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Randomised controlled trial (RCT) of the use of an arthritis self management programme in primary care

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/03/2013	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RDC01907

Study information

Scientific Title

Acronym
DASH

Study objectives
Studies have shown that arthritis self-management programmes (ASMPs) can have a beneficial effect on a variety of outcomes, including pain, depression, and participants' self-perception about their capacity to manage their own condition. There are no controlled trials of such an intervention in primary care. This is the first trial in the General Practice Research Framework (GPRF) run in collaboration with the voluntary sector.

Added 01/03/2013:
The trial aims to find out:
1. Whether participation in an arthritis self-management programme plus provision of a specially designed education booklet improves the quality of life and other psycho-social outcomes of general practice patients with osteo-arthritis of the knees and/or hips when compared with provision of an education booklet alone.
2. In addition, whether the arthritis self-management programme is a cost-effective intervention for the target population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
Current interventions as of 01/03/2013:
1. Group A will receive a leaflet especially designed for the study incorporating information about arthritis and its management.
2. Group B will receive the same leaflet, but also be invited to participate in the intervention involving the Arthritis Self-Management Plan. This group intervention consists of six weekly sessions of 2.5 h each in groups of 12-15 members. The intervention is delivered by a lay member of Arthritis Care, who themselves will have arthritis, at a 'neutral' venue close to the surgery premises. Areas covered within the six sessions include: basic information about arthritis

and its treatment, principles of pain management, the benefits of exercise, principles and practice of problem solving and goal setting, strategies for dealing with depression and anger and communication skills to be used with family and health professionals.

Previous interventions until 01/03/2013:
1. Education in arthritis self-management
2. Standard care

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. The majority of outcome measures will be assessed by postal questionnaires sent to participants at baseline, 4 and 12 months. These will include:
1.1. quality of life
1.2. functional disability
1.3. pain
1.4. anxiety
1.5. depression
1.6. perceived self-efficacy mechanisms
1.7. information required for an economic analysis.
2. A sample of patients in the intervention group will be invited to be interviewed in depth in their homes at three points in time in order to gain more information about participants' perceptions and attitudes towards the intervention.
3. SF 36 to assess Quality of Life.

Key secondary outcome(s)
Current secondary outcome measures as of 01/03/2013:
1. Functional Disability, measured using the WOMAC osteoarthritis index
2. Control over symptoms measured using the Arthritis Self-Efficacy Scale (ASE)
3. Anxiety and Depression measured using the Hospital Anxiety & Depression Scale (HADS)
4. Cost-effectiveness measured using the Client Service Receipt Inventory (CSRI)
5. Euroqol (EQ-5D) health status classification system

Previous secondary outcome measures until 01/03/2013:
1. Womac osteoarthritis index
2. Arthritis Self-Efficacy Scale (ASE)
3. Hospital Anxiety & Depression Scale (HADS)
4. Client Service Receipt Inventory (CSRI)
5. Euroqol (EQ-5D) health status classification system

Completion date
31/03/2004

Eligibility

Key inclusion criteria

Current inclusion criteria as of 01/03/2013:
1. Age 45 years or above
2. Diagnosis of osteoarthritis from General Practitioner (GP) affecting 'central' joints, i.e. neck, shoulders, hips and knees but not lumbar spine alone
3. Duration of problem of at least three months and at least two visits to the GP within the past year because of related problems (eg pain, functional disability)
4. Screening question to patient to establish whether significant pain and/or functional disability associated with the condition during the past month

Previous inclusion criteria until 01/03/2013:
1. Patients aged 50 years or above, with osteoarthritis affecting the knee or hip for at least a year, will be recruited. The aim is to recruit 40 general practices which will be matched with local Arthritis Care groups, and to recruit 30 patients per practice (15 in the intervention arm and 15 controls).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Current exclusion criteria as of 01/03/2013:
1. Too immobile to be able to get to the surgery for the group.
2. Understanding of English insufficient to be able to participate in the group.
3. Referred for consideration of surgery for arthritis.
4. Patients with lumbar back pain alone (this group may form the basis of subsequent trial)
5. Patients with neurological signs e.g. related to cervical disorders
6. Known cognitive impairment or inability to complete questionnaires

Previous exclusion criteria until 01/03/2013:
1. Immobile
2. Understanding of English is insufficient to participate
3. Referred for surgery for their arthritis
4. Associated neurological signs or known cognitive impairment making patients unable to complete questionnaires.

Date of first enrolment
01/12/2000

Date of final enrolment
31/03/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MRC GPRF & Department of Primary Care & Population Sciences
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Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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	28/10/2006		Yes	No
Results article	results	22/09/2009		Yes	No