

# 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

<b>Submission date</b> 02/10/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/10/2017	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 23/10/2020	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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?

Miss Federica Picariello

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## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

24

**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

United Kingdom

England

## Study participating centre

### King's College Hospital

Denmark Hill

Brixton

London

United Kingdom

SE5 9RS

## Study participating centre

### Lister Hospital

Coreys Mill Lane

Hertfordshire

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SG1 4AB

# Sponsor information

## Organisation

King's College London

## ROR

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

## Organisation

King's College Hospital

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Maudsley Biomedical Research Centre

# Results and Publications

## 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?
<a href="#">Results article</a>	results	14/10/2020	23/10/2020	Yes	No
<a href="#">Protocol article</a>	protocol	08/03/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No