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Long term and clinical impact of the Lifestyle Management for Arthritis Programme (LMAP) for people with inflammatory arthritis

Submission date 31/03/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 31/03/2010	**Overall study status** Completed	
Last Edited 26/07/2016	**Condition category** 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
4572

Study information

Scientific Title
Long term and clinical impact of the Lifestyle Management for Arthritis Programme (LMAP) for people with inflammatory arthritis

Acronym
Impact of the LMAP

Study objectives
There have been few long-term evaluations of health profession-led arthritis education programmes' (AEPs) impact on the health status of people with inflammatory arthritis. A randomised controlled trial (n = 167) of a modular group programme (the Lifestyle Management for Arthritis Programme [LMAP]) versus an information-based group AEP similar to typical UK practice identified, at 12-month follow-up, that the LMAP was significantly more effective in reducing pain and improving self-efficacy. The LMAP continues to run as part of our service delivery. We aim to investigate, using postal questionnaires:
1. The longer-term (6 year) effects of the LMAP and typical AEP on health status by following up trial participants
2. Investigate LMAP effectiveness in an uncontrolled setting in a 6 and 12 month observational study (n = 126)
3. Investigate participants' views of the LMAP using individual semi-structured interviews

Results will be analysed to evaluate effects on adherence with health behaviours, pain, self-efficacy and functional, physical, psychological and disease status.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 01/02/2008, ref: 08/H0402/4

Study design
Interventional and observational single-centre treatment cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
Study 1: a long-term (6y) follow up of a previous clinical trial. Patients were randomised to receive the LMAP education programme or a standard arthritis education programme. The LMAP consists of 9 x 2.5 h group meetings: a first module of 4 meetings, a second module of 4 meetings approx. 3 months later and a final review or "booster meeting" 2 - 3 months later. Module 1 "Looking After Your Joints"consists of: information about arthritis and potential consequences, ergonomic approaches.

Follow Up Length: 12 month(s)
Study Entry: Registration only

Intervention Type
Behavioural

Primary outcome measure
Pain using a 10 cm visual analgue scale (0 = no pain; 10 = pain as bad as it can be). Study 1: 6 years

Secondary outcome measures
Study 1: All measurements at 6 year follow-up
Study 2: all measurements at 0, 6 and 12 months

Overall study start date
17/03/2008

Completion date
28/02/2011

Eligibility

Key inclusion criteria
Study 1:
Past participants of RCT evaluating the LMAP.

Study 2:
1. Patients aged over 18 years
2. Diagnosis of either rheumatoid arthritis, inflammatory arthritis or psoriatic arthritis, confirmed by a consultant rheumatologist
3. Referred by a member of the rheumatology multi-disciplinary team as suitable for the education programme

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Planned Sample Size: 293; UK Sample Size: 293

Key exclusion criteria
Study 1:
Past participants considered no longer well enough to participate by their Consultant.

Study 2:
Does not meet inclusion criteria

Date of first enrolment
17/03/2008

Date of final enrolment
28/02/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Rehabilitation and Human Performance Research
Salford
United Kingdom
M6 6PU

Sponsor information

Organisation
Royal Derby Hospital (UK)

Sponsor details
Uttoxeter Road
Derby
England
United Kingdom
DE22 3NE

Sponsor type
Hospital/treatment centre

Website
http://www.derbyhospitals.nhs.uk/

ROR
https://ror.org/005r9p256

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (ARC) (UK)

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