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PARTICIPANT INFORMATION SHEET

PEP-TALK: A study investigating whether having group discussions in addition to physiotherapy improves the amount of physical activity following hip and knee replacement

Invitation to join the PEP-TALK study

We would like to invite you to consider taking part in a research study called PEP-TALK. This study is looking to see if there are better ways of encouraging people who have a hip or knee replacement to undertake more physical activity after their operation.

Before you decide, it is important that you understand why the research is being done and what it would involve. Please take time to read this information carefully, and discuss it with others if you wish. If there is anything that is unclear, or if you would like more information, please ask a member of the local study tem, or call the national PEP-TALK team on 01865 227224, or email them on pep-talk@ndorms.ox.ac.uk.

This leaflet explains why we are doing this research, what the study will involve and exactly what being in the study would mean for you, to help you decide whether you would like to take part.

What is the purpose of the study?

The study is looking at how best to encourage people who have had a hip or knee replacement to do more physical activity.

All patients that have a hip or knee replacement will receive rehabilitation (physiotherapy) after the operation as per standard care and practice in the NHS. Half the study patients will also receive a new treatment designed to help increase physical activity.

Unfortunately, after a hip or knee replacement quite a few people do not do as much physical activity as should be possible after a hip or knee replacement. Researchers want to investigate if adding in something called a behaviour change treatment (which is a group discussion, and then 3 private telephone calls) *PLUS* the standard NHS rehabilitation programmes could improve the amount of physical activity patients do after a hip or knee replacement.

Who is taking part and why have I been invited?

We are hoping to recruit 250 men and women from across the UK who are having either a hip or knee replacement.

You have been invited because you are about to undergo a hip or knee replacement and potentially may benefit from being more physically active.

Do I have to take part?

No. It is entirely up to you to decide whether or not you would like to take part. Please keep this leaflet and use it to make your decision. If you decide to take part, you will be asked to sign a consent form. You are free to leave the study at any time without giving a reason.

Please remember, it is your decision to take part, either now or if you change your mind during the study, this will not change the care you receive.

Should you choose not to participate you will receive the standard NHS treatment for your condition.

What will happen to me if I decide to take part?

If you decide to take part then, during your pre-operative assessment appointment at the hospital, you will be asked to sign a consent form and will be asked to complete some questionnaires on your health and wellbeing. This should take about 30 minutes. Your answers to the questionnaires will not affect whether you enter into the study or not.

A few weeks after that, when you come in to have your new hip or knee replacement, we will check that you are still happy and safe to take part in this study and check that your operation went as planned. If you remain eligible, you will be entered into the study.

A researcher will enter your details into a computer and a computer program will make a decision about which group you will be in whilst in the study. This allocation is made by chance, rather like the toss of a coin. This is important because it ensures that the treatments are tested fairly and no one can guess the group the computer puts you into.

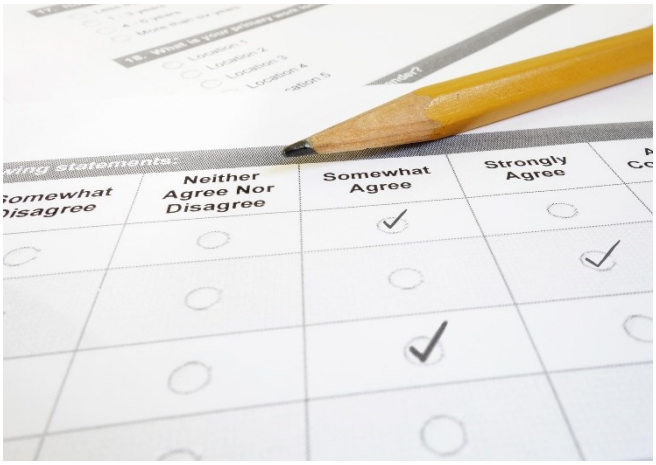
The computer will allocate you to either usual rehabilitation (physiotherapy) or usual rehabilitation (physiotherapy) *PLUS* the behaviour change treatment (group discussion and phone calls).

Either before you leave the hospital or shortly afterwards, you will be provided with your group appointments to either of the groups you are allocated to.
You will then attend rehabilitation sessions (physiotherapy) over 6 weeks – this will generally start at the latest within 4 weeks of your operation, and will be provided by your local physiotherapy team. Each rehabilitation session (physiotherapy) will last no longer than 30 minutes. As part of normal

care, you will also be given home exercises to continue to strength your legs between the exercise sessions.

If you have been allocated to the group discussion – in addition to your rehabilitation sessions (physiotherapy), and home exercises, you will be asked to attend a group discussion meeting before each physiotherapy group over the 6 weeks. Each group discussion will last for no longer than 30 minutes. In these discussion, we will talk to you about things which may stop you being more physically active when you want to be. We will also help you to find out ways to overcome these difficulties, to support you to be more physically active in your everyday lives. Then once your rehabilitation sessions finish, your physiotherapist will telephone you 2, 4 and 6 weeks afterwards to see how you are getting on.

Six-months after your operation, we will send you (either by post or by email) questionnaires similar to the ones we asked you complete before your operation.



This will be used to see the difference your rehabilitation sessions (physiotherapy) have made. We will ask you to complete and return them in a pre-paid envelope.

We will then send the same questionnaires 6 months later (12 months from your operation) to complete and return in the post. Each questionnaire pack will take about 30 minutes to complete. Once the questionnaires have been completed and returned at 12 months that is the end of the study for you. If you forget to complete and return these, we will telephone you up to two times for a reminder.

You will not have to make any extra visits to your doctor or the hospital over and above those needed for your normal care.

Members of the PEP-TALK team based in Oxford may attend some of your rehabilitation sessions (physiotherapy) or the group discussion – this is only to ensure that the sessions are being ran correctly.

Are there any possible disadvantages or risks from taking part?

There are only minimal risks involved in this research.

There is a possible risk of feeling a little sore after exercising or being more active. However you will be guided by your physiotherapist whilst exercising in the classes and will be able to seek their opinions about bone, joint and muscle soreness whilst you are recovering after your hip or knee replacement so they will be able to modify your activities if needed.

There may also be a risk that some of the discussion in the groups may cause minimal distress, particularly when the physiotherapists ask you to think about your own personal challenges in being more physically activity. You will not be asked to share any information which you do not wish to, and, if you do feel distressed in anyway, you will be supported by the physiotherapist leading the group who is trained in helping people when this may happen.

People sometimes feel uncomfortable answering certain questions about their health. If the researcher, physiotherapist, or follow-up questionnaire asks you questions that you are uncomfortable with, then you do not have to answer them.

What are the possible benefits of taking part?

We do not know what the results of the study will be. This is why we are conducting this study.

The study will find out whether getting people to take part in group discussions before rehabilitation (physiotherapy) versus rehabilitation (physiotherapy) only, whether the amount of physical activity people then take part in is different between the two groups. If having the group discussions shows that more people undertake physical activity, then group discussions might then be made to be a part of rehabilitation for all people who have a hip or knee replacement. If they do not show any difference then they would not be continued after this study.

There may not be any benefit to you in taking part in this study, research like this helps to continually improve the treatments and care provided to all patients now and in the future by collecting information on what may or may not help.

Will my General Practitioner/family doctor (GP) be informed of my participation?

With your permission, your GP will be notified of your participation in the study and any test results that they may wish to further investigate.

Will my taking part in the study be kept confidential?

Your medical information and information which you provide will be kept strictly confidential.

Responsible members of the University of Oxford [and the relevant NHS Trust(s)] may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

It should not cost you to participate in the study. You will not be asked to attend any appointments which you would not have to for your regular clinical appointments. If you were required to attend any additional visits, travel costs for these would be reimbursed. All postage and telephone costs will be pre-paid.

What will happen to my data?

The University of Oxford is responsible for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Oxford will keep identifiable information about you for 1 year after the study has finished. This excludes research documents with personal information, such as consent forms, which will be held for 5 years after the end of the study or for longer if you agree to be approached to take part in future studies.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the PEP-TALK Team on 01865 227224.

[Name of NHS Trust] will collect information from you and your medical records for this research study in accordance with our instructions.

[Name of NHS Trust] will use your name, NHS number, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Oxford and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [Name of NHS Trust] will pass these details to the University of Oxford along with the information collected from you and your medical records. The only people in the University of Oxford who will have access to the information that identified you will be people who need to contact you to see how you are at 6 and 12 months after your operation or provide you with the follow-up questionnaire or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

[Name of NHS Trust] will keep identifiable information about you from this study in accordance with local practice.

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

Your participation in the study is entirely voluntary and you may change your mind at a later stage. We will ask you whether you are happy to be sent the questionnaires to continue to collect your results. You can decide whether you want this or not. Withdrawal will not affect the care you receive from the hospital.

What will happen to the results of this study?

We plan to share the results from the research in published academic papers, presenting the results at conferences and online. However you will not be identified from any report or publication placed in the public domain.

At the end of the study, you can read about what we found through our website (https://rehabresearch.ndorms.ox.ac.uk/research/pep-talk-trial).

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Dr Toby Smith, University of Oxford (01865 227668; toby.smith@ndorms.ox.ac.uk) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 (6)16480, or the head of CTRG (email: ctrg@admin.ox.ac.uk).

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact (<insert relevant NHS site phone number and email from the PALS website http://www.ouh.nhs.uk/patient-guide/pals.aspx>).

Who is organising and funding the study?

This study is sponsored by the University of Oxford and funded by the National Institute for Health Research.

NHS National Institute for Health Research

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by South Central – Oxford B Research Ethics Committee.

Participation in future research.

When you agree to take part in a research study, your de-identifiable information resulting from the study may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

We would also like your consent to contact you about future research opportunities. If you agree, we will hold your contact details separately and securely in order to offer you participation in other ethically approved studies in future. Your details will never be shared outside of our department and you can ask us to remove you from our mailing lists at any time. Agreeing to be contacted you in no way obliges you to participate in future research. If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate. If you do not consent to this, you may still take part in this study.

Further information and contact details

Please contact Dr Toby Smith by telephone or e-mail (01865 227668; toby.smith@ndorms.ox.ac.uk) if you have any questions about the study.

Thank you for considering taking part.