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Exercise, cardiovascular disease and rheumatoid arthritis

Submission date
05/09/2012

Recruitment status
No longer recruiting

Registration date
19/10/2012

Overall study status
Completed

Last Edited
19/10/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Patients with rheumatoid arthritis (RA) have an increased risk of developing heart problems. In contrast, physical activity (PA) is generally accepted as one of the best ways to minimise this risk for heart disease. In such populations, PA promotion is primarily carried out via supervised, hospital-based exercise programmes. Although these exhibit short-term benefits, there is no compelling evidence for sustained participation in PA post-programme and long-term improvements in specific outcomes. The aim of this study is to investigate whether a physical activity intervention (treatment) can increase cardio-respiratory fitness. In addition we aim to test whether a psychological intervention encourages the adoption and maintenance of PA sufficient to provide sustained cardiovascular and personal well-being benefits in patients with RA.

Who can participate?
This study is aiming to recruit a total of 100 patients with RA, who attend the rheumatology clinics at the Dudley Rheumatology Department.

What does the study involve?
Participants will be randomly allocated to intervention and control group. At the beginning of the study you will be given a free 3 month subscription to a gym in Dudley. We will develop a specific 3 month exercise program for you based on your needs, preferences and at a time which is convenient for you. You will be asked to complete some assessments before you start the physical activity program, after you have finished the 3 months of training, 6 months and 1 year later. Participants in the intervention along with the 3 month exercise program they will be supplemented with two integrated psychological intervention strategies: firstly, the creation of an exercise environment (by the exercise instructors) and secondly, the provision of a one on one consultation with a SDT-trained counsellor. The assessments can be divided into following main groups:
Tests related to your disease activity and heart functioning
Questionnaires about your health status and views on exercise
Measures of physical activity
Exercise testing to see how fit you are

What are the possible benefits and risks of participating?
Completion of the exercise programme as part of this research may result in improved fitness of your heart and lungs and may also benefit your arthritis. Your personal physical activity training program will be constructed according to the latest scientific evidence and based on your individual needs by experienced exercise physiologists. The training sessions will be held in gym in Dudley where you will be given a free 3-month membership (usual cost approximately £40 per month). The information we will gather from all the people taking part will help us to understand the mechanisms that may be responsible for causing the heart problems in people with rheumatoid arthritis and help us to identify ways to reduce such problems. In the future we hope we will be able to apply this knowledge to many more people with rheumatoid arthritis. However helpful they may be, exercise programs may also carry some risks. Cases of falls, injuries, heart complications (such as heart attacks), even death, have been reported while exercising on less than 1 in 10,000 occasions - this is about 6 times less likely than you being hit by a car in your everyday life. All necessary precautions for this are routinely taken to minimise such risks in the gym where you will be doing your exercise sessions.

Where is the study run from?
This study has been set-up by the University of Birmingham in collaboration with the Dudley Group of Hospitals. The study is run from Russells Hall Hospital.

When is the studying starting and how long is it expecting to run for?
Recruitment for the study began in April 2011. You will be able to enrol on the study until March 2013.

Who is funding the study?
Funding has been provided by the Medical Research Council (National Prevention Research Initiative - Phase 3)

Who is the main contact?
Professor Joan Duda
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10/H1206/59

Study information

Scientific Title
An intervention fostering autonomous motivation, Physical Activity and cardiovascular fitness in Rheumatoid Arthritis (PARA)

Acronym
PARA

Study objectives
It is hypothesized that both the control and experimental conditions will demonstrate an increase in cardiovascular fitness post three month exercise programme. However, it is hypothesized that psychological intervention will foster the adoption and maintenance of PA sufficient to provide sustained cardiovascular and personal well-being benefits in patients with RA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Birmingham East, North and Solihull Research Ethics Committee, 03/02/2011 ref: 1-/H1206/59

Study design
Randomized 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 the contact details to request a patient information sheet

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

Interventions
Psychological Intervention versus Active Control.
Patients in both the active control condition and experimental condition will engage in a 3 month exercise programme. For the patients in the experimental condition, the individualised 3 month exercise programme will be supplemented with two integrated psychological intervention strategies: firstly, the creation of an exercise environment (by the exercise instructors) that is more autonomy supportive, and secondly, the provision of an autonomy supportive one on one consultation with a SDT-trained counsellor. Our physical activity behavioural change counsellor will have one to one contact with each patient at 4 time points during the 3 month exercise programme (i.e., a 1 hr face to face consultation at programme induction, brief consultations via telephone at 1 and 2 months, and an approximately 30 min face to face consultation at 3 months), with a final telephone consultation at 5 months (i.e., 2 months following the end of the exercise intervention).

Intervention Type
Behavioural

Primary outcome measure
Cardio-respiratory fitness, assessed using exercise tolerance testing (ETT)

Secondary outcome measures
1. Physiological outcomes:
BMI, BP and the anlaysis of blood samples for serological risk factors, lips, oxidative stress, von Willebrand factor (vWF), thrombotic variables, and vascular function. In addition detailed analyses of inflammation will include relevant cytokines and pseudopod formation.
2. Physical activity related outcomes:
Physical activity behaviour (Actigraph), self reported PA (IPAQ), Self-efficacy, perceptions of autonomy support from the fitness instructor and PA advisor (i.e., the Health Care Climate Questionnaire), perceptions of autonomy support from important others (i.e., Important Other Climate Questionnaire), perceived competence, autonomy and relatedness with regards to physical activity participation (i.e., Psychological Need Satisfaction in Exercise Scale) and motivational regulations for exercise (i.e., the Behavioural Regulation in Exercise Questionnaire).
3. Health-related outcomes:
Physical function (i.e., Stanford Health Assessment), Anxiety and Depression (i.e., Hospital Anxiety and Depression Scale), Subjective vitality, Multidimensional Assessment of Fatigue Scale, McGill Pain Questionnaire, Pittsburgh Sleep Quality Index, Revised UCLA Loneliness Scale, Health related quality of life, ICECAP-A and economic costs questionnaires.

Overall study start date
02/03/2011

Completion date
31/03/2013

Eligibility

Key inclusion criteria
Patients with Rheumatoid Arthritis (1987 ACR criteria) diagnosed in the past 10 years, without co-morbidities prohibiting exercise

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Fibromyalgia, recent joint surgery (in the preceding 6 months)
2. Recent DMARD or oral steroid changes (in the preceding 3 months)
3. Parenteral steroid administration (in the preceding 3 months)
4. Inability to exercise or follow advice
5. Comorbidity incompatible with exercise as per ACSM guidelines - absolute contraindications include:
5.1. Recent acute cardiac event
5.2. Unstable angina
5.3. Uncontrolled dysrythmias causing symptoms or haemodynamic compromise
5.4. Symptomatic aortic stenosis
5.5. Uncontrolled symptomatic heart failure
5.6. Acute pulmonary embolus
5.7. Acute myocarditis or pericarditis
5.8. Suspected or known dissecting aneurism and acute systemic infection
6. Relative contraindications include:
6.1. Left main coronary stenosis
6.2. Moderate stenotic valvular heart disease
6.3. Outflow tract obstruction
6.4. High degree AV block
6.5. Ventricular aneurysm
6.6. Uncontrolled metabolic disease (e.g. diabetes, thyrotoxicosis, myxoedema)
6.7. Uncontrolled pulmonary disease (e.g. severe COPD or pulmonary fibrosis)
6.8. Mental or physical impairment leading to inability to exercise adequately
7. Patients with relative contraindications may be included, after careful consideration of the risk /benefit ratio, especially if they are asymptomatic at rest

Date of first enrolment
01/04/2011

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Institute of Research and Development
Birmingham Research Park
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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Research council

Funder Name

Medical Research Council (UK) ref: G0802121 (NPRI-3)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	13/03/2015		Yes	No
Results article	results	29/03/2017		Yes	No