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A randomised controlled trial of nurse facilitated self-help treatment for patients in primary care with chronic fatigue syndrome

Submission date
18/05/2001

Recruitment status
No longer recruiting

Registration date
18/05/2001

Overall study status
Completed

Last Edited
29/06/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0200212

Study information

Scientific Title
A randomised controlled trial of nurse facilitated self-help treatment for patients in primary care with chronic fatigue syndrome: the FINE trial (Fatigue Intervention by Nurses Evaluation)

Acronym
FINE

Study objectives
1. Is pragmatic rehabilitation, delivered at home by nurses to CFS patients recruited from primary care, a clinically effective intervention in terms of reduced disability and fatigue when compared with treatment as usual delivered through the primary care team?
2. Is pragmatic rehabilitation, delivered at home by nurses to CFS patients recruited from primary care, a cost effective intervention when compared with treatment as usual delivered through the primary care team?
3. Is supportive listening, delivered at home by nurses to CFS patients recruited from primary care, a clinically effective intervention in terms of reduced disability and fatigue when compared with treatment as usual delivered through the primary care team?
4. Is supportive listening, delivered at home by nurses to CFS patients recruited from primary care, a cost effective intervention when compared with treatment as usual delivered through the primary care team?

Can we demonstrate that the active component of pragmatic rehabilitation operates in addition to a non-specific treatment effect due to contact with a supportive therapist?

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)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
1. Pragmatic rehabilitation
2. Supportive listening
3. Treatment as usual by GP

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measures will be patient-rated to avoid observer bias, and will be supplemented with an objective measure of the patients exercise tolerance. These will be:
1. Score on the physical functioning scale of the SF-36
2. Cost-effectiveness using the Euroquol
3. The score on the 11-item Fatigue Scale

Secondary outcome measures
1. A timed step-test to provide an objective measure of the patients exercise tolerance and cardiovascular fitness
2. Scores on the HAD to provide measures of depression and anxiety
3. A brief four-item sleep scale

Overall study start date
21/06/2004

Completion date
25/07/2008

Eligibility

Key inclusion criteria
Patients 18 and over, who fulfil the Oxford criteria for CFS (Sharpe et al. 1991) [Prior to Feb'2005 the criteria was the Fukuda criteria], and who have a principal complaint of fatigue. Patients must score 4 or more on the 11-item Chalder fatigue scale, and 70% or less on the SF-36 physical functioning scale.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
360

Key exclusion criteria
1. Patients whose fatigue is explained by any active medial condition
2. Patients with schizophrenia, bipolar disorder, dementia, eating disorder, substance abuse, morbid obesity
3. Patients with current suicidal ideation
4. Patients with anti-social, borderline or paranoid personality disorder
5. Patients who cannot read or write English sufficiently well to participate
6. Patients who are incapable of giving informed consent

Date of first enrolment
21/06/2004

Date of final enrolment
25/07/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Manchester
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M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

Sponsor details
Research Office
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Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (G0200212)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	protocol	07/04/2006	Yes	No
Results article	results of qualitative study	23/02/2010	Yes	No
Results article	results of randomised controlled trial	23/04/2010	Yes	No
Results article	results of patient engagement	01/04/2011	Yes	No
Results article	results	22/12/2011	Yes	No
Results article	results	01/09/2012	Yes	No
Results article	results	18/01/2013	Yes	No
Results article	results	14/12/2015	Yes	No