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A randomised controlled trial of a self-management programme for fatigue in multiple sclerosis

Submission date	Recruitment status	[_] Prospectively registered
02/02/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/08/2016	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Peter Thomas

Contact details
Dorset Research and Development Support Unit
Cornelia House
Poole Hospital NHS Foundation Trust
Longfleet Road
Poole
United Kingdom
BH15 2JB
+44 (0)1202 448489
peter.thomas@poole.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 002

Study information

Scientific Title
Multi-centre parallel arm randomised controlled trial to assess the effectiveness of a group-based cognitive behavioural approach to managing fatigue in people with multiple sclerosis.

Acronym
FACETS (Fatigue: Applying Cognitive behavioural and Energy effectiveness Techniques to lifeStyle)

Study objectives
Fatigue is one of the most commonly reported and debilitating symptoms of multiple sclerosis (MS); approximately two-thirds of people with MS consider it to be one of their three most troubling symptoms. It may limit or prevent participation in everyday activities, work, leisure, and social pursuits, reduce psychological well-being and is one of the key precipitants of early retirement. Energy effectiveness approaches have been shown to be effective in reducing MS fatigue, increasing self-efficacy and improving quality of life. Cognitive behavioural approaches have been found to be effective for managing fatigue in other conditions, such as chronic fatigue syndrome and, more recently, in MS. The aim of this pragmatic trial is to evaluate the clinical and cost-effectiveness of a recently developed group-based fatigue management intervention that blends cognitive behavioural and energy effectiveness approaches compared with current local practice.

Primary aim:
To see how those allocated to the group-based cognitive behavioural fatigue management intervention differ in terms of fatigue severity, self efficacy, and MS-specific quality of life from those allocated to current local practice.

Secondary aims:
1. To see how those allocated to a group-based cognitive behavioural fatigue management intervention differ in terms of fatigue impact, mood, general quality of life and activity patterns, from those allocated to current local practice.
2. To see how the group-based cognitive behavioural intervention and current local practice differ in terms of cost effectiveness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Somerset and South Bristol Research Ethics Committee, 21/02/2008, ref: 08/H0106/2

Study design
Multicentre parallel-arm block-randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
Participants will be randomised to either the group-based fatigue management intervention or current local practice.
1. Group-based Fatigue Management Intervention arm:
The manualised intervention consists of six sessions held on a weekly basis. It is designed to be run by two health professionals with experience of working with people with MS and group-work.
The main aim of the group-based intervention is to help people manage their fatigue by:
1.1. Normalising the experience of fatigue
1.2. Using their available energy more effectively
1.3. Developing 'helpful thinking styles' about fatigue
2. Current local practice arm:
Participants randomised to this arm of the trial will receive current local practice. Inevitably, there will be minor variations in the exact composition of what is usually provided, both within and between centres, depending on local resources and patient need. We consider this minor variation in current local practice to be a strength of the trial as it will increase the applicability of the findings to a wider range of centres. Individuals who have recently received substantive fatigue management are not eligible for the trial (see exclusion criteria).

Outcomes will be measured approximately at baseline, 5 weeks and 4, 7, and 15 months post randomisation. A qualitative component will examine what aspects of the fatigue management intervention participants found help/unhelpful and barriers to change. Data on the type and quantity of care received by participants in trial arms will be recorded as part of the health economics evaluation.

Intervention Type
Behavioural

Primary outcome measure
1. Self-reported fatigue severity
The Fatigue Assessment Instrument (FAI) (Schwartz,. Jandorf, & Krupp, 1993) is an expanded version of the unidimensional Fatigue Severity Scale (FSS). The FSS is one of the best known and most used fatigue scales. It principally measures the impact of fatigue on specific types of functioning. The FAI has four subscales: fatigue severity, situation specificity, consequences of fatigue and responsiveness to rest/sleep. Responses are made on a 7-point Likert-type scale. The

fatigue severity subscale of the FAI corresponds almost exactly to the FSS, sharing eight of the original nine items along with three additional items. Scores on this subscale are a primary outcome.
2. Self-reported MS-specific quality of life
The MS Impact Scale (MSIS-29) (Hobart, Lamping, Riazi, 2001) measures the physical (20 items) and psychological impact (9 items) of MS on day-to-day life. It uses 5-point Likert-type scales ranging from not at all to extremely and is based on quality of life in the last 2 weeks. The total score for the MSIS-29 is a primary outcome measure.
3. Self-reported self-efficacy for managing fatigue
The Multiple Sclerosis-Fatigue Self-Efficacy scale (MS-FSE) is adapted from the Control subscale of the MS Self-Efficacy Scale developed by Schwartz et al., 1996. This adapted scale has undergone a preliminary validation in our pilot research.

Secondary outcome measures

1. Self-reported fatigue
Three of the subscales from the FAI (namely, situation specificity, consequences of fatigue and responsiveness to rest/sleep) along with the total score of the FAI.
2. Self-reported fatigue impact
The subscale scores of the MSIS-29 for the physical and psychological impact of MS.
3. Self-reported general quality of life
3.1. The Medical Outcomes Short-form Survey (SF-36) (Ware & Sherbourne, 1992) measures eight dimensions: physical functioning, role limitations because of physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations because of emotional problems, and mental health. It generates scores for the eight dimensions as well as two summary measures (physical health and mental health). It uses a combination of dichotomous and Likert-type response scales. This measure will also be used to calculate Quality Adjusted Life Years (QALYs) for the health economics analysis.
3.2.The EuroQOL (EQ-5D) is a standardised measure of health status developed by the EuroQoL Group (1990) in order to provide a simple, generic measure of health for clinical and economic appraisal. The EQ-5D consists of the EQ-5D descriptive system and the EQ visual analogue scale (EQ- VAS). The EQ-5D descriptive system comprises five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) each rated on three levels (no problems, some problems, severe problems). The EQ VAS records the respondents self-rated health on a vertical, 20 cm visual analogue scale where the endpoints are labelled Best imaginable health state and Worst imaginable health state.
4. Self-reported mood
The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) is a self-report measure consisting of an anxiety and a depression subscale. Each subscale consists of seven items with a four-point Likert-type response scale.
5. Self-reported fatigue severity
The Fatigue Symptom Inventory (FSI) (Hann et al., 1998) is a 14-item self-administered multi-dimensional questionnaire that measures the severity, frequency and diurnal variation of fatigue and its perceived interference on quality of life. Severity is measured using four separate items that assess most, least and average fatigue in the past week, as well as current fatigue. Frequency is measured using two separate items that assess the number of days in the past week that respondents felt fatigued as well as the portion of the day on average they felt fatigued. Diurnal variation is measured using a single item that provides descriptive information about daily patterns of fatigue. Perceived interference is measured using seven separate items.
6. Self-reported sleep quality
These questions have been modified from the MS Clinical Practice Guidelines sleep questionnaire. Questions include duration and quality of night-time sleep, factors that may

prevent or interrupt sleep, and daytime sleeping and sleepiness.
7. Self-reported resource utilisation
A resource utilisation questionnaire will be administered at 4- and 12-month follow-ups (i.e. 7 and 15 months post randomisation). It is adapted from one utilised in a large RCT in Parkinsons disease and includes questions about health and social service contacts in the preceding 3 months.
8. Self-reported fatigue management strategies
At the 4-month follow-up (i.e., 7 months post randomisation) we will administer a semi-structured questionnaire to participants randomised to the FMP arm. In the questionnaire participants will be asked to describe whether they have tried to make any changes to their lifestyle, behaviour or thinking as a result of the intervention; whether these changes have been made successfully or unsuccessfully, and the reasons why.
9. Objective measure of physical activity
The activPAL™ accelerometer classifies an individual's free-living activity into periods spent sitting, standing and walking (www.paltechnologies.com). This information can be used to estimate daily energy expenditure, and time spent resting. Data will be collected at baseline and 1- and 4-month follow-ups (i.e., 5 weeks, 4 months and 7 months post randomisation). A postal method of administration was tested during an earlier research phase.
10. Self-reported satisfaction
Participants in the intervention arm will be asked to complete a brief semi-structured evaluation questionnaire at the end of each session of the fatigue management programme. This questionnaire was used in the pilot phases of the research (Thomas et al., 2010).

Overall study start date
01/07/2007

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. Providing written informed consent
2. Over the age of 18
3. Clinical diagnosis of relapsing-remitting or progressive multiple sclerosis
4. Score on the Fatigue Severity Scale > 4
5. Ambulatory (score on the Adapted Patient Determined Disease Steps Scale <8)
6. Able to attend the intervention sessions
7. English speaking

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Attended a specific fatigue management programme within the last year
2. Received a substantive, specific, fatigue intervention from an Occupational Therapist (OT) or other health professional, consisting of more than general advice, within the previous 3 months
3. Already involved in another research study
4. Cognitive deficits that would preclude engagement in the group format or benefit from the programme. This will be based on the judgement of health professionals/local investigators
5. A relapse within the previous 3 months
6. Individuals who have been on a disease-modifying drug or an anti-depressant for fewer than 3 months
7. Severe psychological disorders (individuals known to be currently under the care of a psychiatrist or addiction services)

Date of first enrolment
01/07/2007

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Poole Hospital NHS Foundation Trust
Poole
United Kingdom
BH15 2JB

Sponsor information

Organisation
Poole Hospital NHS Foundation Trust (UK)

Sponsor details
c/o Mary Burrows
Research Governance Manager
Cornelia House

Poole Hospital NHS Foundation Trust
Longfleet Road
Poole
England
United Kingdom
BH15 2JB
+44 (0)1202 448125
mary.burrows@poole.nhs.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03kdm3q80

Funder(s)

Funder type
Charity

Funder Name
The Multiple Sclerosis Society of Great Britain and Northern Ireland (UK) (ref 846/06)

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 and preliminary evaluation	01/02/2010		Yes	No
Results article	results	16/06/2010		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	follow-up results	19/05/2014		Yes	No

Results article	results	20/10/2015	Yes	No