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Participant-Information Sheet

SELF-BREATHE for Chronic Breathlessness

A multicentre randomised controlled trial comparing usual NHS care to a self-guided internet-based intervention (SELF-BREATHE) plus usual NHS care to reduce breathlessness in adults living with chronic breathlessness

PART 1

We'd like to invite you to take part in our research study.

Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it would involve for you.

Some from the research team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have.

Please feel free to talk to others about the study if you wish.

The first part of the Participant information sheet tells you the purpose of the study and what will happen to you if you take part.

The second part will give you more detailed information about the conduct of the study. Please ask if anything is unclear.

What is the purpose of the study?

Research has shown that Breathlessness clinics, which focus on non – drug ways to self-manage breathlessness have been shown to improve patient's ability to cope with their breathlessness, improving their quality of life. The NHS does not currently provide such services. Therefore, alternative ways of providing patients access to these breathlessness treatments are needed. The internet provides a potential way by which patients could access these treatments. SELF-BREATHE provides one potential solution. SELF-BREATHE is an online breathlessness self-management programme that has been developed alongside people living with breathlessness due to advanced disease. SELF-BREATHE provides patients with simple self-guided non-drug treatments to try and reduce breathlessness such as breathing control exercises, exercises to increase daily activity levels, pacing advice. The aim of SELF-BREATHE is to help patients improve their breathlessness self –

management. We recently conducted a study to test if SELF-BREATHE was feasible to deliver and acceptable to individuals living with breathlessness. In this study we found that SELF-BREATHE is feasible to provide, easy to use and valued by users.

It is **unknown** if SELF-BREATHE improves patients' breathlessness. The aim of this study is to see if using SELF-BREATHE for 6 weeks improves people's breathlessness.

We are looking to recruit people living with chronic breathlessness to help us test SELF-BREATHE. Participants that decide to take part in this study will complete three assessments over a 12-week period: one at the start of the study, seven and 12 weeks later. These assessments will ask you questions about your breathlessness and activity levels. After the first assessment participants will be allocated randomly to either to have access to SELF-BREATHE (treatment group) or not have access to SELF-BREATHE (control group). No matter which group you are in you will still have access to your usual NHS care, so no support is taken away from you.

Why have I been invited?

You have been invited to take part because you have been identified by your doctor / health professional as someone living with chronic breathlessness. Your experiences are therefore highly valuable and relevant to our research.

We expect approximately 248 patients will take part, from across England.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be able to keep this information sheet and think about taking part. Please feel free to discuss the information with anyone you wish including your family and friends. If you agree, we will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

Signing up to the study: If you would like to know more a member of the research team will discuss the study and go through the patient information sheet and answer any questions you may have. If you are happy to take part, they will arrange a date / time to obtain consent that is most convenient for you.

If you are happy to take part, you will be asked to date and sign a consent form.

Consent and the research questionnaire can be completed face to face, over the phone or via video call or via the post, whichever is most convenient for you. If you complete the consent form over

the phone or video call, you will be asked to return the consent form and completed questionnaires using a self-addressed pre –paid envelope that the research team will provide you with.

A typical course of events for you might be as follows: After signing the consent form, the researcher will ask you to complete some questionnaires, about your age, ethnicity, breathlessness, and activity levels. With your consent the research team will look at your medical notes to obtain additional information about your lung disease i.e., your most recent lung function tests (if available within a 12-month period).

Once this initial assessment is completed, you will be allocated randomly (like flipping a coin) to receive either access to the SELF BREATHE online website for 6 weeks, or normal care. There is currently no standardised treatment for chronic breathlessness in the NHS, and there are currently no online, supportive services available to people with chronic breathlessness in the UK.

We will randomly allocate half of the participants to the website group (SELF-BREATHE) and half to the usual care group. To ensure this study is performed in a scientific manner, we cannot select which group you are allocated to, and you will be randomised by a computer system

If you are randomised to the usual care group, you will continue with your routine clinic, hospital appointments / care as normal.

If you are randomly allocated to the online resource group (SELF-BREATHE), you will be provided with log in details, which will provide you with access to SELF-BREATHE. You will be provided with a SELF-BREATHE user guide to help guide you on how to log on and use SELF-BREATHE. Approximately, 24 - 48 hrs after receiving your log on details, a member of the SELF-BREATHE team will call you to see if you have been able to log on to SELF-BREATHE and answer any questions you may have. The expectation is that you will log on to SELF-BREATHE at least twice a week, over 6 weeks. Within SELF-BREATHE you will be provided with information on breathlessness self-management such as breathing exercises, exercise that can be done at home to improve your fitness and breathing, pacing advice etc... By logging on at least twice a week, this will help you learn and practice these new techniques. In early testing of SELF-BREATHE, users reported that they spent approximately 30 – 45 mins on SELF-BREATHE each time they logged on. In addition, each time you log on to SELF-BREATHE you can record how breathless you are, this way you can keep track of your breathlessness. If your breathless scores worsen, this will be flagged by SELF-BREATHE. In this case you will need to seek appropriate medical advice via 111 or your GP. SELF-BREATHE is unable to provide you with medical advice or support if you are unwell.

After seven and 12 weeks both groups will be asked to complete research questionnaires, as they did at the start of the study. You will be asked not to tell the person conducting the assessments which group you have been allocated into.

If you were allocated to the SELF-BREATHE arm of the study, you may be asked if you would be happy to take part in an **OPTIONAL** research interview to explore your experience of using SELF-BREATHE. Taking part in these research interviews is voluntary. If at the end of the study you are happy to take part in the research interview, the research team will discuss this with you in detail and provide you with a participant information sheet specific to these research interviews.

What are the alternatives for treatment?

This study is testing a new online supportive website (SELF-BREATHE) to help patients better manage their breathlessness. There are currently no other online supportive treatments specifically for chronic breathlessness. If you decide not to take part in the trial, you will continue with your usual hospital / clinic visits.

What are the possible benefits of taking part?

For those allocated to the intervention arm using SELF-BREATHE may help their breathlessness, but we can't promise that this will happen. The purpose of the study is to see if there are any benefits to using SELF-BREATHE. Importantly, the information we get from this study will help improve the future treatment of people with Chronic Breathlessness. The main benefit is to help improve the care for future patients. Your involvement in this study will help us answer the question: does using SELF-BREATHE for 6 weeks improve people's breathlessness?

You may also receive a summary of the findings from the research study at the end of the project if you wish.

What are the possible disadvantages and risks of taking part?

If you agree to take part in this study, there will be additional time involved to follow the SELF-BREATHE programme (logging on 2-3 times a week over six weeks) if allocated to the SELF-BREATHE arm of the study and complete the research questionnaires. For all participants in the study, this will involve three research assessments over a 12-week period. To minimise your inconvenience, these research assessments will be scheduled at a time most convenient for you.

Who is organising and funding this study?

The Researcher in charge of this study is Dr Charles Reilly from Kings College Hospital NHS Foundation Trust, London. The study is funded by the National Institute for Health Research (NIHR) and is being managed by King's College Hospital NHS Foundation Trust, London, SE5 9RS.

How have patients and the public been involved in this study?

Service users helped develop the research question, SELF-BREATHE website and what research questions the study asks. Patient and public involvement (PPI) will continue to be involved in the running and oversight of the study.

Who has approved this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the London – Bromley Research Ethics Committee, REC NUMBER: 24/LO/0142. It has also been approved by the Health Research Authority and your local hospital also approved that the study can go ahead.

Expenses and Payments

We have designed the study, so that the research questionnaires can be completed by you at home by yourself or with the help from a member of the research team, therefore there is no need for additional hospital research specific visits. You will not receive any payment for taking part in this research.

What happens when the research study stops?

If you are in the SELF-BREATHE group, access to this website will stop after the 12 weeks. You will continue to receive usual NHS care, as you did during the study. If you are in the other group (the control group) there will be no change. At the end of the study, we will look at the data gathered, which will help us understand if SELF-BREATHE helps improve people's breathlessness e.g., reduce their breathlessness, reduced their need to attend the emergency department because of their breathlessness. Importantly, the information gained from this study will help us know if SELF-BREATHE should be offered as an NHS supportive treatment for people living with breathlessness.

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2

What if new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, someone from the study research team will tell you and discuss whether you should continue in the study.

If you decide not to carry on, your study research team will make arrangements for your care to continue. If you decide to continue in the study, we may ask you to sign a new consent form. This new information that becomes available might specifically affect you and your health. If this happens, your study research team might consider that you should withdraw from the study and they will explain the reasons for withdrawing you from the study and arrange for your care to continue.

If the study is stopped for any other reason, we will tell you and arrange for your continuing care.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time; and if you would like to do so; please contact a member of the research team <**Insert Research team contact details**>

Your decision to withdraw from the study will not affect the care you receive. If you do withdraw from the study during the research project, you will not be required to participate in any further study visits or complete any questionnaires. Any data that has already been collected up until the time you withdraw may still be used.

If you withdraw consent, information that we have already collected about you may be used and cannot be deleted.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the Principal Investigator leading the research at your hospital <INSERT PI DETAILS HERE> who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure by contacting your local Patient Advice Liaison Service (PALS) office. Details of your local office can be obtained by asking your study research team, GP, telephoning your local hospital or looking on the NHS choices website. https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against King's College Hospital NHS Foundation Trust, but you may have to pay your/any legal costs.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study the normal National Health Service complaints mechanisms are available to you. Please contact the research team if you would like more information on this.

Will my taking part be kept confidential?

Yes, all the data you provide will be confidential. Only the research team and individuals supervised by members of the research team will have access to your personal information.

If you consent to take part in the research, any of the information collected about you may be inspected by the sponsor (including representatives of the sponsor). These inspections are solely for the purposes of the research and analysing the results. Your records may also be looked at by the regulatory authorities or ethics committees to check that the study is being carried out correctly.

The organisations listed above will keep information about you confidential and secure. Your name will not be used in any reports about the study and all data is stored in accordance with the principle of the Data Protection Act 2018. However, with your consent the research team may tell your GP about your participation if you agree to enter the study.

Involvement of the General Practitioner/Family Doctor (GP)

With your consent, your GP will be informed of your involvement in the study.

What will happen to the information I provide?

As detailed above, all information will be link-anonymised. This means names, places and other identifiable information will be stored securely and separately, and this information will not be included when the data is analysed and written up.

Anonymous information will be kept in line with your local hospital guidelines for a period of 7 years. This anonymised information may be shared with other researchers in the department for the purpose of additional analysis.

What will happen to the results of the research study?

The findings from the study questionnaires and interviews will be written up and presented at clinical and research conferences, to the funder and in journal publications. Your data included in these publications and reports will be anonymous and not traceable to you.

How will we use your data?

We will need to use information from you and from your medical records for this research project.

This information will include your name and date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- on the Health Research Authority website www.hra.nhs.uk/information-about-patients/
- in a leaflet called: Data Security and Privacy document for SELF-BREATHE study V1 25/09/2023 provided alongside this patient information sheet
- in a leaflet called: How We Will Use Your Data KCH V1 (21-11-19) – available from the study team
- By asking one of the research team
- by emailing the Data Protection Officer at Kings College London who have overall responsibility for the study on kch-tr.dpo@nhs.net

Thank you

Thank you for considering taking part and taking the time to read this information sheet.

If you decide to take part in the study, we will give you a copy of the information sheet and a signed consent form to keep.

Further information and contact details

If the details on this information sheet do not answer all your questions, then please contact:

<INSERT RESEARCH TEAM DETAILS>