



Work Package A - Joint Pain Survey and Blood Sample Collection

Participant Information Sheet

Re:
Mission



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Welcome to the Re:Mission study — led by Professor Louisa Ells and her team at Leeds Beckett University, supported by researchers from the Universities of Leeds, York, Sheffield Hallam, Teesside and Lancaster.

The Re:Mission study is evaluating the NHS Low Calorie Diet Programme and is led by the team of independent researchers from the universities and not an NHS organisation. As part of the study, we would like to understand the impact of the Low Calorie Diet Programme in people with multiple long-term conditions.

What is this study about?

The Re:Mission study will provide important information to the NHS on how and why the NHS Low Calorie Diet (LCD) programme works (or doesn't work) for different people, and whether it is good value for money. In this part of the study, we would like to collect some additional questionnaire data and blood samples from people who have just started taking part in the NHS Low Calorie Diet programme.

Our patient advisory group is concerned about the impact of co-existing joint pain (for example caused by osteoarthritis), on LCD patient experience and success. Research evidence suggests that people who are living with, or at risk of, excess weight and diabetes are more likely to experience joint pain than people who are not who are not living with, or at risk of, excess weight and diabetes. In addition, having joint pain may make it more difficult to lose weight.

In this part of the study we want to understand the impact of joint pain in people taking part in the NHS Low Calorie Diet programme. However, you will be able to take part even if you do not have joint pain. This is so that we can look at differences between people with and people without joint pain. We will also collect blood samples to measure inflammatory biomarkers that are associated with joint pain to understand if these change in response to the LCD programme. This will provide important understanding as to how best to tailor programme support for this patient group.

What will happen if I decide to take part?

If after reading this information sheet, you would like to take part, you will need to provide the central research team with your name, home postcode, and the name of the site that provides the Low Calorie Diet programme for you. You can give us this information either by email or over the phone, and the contact details are at the bottom of this information sheet.

Once the central research team receives your details, a member of the team will contact your local research site. The local research site will then contact you to arrange a convenient time for you to attend to complete the study visits.

In total you will have two study visits. The first will take place as close to the beginning of the Low Calorie Diet programme as possible (less than two weeks after starting total diet replacement). The second will take place approximately 26 weeks later, when you are in the 'maintenance' phase of the programme.

At the first study visit, you will be asked to complete a consent form which allows us to collect data for the study from you. You will be given a copy of the consent form to take home with you. Before signing the consent form you will have an opportunity to ask any questions you may have to a member of the research team.

The two study visits will involve the following assessments:

Questionnaires: These will ask about how your joint pain affects you in relation to your pain, mood and impact on your quality of life. The questionnaires should not take more than 10 minutes to complete.

Blood sample: You will be asked to provide a sample of 9ml blood at each visit (approximately 2 teaspoons) that will be used to understand the relationship between inflammation and joint pain.

Data Linkage: With your permission, we would like to link the results of the joint pain questionnaire and blood sample analysis with data collected in other Re:Mission studies that you might participate in, as well as to the data collected by your service provider about your health and progress on the programme.

What will happen to any samples that I give?

If you consent to giving a blood sample, we will use these samples to conduct research to help us to better understand the link between diabetes, obesity and joint pain. All samples will be stored confidentially and separately from any information that may identify you. The samples that you provide will be stored at Leeds Beckett University until the end of the study.

Any samples that are not used by the end of the study will be transferred to an approved tissue repository at the University of Leeds. We would like to store samples collected from you, confidentially and anonymously, at the end of the study for possible use in research at a later date. The samples and/or data may be made available to researchers who may be in the UK or overseas. They may work in universities, hospitals or in private companies that do medical research. This will be done under strict conditions of confidentiality at all times. You will not be identified in the results of future studies and your donation and/or data will be

used only for medical research which has been approved by an independent Research Ethics Committee. Once your samples have been analysed, the information gained cannot be withdrawn from the study, this is important to ensure that the research as a whole is reliable and accurate.

Will any genetic testing be done on the samples that I give?

No genetic testing will be done on the samples obtained for this study.

How will we use information about you?

We will need to use information from you for this research project. This will include your contact details, which will only be used by your local research site to arrange your study visits, where your programme is provided, your home postcode and your unique referral number. Your unique referral number will be used to link the information you provide in this questionnaire to the data collected from any other Re:Mission sub-studies that you participate in as well as to the data collected by your service provider about your health and progress on the programme. However, anyone who does not need to know who you are will not be able to see your name or contact details, as your data will have a code number instead. This information will be used to do the research or to check your records to make sure that the research is being done properly.

If you lose capacity to consent during the study, you will not take part in any further data collection, however the research team will retain tissue and personal data collected and continue to use it confidentially in connection with the purposes for which consent was given.

Once all participants involved have completed the study, the results will be analysed by specialist statisticians. All information may be stored for up to 10 years after the end of the study, so we can write reports and share the results. Anything we share will be done in a way that no-one can work out that you took part in the study. Should you wish to see the results, or any publications arising from these results, please contact the central research team.

Will the information be kept confidential?

Yes – we will keep all information about you safe and secure. The information you provide will be held on secure servers at Leeds Beckett University and at the University of Leeds. Only our research team and other authorised people will have access. All data will be held in

compliance with the General Data Protection Regulations (GDPR). Professor Louisa Ells is the data controller and can answer any queries about how data is being stored or used.

More information can be found in the [Research Participant Privacy Notice](#).

What will happen if I change my mind about taking part?

You can stop being part of the study at any time, without giving a reason. If you withdraw, we will still keep information we have collected about you, as this is valuable to the study, but we will only keep what we need to keep. A decision to withdraw at any time will not affect your involvement in the NHS Low Calorie Diet programme.

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. If you would like to withdraw from the study please contact us.

What are the possible benefits and risks of taking part?

This information you provide will help the NHS to know whether the programme should be made available to more people. Whilst there are no direct benefits to you for taking part in this study, your participation will be important in helping us to understand how the programme works for different people. You will not be paid for taking part in the study, but you will be able to claim up to £10 in travel expenses for each visit, that you may have incurred in the study.

Participating in the study, specifically completing questionnaires, may evoke some negative thoughts or emotions about your arthritis, the pain you experience and the effect this has on your quality of life. However, you will not have to answer any questions you do not wish to, and you are free to withdraw from the study at any time. There are also some minimal risks associated with giving a blood sample, including minor bruising and discomfort. These are common, but quick to resolve. If your visits raise any concerns about your health or experience on the NHS Low Calorie Diet programme, we would encourage you to speak to your GP or service provider.

Do I have to take part in this study?

No – it is entirely up to you whether to take part. If you decide not to take part this will not affect your involvement in the NHS Low Calorie Diet programme.

Ethical approval

All research is looked at by an independent research ethics committee to protect your interests. This research project (IRAS ID 313211) was approved by the Health Research Authority on 01.09.22 (REC ref: 22/NI/0141).

Contact details

If you would like to take part or would like more information before making a decision, please get in touch with the research team.

If you are interested in taking part or would like more information, please contact the Osteoarthritis Clinical Trials Team: OATRIALS@leeds.ac.uk or 0113 392 4965 or [CLICK HERE](#) to submit your details via secure webform

If you have any complaints please contact Sheila Casey, Academic Quality Support Officer on 0113 812 4312 or email s.a.casey@leedsbeckett.ac.uk who can signpost to the data protection officer of the study sponsor – Leeds Beckett University.
