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Self-management of fatigue in rheumatoid arthritis

Submission date	Recruitment status	[ ] Prospectively registered
16/11/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/05/2011	Musculoskeletal Diseases	

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
N/A

Study information

Scientific Title

Study objectives
Rheumatoid arthritis, an autoimmune disease causing synovitis in multiple small joints. It has varying levels of inflammatory activity that progressively lead to joint destruction, disability, fatigue, pain and potential psychological sequalae. Self-management is key, but fatigue is rarely addressed and patients rate it as important and overwhelming, but do not know how to manage it.

Aim 1: To test the null hypothesis that there will be no difference in change in the impact of fatigue, between Rheumatoid Arthritis (RA) patients participating in a multi-disciplinary, Cognitive Behavioural Therapy (CBT)-based fatigue self-management programme, compared to those receiving standard information alone
Aim 2: To explore the contribution of the different components of the complex multi-disciplinary CBT package

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the North Somerset and South Bristol REC on the 11th January 2007 (ref: 06/Q2006/149).

Study design
Aim 1: Non-blinded, randomised controlled intervention study, with analysis blind to group allocation
Aim 2: Nested qualitative study within the complex intervention arm

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions

The CBT intervention programme will be delivered weekly over six weeks, to groups of seven to ten patients, in sessions lasting two hours. The course will be led by a clinical psychologist, supported by a nurse, physiotherapist, Occupational Therapist and psychology research associate.

Three to four facilitators will attend all sessions to ensure quality CBT and team working, to allow one-to-one goal setting and to ensure patients can receive adequate individual support if issues are discussed that have particular personal implications for them (e.g., effect of fatigue on relationships). Sessions will be supported with handouts, and some work at home in between the weekly sessions is a necessary part of the course, e.g., diary keeping and achieving goals.

The first session will establish:
1. The groups ground rules (e.g., commitment and confidentiality)
2. The purpose and expectations of the course (e.g., management not cure)
3. Defining fatigue and its consequences
4. Differentiating between disease activity flares, pain, stiffness and fatigue

Goal-setting will be introduced in the second session and will form a feature of every session.

Sessions two to six will cover:
1. Energy management (planning, pacing and prioritising activities)
2. Activity cycling
3. Assertiveness
4. Recuperation or restoration of energy
5. Sleep
6. Negative self-talk
7. Graded activity
8. Passivity
9. Reconditioning and increasing physical activity
10. Links between fatigue, pain, stress, and depression
11. Relaxation
12. Management of stress
13. Avoiding and resolving setbacks

Using the theoretical concepts of CBT, enhancing self-efficacy and achieving behaviour change, the course will use delivery methods such as role modelling, group work, addressing barriers, and positive reinforcements (e.g., using a pedometer as a visual aid to increase activity). Patients will be asked to keep a diary of events in order to help them manage their fatigue more effectively. Individually tailored goal-setting and contracting will be used to set individual, realistic goals, which are the means of transferring gains in managing the RA symptoms, into improved quality of life. The aim is that participants will achieve improved functioning in their domestic role and social life, which should in turn raise confidence and reduce emotional distress, including depression.

The information-only arm will involve a single, one-hour group session of seven to ten participants, led by a rheumatology nurse (DP). It will use a largely information-giving approach, based on the two arc leaflets, allowing participants to share and discuss their current experiences and coping mechanisms. The clinical psychologist (NA) will provide support for the researcher before she delivers the control arm sessions (DP), to ensure a CBT approach is not utilised. The approach taken in the control arm will be to provide information and support the current coping strategies the participants already use, as it is not known whether or not a CBT approach is beneficial.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome is change in fatigue impact and will be measured using the Multi-Dimensional Aspects of Fatigue scale (an RA-specific scale).

Secondary outcome measures
The secondary outcomes are:
1. Perceived ability to cope with fatigue, which will be measured with a Visual Analogue Score (VAS)
2. Perceived fatigue severity (VAS) and physical status, which includes pain (VAS), disability (Health Assessment Questionnaire), and sleep (selected question from the Pittsburgh Sleep Quality Index)
3. Mood will be measured using the Hospital Anxiety and Depression Scale, and the Arthritis Helplessness Index
4. Quality of life will be measured using the RA Quality of Life Scale, a simple VAS for the personal impacts of fatigue (impact VAS) and disability (Personal Impact HAQ)

The variables will be measured at all time-points (one, six, ten and 18 weeks). Process measures include number of sessions attended and self-efficacy (RA Self-Efficacy Scale), measured at all time-points.

Overall study start date
01/01/2007

Completion date
01/09/2009

Eligibility

Key inclusion criteria
Aim 1: Patients will have a diagnosis of RA, and a score of more than seven for fatigue during the past week (Visual Analogue Scale [VAS] zero to ten)
Aim 2: Patients attending the intervention arm, purposive sampling for wide range of variables

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants

n=88, ie 44 completed data sets per arm

Key exclusion criteria
Patients will be excluded if they have had a change in drugs likely to alter fatigue just prior to recruitment (within four months for Disease Modifying Anti-Rheumatic Drugs, within six weeks for intramuscular [i/m] glucocorticoids).

Date of first enrolment
01/01/2007

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

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University/education

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ROR
https://ror.org/02nwg5t34

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (UK) (grant)

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	01/06/2011		Yes	No