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A couple-based psychological intervention for chronic fatigue syndrome

Submission date
02/10/2017

Recruitment status
No longer recruiting

Registration date
12/10/2017

Overall study status
Completed

Last Edited
21/01/2020

Condition category
Nervous System Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic fatigue syndrome (CFS) is a condition mainly associated with extreme tiredness that can cause significant levels of disability. Managing life with CFS can be challenging, and people with CFS are at increased risk of experiencing depression and anxiety, with their partners also reporting higher rates of emotional distress. Relationships can interact with physical and mental health in several ways. For example, distressed relationships can increase the risk of depression and other health problems. Conversely, partners and family members can offer valuable support both on an emotional level and in promoting health-related lifestyle changes. There is evidence that cognitive behavioral therapy (CBT) (a type of talking therapy) can help people with CFS to manage their symptoms. However, fatigue and other symptoms experienced by this patient group can make CBT, which is quite an 'active' therapy, quite difficult to engage in.For these reasons, it is believed that involving partners in a constructive manner in a psychological intervention for patients affected by CFS could enhance the effectiveness of the intervention and prove beneficial to partners. Therefore, the aim of this study is to develop a cognitive behavioural couple-based therapy (CBCT) for people with CFS and their partners to explore the effectiveness of the intervention in a group of 10 couples.

Who can participate?
Adults aged 18 and older who are diagnosed with chronic fatigue syndrome.

What does the study involve?
Patients referred to the service with a diagnosis of CFS and who are in a committed relationship will be invited to participate. After a telephone interview, eligible couples are offered a course of 12-15 sessions of CBCT. Participants are asked to complete questionnaire assessments before therapy starts and at the end of therapy, and also six months after the end of therapy.

What are the possible benefits and risks of participating?
Participants may benefit from participating in this study. It could help improve daily functioning and symptoms of fatigue in patients with CFS, and reduce symptoms of anxiety and depression as well as improving relationship satisfaction in both partners. Participants who enrol in the study will be offered a therapy start date within 2-3 weeks of assessment rather then being placed on a waiting list for treatment, so they will be able to access treatment very quickly. With

regard to risk, participant wellbeing and safety will be monitored throughout the study, as is standard practice in Talking Therapies Southwark. Self-reported symptoms of anxiety, depression and general functioning will be collected at every contact, and deteriorations on any of these measures will be discussed as part of treatment and addressed as appropriate. Risk will be monitored throughout the study, and risk management plans will be made and amended as appropriate. This may include onward referral to other services.

Where is the study run from?
Talking Therapies Southwark (UK)

When is the study starting and how long is it expected to run for?
September 2019 to December 2020

Who is funding the study?
British Association for Behavioural and Cognitive Psychotherapies (UK)

Who is the main contact?
Dr Marion Cuddy
marion.cuddy@slam.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Marion Cuddy

ORCID ID
https://orcid.org/0000-0002-5642-3163

Contact details
Talking Therapies Southwark
Middle House
Maudsley Hospital
London
United Kingdom
SE5 8AZ
+44
marion.cuddy@slam.nhs.uk

Additional identifiers

Protocol serial number
35029

Study information

Scientific Title
A couple-based psychological intervention for chronic fatigue syndrome: a pilot study

Study objectives
Research Questions:
1. Is a couple-based CBT intervention acceptable and useful to patients with CFS and their partners with regard to
helping them cope with CFS?
2. Can a couple-based CBT intervention improve fatigue, daily functioning, anxiety, and depression in patients with CFS?
3. Does this intervention improve relationship satisfaction in patients with CFS and their partners?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Westminster Research Ethics Committee IRAS 221300, 17/07/2017, ref: 17/LO/1093

Study design
Non-randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic fatigue syndrome

Interventions
Patients referred to the service with a diagnosis of chronic fatigue syndrome (CFS) and who are in a committed relationship are invited to participate.

Participants referred or who self-refer to Talking Therapies Southwark, who have agreed to be contacted for research and who have a diagnosis of chronic fatigue syndrome are approached. They are sent an information sheet about the study by post, and invited to contact the chief investigator if they would like more information.

The initial letter is followed up by a telephone call one week later from the chief investigator, in order to answer any questions about the study. If the person is interested in taking part, a telephone screening appointment is arranged. Potentially suitable participants are then invited to a face to face appointment with their partner. If they are eligible and interested at that point, they are asked to consent to taking part in the study. It is made clear to participants (both partners) that they can withdraw from the study.

Participants (patients and their partners) are offered up to 12 sessions of a couple-based cognitive behavioural intervention. Therapy is delivered by experienced therapists who are trained in delivering couple-based interventions. Participants are invited to complete assessments at baseline, end of treatment, and six months after the end of treatment. A subgroup of five couples are also invited to provide qualitative feedback through semi-

structured interviews at the end of treatment. Participants are in the study for approximately 12 months including the follow-up period.

Detailed outcome measures will be completed by both partners at the screening, assessment, and start of therapy appointments (pre-therapy), on the day of the final session (post-treatment), and 6 months after end of treatment (follow-up). These questionnaires will measure fatigue, depression, and relationship satisfaction. A small sample of couples will also be asked to take part in a brief interview concerning their experience of therapy. Routine measures of anxiety, depression and daily functioning will be completed at every appointment, as is standard practice in TTS.

Intervention Type
Other

Primary outcome(s)
1. Fatigue is measured using the Chalder Fatigue Scale at baseline, start of therapy, end of therapy and six months
2. Daily functioning is measured using the Work & Social Adjustment Scale at baseline, start of therapy, at every treatment session, the end of therapy and six month follow up
3. Anxiety and depression is measured using the Beck Depression Inventory at baseline, start of therapy, end of therapy and six month follow up; the Generalised Anxiety Disorder Assessment, and the Patient Health Questionnaire are administered at baseline, start of therapy, at every treatment session, the end of therapy and six month follow up
4. Relationship satisfaction is measured using the Couple Satisfaction Index at baseline, start of therapy, at every treatment session, the end of therapy and six month follow up

Key secondary outcome(s))
There are no secondary outcome measures.

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Diagnosis of chronic fatigue syndrome (CFS) made by a GP or other appropriate health professional. The research team will check that a) the participant has had the relevant medical tests to rule out alternative diagnoses in line with the NICE guidelines for CFS, and b) that the participant's symptoms meet the Oxford criteria for CFS.
2. Patient must be in a committed relationship with a duration of at least 6 months
3. Patient and partner must be willing to engage in a couple-based intervention
4. Over 18 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Primary alcohol or drug misuse problem
2. Current psychotic illness
3. Insufficient command of the English language to be able to engage in therapy
4. Illness severity (CFS or other) that would prevent regular attendance of therapy sessions in an outpatient setting
5. Risk to self or others that would be difficult to manage in a primary care setting

Date of first enrolment
01/11/2017

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Talking Therapies Southwark
Middle House
Maudsley Hospital
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
South London and Maudsley NHS Foundation Trust

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
British Association for Behavioural and Cognitive Psychotherapies

Alternative Name(s)
British Association for Behavioural & Cognitive Psychotherapies, BABCP

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes