ISRCTN76652273 https://doi.org/10.1186/ISRCTN76652273

Testing a talking therapy for depression in haemodialysis patients

Submission date
28/01/2026

Recruitment status
No longer recruiting

Registration date
30/01/2026

Overall study status
Completed

Last Edited
24/02/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with kidney failure who need regular haemodialysis often face many challenges, including a higher risk of depression. In Pakistan, there are very few mental health specialists available to provide talking therapies to people receiving dialysis. This study is looking at whether a simple talking therapy called behavioural activation can be delivered by trained dialysis unit staff rather than specialist therapists. The aim of the study is to find out whether this approach is practical and acceptable for patients and staff, and whether it could be tested more fully in a larger study in the future.

Who can participate?
Adults aged 18 years and over who are receiving regular haemodialysis for chronic kidney disease at Jinnah Hospital in Lahore may be able to take part. Participants need to be willing and able to give informed consent and have mild to moderate symptoms of depression based on a short screening questionnaire. Some dialysis staff, such as nurses or technicians, will also take part by delivering the therapy after training.

What does the study involve?
Patients attending their usual dialysis sessions will first be asked to complete a short questionnaire to screen for symptoms of depression. Those who are eligible and agree to take part will be randomly placed into one of two groups. One group will receive behavioural activation therapy, delivered by trained dialysis unit staff during dialysis sessions. This involves up to six weekly sessions focused on helping people engage in positive and meaningful activities. The other group will receive enhanced usual care, which includes information about depression and referral to mental health services if needed. All participants will be followed up about eight weeks after joining the study, and some may be invited to take part in an interview about their experiences.

What are the possible benefits and risks of participating?
Taking part may help patients become more aware of their mental health and encourage them to seek support. Although there is no guarantee that the therapy will improve mood or quality of life, the study may help improve care for dialysis patients in the future. Dialysis staff involved in delivering the therapy may gain new skills that are useful in their work. Talking about mental

health can sometimes be upsetting, and some people may find discussions about depression difficult. Support from hospital mental health professionals will be available if needed.

Where is the study run from?
The study is run by a PhD researcher from the University of York in the United Kingdom and is being carried out at Jinnah Hospital in Lahore, Pakistan.

When is the study starting and how long is it expected to run for?
The study is expected to start in early 2026. Recruitment is planned to take place between February and March 2026, and the overall study is expected to run for about five months.

Who is funding the study?
The study is being conducted as part of a PhD programme funded by the Centre for IMPACT at the University of York. This centre is funded by the National Institute for Health Research Global Health Research programme.

Who is the main contact?
The main contact for the study is the Primary Investigator, Dr Huda Sarwar. She can be contacted by email at hs2195@york.ac.uk

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Huda Sarwar

ORCID ID
https://orcid.org/0000-0002-0826-7485

Contact details
Department of Health Sciences, Seebohm Rowntree Building, University of York
York
United Kingdom
YO10 5DD
+44 (0)1904 321321
hs2195@york.ac.uk

Type(s)
Scientific

Contact name
Prof Mona Kanaan

ORCID ID
https://orcid.org/0000-0001-7956-7576

Contact details
Department of Health Sciences, University of York, Heslington
York

United Kingdom
YO10 5DD
+44 (0)1904 321321
mona.kanaan@york.ac.uk

Additional identifiers

Study information

Scientific Title
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

Study objectives
To assess the feasibility and acceptability of conducting a future, definitive RCT to test the effectiveness of TASK-BA in an outpatient haemodialysis setting.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 16/10/2025, Health Sciences Research Governance Committee (Department of Philosophy, Heslington, University of York, York, YO10 5DD, United Kingdom; +44 1904 323253 /1; stephen.holland@york.ac.uk), ref: HSRGC/2025710/G

2. Approved 29/08/2025, Ethical Review Board, Allama Iqbal Medical College & Jinnah Hospital (Administrative Block, Allama Iqbal Medical College, Allama Shabbir Ahmed Usmani Road, Lahore, 54570, Pakistan; +92 4299231480; erb@aimc.edu.pk), ref: ERB193/17/29-08-2025/AIMC /JHL

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Single

Purpose
Health services research, Treatment, Feasibility study

Study type(s)

Health condition(s) or problem(s) studied
Talking therapy for depression in haemodialysis patients

Interventions
An open label, mixed-methods parallel convergent, single-centre, block randomised study design will be used. Haemodialysis patients presenting for dialysis at Jinnah Hospital, Lahore will be randomised 1:1 to intervention and control group. The study will include two main components: a pilot RCT followed by a qualitative process evaluation. Patients presenting to the dialysis unit for their routine haemodialysis appointments will be screened with Patient Health Questionnaire-9 (PHQ-9) for depression. Those fulfilling the eligibility criteria and consenting to participate will be allocated to Intervention(Behavioural Activation) or Control (Enhanced Usual Care) group using block randomisation technique. The BA intervention, named TASK-BA has been adapted to make it suitable for delivery by Non-Specialist Health Workers (NSHWs) in a haemodialysis context. Allocation will be concealed from the researcher by sealing individual random block combinations in random numbered envelopes by an independent researcher. Those allocated to Intervention group will be offered six, weekly sessions of BA, delivered by trained , NSHWs, while the Control group with be offered information on depression and referral to mental health specialists. The BA sessions will take place during routine haemodilaysis. Follow up will take place at 8 weeks from recruitment for both groups. Qualitative process evaluation will be undertaken towards the end of the study where in-depth interviews will be held with patients in both groups and the NSHWs.

Intervention Type
Behavioural

Primary outcome(s)
1. Eligibility and Recruitment measured using Recruitment rates, assessed as the number of participants eligible, consenting and randomised, out of those screened , reasons for ineligibility /non-participation/ non-consent of participants, length of time required to achieve the required sample size at recruitment

2. Acceptability outcomes including; acceptability of patient participants and HCWs towards the intervention indicated by frequency of session attendance and through qualitative analyses of exit interviews, acceptability of patient and HCW participants towards randomisation, acceptability of outcome measures measured using frequency of session attendance and through qualitative analyses of exit interviews at follow up and exit interviews during process evaluation

Key secondary outcome(s)
1. Data Completeness measured using missing data at at the end of the trial

2. Attrition measured using Number of patients retained till the end of the study, number of participants successfully completing the intervention and reasons for non-completion and the number of sessions completed, retention in treatment reported as the number of sessions attended out of the total number of sessions offered at follow up and during the trial

3. Contamination measured using in depth during the interviews with the patient participants and HCWs. at exit interviews during process evaluation

4. Difference in depression and quality of life measured using PHQ-9 and WHO-QOL BREF Scores at recruitment and follow up

Completion date
15/06/2026

Eligibility

Key inclusion criteria
Patient participants:
1. Adults of all genders, 18 years and above, undergoing regular dialysis for chronic kidney disease at the study hospital.
2. Willing and having the mental capacity to consent to screening.
3. Score of between 5 - 14 in the PHQ-9 screening
4. Willing to participate in the trial and able to provide written informed consent.
5. Patients on medication for depression will be included.

Health Care Workers:
1. Having worked in haemodialysis unit for a minimum of 3 months.
2. A non-mental health specialist member of the multidisciplinary team including nurses, dialysis technicians, healthcare support workers or nursing assistants.
3. Expected to be based at the dialysis unit for the duration of the intervention.
4. Willing to participate and deliver the intervention.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients with cognitive, hearing or memory impairment hindering conversation and comprehension.
2. Patients with altered consciousness or comatose patients.
3. Those with severe depression or mental illnesses (psychosis, bipolar disorder, substance abuse etc)
4. Those unable or unwilling to continue dialysis at the study hospital during the intervention period such as those undergoing renal transplant.
5. Patient unable to consent due to diminished capacity.

6. Patients already receiving psychotherapy for depression.
7. Patients scoring 15 or more on PHQ-9, indicating severe depression or those expressing suicidal ideation.

Date of first enrolment
02/03/2026

Date of final enrolment
27/03/2026

Locations

Countries of recruitment
Pakistan

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type

Funder Name
University of York

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	Feasibility Study Patient version 1.1	05/10/2025	29/01/2026	No	Yes
Participant information sheet	Process Evaluation version 1.1	06/10/2025	29/01/2026	No	Yes
Participant information sheet	Process Evaluation Healthcare Worker version 1.1	06/10/2025	29/01/2026	No	Yes