Activity Increase Despite Arthritis: developing and evaluating an active management booklet for hip and knee pain

Submission date 18/05/2009	Recruitment status No longer recruiting		
Registration date 02/07/2009	Overall study status Completed	[[>	
Last Edited 19/10/2011	Condition category Musculoskeletal Diseases	Ĺ	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

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

ClinicalTrials.gov number

Secondary identifying numbers SPON381-07

Study information

Scientific Title

Developing an active management booklet for hip and knee pain: an interventional single centre randomised controlled trial

Acronym

AIDA

Study objectives

Evidence-based booklet for older patients with hip or knee pain encourages physical activity and promoting autonomy.

Ethics approval required Old ethics approval format

Ethics approval(s)

North East Wales Research Ethics Committee approved on 28th February 2008 (ref: 08/WNo03 /5)

Study design Interventional randomised controlled single-centre study

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Osteoarthritis of hip and knee

Interventions

Participants randomised to the intervention arm will receive new educational booklet. Participants randomised to the control arm will receive a patient information booklet about osteoarthritis produced by the Arthritis Research Campaign (ARC) at 1 month and 3 months follow-up.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Illness beliefs will be measured with the hip and knee pain beliefs questionnaire (HKBQ) measuring illness beliefs; score (1 = strongly disagree, 5 = strongly agree) at baseline, 1 month and 3 months follow-up

2. Treatment beliefs will be measured with a modified Exercise Attitude Questionnaire-18 (EAQ-18); score (1 = strongly disagree, 5 = strongly agree) at baseline, 1 month and 3 months follow-up

Secondary outcome measures

1. Western Ontario McMaster University Arthritis Index (WOMAC) measuring pain, stiffness and difficulty performing daily activities; score (0 = no pain, no stiffness, no difficulty; 10 = extreme pain, extreme stiffness, extreme difficulty) at baseline, 1 month and 3 months follow up 2. Tampa Scale for Kinesiophobia measuring fear of movement/re-injury; score on 4 point likert scale from strongly disagree to strongly agree at baseline, 1 month and 3 months follow-up 3. 12-item short form health survey (SF-12) measuring health and well-being by indicating which statement best describes your health at baseline, 1 month and 3 month follow-up 4. EQ-5D, a measure of health utility by indicating which statement describe health state at baseline, 1 month and 3 months follow-up

5. Client Service Inventory (CSRI) asking about contact with health care services at 3 months follow-up

6. International Physical Activity Questionnaire (IPAQ), a measure of physical activity at baseline, 1 month and 3 months follow up

Overall study start date

20/01/2009

Completion date 30/06/2009

Eligibility

Key inclusion criteria

1. Patients over 50 years old, either sex

2. Presenting in primary care with hip or knee pain within the last 12 months

Inclusion will not be dependent upon any diagnostic criteria for osteoarthritis, as these are inconsistently applied in primary care populations.

Participant type(s) Patient

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Adult

Sex Both

Target number of participants

200 patients in total from four practices, 100 with hip pain, 100 with knee pain

Key exclusion criteria

- 1. Inflammatory joint disease
- 2. Fractures
- 3. Arthroplasty referral
- 4. Prescription of potent opioid analgesia

Patients who have already participated in the focus groups and cognitive debriefing interviews will be excluded from the trial.

Date of first enrolment 20/01/2009

Date of final enrolment 30/06/2009

Locations

Countries of recruitment United Kingdom

Wales

Study participating centre Department of Primary Care and Public Health Wrexham United Kingdom LL13 7YP

Sponsor information

Organisation Cardiff University (UK)

Sponsor details Newport Road Cardiff Wales United Kingdom CF24 0DE AmoakwaEN@cardiff.ac.uk

Sponsor type University/education

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

ROR https://ror.org/03kk7td41

Funder(s)

Funder type Government

Funder Name

Wales Office of Research and Development for Health and Social Care (WORD) (UK) (ref: 06/2 /234)

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?
<u>Protocol article</u>	protocol	04/09/2009		Yes	No
<u>Results article</u>	feasibility study results	01/08/2011		Yes	No