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Cognitive Behavioural Therapy (CBT) for Renal Fatigue (BReF): A feasibility pilot randomised-controlled trial of CBT for the management of fatigue in haemodialysis (HD) patients

Submission date
02/10/2017

Recruitment status
No longer recruiting

Registration date
03/10/2017

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol
Background and study aims
Fatigue (extreme tiredness and weakness) is one of the most common and debilitating symptoms among haemodialysis patients, affecting 49 to 92% of patients. Haemodialysis is a process that removes waste from the blood when the kidneys are unable to do so. Currently, management of fatigue in this setting revolves around pharmacological (medicine) treatments or exercise, with limited benefits and not always suitable. There is growing evidence in support of psychological treatments for the management of fatigue in other long-term physical conditions, like Multiple Sclerosis. Based on the findings of a qualitative study, a prospective study, and reviews, a cognitive based therapy (CBT) for the management of fatigue in haemodialysis has been developed. The aim of this study is to assess whether this psychological fatigue intervention is feasible, acceptable, and potentially beneficial for fatigue of patients undergoing in-centre haemodialysis (HD).

Who can participate?
Adults aged 18 and older who have a confirmed ARD diagnosis who are receiving in-centre haemodialysis.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the BReF programme, which is a CBT-based programme, designed to help them manage fatigue, over a 4 to 6-week period. They also receive a manual about managing their fatigue as well as three or five sessions with a therapist. The programme consists of two units, the basic unit or the advanced unit. The first and last sessions are face-to-face lasting one hour, while the remaining sessions are over the phone, and last 30 minutes. Those in the second group receive their usual care and receive the therapy materials at the end of their participation in the study. All participants are asked to complete a follow-up self-report questionnaire after three months. A small group of participants are interviewed about their experiences of the intervention by an independent from the delivery of the intervention researcher.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their negative emotions and fatigue symptoms. Risks to participants are small. Participants may find discussing fatigue and the illness, as part of the intervention, distressing. However, these effects are anticipated to be short lived, as participants will learn psychological techniques during the intervention that can help them manage negative emotions and fatigue better.

Where is the study run from?
1. King's College Hospital (UK)
2. Lister Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2017 to November 2018

Who is funding the study?
NIHR Maudsley Biomedical Research Centre (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35183

Study information

Scientific Title
Cognitive Behavioural Therapy (CBT) for Renal Fatigue (BReF): A feasibility pilot randomised-controlled trial of CBT for the management of fatigue in haemodialysis (HD) patients

Acronym
BReF

Study objectives
The overarching aim of this trial is to assess the feasibility, acceptability, and potential efficacy of the BReF CBT-based programme, via the following objectives:
Objective 1: To explore rates of recruitment and retention into the trial.
Objective 2: To examine willingness to be randomised to either the intervention arm or control arm by recording participant reasons for non-consent into the study (if disclosed).
Objective 3: To explore the level of adherence to therapist support sessions (intervention arm only).
Objective 4: To estimate the standard deviation of fatigue in this patient population in order to compute a more robust estimate of the sample size required for an efficacy trial.
Objective 5: To assess the psychometric properties, reliability, validity, and sensitivity to change (responsiveness) of the self-report instruments used.
Objective 6: To explore the potential efficacy of a CBT-based intervention with therapist support at reducing fatigue severity and fatigue-related functional impairment as compared to the waiting-list control.
Objective 7: To explore the potential efficacy of a CBT-based intervention with therapist support at reducing depression and anxiety and improving sleep quality as compared to the waiting-list control.
Objective 8: To examine change in fatigue-related cognitions and behaviours, and whether their effect differs between the intervention and control arm.
Objective 9: To qualitatively explore patient perceptions of the acceptability and usefulness of the intervention and identify areas of improvement for a future efficacy trial.
Objective 10: To explore any intervention-specific issues, particularly setting and mode of delivery of the intervention and number of sessions/chapters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Bridge Research Ethics Committee, 12/09/2017, ref: 17/LO/1406

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Renal disorders, Primary sub-specialty: Renal disorders; UKCRC code/ Disease: Renal and Urogenital/ Renal failure, Other/ General symptoms and signs

Interventions
The intervention is a tailored CBT-based self-management intervention with therapist support. The purpose of this intervention is to target individuals' fatigue beliefs and behaviours in order to facilitate coping with renal fatigue.

This study is a two-armed parallel feasibility randomised-controlled trial (RCT) with a nested qualitative study to explore the feasibility, acceptability, and potential benefits of CBT-based intervention for fatigue in haemodialysis. Participants are randomly allocated to the intervention group or the waiting list group. The structure of the intervention is stepped, consisting of a basic unit, where all participants cover four chapters of a self-management manual and this is accompanied by three sessions with a therapist, and an additional unit, for those engaging well, where an additional two chapters are covered with a therapist in two telephone sessions on changing unhelpful thoughts. The intervention lasts approximately between four to six weeks. Participants complete a baseline questionnaire before randomisation and a follow-up questionnaire at 3-months post-randomisation.

Participants allocated to the waiting-list control continue to receive their usual care without any additional support. However, at the end of their participation in the study, they receive the therapy materials to complete on their own.

Participants in both groups are asked to complete a follow-up self-report questionnaire three-months post-randomisation. A qualitative study is nested within this feasibility trial. A subgroup of participants, who received the intervention, are interviewed about their experiences of the intervention by an independent from the delivery of the intervention researcher.

Intervention Type
Other

Primary outcome measure
1. Descriptive data on recruitment and retention rates and willingness to be randomised
2. Degree of adherence to the intervention

Secondary outcome measures
1. Fatigue severity is measured using the Chalder Fatigue Questionnaire (CFQ) at baseline and 3-months post-randomisation
2. Fatigue-related functional impairment is measured using the Work and Social Adjustment Scale (WSAS) at baseline and 3-months post-randomisation
3. Depression is measured using the Patient Health Questionnaire-9 (PHQ9) at baseline and 3-months post-randomisation
4. Anxiety is measured using the the Generalised Anxiety Disorder-7 (GAD7) at baseline and 3-months post-randomisation

5. Sleep quality is measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline and 3-months post-randomisation
6. Fatigue perceptions is measured using the Brief Illness Perceptions Questionnaire (BIPQ) at baseline and 3-months post-randomisation
7. Cognitive and behavioural responses to fatigue is measured using the Cognitive and Behavioural Responses to Symptoms Questionnaire (CBSQ) at baseline and 3-months post-randomisation
8. Sleep hygiene behaviours is measured using the Sleep Hygiene Index (SHI) at baseline and 3-months post-randomisation
9. Physical activity as measured by the International Physical Activity Questionnaire (short-form) (IPAQ-SF) at baseline and 3-months post-randomisation
10. Patient perceptions of the acceptability and usefulness of the intervention is assessed through the qualitative interviews. Qualitative interviews will be conducted by an independent from the trial researcher with a subset of participants who received the intervention following completion of the follow-up questionnaire at 3-months post-randomisation.

Overall study start date
05/01/2017

Completion date
02/12/2018

Eligibility

Key inclusion criteria
1. Are over 18 years of age
2. Have a confirmed ARD diagnosis
3. Are experiencing clinical levels of fatigue defined as scoring >18 on the Chalder Fatigue Questionnaire, when using the continuous scoring (Chalder et al., 1993; White et al., 2011)
4. Have full verbal and written proficiency in English
5. Receiving in-centre haemodialysis
6. Length of time on dialysis > 90 days
7. Are willing and able to take part in the study and intervention

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 25; UK Sample Size: 25

Total final enrolment

Key exclusion criteria
1. Do not provide informed consent or refuse to be randomised,
2. Have any known cognitive impairments
3. Have a severe mental health disorder, for example, psychosis, bipolar disorder
4. Do not have full verbal and written proficiency in English
5. Are currently receiving psychotherapy
6. Are currently participating in any other trial
7. Are failing on dialysis and approaching end of life (supportive care/palliative care pathway)
8. Have a fatigue (CFQ) score below the cut-off at the pre-randomisation assessment (spontaneous improvement after screening)

Date of first enrolment
30/10/2017

Date of final enrolment
30/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College Hospital
Denmark Hill
Brixton
London
United Kingdom
SE5 9RS

Study participating centre
Lister Hospital
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Sponsor information

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SE1 4UL

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Organisation
King's College Hospital

Sponsor details
King’s College Hospital NHS Foundation Trust
161 Denmark Hill
London
England
United Kingdom
SE5 8EF

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NIHR Maudsley Biomedical Research Centre

Results and Publications

Publication and dissemination plan
We will endeavour to publish this study in a peer-reviewed journal, present the findings at relevant conferences and the findings will also contribute to a doctoral thesis.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/03/2018		Yes	No
Results article	results	14/10/2020	23/10/2020	Yes	No
HRA research summary			28/06/2023	No	No