Participant Information Sheet
(Final version 1.2: 23.03.2021)

IRAS Project ID: 292227

Title of Study: **Development of a return-to-work intervention for COVID-19 patients.**

Name of Chief Investigator: Professor Richard Morriss

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

We are developing an intervention to support those who had COVID-19 and as a result, are struggling to return to work after recovery.

COVID-19 is an infectious disease targeting the respiratory system which has caused a worldwide pandemic. The few months following the first recoveries gave rise to issues linked to patients struggling to return to their normal life after recovery with some patients who were hospitalised with COVID-19 developing a post-COVID-19 syndrome that is not resolving after several months. Notably, these patients are struggling to return to work as they feel they may still be ill. The aim of the study is to assess the intervention effectiveness before testing it on a larger scale.

The intervention will be delivered remotely over up-to-12 weeks and involve sessions with an occupational therapist. There is also a possibility to involve your employer. In addition to attending classes, you will be required to go through 4 telephone assessments (before, during after, a month later) so that we can assess your progress. Each assessment will last about an hour. Following the intervention, participants will be interviewed to discuss the acceptability of the intervention.

Why have I been invited?

You have been invited because of your recent diagnosis of COVID-19 in the recent past and currently attending rehabilitation clinics. You are not diagnosed with any other respiratory illness and you do not suffer from any physical or mental health that could cause deconditioning, defined as a decline in ability to exercise or be active often due to a lack of physical activity causing deterioration of the muscles, bones or mind.

We are aiming to recruit 6 participants for this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form – you will be emailed a copy of your signed consent form. Your participation is voluntary, so if you decide to take part, you are free to withdraw at any time and without giving any reason. This would not affect your medical care or legal rights.

What will happen to me if I take part?

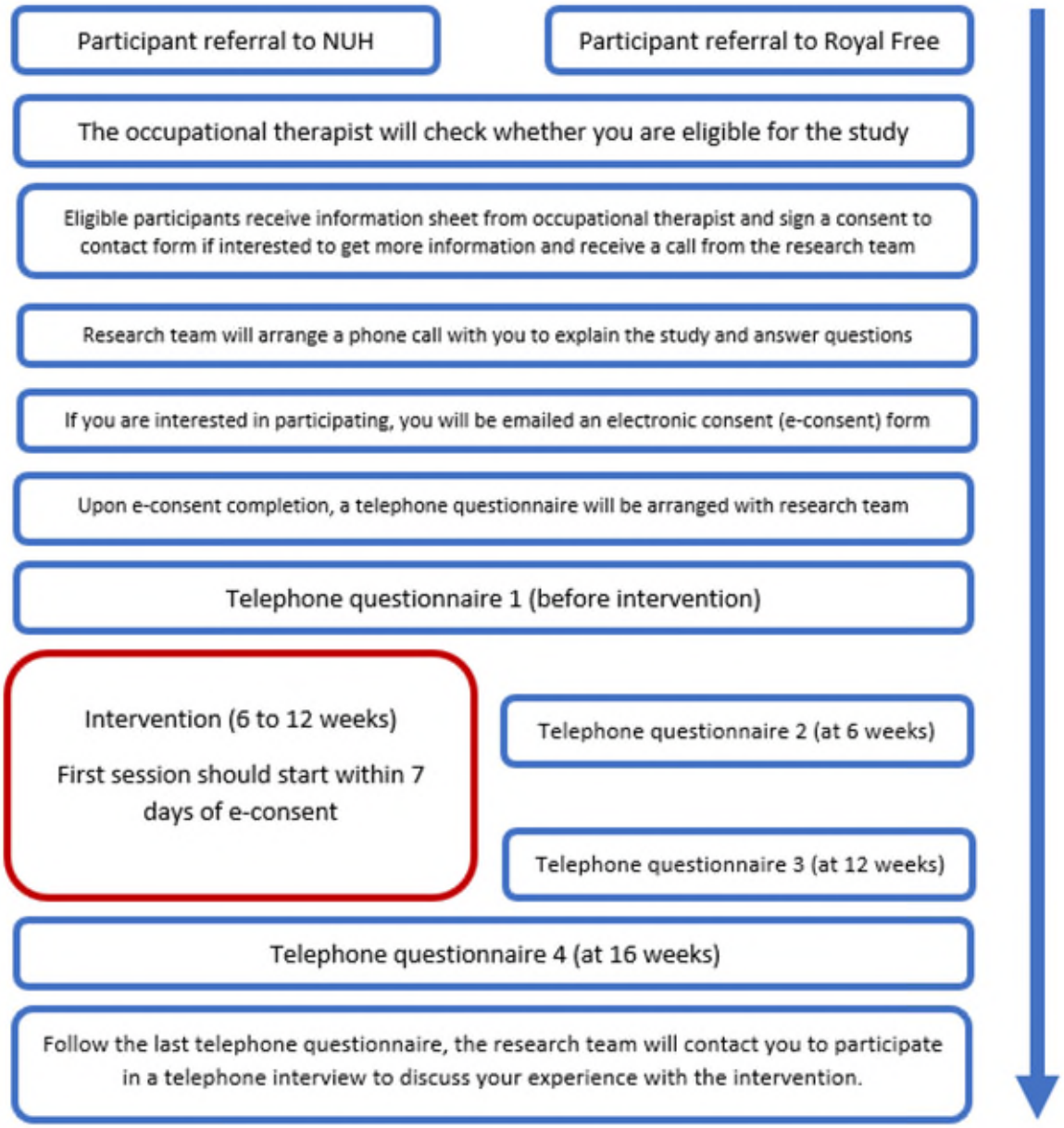
Once you have received a phone call from the research team to discuss the study and you have had the opportunity to ask any question you may have, you will be sent an electronic consent form via email. If you agree to take part in the study, you will receive a copy of your consent form and a member of the research team will contact you to arrange a telephone assessment session once you have consented to participate in the study.

Questionnaires: You will be invited to attend a telephone questionnaire to collect research data before the start of the intervention where we will ask you questions about your physical and psychological symptoms which should last about an hour. The questionnaire session will be repeated after 4, 12 and 16 weeks to see whether you are benefiting/have benefited from the intervention.

Intervention: The intervention is delivered digitally via telephone or Microsoft teams and will aim to lessen the impact of COVID-19 by assessing and addressing related restrictions on functions and activity limitations which might have a direct impact on work activities/demands. You will be attending hourly sessions with an occupational therapist within 7 working days following consent. The number of sessions, the content and intensity will be determined by participant need, preferences, and employment context. In some occasions, it might be beneficial for your employer to be involved in the intervention to see how they can support your return to work in line with the OT's guidance. Your employer will only be contacted if you consent to it.

Acceptability interview: a one-to-one telephone interview with the researcher. The researcher will ask you questions related to your personal experience of the intervention. This interview will be recorded by a digital audio recorder, so that we can capture all the information discussed. We don't want to miss any of the details you give as this will be important for the analysis of the interviews. So that the data can be analysed, the recordings will be transcribed by an external agency with which a confidentiality agreement will be in place to protect your privacy. The transcripts will also be anonymised, password protected, and identifiable data will be removed. Some direct quotes from the interview may be used in the study report, but they will be kept anonymous. Your interview recording will be destroyed once the transcription has been checked, within a week of recording the interview. You can refuse to answer any questions you feel uncomfortable with and you can stop the interview at any time without giving reason. The interview will take 30 minutes.

Your step-by-step involvement in the study:



Expenses and payments

You will be reimbursed any expenses occurred as a result of the participation in this study (for example, the purchase of data for mobile video-conferencing).

Participants will be paid an inconvenience allowance to participate in the study £15.

What are the possible disadvantages and risks of taking part?

Some of the questions we will be asking will enquire about symptoms including emotions such as feeling anxious or low. Whilst most people do not mind answering these questions, some may feel upset. It is important that we ask these questions to understand the challenges that the participants face and find out if an intervention can improve these symptoms. Many people find that talking or sharing concerns can be helpful. We will only ask what is necessary for the study. Following the questionnaires, should

you have negative feelings, we will provide you with the contact details of relevant helplines that can support you.

The intervention will require an hour of your time every week for up-to-12 weeks (or as frequently as agreed between you and your therapist) and you will be attend telephone questionnaires 4 times – each one lasting an hour. Participants will also be required to attend a 30 minutes telephone acceptability interview. At this stage, we cannot guarantee that it will be helpful. Please note that the intervention will be delivered remotely either via videoconferencing using Microsoft Teams or via telephone.

What are the possible benefits of taking part?

We cannot promise that the intervention will help you, but the information we get from this study may help us determine whether the intervention helps participants to return to work and possibly develop the intervention further for a larger study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet.

If you wish to contact someone who is not involved in assessment in the research team, you can contact:

Professor Richard Morriss, Richard.morriss@nottingham.ac.uk,

If you remain unhappy and wish to complain formally, you can do this by contacting PALS.

Local Patient Advice and Liaison Service (PALS) –

Service Liaison Department

Telephone: 020 74726446 or email: rf.pals@nhs.net

If you wish to take further a concern, please choose one of the following options:

- Write to the Royal Free patient affairs team (address below)
- Email rf.complaints@nhs.net
- Complete an NHS complaints registration form
- Complete and mail an NHS complaints registration form to:

Patient affairs team

Royal Free London NHS Foundation Trust

Pond Street

London NW3 2QG

The concern or complaint should be expressed within 12 months of discovering that you have cause to complain, and provide as much relevant information as possible: name, address, date of birth, a full description of all the with relevant dates and times etc. If you have more than one concern, it helps to number the points you are making.

A letter of acknowledgement will be sent to you within three working days. Providing we have all relevant information; the investigation will commence. A response should be provided within 35 working days or within an alternative negotiated timescale. The response will offer a full explanation of the circumstances which led to your complaint and, where appropriate, advise what action we will take to make improvements. Your complaint is not kept in your medical notes, so it will not affect your future care in any way.

The NHS Complaints Advocacy Service offers free independent and confidential advice to help people make a complaint or express a concern about the trust or any other NHS service. They can provide help to make a complaint and give advice about using the complaints system. They can offer support to help you through the complaint process.

Telephone: 0203 553 5960 or 0300 456 2370 (Monday to Friday - 8am to 6pm)

Email: LondonIHCAS@pohwer.net

Text: send the word pohwer with your name and number to 81025

Website: www.pohwer.net

For queries or difficulties please contact the patient affairs team on 020 7794 0500 ext 33227 or 38263.

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 the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you and your medical records during the course of the research. This information will be kept strictly confidential, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named below) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at: https://www.nottingham.ac.uk/utilities/privacy.aspx

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. The research team will not access medical records or extract any data from them, access to medical records by the sponsor may be required for auditing/monitoring purposes. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty. Your contact information will be kept by the University of Nottingham for 12 months after the end of the study so that we are able to contact you

about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it.

All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information, we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

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

Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your medical care or legal rights being affected. This would not affect the standard of care you receive from your usual doctors and nurses or your legal rights.

If you withdraw then no more data will be collected. However, the information collected so far cannot be erased and this information may still be used in the data analysis as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses and study report. The data will be kept anonymised for a duration of at least seven years - data will be kept for longer if it is still being used or of historical importance.

Those who withdraw from the study may be contacted for an acceptability interview to ask about personal experience of the intervention, unless they asked not to be contacted. Participation in this interview is voluntary and you can refuse to answer any questions you feel uncomfortable with and you can stop the interview at any time without giving reason. The interview will take 30 minutes.

Involvement of the General Practitioner/Family doctor (GP)

If you do decide to take part in the study, we will inform your GP and provide them with a copy of this information sheet.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons. If appropriate you may be signposted by the research team to the local 24-hour crisis team in secondary mental health services or if you are in poor physical health to the local accident and emergency department. The research team may also inform your GP or Psychiatrist.

What will happen to the results of the research study?

A summary of results from the study will sent to everyone who participates, and the results will be published in peer-reviewed academic journals. You may request copies of any published articles related to this study. You will not be identified in any report or publication.

Who is organising and funding the research?

The research study is being organised by the University of Nottingham and the NIHR MindTech Medical Technology and in Vitro Centre, and funded by the University of Nottingham.

All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Nottingham 1 Research Ethics Committee.
We also developed the project with patient and public involvement and engagement (PPI/E) representatives.

Further information and contact details

Thank you very much for considering taking part in our study. If you have any queries or would like to talk more about the study, you can contact:

Clem Boutry, Research assistant

Tel: 07929 852207

Email: clem.boutry@nottingham.ac.uk

Chief investigator

Richard Morriss

Email: richard.morriss@nottingham.ac.uk

Principal investigators

<u>London site</u>

Carina Knight, carina.knight@nhs.net