ISRCTN37461058 https://doi.org/10.1186/ISRCTN37461058

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

Registration date
25/04/2003

Overall study status
Completed

Last Edited
08/11/2022

Condition category
Signs and Symptoms

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Hazel O'Dowd

Contact details
Clinical Psychology (Health Specialty)
North Bristol NHS Trust
Pain Management Centre
Frenchay Hospital
Frenchay Park Road
Bristol
United Kingdom
BS16 1LE

Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/01/2004

Eligibility

Key inclusion criteria
Patients suffering chronic fatigue syndrome

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

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
United Kingdom

England

Study participating centre
Clinical Psychology (Health Specialty)
Bristol
United Kingdom
BS16 1LE

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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