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Effect of Assistive Technology in patients with Hand OsteoArthritis: A randomised, controlled trial

Submission date 16/08/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/09/2007	**Overall study status** Completed	
Last Edited 12/09/2008	**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
N/A

Study information

Scientific Title

Acronym
ATHOA

Study objectives
Study hypothesis updated as of 08/04/2008:
Although use of assistive technology is a frequent self help strategy in persons with hand osteoarthritis, there is a lack of high quality studies that examine the effect of assistive devices in this group. The aim of this study is to evaluate the effect of provision of assistive technology and patient education compared to patient education alone.

Study hypothesis provided at time of registration:
Although provision of assistive technology is one of the most frequent non-pharmacological, non-surgical interventions for persons with inflammatory rheumatic diseases, there is a lack of high quality studies that examine the effect of this intervention. The aim of this study is to evaluate the effect of provision of assistive technology and patient education compared to patient education alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee for Medical Research and the Norwegian Data Inspectorate. Date of approval: 05/03/2008 (ref: 182-07240b 1.2007.1941)

Study design
Randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Other

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
Hand osteoarthritis

Interventions
Please note that, as of 08/04/2008, the anticipated start date of this trial was updated from 01 /09/2007 to 15/04/2008.

Participants will be randomly allocated to the following two groups:

Group 1: Provision of assistive technology and patient education
Group 2: Patient education only

Provision of assitive technology includes involving the participants in selecting appropriate device(s) and training in use of the device(s).

Patient education includes provision of information about diagnosis and prognosis, and teaching of energy conservation and alternative working methods.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary outcome measures amended as of 22/04/2008:
The following will be assessed at baseline and three months:
1. Activity and participation, measured with the Canadian Occupational Performance Measure (COPM)
2. Pain during performance of prioritised activities, measured on visual analogue scales

Primary outcome measures provided at time of registration:
The following will be measured at baseline, 6 and 12 months:
1. Activity and participation, measured with the Canadian Occupational Performance Measure (COPM)
2. Pain during performance of prioritised activities, measured on visual analogue scales

Secondary outcome measures
Secondary outcome measures amended as of 22/04/2008:
The following will be assessed at baseline and three months:
1. Hand function, measured with the pain, stiffness and function subscales of the Australian /Canadian hand osteoarthritis measure (AUSCAN)
2. Functional ability, measured with the Modified health Assessment Questionnaire (MHAQ)
3. Hand pain, general pain, fatigue and disease activity, measured on visual analogue scales
4. Cost-effectiveness, measured with the Quality of Life Questionnaire (EQ-5D) and patient reported use of medication and health care resources

Secondary outcome measures provided at time of registration:
The following will be measured at baseline and 6 and 12 months:
1. Fatigue, measured with the Fatigue Impact Scale (FIS)
2. Quality of life, measured with the Arthritis Impact Scale (AIMS2)
3. Pain, fatigue and disease activity, measured on visual analogue scales.

4. Functional ability, measured with the Modified Health Assessment Questionnaire (MHAQ).
5. Cost-effectiveness, measured with the Quality of Life Questionnaire (15D) and patient reported use of medications and health care resources

Overall study start date
15/04/2008

Completion date
31/12/2009

Eligibility

Key inclusion criteria
Inclusion criteria updated as of 08/04/2008:
1. Age between 18 and 80 years
2. Hand osteoarthritis according to the American College of Rheumatology (ACR) criteria
3. Ability to communicate in Norwegian

Inclusion criteria provided at time of registration:
1. Age between 18 and 75 years
2. Rheumatoid Arthritis (RA), Juvenile Ideopatic Arthritis (JIA) or Psoriatic Arthritis (PsA) according to the American College of Rheumatology (ACR) criteria
3. Ability to communicate in Norwegian

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
Target number as of 08/04/2008: 70. Target number at time of registration: 100

Key exclusion criteria
Exclusion criteria updated as of 08/04/2008:
1. Cognitive or mental impairment
2. Hand surgery within the last 6 months
3. Change in medication within the last month
4. Impaired hand function due to trauma or diseases other than hand osteoarthritis

Exclusion criteria provided at time of registration:
1. Surgery within the last 6 months

2. Cognitive impairment or mental disease
3. Change in medication within the last month
4. Need for assistive technology due to surgery or to be able to be discharged from hospital

Date of first enrolment
15/04/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Norway

Study participating centre
Diakonhjemmet Hospital/NRRK
Oslo
Norway
0319

Sponsor information

Organisation
Diakonhjemmet Hospital (Norway)

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administrasjon@diakonsyk.no

Sponsor type
Hospital/treatment centre

Website
http://www.diakonsyk.no

ROR
https://ror.org/02jvh3a15

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The National Resource Center for Rehabilitation in Rheumatology, Diakonhjemmet Hospital, Oslo (Norway)

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