

Preliminary evaluation of the 'Living Well on Haemodialysis' programme

Submission date 18/02/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/02/2022	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/10/2023	Condition category Urological and Genital Diseases	<input checked="" type="checkbox"/> 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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

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

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Internet/virtual

Study type(s)

Quality of life

Participant information sheet

Not available in web format. Please use contact details to request a participant information sheet

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.

Taking 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 measure

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)

Secondary outcome measures

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

Overall study start date

01/09/2021

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

10

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

England

United Kingdom

Study participating centre

University of Derby
Kedleston Road

Derby
United Kingdom
DE22 1GB

Sponsor information

Organisation

University of Derby

Sponsor details

Kedleston Road
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Sponsor type

University/education

Website

<https://www.derby.ac.uk/>

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

Publication and dissemination plan

Planned publication in a peer-reviewed high-impact journal, and dissemination to a network of clinical researchers and practitioners.

Intention to publish date

28/02/2023

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?
Dataset			04/09/2023	No	No
Dataset			04/09/2023	No	No
Statistical Analysis Plan			04/09/2023	No	No
Results article		01/10/2023	02/10/2023	Yes	No