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'.

Process Evaluation 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.

The project aims to test the suitability of training health workers to deliver behavioural activation to haemodialysis patients in a dialysis unit. Testing this at a small scale will provide us important information on what parts of the intervention are suitable and which parts need to be improved upon. Earlier in the study, the intervention was adapted to suit the highly specialised haemodialysis unit setting and the unique symptoms experienced by haemodialysis patients. In this stage of the study, the adapted intervention was tested within routine service provision, to see whether it is workable for the patients and the healthcare workers delivering it. This is called a 'feasibility study'.

In order to find out what parts of the programme work well and what we need to change before starting a larger study, we need to gather all the information from the participants, this is called 'Process Evaluation'. This involves gathering data on the experiences of the participants of the feasibility study. This will be done by holding detailed discussions with the healthcare staff who delivered the intervention as well as some of the patients. This information will help us improve the intervention design to make it more suitable for future trials of the intervention.

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 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 were a part of the feasibility study.

Do I have to take part?
You do not have to take part. If you do take part, you are free to stop the feedback session at any point without giving a reason. Your decision will not impact the care that you receive.

What will be involved if I take part in this study?
If you decide to take part, you will be asked to provide feedback on your experience of the study. You will discuss with the researcher, in detail, your opinions and experiences about the process of the study and the intervention. If you were in the Control group, you will be asked to provide feedback on that. The interview will be audio recorded and will take place at a time and place of your choosing. The interview will last for approximately one hour.

What are the advantages or benefits of taking part?
We cannot promise that taking part will benefit you. However, you will be helping us to understand how we can improve our behavioural activation programme and how to improve our study methods for the larger study that is planned. You will also be helping us to learn more about how we can improve the mental health and well-being of people receiving haemodialysis.

What are the disadvantages or risks of taking part?
Some people find interviews uncomfortable; the researcher will endeavour to reassure you and answer any queries that you might have about it. The feedback session will take up some of your time. We will arrange to speak to you at a day, time and location that is most convenient for you.

Can I withdraw from the study at any time?

You can choose to withdraw from the interview at any time, without giving a reason, and without it impacting the care you receive. If you wish to withdraw and request for your interview to be deleted, you may do so with in 2 weeks after the interview. After this period, the interview findings will be incorporated into the results, and it will be not possible to delete them.

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/).

The audio recording from the interview will be transcribed i-e converted into written text. This text will be anonymous and will be used for further and synthesising results. The recordings will be deleted after transcription. 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 they will be destroyed, following ethical guidelines outlined in the retention policy.

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.