UNIVERSITY of York
The Department of Health Sciences

'Feasibility of TASK-BA (Task shifting for Addressing depreSsion in Kidney failure - Behavioural Activation) delivered by non-specialist healthcare workers in a low resource setting'.

Feasibility Study Patient Participant Information Sheet

Title of Study

I would like to invite you to help with testing the suitability of an intervention for depression in haemodialysis patients. The title of the study is **'Feasibility of TASK-BA (Task shifting for Addressing depreSsion in Kidney failure -Behavioural Activation) delivered by non-specialist healthcare workers in a low resource setting'**. However, before you decide, please read the following information.

What is the purpose of this study?

People receiving haemodialysis are more likely to experience depression, and they can find it more challenging to stick to their treatment. They can also experience worse symptoms of their kidney disease and are more likely to die earlier than people who do not experience depression. However, in Pakistan, there are not enough mental health professionals to support everyone experiencing depression. Healthcare workers such as nurses and dialysis technicians who care for people receiving haemodialysis are not trained to identify and manage depression among their patients.

We want to train kidney care professionals to deliver a mental health therapy for depression to people who are receiving haemodialysis. The therapy is called Behavioural Activation, which is a type of talking therapy that can be delivered in medical settings by trained workers who are not mental health specialists. The trained health workers will help patients experiencing depression identify simple, positive activities that they have stopped doing due to low mood (e.g., calling a friend, going for a walk) and support them in starting these activities again. These activities are likely to provide a sense of accomplishment or pleasure, which can improve mood and energy, making it easier to do other things that they enjoy, therefore, gradually improving their mood. The purpose of this research project is to test whether dialysis unit health workers can successfully deliver behavioural activation to patients during haemodialysis.

This study is looking to design and test a support programme that will improve symptoms of depression for people with kidney failure receiving haemodialysis. We have adapted behavioural activation with the help of patients, carers, and healthcare workers, and now we want to see what people think about the adapted support programme, and whether people are happy to take part in a study to see if the programme works at improving symptoms of depression. This is called a '**feasibility study**', and it will tell us what parts of the programme work well and what we need to change before starting a larger study to see if it works.

Who is doing the study?

The Primary Investigator for this study is Dr Huda Sarwar, who is a PhD student at the University of York, UK. She is being supervised by Prof Mona Kanaan at the University of York, UK. Prof Shafiq Cheema, the Head of the Department of Nephrology at Allama Iqbal Medical College is the local collaborator on the research.

Why have I been asked to participate?

You have been asked to participate in the study because you get regular haemodialysis treatment from this hospital, and because the screening form that you filled out shows that you may be experiencing some of the symptoms of depression.

Do I have to take part?

No, it is entirely up to you to decide whether to take part or not. Please feel free to contact us if you have any questions you would like to ask us. Please also discuss the study with family, friends or healthcare professionals if you wish.

You will be asked to sign a consent form if you decide to take part to confirm that you are happy to participate in the study and that you understand what is involved. Even if you agree to take part in the study, you are free to withdraw at any time, and you do not have to give a reason. We will still use the information we have received from you up to the point you stop taking part. The care or any benefits you normally receive will not change if you decide not to participate, or if you decide to stop taking part in the study after you have joined.

What will be involved if I take part in this study?

If you decide to take part, you will be asked to sign the consent form. You will then be asked to provide some information about your life such as your employment, family and marital status. You will also be asked some questions about your health condition at a time and place of your choosing inside the dialysis unit at Jinnah Hospital. You can choose to have us gather this information from you during your haemodialysis session, or at a private office within the dialysis unit, in which case you will have to arrive early or stay after your regular dialysis session.

We will be using a process called 'randomisation'. This means that people who sign up will be randomly assigned to two different groups, like flipping a coin. This means you will have an equal chance of being in either group. Depending on what group you are put in, you will either be randomly allocated to receive the new programme, called the intervention group, or receive enhanced usual care, called the control group.
If you are put in the intervention group, you will receive 6-8 sessions of the behavioural activation therapy from a trained healthcare worker. Each session will last about 20-40 minutes and will happen once a week during your routine haemodialysis treatment, so you will not need to set aside your free time to attend these sessions. You will also be given some handouts or worksheets to fill out about your daily activities. This is to document your progress. The worksheets will have pictures in addition to written words to make it easy to understand and read.
If you are randomly assigned not to receive the intervention you are in the 'control group' and will receive 'enhanced usual care' or EUC. A healthcare worker will give you information on depression and the treatment options available in the hospital to manage it. This may include, with your consent, a referral to the hospital's mental health services.
You will also have a 'follow up' at 8-10 weeks after you are randomised to Intervention or Control group. This will involve the researcher asking you some questions about your mood and your experiences of the study. This will be done during your routine dialysis session.

What are the advantages or benefits of taking part?
You will be offered a small monetary compensation for the extra effort you will be putting in. Although we cannot promise that taking part in this study will help you, by participating in this study, you could help improve the future treatment of depression for people receiving haemodialysis in Pakistan.

What are the disadvantages or risks of taking part?

You will be provided the therapy sessions during your regular haemodialysis appointment. This may make you feel anxious or overwhelmed. You can ask the healthcare worker delivering the therapy to stop at any time this happens. You can choose to have your session during your next appointment if you wish.
Sometimes talking about depression can cause people to become triggered or upset during the therapy session. If that happens, the therapy session will be stopped and rescheduled, and you may be referred to mental health specialists for looking after your symptoms with your consent. The researcher will be available for help and support if needed.

Can I withdraw from the study at any time?

You can choose to withdraw from the study at any time, without giving a reason, and without your care being affected. We will still use the information we have received from you up to the point you stop taking part.

How will the information and personal data I give be handled?

The handling of participants' information and personal data in this study is governed by GDPR (General Data Protection Regulation) regulations to ensure privacy and security. The Information Sheet provided includes a link to the University of York's Privacy Notice for Research Participants, offering detailed insights into data management practices (https://www.york.ac.uk/records-management/dp/your- info/privacynotice-researchparticipants/).

We will collect your personal details and data related to your illness with your consent. You will be assigned a number such as FS-001 when you consent to participate, and this number will be used in all your stored data. Information sheet with identification details such as name, that will link this study number to you, will only be available to the researcher and some of the hospital staff. This 'key' linking your identity to the study number will be destroyed once the study is complete. No personal identifiable information will be used in any publication or presentation. We will store your consent forms securely for up to 10 years at the study hospital's archives and then destroyed, following ethical guidelines outlined in the retention policy. While every effort will be made to maintain your privacy, absolute anonymity cannot be guaranteed.

What will happen to the results of the study?

The PhD thesis will make use of the findings, which will also be published in academic journals and presented at academic conferences. A summary of the results will be shared with the study participants, and the community will have access to a summary of the results through the hospital newsletter.

Who has reviewed and approved this study?

This study has been reviewed and approved by the University of York's Health Sciences Research Governance Committee (***HSRGC/2025710/G)***, as well as the Ethical Review Board at AIMC/Jinnah Hospital Lahore.

Who do I contact for more information about the study?

Please contact Dr Huda Sarwar, 00923226622311, hs2195@york.ac.uk for more information.

Who do I contact in the event of a complaint?

For general complaints you can contact:

Head of the Department of Nephrology AIMC

Prof. Shafiq Cheema

Tel: +92429231400 Ext.2304

Email: nephask@gmail.com

You can also contact:

Prof Mona Kannan

Email: mona.kanaan@york.ac.uk .

If you are unhappy with the way your personal data has been handled, you have a right to complain to the University's Data Protection Officer at dataprotection@york.ac.uk; if you are still unsatisfied, you have a right to report concerns to the Information Commissioner's Office at www.ico.org.uk/concerns.

Thank you for taking the time to read this information sheet.