Cognitive behavioural therapy (CBT) in Chronic Fatigue Syndrome (CFS): A randomised controlled trial of an outpatient group programme

Submission date	Recruitment status No longer recruiting	Prospectively registered		
25/04/2003		Protocol		
Registration date 25/04/2003	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
08/11/2022	Signs and Symptoms			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 97/41/08

Study information

Scientific Title

Cognitive behavioural therapy (CBT) in Chronic Fatigue Syndrome (CFS): A randomised controlled trial of an outpatient group programme

Study objectives

To test the hypothesis that group CBT will produce an effective and efficient management strategy for patients in primary care with Chronic Fatigue Syndrome.

Please note that, as of 14 January 2008, the anticipated start and end dates of this trial have been updated from 1 July 1999 and 31 December 2002 to 1 August 2000 and 31 January 2004, respectively.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Symptoms and general pathology: Other symptoms and general pathology

Interventions

- 1. CBT
- 2. Support/Education (control for non-specific group factors)
- 3. Standard Medical Care

Assessment: pretreatment, 6 months, 1 year follow-up.

Setting: Consecutive referrals from primary care and secondary outpatient clinic (this combines services from 2 NHS Trusts).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Conventional standardised outcome measures will be used.

Within this the main measures include SF36, Physical Function Measure (STET), HADS, CFS Neurocognitive battery and the Fatigue Scale. The study will compare both the outcomes and costs. Relevant resource use includes not only the direct costs of the interventions, but also the costs of managing the symptoms of CFS.

The cost benefit analysis will adopt specific outcome criteria for functional performance and emotional distress to derive the number needed to treat (NNT) ratio in order to compare the three groups. Assumptions and uncertainties in either resource use or outcome will be tested using sensitivity analysis.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/2000

Completion date

31/01/2004

Eligibility

Key inclusion criteria

Patients suffering chronic fatigue syndrome

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

153

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/2000

Date of final enrolment

31/01/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Clinical Psychology (Health Specialty)

Bristol United Kingdom BS16 1LE

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/en/index.htm

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	HTA monograph	01/10/2006		Yes	No