

Participant Information Sheet

Consultation with clinicians to investigate the effectiveness of the Rafi-Tone app (in conjunction with the Able Spacer)

We would like to invite you to take part in an evaluation study. Before you decide, we would like to provide you with information about why the evaluation is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please don't hesitate to let us know. We will be happy to discuss any point. Participation is entirely voluntary. Thank you for your time.

What is the purpose of the study?

We are Clin-e-cal, a digital health company. We have created the Rafi-Tone app, designed for children age 2-5 using inhalers with a spacer and a mask, Rafi-Tone is a fun app to make inhaler use less scary. It works alongside the Able Spacer and innovative whistle mask specifically designed to encourage good technique and develop confidence to help children use their inhaler and spacer correctly. Correct use of the spacer triggers a game on the app that children can enjoy.

We are currently seeking to evaluate Rafi-Tone. We are asking clinicians who are prescribing asthma inhaler spacers for their feedback. It is not necessary for you to be familiar with Rafi-Tone to be able to contribute to this study.

All responses to our questionnaire will be shared with the University of Chester for the purpose of analysis and production of a written report. The report will be shared with AHSN (Innovation Agency / Health Innovation Manchester) and will inform future market development opportunities.

Why have I been chosen?

You have been chosen because you are a clinician prescribing medication and medical devices for the treatment of asthma.

Do I have to take part?

It is up to you to decide whether or not to take part. We have sent you the invite by email so that you have a copy of this information sheet to keep. Participation is via an online questionnaire. Completion of the questionnaire will indicate your consent to participate. If you decide to take part you are still free to withdraw up to the point where you submit your responses to the questionnaire. You do not need to give any reason for not participating.

What will happen if I take part?

If you decide to take part, your submitted response to the online questionnaire will indicate that you have consented to participation in the study.

Responses collected via the online questionnaire will be analysed by the University of Chester in order to answer the evaluation questions pertinent to the Real World Validation of Rafi-Tone.

You will not be required to participate in any additional activities for this study and your contact data collected for the purpose of inviting you to participate will not be shared.

No individuals or practices will be identifiable in the final report but volume of responses and the job titles of clinicians will be included.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks foreseen in taking part in the study.

What are the possible benefits of taking part?

The purpose of this study is to provide a robust evaluation of Rafi-Tone. Your participation will provide a unique insight informed by your professional practice and experience. This will be very valuable to inform the real world validation.

What if something goes wrong?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please contact:

Dr Elizabeth Crawford
Room 7 Harefield House
Alderley Road
Wilmslow
SK9 6LL
Email: lizzie@clin-e-cal.com
Tel: 07773393716

If you are harmed by taking part in this evaluation project, there are no special compensation arrangements. Clin-e-cal does not accept liability for harm which does not result from its negligence. In the event that something does go wrong and a participant is harmed during the evaluation, and the harm sustained is due to the negligent acts of those undertaking the evaluation, then the participant may have grounds to bring legal action. Anyone bringing such legal action may incur legal costs.

Will my taking part in the study be kept confidential?

All contact information which is collected during the course of the evaluation will be kept strictly confidential. Data will be used only for the purposes outlined in this document. All data will be stored on password protected, secure computer systems accessible only by relevant employees of the company.

Only anonymised responses to the questionnaire will be supplied to the University of Chester for the purposes of analysis and reporting.

What will happen to my data?

Participants should note that data collected from this project may be retained and published in an anonymised form. By agreeing to participate in this project, you are consenting to the retention and publication of data.

What will happen to the results of the evaluation study?

The results will be written up into a report and shared with the AHSN and other parties. The report will be available for the University of Chester, the AHSN or the SME to share further and to reference in future publications.

Individuals and practices who participate will not be identified in any subsequent report or publication.

Who is organising and funding the evaluation?

The evaluation is funded by the ERDF, via the Health MATTERS Programme.

The University of Chester works in partnership with the Innovation Agency North West to deliver Priority 3 European Regional Development Programme Health MATTERS. The Innovation Agency identifies businesses that have services and products that can be of benefit to Health and Social Care services and offers them help and support to commercialise their offering.

Who may I contact for further information?

If you would like more information about the evaluation before you decide whether or not you would be willing to take part, please contact: If you would like more information about the evaluation before you decide whether or not you would be willing to take part, please contact: lizzie@clin-e-cal.com

Thank you for your interest in this evaluation.