Participant information sheet

Feasibility of Cognitive Behavioural therapy on chronic back pain patients

You are invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact me if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of the study?

The purpose of the study is to understand the feasibility of using cognitive behavioural therapy (CBT) in managing chronic low back pain in Malawi. CBT is not commonly used in Malawi; however, it has shown to be effective in managing chronic pain. As such, the study would like to find out if it is feasible to use this intervention in our setting and explore how this compares to traditional physiotherapy.

Why have I been asked to take part?

You have been asked to take part because you are currently experiencing chronic low back pain.

Do I have to take part?

No, it is up to you to decide whether to take part. If you do decide to take part, you will be asked to sign a paper-based consent form and you will be given a copy of this information sheet to keep. If you agree to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare services that you receive, or your legal rights.

What will happen if I take part?

You will be randomly allocated to receive either CBT or control group. In the CBT group, your beliefs towards back pain will be assessed and the exercises will involve restructuring those beliefs and general body exercises. In the control group, an infrared bulb, exercise and soft tissue manipulation will be used. The study will require you to come for the in-person sessions 6 times in a period of 3 months. You will be asked to complete questionnaires before and after the intervention on attitudes and beliefs of low back pain, disability level and quality of life. At the end of the CBT intervention, you will be invited to attend an interview where you will be asked for information such as the challenges faced when receiving the therapy, your understanding of the intervention, satisfaction level, appropriateness of the intervention, why you did not withdraw from the intervention and how the delivery of therapy can be improved. The interview will be audio recorded using an encrypted recorder and then a written copy of the conversation will be made. The written copy will be securely stored, and

the audio recording will be deleted. We will remove your name and any other data that might identify you. The interview is expected to last for between 30 minutes.

What are the possible benefits of taking part?

You will not get a direct benefit from taking part in the study. The findings might help to improve the quality of care for patients with chronic low back pain.

What are the possible disadvantages and risks of taking part?

You will be required to come for therapy sessions for 6 times withing a period of 3 months. This might take your time and determination. However, we do not anticipate that you will experience any harm during the sessions. If at any point you feel uncomfortable with the treatment you are receiving, you are free to discontinue, and this will not affect your legal or health rights. At the end of the intervention, we may invite you to an interview, where we will ask you to give up some time to take part in an in-person interview lasting a maximum of 30 minutes.

Will my taking part in the study be kept confidential?

All the information we collect during the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

People who do not need to know your personal data and will not be able to see your name or contact details. Your data will have a code number instead. We will read all interview records to look for themes Once we have finished the study, we will keep the written interview records so we can check the results. We will write our results in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

If you decide you no longer want to take part, you can request that your information is withdrawn from the study up until the analysis is complete (the end of March 2025). You can request this by contacting Grace Mukoka via email grace.mukoka@napier.ac.uk

What are your choices about how your information is used?

You can find out more about how we use your information from our privacy notice. This is included in this information pack.

What happens when the study is finished?

When the study is finished, anonymised data will be stored by Edinburgh Napier University. These anonymised data may be made available to other researchers for further analysis once the results of the research have been published. This would only be after an official request, consideration of suitability for sharing, and subject to a data sharing agreement between Edinburgh Napier University and the researcher requesting the data. The data will be stored for at least 10 years.

What will happen to the results of the study?

The data will be analysed and written up within a PhD thesis and the findings may be published in healthcare journals and presented at conferences. However, it will not be possible to identify any individual participant from these reports or publications. Quotes may be used in the presentation findings but names will be replaced with pseudonyms so these will not be identifiable to an individual.

Who is organising the research and why?

The principal investigator organising the study is Grace Mukoka, a PhD student at Edinburgh Napier University with a special interest in back pain management. The project is being conducted as part of my PhD thesis.

Who has reviewed the study?

A favourable ethical opinion has been obtained the School of Health and Social Care Research and Integrity Committee at Edinburgh Napier University (REF: SHSC3502561); and from Kamuzu University of Health Sciences (REF: P.08/23-0176).

Researcher contact details

If you have further questions about the study, please contact: Grace Mukoka via email: grace.mukoka@napier.ac.uk

Independent contact details

If you would like to discuss this study with an independent person please contact: Dr Stephanie Valentino, Senior Research Fellow (Edinburgh Napier University) at s.valentin@napier.ac.uk