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Behavioural activation on haemodialysis

Submission date
22/11/2025

Recruitment status
Recruiting

Registration date
09/02/2026

Overall study status
Ongoing

Last Edited
08/05/2026

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 receive haemodialysis have a very high risk of mental health issues, such as depression and anxiety. Haemodialysis requires people to attend the hospital three times a week, for at least four hours each visit. Patients also have strict diet and fluid restrictions and have many physical symptoms. As a result, treatment for kidney failure can affect a person's mental health. There are limited options to support the mental health of people receiving haemodialysis, and patients can find additional appointments or medication difficult due to the burden of kidney failure treatment. There are low-intensity treatments, such as behavioural activation, which can significantly improve symptoms of depression in patients with long-term conditions and can be provided by people who are not mental health professionals. Behavioural activation focuses on making small changes in daily life, at the person' s preferred pace, to improve their mood. Behavioural activation could be delivered during haemodialysis. We want to see if it is possible to provide a behavioural activation intervention during haemodialysis to address depression and anxiety in people with kidney failure.

Who can participate?
Patients with kidney failure who are aged 18 or over, receiving haemodialysis at one of our participating sites, and who are experiencing low mood.

What does the study involve?
Recruitment will open at two sites, one in Hull and one in London. Participants will be able to take part if they are receiving regular haemodialysis and have symptoms of depression based on the Patient Health Questionnaire. Participants at each site will be grouped according to the days of the week they attend haemodialysis, and the shifts will be randomly assigned to either receive behavioural activation or receive standard care (as a control group). Participants who are assigned to behavioural activation will have 6-8 sessions during their usual haemodialysis treatment; sessions will be delivered by a trained kidney healthcare worker. The study will measure participants' depression and anxiety before they start behavioural activation and three months later. The study will interview people who participated, as well as their carers, and healthcare workers, to see what they thought about the intervention and the study overall.

What are the possible benefits and risks of participating?
Taking part could help improve future support for people who are receiving haemodialysis and experiencing depression. Although there are no promises that taking part in this study will help

the individual participants, they may learn more about depression, which could help them manage it better, even if they are in the usual care group. This study, including the support programme and any data collection, will take place during routine haemodialysis appointments, so participants do not need to attend for any additional appointments. However, they will have to spend time during their haemodialysis appointments participating in the study.

Where is the study run from?
Tees Esk and Wear Valleys NHS foundation trust, with collaborators in the Department of Health Sciences at the University of York, Institute of Psychiatry, Psychology & Neuroscience at King's College London, Hull University Teaching Hospitals NHS Trust and King's College Hospital NHS Foundation Trust.

When is the study starting, and how long is it expected to run for?
The study commenced in September 2025, with recruitment planned to start by March 2026. Data collection is expected to run until December 2026. The full study, including data analysis, will finish by September 2027.

Who is funding the study?
The National Institute for Health and Care Research (NIHR), through the Research for Patient Benefit funding scheme.

Who is the main contact?
Dr Claire Carswell, claire.carswell@york.ac.uk.

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
361821

Central Portfolio Management System (CPMS)
71878

Study information

Scientific Title
An integrated behavioural activation intervention to improve depression amongst people with kidney failure undergoing haemodialysis: a feasibility study

Acronym
BEACH

Study objectives
This study aims to establish the feasibility and acceptability of a behavioural activation intervention, integrated into haemodialysis care, to address symptoms of depression and anxiety amongst people with kidney failure who are receiving maintenance haemodialysis. The following objectives are planned to achieve this:

1. Determine the feasibility of recruiting, randomising, and retaining participants, including screening for depression using the PHQ-4, in a definitive cRCT.
2. Evaluate the feasibility of data collection methods within a cRCT.
3. Evaluate the feasibility of conducting a future economic evaluation of an integrated behavioural activation intervention.
4. Explore the acceptability of the integrated behavioural activation intervention for patients, healthcare professionals and informal carers.
5. Refine the process for evaluating intervention fidelity in a definitive cRCT.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/01/2026, London - Dulwich Research Ethics Committee (Health Research Authority 2nd Floor 2 Redman Place Stratford, London, E20 1JO, United Kingdom; +44 (0)207 104 8290; dulwich.rec@hra.nhs.uk), ref: 25/LO/0920

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Treatment of depression among people with kidney failure receiving in-centre haemodailysis

Interventions
Participants will be randomised at a cluster level according to haemodialysis shift (Monday /Wednesday/Friday, Tuesday/Thursday/Saturday) as the intervention will be administered during haemodialysis. Participants randomly allocated to the intervention group will receive an adapted behavioural activation intervention, while those allocated to the control group will receive enhanced usual care (they will be provided with information on accessing usual care services, including GP services and third-sector organisations).

Intervention group - Integrated behavioural activation (delivered during haemodialysis treatment):
The integrated BA intervention will be delivered over a period of 6-8 weeks. Each participant allocated to the intervention group will receive a minimum of 6 one-to-one sessions, delivered at their bedside during their haemodialysis treatment. Participants will receive a BA workbook to support the content of each one-to-one session and to refer to between sessions.
At the end of each session, the facilitator and participant will plan take-away activities to do outside of the sessions. In each follow-up session, the participant will begin by checking in with the facilitator and reviewing their progress from the previous week. While the content will be organised into 6 core sessions, the pacing of session content will be tailored to the participants' needs.

Using a standardised training programme, kidney health professionals will be trained to deliver the BA intervention as facilitators. The training will be delivered in one face-to-face workshop. The workshop includes both a theoretical component to explain what BA is and how it works, as well as a skills-based component featuring case scenarios and role-plays. A train-the-trainer approach will be used when recruiting further facilitators, with initial sessions supervised by the initially trained BA facilitators.

Control group - Enhanced Usual Care
There is no standardised usual care for depression provided within haemodialysis units across the UK, and few units implement NICE guidelines for the assessment and management of depression in long-term conditions. Usual care typically takes the form of either internal or external signposting to services, either within the NHS, primary care or through third-sector providers such as Kidney Care UK. Therefore, the control group participants will be provided with information on available services and sign-posted to the relevant service if they wish to receive additional support (for example, the counselling service provided by Kidney Care UK).

Intervention Type
Other

Primary outcome(s)
1. Willingness to screen measured using data collected in the screening logs on the proportion of individuals who agree to undergo the initial screening for depression with the Patient Health Questionnaire-4 (PHQ-4) at one time point

2. Eligibility criteria suitability measured using data collected in the screening logs on the number of individuals excluded from the trial and the specific reasons for exclusion at one time point

3. Willingness to participate/ recruitment rate measured using data collected at recruitment on the proportion of eligible individuals who consent to participate in the trial at one time point

4. Retention rates measured using data collected on the proportion of randomised participants who remain in the study and complete the follow-up assessments. Follow-up contact will be made, where possible, to ascertain reasons for discontinuation in cases where participants have dropped out at the 3-month follow-up.

5. Intervention adherence measured using data recorded in the session logs on the proportion of participants allocated to the intervention group who complete the intervention, as well as the proportion of missed and incomplete sessions, at the 6-week follow-up

6. Time required for data collection and analysis measured using the time for screening, consent, and follow-up recorded via timesheets to inform timelines and milestones in a future trial at follow-up and analysis

7. Feasibility of outcome measures measured using the proportion of missing data from each of the outcome measures at baseline, 6-weeks and 3-months

Key secondary outcome(s)
1. Acceptability of the intervention measured using semi-structured interviews with patients, facilitators, healthcare professionals and carers at 6-weeks and three-month follow-up

2. Acceptability of the trial procedures measured using semi-structured interviews with patients, facilitators, healthcare professionals and carers at 6-weeks and 3-month follow-up

3. Feasibility of intervention fidelity measures measured using the proportion of missing data from the aspects of care questionnaire, and interviews with patients, healthcare professionals, facilitators and carers at 3-month follow-up

4. Feasibility of healthcare resource use questionnaires measured using the proportion of missing data from the healthcare resource use questionnaire, and interviews with patients, healthcare professionals, facilitators and carers at 6-weeks and 3-months

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. Are over the age of 18 years (no upper age limit)
2. Are receiving maintenance in centre haemodialysis for > 3 months
3. Have the capacity to provide informed consent.
4. Score > 3 on the PHQ-4

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Started antidepressant medication or forms of talking therapy within the previous three months.
2. Are receiving haemodialysis for acute kidney injury
3. Have a planned kidney transplant within the study period
4. Are planning to move from the dialysis unit during the study period, either because they are moving home to a different catchment area, are planning to move to a satellite dialysis unit, or are planning to start home haemodialysis
5. Do not have the capacity to provide informed consent. The clinical judgement of the dialysis team will determine the capacity to consent. There will be recruitment materials for participants who may require additional communication support, in line with ASSENT guidance, to ensure that eligible patients are not unfairly excluded.
6. Are unable to understand and communicate effectively in the English language.

Date of first enrolment
29/06/2026

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road

Hull
England
HU3 2JZ

Study participating centre
Kings College Hospital Renal Dialysis Unit
Kings College Hospital
Denmark Hill
London
England
SE5 9RS

Sponsor information

Organisation
Tees, Esk and Wear Valleys NHS Foundation Trust

ROR
https://ror.org/04s03zf45

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from the chief investigator, Claire Carswell, claire.carswell@york.ac.uk, at the University of York. We have included information on sharing data in the participant information sheet and consent forms. Datasets that have been pseudonymised will be shared on reasonable request for non-commercial research purposes. It may not be possible to fully remove all identifiable information from the qualitative datasets, so these may not be available for sharing (or only a limited subsection of the dataset may be available).

IPD sharing plan summary

Available on request