

The effect of graded exercise and counselling with usual care plus a booklet for patients with fatigue in primary care

Submission date 13/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/10/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 20/12/2012	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Leone Ridsdale

Contact details

Unit of Population Neurology
Department of Clinical Neuroscience
PO 41, Institute of Psychiatry
Camberwell
London
United Kingdom
SE5 8AF

Additional identifiers

Protocol serial number

001; 068474

Study information

Scientific Title

Graded exercise therapy and counselling versus a booklet provided with usual care in adult patients with fatigue in primary care: a pragmatic randomised controlled phase III trial

Study objectives

In the management of fatigue in primary care:

1. Graded exercise therapy (GET) will be significantly more effective than a booklet plus usual care (B+UC)
2. Counselling will be significantly more effective than a booklet plus usual care (B+UC)

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Midlands multicentre research ethics committee (MREC) approved on the 3rd October 2002 (ref: MREC/01/7/71)

Primary study design

Interventional

Study design

Pragmatic randomised controlled phase III trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Fatigue

Interventions

Graded exercise patients will be shown how to take their own pulse, and home exercise will be prescribed on a gradually increasing basis up to a maximum of 30 minutes per day. The intensity and duration of this exercise and activity will be monitored using record sheets. The main exercise will be walking, with patients advised not to exceed the maximum prescribed each week (an instruction manual is available).

Counselling in general practice settings has generally taken the form of a non-directive, client-centred intervention, which is based on the theories of the American psychotherapist, Karl Rogers. The role of the counsellor is to encourage the client to express their feelings and thoughts about their situation, and to reflect on them and to come to their own decisions about themselves and the future (an instruction manual is available). Some sessions will be recorded, and therapy supervised by an independent exercise therapist.

Patients will have 8 sessions of treatment at two-week intervals followed by 2 telephone calls one month apart. To promote engagement the duration of the first assessment session will be approximately 60 minutes for all patients. After this, session length will be determined individually by each therapist and recorded.

Follow-up will be at 6 months and one year. The main outcome will be measured for all patients one year after recruitment to the study.

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

Fatigue questionnaire, scored according to the Likert System (0, 1, 2, 3), from 4 to 33. It focuses measurement on the patients' self-reported symptom and has been tested for reliability and validity. Using this we have data from our own three studies, which include a cohort study and two trials, and data provided to us by other investigators. Binary scoring (0, 0, 1, 1) determines fatigue 'caseness', with a cut-off of 4 indicative of clinically significant fatigue. Patient's preference for treatment will be recorded at baseline.

Key secondary outcome(s)

1. Anxiety and depression (Hospital Anxiety and Depression Scale [HADS])
2. Degree of functional impairment (Work and Social Adjustment Scale [WSAS]) (0 - 32)
3. Certified sickness absence
4. Illness attributions (physical = 1; psychological = 5)
5. Health-related quality of years using the EuroQol/EQ-5D instrument, which allows quality adjusted life years (QALYs) to be generated

Completion date

31/03/2006

Eligibility**Key inclusion criteria**

1. Age 16 to 75 years inclusive, either sex
2. Fatigue of 3 months or more
3. Patient presents fatigue as a main/important problem
4. Patient may have other physical problems, which in the doctor's judgement are unlikely to have caused their fatigue
5. Patient may be on stable drug regime for physical and/or psychological problems
6. Patient has had a normal full blood count, erythrocyte sedimentation rate (ESR) and thyroid function test during the six months prior to entering the study, or on entry to the study
7. Patient gives consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. A score of less than 4 on a fatigue scale
2. Patient has a physical condition/problem which does, or is likely to cause fatigue
3. Patient is suffering from psychotic illness, organic brain syndrome, or substance dependency
4. Patient is currently receiving treatment from a psychiatrist, counsellor, psychologist, Community Psychiatric Nurse (CPN), physiotherapist, or other exercise specialist
5. Patient is unable to come to the surgery for the treatment intervention
6. Patient has severe asthma, chronic obstructive airway disease and/or ischaemic heart disease that would contraindicate graded exercise

Date of first enrolment

01/10/2002

Date of final enrolment

31/03/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Unit of Population Neurology

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 068474)

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	20/08/2012		Yes	No