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

Condition category
Mental and Behavioural Disorders
Date applied
18/05/2001
Date assigned
18/05/2001
Last edited
29/06/2016

Prospective/Retrospective
Prospectively registered
Overall trial status
Completed
Recruitment status
No longer recruiting

Plain English Summary
Not provided at time of registration

Trial website

Contact information
Type
Scientific
Primary contact
Dr Alison Wearden

ORCID ID

Contact details
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 hypothesis

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
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Trial setting
Home

Trial type
Treatment

Patient information sheet
Not available in web format, please use contact details to request a participant information sheet
Condition
Chronic fatigue syndrome (CFS)

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

Intervention type
Other

Phase
Not Specified

Drug names

Primary outcome measures
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 Euroqol
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 trial start date
21/06/2004

Overall trial end date
25/07/2008

Reason abandoned

Eligibility

Participant 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
Patient

Age group
Adult

Gender
Both

Target number of participants
360

Participant 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

**Recruitment start date**
21/06/2004

**Recruitment end date**
25/07/2008

**Locations**

**Countries of recruitment**
United Kingdom

**Trial participating centre**
University of Manchester
Manchester
M13 9PL
United Kingdom

**Sponsor information**

**Organisation**
University of Manchester (UK)

**Sponsor details**
Research Office
Oxford Road
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M13 9PL
United Kingdom
+44 (0)161 275 2227
john.rogers@manchester.ac.uk

**Sponsor type**
University/education

**Website**

**Funders**

**Funder type**
Research council

**Funder name**
Medical Research Council (MRC) (UK) (G0200212)

**Alternative name(s)**
MRC

**Funding Body Type**

government organisation

**Funding Body Subtype**
Federal/National Government
Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
Not provided at time of registration

Participant level data
Not provided at time of registration

Results - basic reporting

Publication summary


Publication citations

1. Results of qualitative study
  - PubMed Abstract
  - Publisher Full Text

2. Results of patient engagement
  - PubMed Abstract
  - Publisher Full Text

3. Results
  - PubMed Abstract
  - Publisher Full Text

4. Results
  - PubMed Abstract
  - Publisher Full Text

5. Results
  - PubMed Abstract
  - Publisher Full Text

   - PubMed Abstract
   - Publisher Full Text


   - PubMed Abstract

8. Results


   - PubMed Abstract
   - Publisher Full Text

Additional files

Editorial Notes

29/06/2016: Publication reference added.