see when the app has been used. One of the things we are hoping to understand from this research is how often people need or want to use the Clip-Tone system to improve their inhaler technique, so it doesn't matter if you haven't used it every time you have used your inhaler. We just ask that you continue to use it as often as you can.

Visit at 6 months (V4)

This will be very similar to visits 1 and 2 but, like the baseline visit, we will also video record you using your inhaler. This is so we can independently score your inhaler technique. If you do not wish to be video recorded it is possible to opt-out of this part of the study.

This will be the last visit of the study. When all participants have completed the study our research team will analyse all the data to see if there are any differences between the two groups. We will share the results with you once the analysis has been completed.


Greater Manchester primary care practices search databases and inform patients though to meet criteria (approx. 6800).
Patients self-identify as meeting criteria
Patients visit web portal and answer a short series of questions to initially screen eligibility.
Patient does not meet screening criteria
Patient is automatically informed of reason for ineligibility, they are provided a contact email if they want to discuss further.
Researcher contacts eligible patient and arranges initial appointment.
Est N=140
Study explained, patient consent obtained
Inhaler technique is checked and score recorded.
ACQ score recorded.
Additional questionnaire completed.
Patient is randomised to care as usual or intervention group.
N=126
Baseline appointment
Intervention group
Usual care
Patient is sent Clip-Tone and provided with app. Short appointment made to show patient how to fit the Clip-Tone and ensure correct use.
Usual Clinical care ensured
Initial trial arm Set up
Inhaler technique is observed and scored.
Patient can use Clip-Tone and app.
ACQ questions are asked.
Inhaler technique with no app. is observed and scored
ACQ questions are asked.
Visit 1 (1 Month)
Inhaler technique is observed and scored.
Patient can use Clip-Tone and app.
ACQ questions are asked.
Inhaler technique with no app. is observed and scored
ACQ questions are asked.
Visit 2 (3 Months)
Inhaler technique is observed and scored.
Patient can use Clip-Tone and app.
ACQ questions are asked.
Inhaler technique with no app. is observed and scored
ACQ questions are asked.
Visit 3 (6 Months)
A final inhaler technique effort recorded for all patients (no Clip-Tone) for blind assessment against scoring criteria.
Minimum N=100 at study completion

Those in the "Clip-Tone system" group are welcome to keep the system at the end of the study and continue using it should they wish.

For those of you in the "Usual care group ", we will happily send the Clip-Tone system to you to keep should you like to give it a try.

- **What are the possible disadvantages and risks of taking part?**

By taking part in the research, we will be asking you to agree to provide some personal information. This will not be shared outside of the research team. It is necessary to collect this information so that we can contact you during the study and so that we can understand if there are any factors which may influence the results of the research. All data will be kept securely in a secure database. The data that is analysed and published will not contain any of your personal information and there will be no way of identifying you as an individual from the information.

We don't anticipate that there will be any risk of harm to you by taking part.

- **Will I be compensated for taking part?**

You will receive £15 for each visit you attend. This is to cover any expenses you may incur and to compensate for your time. The payment will be made soon after the visit has completed.

If you think you may incur additional expenses by taking part please talk to the research team.

- **What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to take part. By responding to the contact from the researcher you will indicate that you are considering taking part. If you do not wish to, please let the researcher know or simply do not respond. If you do decide to take part, you will be given this information sheet to keep. At the first visit the researcher will talk to you about the study and you will be able to clearly indicate to the researcher whether or not you wish to take part and you will be asked to provide verbal consent. Even if you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to you or affecting your medical care in any way. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part, you do not need to do anything further.

At two points in the study, we will ask for your specific consent to video record you taking your inhaler. This is so that your technique can be independently assessed by an expert who does not know whether you have been using the Clip-Tone system or not. You are free to opt out of the video recording but continue in the rest of the study, should you wish. It is important that you always feel comfortable with the recording, and you will be able to request it is stopped at any point. The expert assessor will be a qualified nurse and a contract will be in place to ensure that confidentiality is protected at all times. They will not have any knowledge of any personal details about you (e.g., your name).

Data Protection and Confidentiality

- **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically, we will need to collect:

- Some personal data, including your name, age, gender, ethnicity and part of your postcode.
- Some information about your medical history, particularly related to your asthma. We may also ask if you have other conditions which may affect your asthma or your ability to take part in the study.

It is important that we collect this information so that we can find out if the Clip-Tone system is particularly beneficial for certain groups of people. We also want to know if we have included a diverse group of participants.

Identifiable data (including consent forms) will be stored in a secure electronic database. The database is specifically designed for holding clinical trial information and has the highest security standards.

Data taken from the secure database will be anonymised before it is exported. Other research data will be stored for 5 years after publication or public release of the work of the research.

We will also need to ask you for some personal information to allow you to receive payments described. This will need to be shared with personnel making the payments on our behalf. Once the payment has been made the information will not be stored.

The researcher and immediate research team will have access to all of the research data.

The anonymised data will be shared with other collaborators helping with the study. Nothing in this data will be able to identify you as an individual.

We will also ask your permission to use this data in future studies, and to share this with other researchers (e.g., in online databases). It will not be possible to identify any person individually from this data.

When we ask for permission to take video recordings, the recordings will be taken side on of your head and shoulders. We will capture the whole process of you taking your inhaler and will only ask you to speak to confirm that you have consented to the recording.

Where appointments are taking place remotely, we will use the video conferencing software Zoom to make the recordings. In this circumstance, your personal data will be processed by Zoom. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third-party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

Where appointments are face-to-face, recordings will be taken using the researcher's device. The recordings will added to the electronic clinical record form as soon as possible and will be permanently removed from the device.

- **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

- **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including the video recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research (http://documents.manchester.ac.uk/display.aspx?DocID=37095).

- **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester and Clin-e-cal Ltd will be joint Data Controllers for this study. This means that both organisations are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. The University of Manchester has primary responsibility for compliance with the UK data protection obligations.

All researchers are trained with this in mind, and your data will be looked after in the following way:

1) To ensure confidentiality, when you enrol in the study you will assigned a participant ID. The data we collect about you in the study will only be stored with this unique ID number and with no identifying features (e.g., name, date of birth, postcode). The link between this ID and your identity along with your personal and contact details will stored in a password protected encrypted database separately from your study data and will only be accessible only to the researcher and the chief investigator of the study.
2) When your data is being analysed all identifiable data, including the random participant ID, will be removed and the data will not be able to be linked to you as an individual. This is complete anonymisation.
3) The data will be stored in a secure cloud database on servers located in the EU. This is fully compliant with EU and UK data protection laws. Only fully anonymised data will be exported from the database.
4) We will share data with external organisations if it is considered necessary (for example if additional expert analysis is required). If this is necessary, it will only be completely anonymised data that is transferred, and this will be done via secure transfer. Data sharing agreements will be in place which ensure that data is not used for any purpose not agreed.
5) Once the study is complete, the key linking the data to your identity will be retained for up to 1-year. This is in case we need to contact you for any reason whilst the data is still being analysed. Once all analysis has been completed, we will no longer keep your personal and contact details.

The study team at The University of Manchester will have access to your personal information in order that they can contact you during the study. As we discussed above you are free to withdraw from the study at any point and request that the team no longer

contacts you. During the study the research team will contact you to remind you of study visits. They will contact you a maximum of 3-times if no response is obtained.

When you agree to take part in a research study and with your informed consent, the information about you may be provided to researchers running other studies here or at other organisations. With your consent your information will be [shared/archived] in order to support additional research in accordance with the UK Policy Framework for Health and Social Care Research.

When shared, this information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of a public interest task" and "a process necessary for research purposes and cannot be used to contact you regarding any other matter.

The video recordings will be shared with an external clinical expert, via a secure portal, for the purposes of validating the inhaler technique assessment. The videos will not be linked to any personal information, just be labelled with your study ID Number. Once the assessment is complete the external expert will destroy the recordings and will no longer be able to access them. The videos will be retained along with other data in the case record.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

- **Will you inform my GP that I am taking part?**

With your permission we will send a letter to your GP to let them know that you are participating in the study. The letter will be added to you file, but it will not affect any care that you need or receive. When we ask for your consent to take part in the study you will be asked about whether you are happy for us to send a letter to your GP, this is entirely optional. If you do not wish your GP to be informed you can still participate in the study.

What if I have a complaint?

If you have a concern about any aspect of this study, please contact the researcher or the Chief Investigator, Professor Clare Murray (see contact details below), and we will do our best to answer your query.

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

- The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email:

- dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information

- https://ico.org.uk/concerns Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part, then please contact the researcher or chief investigator on the email or number below:

Primary Researcher

Name xxxxxxx
[name and contact details tbc
Name, address, email, telephone]

ERC, Wythenshawe Hospital, Manchester, M23 9LT

Chief Investigator

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