ISRCTN11609964 https://doi.org/10.1186/ISRCTN11609964

Implementation of a formula low-energy diet programme for weight loss in a renal transplant service

Submission date
18/03/2026

Recruitment status
Recruiting

Registration date
31/03/2026

Overall study status
Ongoing

Last Edited
31/03/2026

Condition category
Urological and Genital Diseases

[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
Unequal access to kidney transplantation for those people living with obesity continues, despite guidelines recommending that obesity should not stop someone from being assessed for a kidney transplant. At present, there is limited scientific evidence informing clinical practice related to weight management and support of people living with obesity and kidney failure on haemodialysis to lose weight to get listed for a kidney transplant.

This study aims to address these issues by running a randomised feasibility study in the use of a low-energy formula-based total diet replacement intervention (INFILTRATE) to help people with kidney failure on haemodialysis lose weight and be listed for kidney transplantation.

Who can participate?
Adults (>18 years old) living with kidney failure and obesity, on haemodialysis and awaiting to be listed for a kidney transplant.

What does the study involve?
If individuals agree to take part in the study, there will be six face-to-face visits with them at their dialysis unit. The first visit is a screening visit for the research team to assess eligibility to take part in the study, which will take approximately 1 hour. The key assessment visits will be face-to-face and will last up to 3 hours. These will be at baseline, 3, 6, 9, and 12 months. If individuals are in the low-energy diet group programme, they will also receive an additional eight online check-ups, which will last around 30 minutes.

Screening visit
If individuals decide to take part, the research team will arrange a screening visit. This will take place at a convenient time for them, i.e. during their haemodialysis session at their hospital. A member of the research team will explain the study to ensure that they understand the purpose of the study and to answer any questions. If individuals are happy to proceed, they will be asked to sign a consent form and will be given a photocopy for their records. If they are eligible following screening, a convenient time will be arranged for the baseline visit, where additional

measurements will be taken; these are described in the supporting participant information sheet.

Baseline visit
At the first visit, initial measurements will be taken before the start of the study. These will be like the screening visit and include weight, measurement of body fat and blood pressure. These are to make sure that any changes to their health or medications are known during the study. In addition, they will also be asked to complete a series of tests, including questionnaires, blood tests, and physical measurements.

Randomisation
Following the baseline visit, individuals will be put into either receiving the intervention, which is a formula low-energy diet programme, or usual care. The number of patients in each group will be the same and individuals will have an equal chance of receiving either treatment. The decision which group they are in will be decided by chance, which is much like tossing a coin. This process is called 'randomisation.'

Low-energy formula-based diet programme
If individuals are randomised into the intervention group, they will be asked to follow a low-energy formula-based diet (LED) made up of meal replacement products which are nutritionally balanced and designed to support weight loss. These will be a mixture of shakes, soups and porridges and will provide approximately 850kcal/day. These will be provided by the Counterweight Plus.

Individuals will receive the LED products at no cost and will have appointments with a member of the research team every 4 weeks via telephone/face to face, in addition to regular appointments with a research dietitian via the Counterweight app to check progress and safety. Fluid and dietary advice will be tailored to their individual needs.

In addition, they will get access to a 12-week health coach-led physical activity programme (Move), group sessions to help with emotional wellbeing (Mindset) and a peer support group.

Usual care
If individuals are randomised to the usual care, they will continue to be followed up by their clinical team as usual. As part of the standard care, they may receive lifestyle advice to optimise blood pressure, cholesterol and blood sugar control from a consultant nephrologist and have a standard appointment with a specialist dietitian. Individuals will be asked to attend their usual kidney clinic visits, and there will be no change to the frequency of appointments with their team.

Individuals in the control group will also be seen by the research team at the five assessment visits every 3 months to help encourage them.

What are the possible benefits and risks of participating?
Benefits:
There are no direct benefits to being involved in this study. Participants may lose weight and become eligible for transplantation sooner, though this is not guaranteed. All participants will be compensated for their time, where a £25 voucher will be given on completion of each study visit. Participation is an opportunity to contribute to the design of an obesity management intervention that is focused on helping patients living with overweight and obesity to become eligible for life-changing transplantation. Participants may also learn more about their condition, which may feel empowering.

Risks:
There might be a chance that they do not lose weight and get listed for transplantation despite following the dietary advice. For those on the LED programme, the diet can have side effects, and not all side effects are known; these are usually mild and last for a short period of time. When they come for their hospital visit, a member of the research team will ask them about any side effects they have experienced. A member of the research team will monitor them closely for any possible side effects and they may suggest additional investigations if they consider it appropriate.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
April 2026 to April 2028.

Who is funding the study?
The National Institute for Health Research (NIHR) through an Advanced Fellowship, UK.

Who is the main contact?
Dr Adrian Brown, a.c.brown@ucl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Adrian Brown

ORCID ID
https://orcid.org/0000-0003-1818-6192

Contact details
Centre for Obesity Research, University College London, Rayne Building, 5 University Street
London
United Kingdom
WC1E 6JF
-
a.c.brown@ucl.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
365381

Central Portfolio Management System (CPMS)
71292

National Institute for Health and Care Research (NIHR)

303041

Study information

Scientific Title
INFILTRATE: ImplemeNtation of a Formula low energy diet programme for weight loss In a renaL TRansplAnT sErvice Study - Work package 3 Feasibility Study

Acronym
INFILTRATE Feasibility Study

Study objectives
This randomised feasibility study aims to assess the feasibility, acceptability, and safety of a formula LED lifestyle programme to help people living with obesity and kidney failure on haemodialysis lose weight and be listed for a kidney transplant. This study will test the trial methodology procedures to demonstrate if a full-scale RCT is possible.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/02/2026, South Central - Oxford A Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; oxforda.rec@hra.nhs.uk), ref: 26/SC/0041

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Renal, Primary sub-specialty: Renal Disorders; Health Category: Renal and Urogenital; Disease/Condition: Obesity and other hyperalimentation, Renal failure

Interventions

Randomisation: The study uses a specialised company that provides randomisation service, which will not involve any members of the research team.

Intervention: The intervention arm involves using a total diet replacement (TDR) formula LED behavioural programme, including structured physical activity, psychological and peer support.

Diet: Participants in the intervention arm will receive a total diet replacement low-energy formula-based diet for 12 weeks, providing ~850kcal/day and then will have gradual food reintroduction over 8 weeks from 1000kcal/day to 1200kcal/day and then a maintenance phase. Participants will receive individualised dietary advice based on the dietary guidelines for haemodialysis patients and tailored to the individual to achieve weight maintenance.

Physical activity: Participants in the intervention arm will be encouraged to engage in regular physical activity. Each participant will be encouraged to accumulate 150 min per week of moderate intensity aerobic activity or 75 min per week of vigorous activity, and to do muscle resistance training on 2 days of the week. In additional they will get access to a 12-week health coach-led physical activity programme.

Psychology: Participants in the intervention arm will have access to psycho-educational material and monthly groups, alongside a peer support group on a monthly basis.

Control (usual care): Participants in the control group will attend usual kidney clinic visits with treatment and receive standard care. There will be no change to the frequency of usual nephrologist care, dietitian, other kidney team, or general practitioner shared care monitoring.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment measured using the percentage of participants who are recruited out of the recruitment target at baseline, 3, 6, 9 and 12 months

2. Retention measured using the percentage of participants followed up at baseline, 3, 6, 9 and 12 months

3. Completeness of data measured using the number of participants completing follow-up assessments and each outcome measure at baseline, 3, 6, 9 and 12 months

4. Acceptability measured using the Renal Treatment Satisfaction Questionnaire (RTSQ) at baseline, 3, 6, 9 and 12 months

5. Acceptability of the intervention measured using a qualitative interview at 3, 6 and 12 months

6. Diet adherence measured using clinical interviews and use of 24-hour recalls and EPIC Food Frequency Questionnaire at baseline, 3, 6, 9 and 12 months

7. Mean percentage difference in dry weight change (%) measured using weighing scales at baseline, 3, 6, 9 and 12 months

Key secondary outcome(s)
1. Listed for a kidney transplant measured using the number of people activated on the transplant list at baseline, 3, 6, 9 and 12 months

2. Body composition measured using bioelectrical impedance analysis at baseline, 3, 6, 9 and 12 months

3. Biochemistry (including lipids, liver, urine and urea, potassium, phosphate) measured using a blood test at baseline, 3, 6, 9 and 12 months

4. Waist-to-height ratio measured using a tape measure at baseline, 3, 6, 9 and 12 months

5. Blood pressure measured using a digital sphygmomanometer at baseline, 3, 6, 9 and 12 months

6. Cardiometabolic risk factors measured using medical records, physical examination and blood tests at baseline, 3, 6, 9 and 12 months

7. Appetite measured using a Visual Analogue Score (VAS) at baseline, 3, 6, 9 and 12 months

8. Sleep measured using the actigraph wGT3X-BT at baseline, 3, 6, 9 and 12 months

9. Activity measured using the actigraph wGT3X-BT and questionnaire at baseline, 3, 6, 9 and 12 months

10. Physical function measured using a hand dynamometer and sit-to-stand test at baseline, 3, 6, 9 and 12 months

11. Fatigue measured using the FACIT fatigue scale at baseline, 3, 6, 9 and 12 months

12. Quality of life measured using the Kidney Disease Quality of Life Short-Form survey (KDQOL SF1.3 MCS) at baseline, 3, 6, 9 and 12 months

13. Health-related quality of life measured using the EQ-5D at baseline, 3, 6, 9 and 12 months

14. Mental health measured using the PHQ-4 at baseline, 3, 6, 9 and 12 months

15. Weight bias measured using the Weight Bias Internalisation Scale at baseline, 3, 6, 9 and 12 months

16. Eating behaviour measured using the TFEQ and BES at baseline, 3, 6, 9 and 12 months

17. Dietary Intake measured using 24-hour recalls and EPIC Food Frequency Questionnaire at baseline, 3, 6, 9 and 12 months

Completion date
01/05/2028

Eligibility

Key inclusion criteria
Patients will be considered for the study if they meet the following criteria:
1. Adults (18-70 years)
2. Chronic Kidney Disease Stage 5 (KF) on HD

3. Waiting to be listed for renal transplant with obesity identified as the only/main barrier that has precluded listing
4. BMI 32.5-45kg/m2 or BMI 30-45kg/m2 for ethnic minority groups or an increased waist circumference (approximately <88cm for women and over <108cm for men)
5. Within 15% of their target weight for transplantation
6. Weight stable at time of recruitment, defined as <5% variation in dry body weight over the preceding 3 months – including those on obesity management medications, with participants needing to be established for 3 months on maximal tolerated dose and weight stable (e.g. Semaglutide; Tirzepatide).
7. Able to comply with study protocol
8. Able to access the internet
9. Able to read and write in English
10. Medically safe to participate in formula LED programme – determined in the opinion of the investigator or clinical team
11. Willing and able to provide written informed consent.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Patients will be excluded for any of the following reasons:
1. Peritoneal dialysis
2. Contraindication for a low energy diet programme
3. Diagnosed or known with uncontrolled depression or psychiatric disorder in the opinion of the investigator or clinical team.
4. Diagnosed with active uncontrolled eating disorder e.g. binge eating disorder, anorexia nervosa.
5. Previous bariatric surgery.
6. Recently started on obesity management medication within last 3 months or titrating the medication (e.g. Semaglutide; Tirzepatide) and currently losing weight.
7. Pregnancy or lactation.
8. Participating in another clinical intervention trial
9. Any diagnosed food allergy, or other allergies which limit the ability to adhere to the intervention diet

10. A current history of drug or alcohol misuse
11. Recurrent persistent pre-dialysis hyperkalaemia (high potassium) >6mmol/L
12. Any other factor making the participant unsuitable in the view of the investigator

Date of first enrolment
13/04/2026

Date of final enrolment
01/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Free Hospital
Pond Street
London
England
NW3 2QG

Study participating centre
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
England
SE5 9RS

Sponsor information

Organisation

University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

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

IPD sharing plan summary
Data sharing statement to be made available at a later date