

The iADJUST study: a feasibility trial of a digital psychological intervention for people living with chronic kidney disease

Submission date 10/06/2026	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 26/06/2026	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 25/06/2026	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Living with chronic kidney disease (CKD) can be challenging. Many people experience worry, uncertainty, low mood, stress, or difficulties adjusting to life with CKD following their diagnosis. Changes such as managing symptoms, taking medications, attending medical appointments, and adapting to lifestyle recommendations can affect emotional well-being and quality of life. Despite these challenges, psychological support is rarely offered in routine kidney care clinics.

iADJUST is a digital psychological intervention designed to support adjustment and emotional well-being in people living with CKD. Delivered through the Kidney BEAM platform, iADJUST provides practical strategies and psychological support to help people manage the emotional challenges associated with living with CKD.

This study aims to determine whether iADJUST can be delivered feasibly and acceptably to people living with CKD. By providing early psychological support, the study aims to improve emotional well-being and inform the development of future psychological support programmes for people living with kidney disease.

Who can participate?

Adults aged 18 years and over with chronic kidney disease who are not receiving dialysis and have not previously received a kidney transplant may be eligible to participate. Participants must have access to an internet-enabled device, be able to understand written and spoken English, and be able to provide informed consent.

What does the study involve?

Participants who agree to take part will complete an online consent form and baseline questionnaires. They will then be randomly allocated to one of two groups.

Participants in the intervention group will receive immediate access to iADJUST for 12 weeks alongside their usual kidney care. iADJUST consists of six online sessions that include video and audio content, guided reflections, and practical strategies designed to support adjustment and

emotional well-being. Participants will also receive brief support contacts from a member of the research team to support engagement with the programme.

Participants in the control group will continue to receive their usual kidney care during the first 12 weeks of the study.

All participants will complete follow-up questionnaires after 12 weeks. Following completion of the 12-week assessment, participants in both groups will receive access to the Kidney BEAM programme. A final follow-up assessment will take place at 24 weeks.

Participants allocated to the control group will be offered access to iADJUST after completing the final assessment.

What are the possible benefits and risks of participating?

Participants may find that the intervention helps them better understand and manage some of the emotional challenges associated with living with CKD. However, improvement cannot be guaranteed. The information gathered may help improve psychological support for people living with CKD in the future.

The study is considered low risk. Some participants may find that reflecting on their experiences of living with CKD causes temporary emotional discomfort. Participants can stop at any time and will be provided with information about appropriate sources of support if needed.

Where is the study run from?

The study is organised by King's College London and King's College Hospital NHS Foundation Trust. It will recruit participants from NHS kidney services across the United Kingdom involved in the Kidney BEAM study.

When is the study starting and how long is it expected to run for?

Recruitment is expected to begin in July 2026 and continue until December 2026. Individual participation in the study will last approximately 24 weeks.

Who is funding the study?

The study is funded by the National Institute for Health and Care Research (NIHR) Maudsley Biomedical Research Centre (BRC), UK.

Who is the main contact?

Pooja Schmill and iADJUST Study Team, iadjust@kcl.ac.uk

Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
291403

Study information

Scientific Title
The iADJUST study: a randomised waitlist-controlled feasibility trial comparing a digital psychological intervention versus usual care for improving psychological well-being in adults with chronic kidney disease

Acronym

iADJUST

Study objectives

1. To assess the feasibility of recruitment to a randomised feasibility trial of iADJUST.
2. To assess participant retention throughout the study.
3. To assess the acceptability of study procedures, including consent, randomisation, and outcome data collection.
4. To assess intervention uptake, engagement and completion.
5. To assess the feasibility of delivering iADJUST remotely through the Kidney BEAM platform
6. To estimate the completeness and variability of selected patient-reported outcome measures.
7. To describe uptake and engagement with the Kidney BEAM programme after completing iADJUST.
8. To inform progression decisions and the design of a future definitive trial.

Ethics approval required

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Ethics approval(s)

Approved 19/12/2024, Health Research Authority London - Bromley Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -, bromley.rec@hra.nhs.uk), ref: 21/LO/0243

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Chronic kidney disease (CKD) and psychological adjustment to living with CKD

Interventions

This is a two-arm, parallel-group, randomised waitlist-controlled feasibility trial. Following informed consent and completion of baseline assessments, approximately 50 adults with chronic kidney disease (CKD) will be randomised in a 1:1 ratio using a secure computer-generated allocation sequence to receive either iADJUST plus usual care or usual care alone.

Participants allocated to the intervention arm will receive immediate access to iADJUST for 12 weeks in addition to usual kidney care. iADJUST is a six-session self-guided, digital psychological intervention delivered through the Kidney BEAM platform. The programme includes psychoeducation, guided audio reflections, behavioural strategies, and self-directed activities designed to support psychological adjustment and emotional well-being in people living with CKD. Participants will also receive brief therapist support contacts delivered remotely by trained members of the research team to facilitate engagement. Participants allocated to the waitlist-control arm will continue to receive usual kidney care during the first 12 weeks of the study.

Outcome measures will be collected at baseline and primary endpoint at 12 weeks. Following completion of the 12-week assessment, participants in both groups will receive access to the Kidney BEAM programme. Kidney BEAM uptake and engagement will be assessed at 24 weeks. Following completion of the final 24-week assessment, participants allocated to the control arm will be offered access to iADJUST.

Intervention Type

Behavioural

Primary outcome(s)

1. Recruitment rate measured using study data on the proportion of eligible participants who consent and are recruited throughout the recruitment period at one timepoint
2. Retention rate measured using study data on the proportion of participants completing the post-intervention assessment 12-weeks post randomisation at one timepoint
3. Outcome measure completion measured using study data on the proportion of participants completing study questionnaires 12-weeks post randomisation at one timepoint
4. iADJUST uptake measured using study data on the proportion of participants commencing at least one iADJUST session during the 12-week intervention period at one timepoint
5. iADJUST engagement measured using study data on the proportion of participants completing at least 60% of iADJUST during the 12-week intervention period at one timepoint
6. iADJUST full intervention completion measured using study data on the proportion of participants completing 100% of iADJUST during the 12-week intervention period at one timepoint

Key secondary outcome(s)

1. Depression measured using the Patient Health Questionnaire-8 (PHQ-8) score at baseline and 12-weeks post randomisation
2. Anxiety measured using the Generalised Anxiety Disorder-7 (GAD-7) score at baseline and 12-weeks post randomisation
3. Psychological distress measured using the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) score at baseline and 12-weeks post randomisation
4. Fatigue measured using the Chalder Fatigue Questionnaire (CFQ) score at baseline and 12-weeks post randomisation

5. Functional Impairment measured using the Work and Social Adjustment Scale (WSAS) score at baseline and 12-weeks post randomisation
6. Kidney BEAM uptake measured using study data on the proportion of participants registering for the Kidney BEAM programme 12-weeks post randomisation at one timepoint
7. Retention at final follow-up measured using the proportion of participants completing the 24-week assessment at one timepoint
8. Kidney BEAM engagement measured using study data on Kidney BEAM platform usage metrics at 24-weeks post randomisation
9. Health-related Quality of Life measured using the Short Form Health Survey (SF-12) at baseline and 12-weeks post randomisation

Completion date

01/09/2027

Eligibility

Key inclusion criteria

1. Adults aged ≥ 18 years
2. Diagnosis of CKD
3. Access to an internet-enabled device
4. Able to engage with a self-guided, digital programme
5. Able to understand written & spoken English
6. Able to provide informed consent

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. Acute kidney injury without established CKD
2. Current renal replacement therapy or previous kidney transplant
3. Receipt of structured psychological therapy within the previous three months

4. Participation in Kidney BEAM or structured exercise programme within the previous three months
5. Current severe mental illness or psychiatric instability judged to make participation unsuitable, including recent suicidal ideation, suicide attempt, or active risk requiring urgent mental health intervention
6. Severe cognitive, sensory (e.g., visual or hearing), communication, or other impairments, or medical conditions judged by the clinical team or Principal Investigator to make participation inappropriate

Date of first enrolment

01/07/2026

Date of final enrolment

01/02/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Kings College Hospital

Denmark Hill

London

England

SE5 9RS

Study participating centre

Guy's and St Thomas' Hospitals

Trust Offices

Guy's Hospital

Great Maze Pond

London

England

SE1 9RT

Sponsor information

Organisation

King's College London

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Funder Name

NIHR Maudsley Biomedical Research Centre

Alternative Name(s)

Maudsley Biomedical Research Centre, NIHR Maudsley BRC, National Institute for Health Research Maudsley Biomedical Research Centre, Maudsley BRC, NIHR BRC, BRC

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication