Participant Information Sheet (Healthcare Professional)
Final version 2.0
IRAS Project ID: **313470**

The ReStARt study

(Reducing **St**iffness **A**fter knee **R**eplacemen**t)**

Development of an optimal physiotherapy intervention for arthrofibrosis following total knee replacement (TKR)

Name of Chief Investigator: Dr Michelle Hall
Local Researcher: Dr Melanie Narayanasamy

We would like to invite you to take part in our research study. Before you decide, we want you to understand why we are doing the research and what it will involve. Please read this information sheet, and if you require, one of our team can go through it 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. Contact details for the research team are provided on page 8.

The information in this invitation is in two parts.

Part 1 tells you the purpose of the study and what will happen if you take part.

Part 2 gives you more detailed information about how the project will happen**.**

Acronyms
HCP[s] – Healthcare Professional[s]
MUA – Manipulation Under Anaesthetic
PALs – Patient Advice and Liaison Service
PPI – Public & Patient Involvement
REC – Research Ethics Committee
ReStARt – Reducing Stiffness After Knee Replacement

Part 1

What is the purpose of the study?

People who develop arthrofibrosis following a knee replacement will usually have additional physiotherapy, but it is unclear what this should include and how it can be best delivered. Patients have told us they have received conflicting advice and the treatment available can differ.

Patients who do not improve with physiotherapy may undergo a manipulation under anaesthetic (MUA) to break the adhesions but there is a risk of fractures and tendon rupture associated with this. Additionally, patients who undergo MUA are 5 times more likely to need revision surgery for a new knee within 6 years. We want to develop an optimal physiotherapy intervention to improve outcomes for patients and reduce the need for MUA and further surgery.

To do this we will review the current research available and:

- interview patients and healthcare professionals (HCPs) to understand how arthrofibrosis affects people and their experiences of treatment and care
- conduct a Delphi survey with patients and HCPs to agree what components should be included in the physiotherapy intervention and which outcomes are important
- run a workshop with patients, HCPs and healthcare commissioners to finalise how the intervention can be best delivered in the NHS

By involving everyone, we hope to develop an intervention that will be acceptable to patients and can be delivered in the NHS

Why have I been invited?

You are being invited to take part because you are a HCP (Physiotherapist, Orthopaedic Surgeon, Occupational Therapist or Nurse) who has experience in treating patients with arthrofibrosis following knee replacement or you commission NHS services in this area. We are inviting a range of HCPs to take part, up to 25 in the interviews, 60 in the online-survey and 9 HCPs along with 3 healthcare commissioners to take part in the workshop.

Do I have to take part?

It is up to you to decide whether or not to take part. You can take part in the interviews, survey and or the workshop. You can indicate this on the reply form. If you do decide to take part you will be given this information sheet to keep and be asked to complete a consent form (if appropriate – as completion and return of a questionnaire as part of the online survey will be taken as consent). If you decide to take part you are still free

to withdraw at any time and without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

If you tell us you are interested, our researcher will call you to discuss the study with you, answer any questions you might have and undertake consent. Your consent can be taken verbally or in writing and it consists of a series of statement to ensure you have fully understood what is involved. For the online survey, completion and return of a questionnaire will be taken as consent.

You can decide to take part in the interviews, survey and/or workshop.

If you take part in the interviews:

Our researcher will call you at the arranged time by phone or video call. They will ask about your experiences of managing arthrofibrosis. Key questions will focus on:

- Identification of patients at risk of, or with arthrofibrosis, beliefs around the prognosis, and consequences of arthrofibrosis
- Current care pathways, factors influencing treatment decisions, and clinical outcomes
- Barriers and facilitators to optimal management and delivery of care

We expect these one-off interviews to last between 20 and 40 minutes. The interviews will be recorded but no-one outside of the research team will have access to this, and we will only use it for research purposes.

If you agree to take part in the online survey:

The purpose of the survey is to vote and agree on the important components for the physiotherapy intervention and identify the most important outcomes.

You will be asked to complete 3 or 4 questionnaires over a 3 or 4-month period. This type of survey is called a Delphi study. We expect that each questionnaire could take up to 40 minutes to complete. Full instructions will be included with the questionnaire. We will be asking 15 patients who have had severe stiffness following TKR and 60 healthcare professionals with relevant experience to take part.

If you agree to take part in the workshop:

We will run the workshop at the University of Nottingham around July 2023. It will be attended by 6 patients, 9 healthcare professionals and 3 healthcare commissioners, and the research team. It will run over a day and include presentations on our research to date and a draft of the intervention. Group discussions and activities will help us

decide how the final physiotherapy intervention can be best delivered in the NHS. Full details will be sent nearer the time. If necessary, we can run the workshop online.

Expenses and payments

The study is entirely voluntary. You will receive no payment for your participation in the interview or survey. Travel expenses, lunch, and a thank-you voucher will be offered if you take part in the workshop.

What are the possible benefits of taking part?

Taking part will not benefit you directly but you will be contributing to research in an area of high priority and need.

What are the possible disadvantages and risks of taking part?

Taking part will take time but we do not anticipate any risk in taking part.

This completes Part 1 of the Information Booklet.
If the information in Part 1 has interested you and you are considering taking part please continue to read the additional information in
Part 2 before making any decisions.

Part 2

What happens when the research study stops?

The information from the interviews, survey and workshops will be analysed in detail and will be used to develop a physiotherapy programme to improve outcomes for patients.

We will also write up the results of the study in medical journals and share the results with other healthcare professionals at conferences. We can share our results with you if you give us permission to keep your contact details.

Will my taking part in the study be kept confidential?

Yes. All the information about you and your participation in this study will be kept confidential. All of the interview and survey data will be anonymised. We will follow ethical and legal practice and all information about you will be handled in confidence.

All information collected from you 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

(Michelle Hall) 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 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. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Your consent form and contact information will be kept by the University of Nottingham for 1 year after the end of the study so that we are able to contact you about the findings of the study (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. This may include review studies or other studies into treating knee stiffness after joint replacement. 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 legal rights being affected. If you withdraw, we will no longer collect any information about you or from you, but we will keep the information about you that we have already obtained 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. To safeguard your rights, we will use the minimum personally identifiable information possible.

Who is organising and funding the research?

This research is being organised and conducted by the University of Nottingham and Kings College London. It is funded by National Institute for Health and Care Research (part of the NHS).

Who has reviewed the study?

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 the East of England - Cambridge South Research Ethics Committee (22/EE/0205).

What if there is a problem?

If you have a concern about any aspect of this study, please speak to the researchers who will do their best to answer your questions. Michelle Hall is leading the research and her details are at the end of this information sheet.

If you remain unhappy, and wish to complain formally, please contact Professor Joanne Lymn who is the Head of the School of Health Sciences, University of Nottingham:

By telephone: **0115 82 30805**
By email: joanne.lymn@nottingham.ac.uk
By post: **Room B234 B Floor Link Corridor, Medical School Building Queen's Medical Centre, Nottingham, NG7 2UH, UK**

Further information and contact details:

Dr Michelle Hall (Lead for the ReStARt research study)
Room B317, School of Health Sciences, University of Nottingham, Nottingham NG7 2HA
Telephone: 0115 82 31794 Email: Michelle.Hall@nottingham.ac.uk

Dr Melanie Narayanasamy (Researcher for the ReStARt research study)
Room B302, School of Health Sciences, University of Nottingham, Nottingham NG7 2HA
Telephone: 0115 82 30940 Email: Melanie.Narayanasamy@nottingham.ac.uk

These telephone lines are not monitored 24/7, so if we are unable to take your call, please leave a message, and we will get back to you as soon as possible.

Meet the ReStARt research team

Dr Michelle Hall
(ReStARt study lead)

Dr Fiona Moffatt
(ReStARt lead researcher)

Dr Melanie Narayanasamy
(ReStARt researcher)

Dr Joanne Stocks
(ReStARt lead for Patient and Public Involvement)

Thank you very much for taking the time to read this information.
Please keep this copy of the information sheet.

What happens next?

If you wish to take part in this study, please submit your details via an online form at:
http://bit.ly/3l0Zxxx
This will give permission for our researcher to contact you.

Alternatively, if you have a smartphone, you can scan the QR code below using the QR reader or camera on your phone to access and complete the online form using your phone:

Once we have received your responses to the online form, our researcher will be in touch. This may involve discussing any questions you may have, obtaining your consent, and discussing any arrangements for taking part.