ISRCTN74156610 https://doi.org/10.1186/ISRCTN74156610

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

Submission date	Recruitment status	[X] Prospectively registered
18/05/2001	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/05/2001	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/06/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Alison Wearden

Contact details
School of Psychological Sciences
Coupland 1 Building
Oxford Road
Manchester
United Kingdom
M13 9PL

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

England

Study participating centre
University of Manchester
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
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
Protocol article	protocol	07/04/2006		Yes	No