ISRCTN10070371 https://doi.org/10.1186/ISRCTN10070371

Preliminary evaluation of the 'Living Well on Haemodialysis' programme

Submission date
18/02/2022

Recruitment status
No longer recruiting

Registration date
23/02/2022

Overall study status
Completed

Last Edited
02/10/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Hemodialysis is a process used to purify the blood of a person whose kidneys are not working normally. It can extend the lives of people with end-stage kidney disease, but it is an extremely burdensome, invasive treatment that imposes significant limitations and restrictions on the lives of the people receiving it. It is therefore important to find the most effective ways to support people receiving dialysis to maintain their wellbeing and quality of life in spite of the difficulties it creates for them. Acceptance and Commitment Therapy (ACT) is a mindfulness-based therapy designed to enable people to lead rich, meaningful lives while accepting the pain and suffering of life. ACT uses metaphor, paradox, mindfulness skills and experiential exercises to promote psychological flexibility, which involves being open, aware and in contact with the present moment, and engaging in activities consistent with one's goals and values. ACT has been shown to be useful for people with a range of physical conditions, and a set of ACT-based materials and exercises were recently adapted specifically for people receiving dialysis and presented as a series of short videos (the published report of the adaptation exercise is available here: https://doi.org/10.1186/s12894-021-00921-5). The aim of this study is to assess how feasible a programme of those materials is and whether the materials are acceptable to people with chronic kidney disease who are receiving in-centre haemodialysis. The researchers will use the results of this small preliminary trial to prepare for a larger, randomised controlled trial.

Who can participate?
Patients aged over 18 years of age with chronic kidney disease who received in-centre haemodialysis for at least 90 days in the last 2 years and who are able to converse in English.

What does the study involve?
Talking part in the study involves completing some questionnaires and then spending about an hour a week over 4 weeks, trying out a programme of exercises and materials in the form of short films. The programme is called 'Living Well on Haemodialysis'. Each week there are four short films to watch – one story film, in which a person with chronic kidney disease talks about their own experience of dialysis and the techniques they found helped them to live better with dialysis, and three explainer films, which explain how to use the techniques described in the story film. All participants receive the same treatment. There will be a focus group for participants to talk about their experience of following the programme. After the programme

and 4 weeks later, participants will complete similar questionnaires as those presented before the programme.

What are the possible benefits and risks of participating?
It is hoped that participants will find taking part interesting and they may learn some techniques to help them live better on dialysis. The researchers will use the results of the trial to improve the materials further and make them more widely available so that we hope larger numbers of people in the future will benefit from participants' involvement. As a gesture of appreciation for the time and effort involved, people who complete all the stages of the study will receive a £30 shopping voucher.
There is a small risk that participants might find the content of the videos mildly distressing because they involve discussion about people encountering challenges and difficulties associated with kidney disease and dialysis, and then finding ways to overcome those challenges and difficulties in order to feel better about dialysis and get more benefits from the treatment.

Where is the study run from?
University of Derby (UK)

When is the study starting and how long is it expected to run for?
September 2021 to April 2022

Who is funding the study?
1. Kidney Care UK and the British Renal Society.
2. University of Derby (UK)

Who is the main contact?
Prof. James Elander
j.elander@derby.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof James Elander

ORCID ID
https://orcid.org/0000-0001-7665-5482

Contact details
School of Psychology
University of Derby
Kedleston Road
Derby
United Kingdom
DE22 1GB
+44 (0)1332 593048
j.elander@derby.ac.uk

Additional identifiers

Protocol serial number
ETH2122-0671

Study information

Scientific Title
Feasibility and acceptability trial of intervention materials based on Acceptance and Commitment Therapy for people receiving in-centre renal haemodialysis

Acronym
ACT-for-dialysis

Study objectives
The objectives are to:
1. Assess the feasibility of recording recruitment, retention, fidelity, adherence and adverse events during participation.
2. Assess the acceptability of the materials by collecting direct evaluative feedback.
3. Explore participants' experiences of the materials using focus groups.
4. Inform the design of a larger-scale randomised controlled trial by collecting pilot data on changes in primary and secondary outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/11/2021, University of Derby Health, Psychology and Social Care Research Ethics Committee (Kedleston Road, Derby, DE22 1GB, UK; +44 (0) 1332 590500; hpsccrec@derby.ac.uk), ref: ETH2122-0671

Primary study design
Interventional

Study design
Single-centre single-group before-and-after trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Improvement of quality of life among people with end-stage renal disease receiving in-centre haemodialysis

Interventions
Single-group before-and-after study, with baseline (pre-intervention) measures, then a 4-week intervention programme, post-intervention measures and 4-week post-intervention follow-up.

Talking part in the study involves completing some questionnaires and then spending about an hour a week over 4 weeks trying out a programme of exercises and materials in the form of

short films. The programme is called ‘Living Well on Haemodialysis’. Each week there are four short films to watch – one story film, in which a person with chronic kidney disease talks about their own experience of dialysis and the techniques they found helped them to live better with dialysis, and three explainer films, which explain how to use the techniques described in the story film. All participants receive the same treatment. There will be a focus group for participants to talk about their experience of following the programme. After the programme and 4 weeks later, participants will complete similar questionnaires as those presented before the programme, including the Illness Acceptance Questionnaire, the Acceptance and Action Questionnaire, and the Kidney Disease Quality of Life questionnaire.

Intervention Type
Behavioural

Primary outcome(s)
Physical, mental and kidney disease-specific quality of life, measured using the Kidney Disease Quality of Life Short Form (KDQOLSF) at baseline, 4 weeks (post intervention) and 8 weeks (4-week post intervention follow-up)

Key secondary outcome(s)
1. Psychological flexibility measured using the Acceptance and Action Scale at baseline (pre-intervention), 4 weeks (post-intervention) and 8 weeks (4-week post-intervention follow-up)
2. Acceptance of illness measured using the Acceptance of Illness Scale at baseline, (pre-intervention), 4 weeks (post-intervention) and 8 weeks (4-week post-intervention follow-up)
3. Feasibility assessed by recording recruitment and retention, plus fidelity, adherence and adverse events during the intervention and post-intervention
4. Acceptability assessed by collecting direct evaluative feedback using ratings scales and free-text open response formats, plus a focus group, to assess how participants experienced the intervention at post-intervention

Completion date
11/04/2022

Eligibility

Key inclusion criteria
1. Age over 18 years
2. Received in-centre dialysis for at least 90 days in the last 2 years
3. Able to converse in English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
13

Key exclusion criteria
1. Not able to use the intervention because of a medical condition, active infection or malignancy
2. Unable or unwilling to give informed consent
3. Unable to take part in online data collection because of technical limitations

Date of first enrolment
01/02/2022

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Derby
Kedleston Road
Derby
United Kingdom
DE22 1GB

Sponsor information

Organisation
University of Derby

ROR
https://ror.org/02yhrrk59

Funder(s)

Funder type
University/education

Funder Name
Kidney Care UK and British Renal Society Joint Grants Partnership (Ref 18-005)

Funder Name
University of Derby

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

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 Prof. James Elander (j.elander@derby.ac.uk). This data will be available from between Summer 2022 and December 2022, depending on the time needed to prepare, anonymise and review the datasets to ensure they are consistent with participants' consent.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2023	02/10/2023	Yes	No
Dataset			04/09/2023	No	No
Dataset			04/09/2023	No	No
Statistical Analysis Plan			04/09/2023	No	No