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

The ReStARt study

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

Helping you decide whether or not to join our research study

We would like to invite you to take part in our research study. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve. Please read the following information to help you to decide whether or not you wish to take part.

If there is anything you do not understand, or if you would like further information, please contact Dr Michelle Hall on **0115 8231794** or at:
michelle.hall@nottingham.ac.uk

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 severe stiffness 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 treatment can differ. If physiotherapy does not work, patients may have to undergo a manipulation under anaesthetic (MUA) to free the scar tissue around the knee. This involves an overnight stay in hospital, which may be inconvenient to patients. Also, these patients are more likely to have poorer outcomes and need a new knee replacement in the future.

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:

1. Ask patients and healthcare professionals (HCPs) with relevant experience about their experiences and opinions to help understand the condition and how it is currently treated.
2. Conduct a survey with patients and HCPs to reach agreement regarding what are the most important things to be included in a physiotherapy intervention and what outcomes are important.
3. Run a workshop with patients, HCPs, and NHS funders to finalise how the intervention can be best delivered in the NHS.

By involving patients and HCPs, we hope to develop a physiotherapy 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 have had a knee replacement and have either undergone a MUA procedure or are currently listed for a MUA procedure for severe stiffness following a knee replacement. We are inviting up to 25 participants like you to take part in the interviews, up to 15 to take part in the online survey, and 6 to participate in the workshop.

Do I have to take part?
No, it is up to you. You do not have to give a reason for deciding not to take part. Your decision will not affect, in any way, the standard of treatment you are receiving or any treatment you may have in the future.
You are free to withdraw from the study at any time and without giving a reason. This would not affect any treatment you may receive or 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 and answer any questions you might have. They will arrange to record your consent to make sure you have fully understood what is involved. The consent process may take around 5-10 minutes.

You can decide to take part in the interview and/or survey and/or workshop. You can state which part(s) of the study you wish to participate in by speaking to the researcher and/or by indicating this on the patient reply form.

If you take part in the interviews:
Our researcher will arrange to call you by phone or video call to discuss how your knee stiffness affects your day-to-day life including your employment, social life, and general well-being. They will ask about your experiences of care and what outcomes are important to you.

The one-off interview is expected to last between 30 and 60 minutes. They 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:
You will then be asked to complete 3 or 4 questionnaires over a 3 or 4-month period. It is expected that each questionnaire will take up to 40 minutes to complete, and you will be given a period of 2 weeks to complete and submit each one. Full instruction will be included with the questionnaire.

We will be asking at least 75 people to take part including 15 patients who have had severe stiffness following a total knee replacement operation and healthcare professionals with relevant experience.

If you agree to take part in the workshop:
We will run the one-day workshop at the University of Nottingham around July 2023. It will be attended by 6 patients, 9 healthcare professionals, 3 NHS funders and the research team. It will run over a day and include presentations, small group discussions, and activities to help decide how the final physiotherapy intervention can be best delivered in the NHS. 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 and risks 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. A possible disadvantage is the time it takes to take part. During the interview, you will be asked questions about your personal experiences of having a total knee replacement operation and dealing with stiffness in the knee, which some individuals may find difficult. However, the Research Team are trained to ask questions in a sensitive manner, and they will not expect you to answer anything which you do not want to.

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 and used to develop a physiotherapy intervention to improve outcomes for patients. We will apply for further funding to see if this physiotherapy intervention is acceptable to patients and can be delivered in the NHS, and if it works better than what is currently provided.

We will 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 the interview, survey and workshop data will be anonymised. A unique identifying code will be assigned by the research team to each participant to ensure that their identity is kept anonymous. 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 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 will be informed of 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.

Involvement of the General Practitioner/Family doctor (GP)
The interviews, online-survey and workshop are being carried out for research purposes only and your GP will not be informed of your participation in the study.

Who is organising and funding the research?
This research is being organised by the University of Nottingham and King's College London and is being 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, the Patient Advice and Liaison Service (PALs) provide a confidential service and can also advise you regarding the NHS complaints procedure. They can be contacted:

By telephone: **Freephone: 0800 183 0204** (free from a UK landline)

By email: pals@nuh.nhs.uk

By text message: If you are deaf or hard of hearing and would prefer to send them a text message, you can text them on: **07812 270003**

By post: **NUH NHS Trust, c/o PALS, Freepost, NEA 14614, Nottingham NG7 1BR**

Further information and contact details:

Dr Michelle Hall (Lead for the ReStARt research study)
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NG7 2HA
Telephone: 0115 82 31794 Email: Michelle.Hall@nottingham.ac.uk

Dr Melanie Narayanasamy (Researcher for the ReStARt research study)
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NG7 2HA
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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 complete the reply form and return it using the prepaid envelope provided.

If you would prefer to complete the reply form online, we have provided instructions on how you can do this – please read the front page of the reply form for more details.

Once we have received your responses to the reply 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.