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Reducing Arthritis Fatigue - clinical Teams using cognitive behavioural approaches (RAFT)

Submission date
08/11/2013

Recruitment status
No longer recruiting

Registration date
08/11/2013

Overall study status
Completed

Last Edited
30/01/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Rheumatoid Arthritis (RA) is a lifelong condition leading to joint damage and disability. Up to 70% of people with RA are tired and experience overwhelming and unmanageable physical exhaustion or 'wipe-out'. Physical, mental and emotional tiredness disturbs social and work activities, concentration and memory, causing frustration and tearfulness. RA fatigue may be caused by combinations of inflammation, pain, disability, depression, stress, poor sleep, and behaviour. Many patients are unable to manage their fatigue and report that clinical staff don't help. Recent research has highlighted the critical role of patient self-management in persistent RA fatigue and the need for self-management methods. Cognitive-behavioural therapy (CBT) helps patients make links between beliefs, feelings, behaviours and symptoms in order to help them alter their behaviour. The key self-management skills of problem-solving and goal-setting can be enhanced by sharing the learning process in groups. Additionally, using other patients as role models can help increase self-belief and confidence. We recently developed and studied a psychologist-led CBT approach course to help people manage RA fatigue. The intervention proved to be effective in improving fatigue impact, severity and coping, mood, sleep and disability. We understand that few rheumatology teams have psychologists and have now designed a more practical method suitable for delivery by rheumatology health professionals who are not CBT therapists, using a detailed manual. This study aims to find out how well this method works and the cost/savings to the NHS in comparison to usual fatigue management.

Who can participate?
Patients with confirmed RA and severe fatigue that they consider a persistent problem.

What does the study involve?
Patients who agree to join the trial will be assigned randomly to either RAFT (CBT intervention) or to usual care. Patients in both groups will receive the Arthritis Research UK fatigue self-management booklet, which is the most recent information available. We will look for change in fatigue impact at 6 months. We will also measure fatigue severity and coping, pain, disability, mood, sleep, quality of life, and return to valued activities (e.g., hobbies). To evaluate the cost of this intervention to the NHS we will ask patients to record their use of health services in daily diaries, and will ask staff to record time spent on this intervention. To find out how long any effects will last, we will follow patients for 2 years, which may provide helpful information on

whether (and when) a booster session is needed. We will interview staff to understand how easy or hard it was to learn CBT approaches and whether the new skills have influenced how they work with patients in their wider clinical practice (and if so, how).

What are the possible risks and benefits of participating?
We do not expect any side effects from receiving the booklet, taking part in the workshop sessions, or completing the questionnaires. However, if looking at the booklet or attending the workshops causes participants any concerns they will be referred to the local rheumatology clinical team for further support. All participants will receive information that may help them to manage their fatigue and improve their day-to-day life with RA. We cannot guarantee this, but taking part and completing the questionnaires will help us test this formally. The results may help future patients with arthritis and fatigue.

Where is the study run from?
The study is run from the following sites in the UK:
1. University of Bristol & Bristol Royal Infirmary
2. Cardiff University & University Hospital Wales
3. North Bristol NHS Trust, Southmead Hospital
4. Weston Area Health NHS Trust, Weston Hospital
5. S Devon NHS Foundation Trust, Torbay Hospital
6. Poole NHS Foundation Trust, Poole Hospital
7. Ashford & St Peters' NHS Trust, St Peter's Hospital

When is the study starting and how long is it expected to run for?
Recruitment is due to begin in February 2014 and end in September 2015. Follow-up is expected to be complete by October 2017.

Who is funding the study?
The study is funded by the National Institute for Health Research (NIHR), UK.

Who is the main contact?
Dr Zoe Plummer
Zoe.Plummer@uwe.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Sarah Hewlett

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15475

Study information

Scientific Title
Reducing Arthritis Fatigue - clinical Teams using cognitive behavioural approaches (RAFT): a multi-centre randomised controlled trial

Acronym
RAFT

Study objectives
We hypothesise that there will be a clinically important difference in the impact of fatigue between patients participating in a group cognitive-behavioural self-management course for RA fatigue delivered by the clinical rheumatology team using a detailed manual, in addition to usual care; compared to patients receiving usual care, which includes written fatigue self-management information.

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=15475

Ethics approval required
Old ethics approval format

Ethics approval(s)
13-EE-0310; First MREC approval date 25/09/2013

Study design
Randomised; Interventional; Design type: Not specified, Treatment

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 contact Dr Zoe Plummer, Trial Manager at Zoe.Plummer@uwe.ac.uk or 0117 342 3276 to request a patient information sheet.

Health condition(s) or problem(s) studied
Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Inflammatory Arthritis

Interventions
Each of the seven centres will recruit four cohorts of patients over a two-year period. For every cohort in every centre, 10-16 interested and potentially eligible patients will be invited to attend a 1 hour baseline visit for written consent, baseline assessments and usual care. When all baseline visits are complete for the current cohort, the Trial Manager in Bristol will obtain randomizations from the Bristol Randomized Trials Collaboration. Randomization is stratified by centre; and within centres stratified by cohort number (1-4). Allocation will be 1:1 but in the event of an odd number, the CB intervention arm will receive an additional patient. The local research nurse will inform patients of their allocation and will confirm CB course dates and times with those receiving the intervention.

The intervention is a CB approach self-management programme for fatigue. Patients attend 6 2-hour sessions (weeks 1-6) and a 1 hour consolidation session (week 14). Sessions are co-facilitated by a pair of tutors who facilitate group discussion in the first hour and each take half the group for goal setting in the second hour. Tutors are trained in the delivery of each session and work from a standardised RAFT programme manual that contains instructions, key points to be drawn from patients, sample conversations, suggested timings, materials provided and how they are to be used. Sessions cover the following topics: fatigue, sleep and rest, stress and relaxation, assertiveness, communicating needs, reviewing self-help tools and dealing with setbacks.

Outcomes will be collected for all randomised patients at Weeks 0 (baseline visit), 6, 10, 18, 26, 52, 78, and 104 using validated RA measures.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Fatigue impact at 26 weeks measured by a single numerical rating scale (NRS) that has been developed for and validated in Rheumatoid Arthritis: The Bristol RA Fatigue NRS Impact (BRAFNRS Impact)

Secondary outcome measures
1. Acceptability of intervention and control; Timepoint(s): 26 weeks
2. Cost-effectiveness (work, personal, social and NHS costs); Timepoint(s): 0, 6, 26, 52, 78, 104 weeks
3. Fatigue severity, coping; Timepoint(s): 0, 6, 10, 18, 26, 52, 78, 104 weeks
4. Helplessness, self-efficacy; Timepoint(s): 0, 6, 26, 52, 78, 104 weeks
5. Pain, disability, quality of life, sleep, mood, valued life activities, disease activity; Timepoint(s): 0, 6, 26, 52, 78, 104 weeks

Overall study start date
01/02/2014

Completion date
05/04/2018

Eligibility

Key inclusion criteria
Participants may enter the study if ALL of the following apply:
1. Diagnosis of RA
2. Fatigue measured by severity on the Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scales (BRAF NRS) > 6/10
3. More than 1 episode of fatigue

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 333; UK Sample Size: 333

Total final enrolment
333

Key exclusion criteria
Participants may not enter the study if ANY of the following apply:
1. Change in major RA medication in last 16 weeks
2. Increase in oral or ANY i/m or i/v glucocorticoids in last 6 weeks
3. Insufficient English to participate in group discussions
4. Lack of capacity for informed consent

Date of first enrolment
01/02/2014

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Royal Infirmary
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

Sponsor details
Education Centre, Upper Maudlin Street
Bristol
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BS2 8AE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Health Technology Assessment, Grant Codes: 11/112/01

Results and Publications

Publication and dissemination plan
Planned publication of the clinical, economic and qualitative results are planned for high-impact peer-reviewed journals by May 2019.

Intention to publish date

01/05/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Professor Sarah Hewlett on Sarah.Hewlett@uwe.ac.uk. Access to the available anonymised data may be granted following review.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/08/2015		Yes	No
Results article	results	01/04/2019	24/04/2019	Yes	No
Results article	results	01/10/2019	14/10/2019	Yes	No
Results article	qualitative results	27/08/2019	22/10/2019	Yes	No
Results article	results	01/04/2019	30/01/2020	Yes	No