Participant Information Sheet PHASE 2

Study Title: **Reducing fatigue in 'Long COVID-19': A feasibility study of a self-help intervention to reduce fatigue-related symptoms among patients in general practice**

Short Title: **Reducing fatigue in 'Long COVID-19' PHASE 2**

Principal Investigator: Dr Adrian Heald

1. Introduction

The Northern Care Alliance NHS Foundation Trust (NCAFT) is a group of four Care Organisations comprising Salford, Oldham, Bury and Rochdale. These organisations operate within the NCAFT and are highly research active.

You are being invited to take part in a study being sponsored by the Northern Care Alliance NHS Foundation Trust. Before you decide it is important for you to understand why this research 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. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

2. Why have I been invited to take part?

You are being invited to take part in this study because you have previously tested positive for COVID-19 (SARS-CoV-2 test) and are registered with a GP in Salford. You have already taken part in our Phase 1 survey and reported you are still experiencing some fatigue that we think might be associated with what is called Long COVID.

3. What is the purpose of the research?

Phase 1 helped us to understand the number of people experiencing longer term symptoms such as fatigue. Phase 2 is a research study to see if it is possible to help reduce this fatigue and what the best time to offer this self-help intervention is.

Our intervention is adapted from a self-help treatment that is currently used by patients with Chronic Fatigue Syndrome / Myalgic Encephalomyelitis (CFS/ME).We know that the fatigue you are experiencing is similar to CFS/ME, although there is much uncertainty around how alike the conditions are.

The treatment is based on a theory for the cause of symptoms fatigue in both CFS/ME and Long Covid, which is one of several. The underlying mechanism(s) have not yet been established.

We know that the fatigue you are experiencing is similar, so this research is to see if this approach will help patients with Long COVID. This does not mean that you have CFS/ME, just that we are testing some of the treatments used to see if we can help symptoms of Long COVID.

4. What will happen if I take part?

If you agree to participate in this study, we will ask you to provide your name and contact details (email and telephone number). A member of our research team will telephone you and ask if you have any questions. They will read the consent form to you over the phone, and you will be asked to confirm each point on the written consent form you received alongside this Participant Information Sheet. You will then be asked for your address. Your GP will be informed that you are taking part in the study.

The information collected about you may be used to support other research in the future, and may be shared anonymously with other researchers.

Participants who agree to participate in the study will then be allocated at random to one of two groups:

Group A: Immediate Intervention Group
You will be sent a pack by post containing all the items recommended to use. These will be provided free of charge by the research team. The pack will contain:

Instruction leaflet and link to online demonstration (or DVD if preferred)
Bottle almond oil or non-nut oil as alternative (fragrance free)
Long handled back massager
Hot water bottle
Gel cool pack

You will be asked to follow the instructions provided daily; this comprises:

Self-massage of the head, neck and chest
Gentle mobility exercises
Breathing exercises
Alternating warm and cool packs on the upper spine
'Active head rest'

The total amount of time that you spend is up to 45 minutes per day

Your current treatment will not be affected

You will be provided with the name and contact details for one of our Fund for Osteopathic Research into ME
(FORME) Patient liaison advisors who can assist with any questions you have around following these instructions. There is no time limit to your using the intervention, although we would like you to use it for three months if possible. We will ask you to complete a tick sheet, so we know how long you have used the intervention for and you are free to keep the equipment provided after the study ends.

Group B: Waiting-list Intervention Group
You will receive your pack exactly the same as the participants in Group A, but in 3 months' time when you start the intervention itself. This is unlike most research studies where only one group of participants receive the intervention being tested and is called a cross-over study.

Your pack will be posted to you as soon as we receive your 3-month follow-up survey question responses (see follow-ups below).

Follow-ups: We will ask you questions in 3 and 6 months from now.
Participants in both groups (A&B) will be asked to complete the same questions on fatigue, functioning and quality of life that you first completed in Phase 1. In addition, we will ask how

often you have managed to complete the self-massage, mobility exercises and using the alternating warm and cool packs. There are no right or wrong answers, and we are only interested in how they are being used. We expect this to take 10-15 minutes in total.

You will therefore be asked these questions twice in Phase 2 of the study.

Qualitative Interviews: Around 20 participants (including people in both group A&B) will be invited to participate in a telephone interview about their experience of using the intervention and taking part in the study. The interview will be at a convenient time for you and will be audio-recorded by the interviewer. The interview will use your study number and you will not be identifiable. The audio-recording will be transcribed (turned into a word document) and used to look at what participants find helpful, difficult and how the study could be improved as well as the impact that they feel it has had. You can request a written copy of this interview if you wish.

There will only be one interview for each person. Should the questions cause any distress you must let the interviewer know and the interview may terminated at that point.

Audio recordings will be destroyed after transcription.

Medical Records: We will ask you GP for some information from your medical records - the information that we require from your GP record is past medical history and current documented problems, current medication and COVID-19 test results since March 2020.

5. Do I have to take part?

No, taking part is voluntary and it is up to you to decide whether or not to take part. Any help you give is very much appreciated. If you decide to take part, you are free to withdraw at any time without giving a reason. A decision to withdraw at any time will not affect the standard of any care you receive. If you decide not to take part, you do not have to give a reason.

6. What are the possible benefits of taking part?

The study may not have a direct benefit to you but will help our understanding of the symptoms of Long COVID and how we can best help to reduce fatigue.

Unlike most research studies where only one group of participants receive the intervention being tested, all participants will receive the intervention and be provided with all the items necessary to carry out the self-help free of charge.

In Phase 2 of the research, you will be given a self-treatment strategy that currently is not normally available within the National Health Service. This may reduce your symptoms and benefit your overall state of health.

You will be provided with all the materials to enable you to carry out the home routine including a British Standard approved hot water bottle and cool pack, a hand-held massage device and a DVD with easy-to-follow instructions.

You will be free to keep the equipment, allowing you to continue using the equipment after you have completed your participation in the study.

Throughout the study, if you have any concerns, you will be able to contact our patient liaison officer who will answer any queries and offer advice regarding the self-help intervention.

7. What are the possible disadvantages and risks of taking part?

Although it is easy to carry out the self-treatment strategy, it does take some time to complete on a daily basis (around half an hour in total for a few minutes at a time).

The intervention may initially lead to side effects such as nausea and headaches. However, these symptoms are temporary and should pass as you continue with the self-treatment.

8. *a)* How will we use information about you?

We will need to use information from you for this research project.

Only members of the research team will have access to your name and contact details. Your data will have a code number instead. We will be able to link your code number to your GP practice.

We will need your contact details if you wish to participate in Phase 2 to be able to consent you into the study and to be able to send you the intervention pack by post. We will also use this information to be able to invite you to participate in a qualitative interview if you are selected.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

Any information that you provide during the qualitative interview will not be attributed directly to you and with your permission if we wish to publish any quotes you make, we will ensure that neither you nor your GP are identifiable.

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.

8. *b)* 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.

8. *c)* Where can you find out more about how your information is used?

You can find out more about how we use your information

a) at www.hra.nhs.uk/information-about-patients/
b) our leaflet available from https://www.ncaresearch.org.uk/patients-public/
c) by asking one of the research team (details below)
d) by contacting the Northern Care Alliance NHS Foundation Trust Data Protection Officer DataProtection.Officer@nca.nhs.uk
e) by viewing the Sponsor's privacy link http://srft.nhs.uk/for-patients/information/privacy-notice-adults/

9. Expenses and payments?

We are unable to pay you for participating in this study, but we will provide the equipment you need to take part.

10. What will happen to the results of the research study?

The final outcomes from the study will be communicated via presentations in scientific meetings and by peer reviewed publications. This can be shared with participants if they wish. We will aim to publish the results approximately 12 months after people join the Phase 2 study.

11. Who is organising and funding the research?

The research is organised by a team of researchers at Salford Royal Care Organisation and the University of Manchester. The research is funded by Fund for Osteopathic Research into ME (FORME) with management oversight (Sponsorship) is provided by Northern Care Alliance NHS Foundation Trust.

12. Who has reviewed this study?

We can confirm that the study has been reviewed and approved by an appropriate NHS Research Ethics Committee, (London-Chelsea Research Ethics Committees).

13. What if there is a problem?

If taking part in the study harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you have a concern about any aspect of the way you have been approached or treated during this study, you should speak to the researchers who will do their best to answer your questions (see contact details below).

If you have any complaints about the treatment you have received as part of this study, you can contact the hospital PALs (Patient Advise and Liaison Services) team:

Patient Advice and Liaison Service
Northern Care Alliance NHS Foundation Trust,
Salford Care Organisation
Stott Lane, Salford M6 8HD
Telephone: 0161 206 2003

Contact Names and Details for Further Information

If you have any questions about this research please write to us or call us on 0161 206 2188
Thank you for taking the time to read this information sheet.

Principle Investigator Dr Adrian Heald
Telephone: 0161 206 0108
Email:Adrian.heald@nca.nhs.uk

Research Practitioner: Gemma Squires
Telephone: 0161 206 2188
Email: gemma.squires@nca.nhs.uk

Study Coordinator Dr Lisa Riste
Email: lisa.riste@manchester.ac.uk

Thank you for taking the time to read this participant information sheet. Please do not hesitate to contact the study team as above for any further information or if you have any questions