Participant Information Sheet

A 6-week knee moment and gait pattern biofeedback gait retraining programme in people with knee osteoarthritis and its translation in daily life

We are inviting you to take part in a research project of a novel walking retraining with personalised feedback for knee osteoarthritis. Your doctor has agreed that you would benefit from treatment for knee osteoarthritis. You do not have to take part if you do not want to. Please read this information which will help you decide.

Data collection of this study will be led by PhD student Miss Yi wan, with guidance by three academic supervisors.

1. What is the purpose of the project:

Gait retraining is commonly used in physiotherapy routine to treat knee osteoarthritis (OA). It can help to relieve the pressure on knee joints (knee loading) by changing the way someone walks, which can slow down the progression of knee OA and reduce pain. Personalised feedback combined with gait retraining has been proved to enhance the treatment outcome. However, we do not know which types of feedback work best with gait retraining.

In order to find out whether knee loading feedback or gait pattern feedback is better, we are inviting participants like you to take part in a research project in which some participants will be given knee loading feedback gait retraining, some participants gait pattern feedback gait retraining, and some participants no feedback gait retraining, and the three groups of participants compared.

We hope this research can help to continually improve the treatments and routine practise provided to all patients now and in the future in NHS care.

2. What would taking part involve?

If you agree to take part in this research, you will be allocated to either knee loading feedback group, gait pattern feedback group, or no feedback group, all of which will involve one-on-one weekly walking retraining sessions for six continuous weeks at the University of Bath. If you are allocated to no feedback group, you will have a choice to perform the 6-week gait pattern feedback walking retraining after you complete the study.

There will be three assessment sessions before, right after and 1-month after you finish the six waking retraining sessions. In total, you will need to come to the lab nine times across 11 weeks. During training sessions and assessment sessions, we will attach reflective markers (plastic balls) and muscle sensors (electrodes) across your body to track your movement and muscle activity. All techniques in this study are 100% non-invasive and do not present any risk to you. You will be required to perform all activity with tight sports top, shorts, and trainers.

At the end of the research, or earlier if you experience any unpleasant effects such as increased knee pain, a senior physiotherapist in our team will discuss with you whether you should continue with the walking retraining session you are in or stop the programme.

Please see below the detailed arrangement across these 11 weeks.

Week zero (baseline assessment session A; ~ 2.5 hours): Upon arrival to the lab, you will complete two questionnaires designed to examine your level of knee pain and functional capacity activity related to knee OA. We will also take measurements of your height and bodyweight. Then, reflective markers and muscle sensors will be attached on your body. You will be instructed to perform several maximum contraction tests on the target leg, and then you will be instructed to perform three daily activities at your preferred speed, which are overground walking, sit-to-stand and stair climbing with different gait patterns.

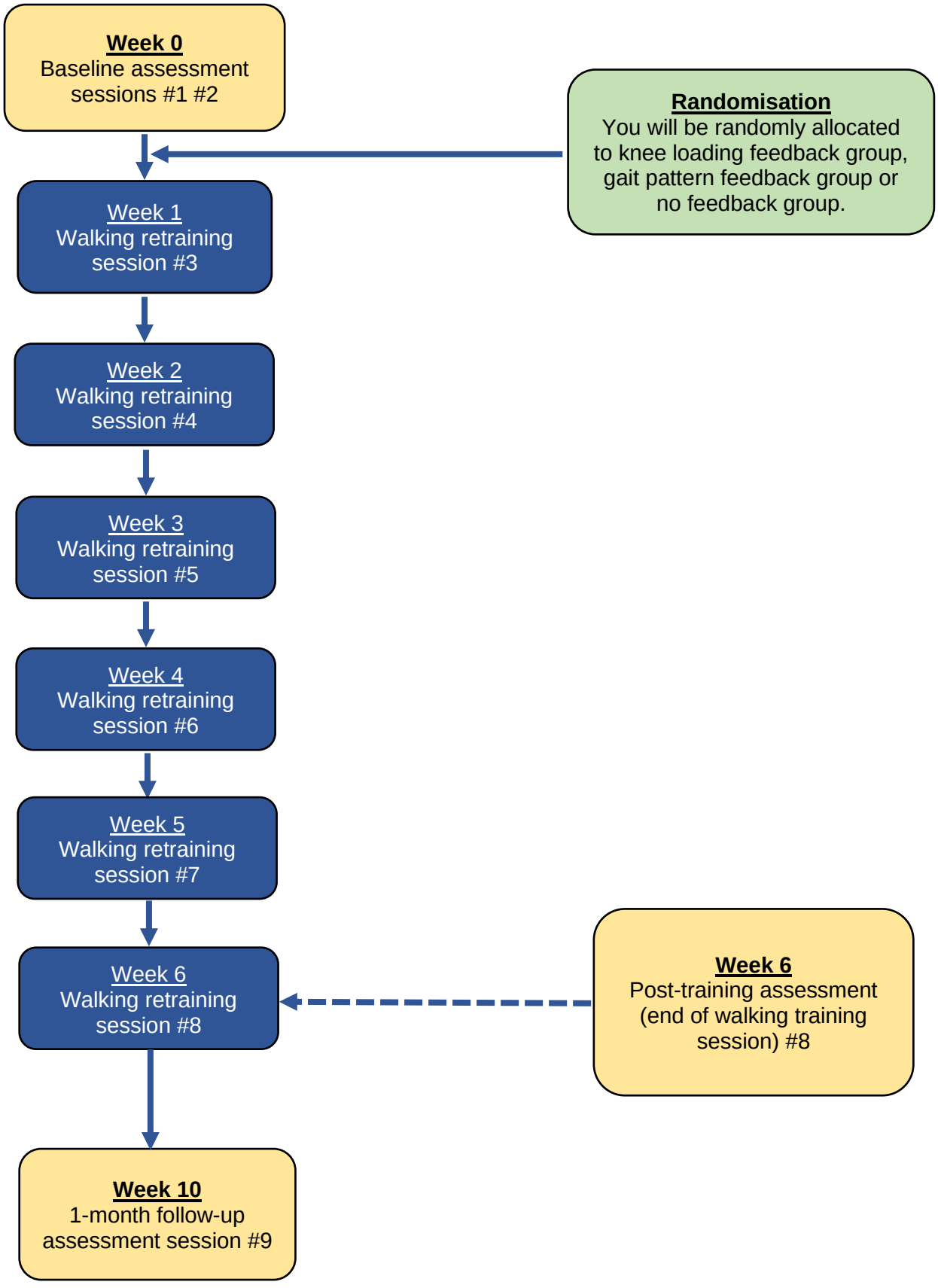
Week zero (baseline assessment session; 1 hour): Reflective markers will be attached across your body. If you are allocated to either of the two feedback groups, you will be instructed to walk on the treadmill and to try various walking patterns (foot progression angle, step width and step length). This is to identify a new walking technique that can reduce your knee loading in a symmetric, pain free and sustainable method.

Week one to six (walking retraining sessions; 1 hour): Reflective markers will be attached across your body. You will be instructed to walk on the instrumented treadmill with or without the real-time feedback displaying on the screen in front of you, depending on which group you are in. You will be instructed to adjust your walking pattern according to the feedback during the session. At the end of each training session, you will be instructed to perform a dual task (Visual Stroop test) while walking on the treadmill.

Outside the lab, you will be asked to practice the new walking pattern on your own at least 10 minutes per day as well as try to maintain this pattern during the rest of your daily walking. Weekly activity log and accelerometer will be provided to record and measure your overall physical activity level.

Week six (post-training assessment; 1 hour): At the end of week six walking retraining session, you will be instructed to perform several maximum contraction tests on the target leg, and then to perform the three daily activities (walking, sit-to-stand and stair climbing) at your preferred speed. You will also need to complete a knee pain questionnaire.

Week ten (follow-up assessment; 2 hours): You will need to complete a knee pain questionnaire. Then, reflective markers and muscle sensors will be attached on your body. You will be instructed to perform several maximum contraction tests on the target leg, and then walking, sit-to-stand and stair climbing at your preferred speed.



3. Do I have to take part?

It is completely up to you to decide if you would like to participate. Before you decide to take part, we will describe the project and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. However, if you change your mind during data collection and no longer wish to take part in this project, then you are free to withdraw at any time without giving a reason.

4. Who can take part in this study?

- Be diagnosed with knee osteoarthritis.
- Aged between 45 and 69 years.
- BMI ≤ 40.0 kg/m^2. (BMI is body mass divided by the square of the body height)
- Current knee pain (at least 2 out of 10).
- Oxford Knee Score 20-35 (this will be assessed by us at the baseline session).
- No use of any orthotic equipment (such as knee brace, shoe insoles).
- Normal or corrected-to-normal vision.
- Be able to walk without an assistive device for at least 15 consecutive minutes.
- Be able to understand the protocol and sign the informed consent forms yourself.

5. Who is unable to take part in this study?

You should not take part in this study if your physical condition is not sufficient to undergo the training. For example, you are unable to adopt an altered walking technique due to previous injury or surgery on the lower extremities or you are unable to walk for 15 consecutive minutes. You should not take part if you are unable to read and complete the questionnaires. You should not take part if you have participated in a new structured exercise programme within the past 3 months.

6. Benefits of this study

We offer travel expenses and parking permit to you for taking part in this study. Travel expense will be reimbursed as 30 pence/mile according to University of Bath Expensed Claim regulation. Besides, by identifying your optimal walking pattern during this study, we believe there will be physical benefits such as pain reduction, reduced OA progression, and improved quality of life.

7. Possible disadvantages and risks of this study

There is a small risk of falling if you lose your balance when conducting movement tasks, but the risk of falling during the trial is considered very low and certainly no

greater than when conducting these daily activities outside the laboratory. In addition, we have put railings around the treadmill and the staircase, which largely reduces the risk of falling. Walking retraining session require changes in walking patterns, which have a very small possibility of causing discomfort of a slight amount of pain during walking. If this happens, we will adjust the target walking patterns to reduce pain as soon as possible. If this pain continues, for your safety, you will be required to withdraw from the study.

Attachment of reflective markers and muscle activity electrodes will be performed using double sided adhesive tape. In very rare circumstances this may cause skin irritation. If you have any known skin irritations, then please let the researchers know about this prior to testing. If you do exhibit itchy or painful symptoms due to the tape once applied, then the testing session will end immediately. Electrode will be shaved by standard disposable razors and abraded using an abrasive tape designed specifically for this purpose. The use of the abrasive tape is equivalent to exfoliation brushes used in everyday life and therefore should only cause a very mild discomfort to the skin. The electrode location will then be cleaned with alcohol wipes to remove any loose dead skin cells.

While COVID-19 restrictions are in place, additional safety precautions will be employed to minimise risk of transmission to both you and the researcher. You will be required to complete a COVID-19 screening form 24 hours prior to the data collection session. You will be asked to sanitize your hands before and after touching paperwork and writing utensils and all surfaces will be cleaned immediately after use. Two metre social distancing will be maintained where possible and face masks must be worn by both you and the researcher during the entire data collection session. The researcher will wear gloves during all periods where equipment must be placed on your body and therefore the two-metre rule cannot be maintained (e.g., markers attachment). All equipment that has been touched during data collection will be thoroughly cleaned after each session. Prior to your arrival, and immediately after your departure, all tables, chairs, equipment, and lab space used will be thoroughly cleaned and disinfected.

8. Will my participation involve any discomfort or embarrassment?

For dynamic movements where reflective markers and muscle activity stickers will be placed on the body, you will be required to perform with close-fitting shirt and close-fitting shorts so that skin on your thighs is accessible.

9. Who will have access to the information that I provide?

The University of Bath is the sponsor for this study based in the United Kingdom. We will need to use information from you for this research project. This information will include your:

- name
- contact details
- age
- height and body mass

- Oxford Knee Score (It is a patient-reported questionnaire to assess function and pain.)
- Kellgren-Lawrence grade (It is a common method of classifying the severity of osteoarthritis.)
- Knee pain score
- WOMAC questionnaire score (It is a widely used self-administered health status measure used in assessing pain, stiffness, and function in patients with osteoarthritis.)
- Biomechanical data (e.g., pressure on the knee joints, gait pattern)
- Weekly activity log

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took park in the study.

10. More information about taking part

How will my information be kept confidential?

All data collected during the project including personal, identifiable data will be treated as confidential and kept in a locked cabinet in a locked room or on a password protected file on the University of Bath's secure server (X drive). Storage of this data will be done in accordance with GDPR. Your name or other identifying information will not be disclosed in any presentation or publication of the research.

What will happen to the results of this study?

Results from this study will be published in scientific peer-reviewed journals and presented as scientific conferences. The results from this study may also be published in mainstream media to promote any significant findings. Only the results from the study will be published, no personal information will be published about you or any other participants in this study. This means published materials will not include any personal information, identifiable images, or identifiable videos.

Who has reviewed the project?

This project has been approved and given favourable opinion by the United Kingdom National Health Service [REC: 305860] as well as the University of Bath, Research Ethics Approval Committee for Health (REACH) [REF……].

How can I withdraw from the project?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

- 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.

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to yw2984@bath.ac.uk

What happens if there is a problem?

The University of Bath 's insurance arrangements are in place for the study. If you have a concern about any aspect of the project, you should ask to speak to the researchers who will do their best to answer any questions. If they are unable to resolve your concern or you wish to make a complaint regarding the project, please contact the Chair of the Research Ethics Approval Committee for Health:

Professor James Betts
Email: j.betts@bath.ac.uk
Tel: +44 (0) 1225 3448

If I require further information, who should I contact and how?

Thank you for expressing an interest in participating in this project. Please do not hesitate to get in touch with us if you would like some more information.

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