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

Submission date	Recruitment status	[_] Prospectively registered
13/10/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/10/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/12/2012	Signs and Symptoms	

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
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)

Study design
Pragmatic randomised controlled phase III trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/10/2002

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

Age group
Adult

Sex
Both

Target number of participants
240 patients

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
England

United Kingdom

Study participating centre
Unit of Population Neurology
London
United Kingdom
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Sponsor information

Organisation
King's College London (UK)

Sponsor details
c/o Sylvia Bediako
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Sponsor type
University/education

Website
http://www.iop.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

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

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?

Results article	results	20/08/2012	Yes	No