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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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