Interdisciplinary Innovative model of care for people with Hand OsteoArthritis

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
02/05/2012		☐ Protocol		
Registration date 17/05/2012	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 12/11/2018	Condition category Musculoskeletal Diseases	[] Individual participant data		

Plain English summary of protocol

Background and study aims

Hand osteoarthritis is one of the most common rheumatic diseases, concerning 60-70% of the population over 65 years. The small finger joints are affected in particular. This causes pain and swelling. In addition, people often have problems using their hands, which makes everyday activities more difficult.

There are drug and non-drug treatments for hand osteoarthritis. Treatments are provided by various health professionals, such as rheumatologists, nurses, occupational therapists and physiotherapists.

The aim of this study is to assess how well an interdisciplinary intervention works (when the various health professionals work together and learn from one another).

Who can participate?

Patients with hand osteoarthritis.

What does the study involve?

Participants will be randomly allocated to one of two groups: standard treatment group or interdisciplinary intervention group.

The interdisciplinary intervention group will have access to: exercise programs, products and tools (called assistive devices) that can make life with hand osteoarthritis easier, splints, weight reduction advice, information about exercise, self-management, when to consider surgery, pain and pain management, and telephone follow-up.

What are the possible benefits and risks of participating?

Participants will have consultations with different health professionals.

There are no risks involved and participants can contact health professionals immediately and directly in case of adverse events.

Where is the study run from?

The study will be done by researchers of the Medical University of Vienna/ Department for Rheumatology (Austria). Participant consultations will take place there.

When is the study starting and how long is it expected to run for? May 2012 to May 2014.

Who is funding the project?
Physio Austria Professional Association of Physiotherapists (Austria)
Ergo Austria Professional Association of Occupational Therapists (Austria)
FH Campus Wien, University of Applied Sciences (Austria)
Medical University Vienna, Department of Rheumatology (Austria)

Who is the main contact? Michaela Stoffer michaela.stoffer@meduniwien.ac.at

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 9/2/2012

Study information

Scientific Title

An Interdisciplinary Innovative model of care for people with Hand OsteoArthritis (IIHOA) :a randomised controlled trial

Acronym

IIHOA

Study objectives

An interdisciplinary innovative model of care significantly improves grip strength in people with hand osteoarthritis (OA) compared to routine clinical care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Medical University of Vienna, 27 March 2012, ref: EK Nr: 1083/2012

Study design

Randomised 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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Hand Osteoarthritis

Interventions

Patients will be randomised into two groups. Each group receives an intervention, either the standard treatment in agreement with the rheumatologist or the interdisciplinary intervention. Patients randomised into the standard treatment group will be given the offer to receive the interdisciplinary intervention after two months if they wish to.

Interdisciplinary intervention includes:

- 1. Exercise program
- 2. Information about physical activity
- 3. Assistive devices for daily living
- 4. Splints if needed
- 5. Weight reduction if needed
- 6. Information for self management to increase self-efficacy
- 7. Physical methods
- 8. Information about when to consider surgery
- 9. Information about pain and pain management
- 10. Telephone follow-up

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Grip strength measured using a vigorimeter at baseline and two months later

Secondary outcome measures

- 1. Hand function measured by a test (sub-test of the Jebsen-Taylor-Hand-Function-Test) and a self-report questionnaire (AUSCAN)
- 2. Self-reported assessment of pain and satisfaction of patients with their health care and health status (on a 11-point Likert scale)

Measured at baseline and two months later.

Overall study start date

31/05/2012

Completion date

31/05/2014

Eligibility

Key inclusion criteria

- 1. Patients meeting the American College of Rheumatology (ACR) criteria for hand OA
- 2. In order not to exclude patients with hand osteoarthritis in an early stage, patients will also be eligible to participate in this study if they have bony swelling of at least one interphalangeal (IP) joint of the 2nd to 5th finger and/ or pain or bony swelling of at least one carpometacarpal (CMC) 1 joint
- 3. To have a potential for improvement (and motivation for adherence to the treatment), eligible patients have to be above or equal to an 11- point Likert scale of hand pain of at least 3 at two time points

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

140

Key exclusion criteria

- 1. Patients with evidence of rheumatoid arthritis or any rheumatic disease other than OA
- 2. Furthermore, persons with elevated C-reactive protein levels (>0.5 mg/dl) as a sign of active inflammation at the test visit and/ or with soft tissue swelling of any of the finger joints on either hand

- 3. Patients who have received steroid injections within the last four weeks
- 4. Patients who have undergone hand surgery within the last year
- 5. Patients who plan to receive steroid injections or hand surgery during the study period

Date of first enrolment

31/05/2012

Date of final enrolment

31/05/2014

Locations

Countries of recruitment

Austria

Study participating centre Währinger Gürtel 18-20

Vienna Austria 1090

Sponsor information

Organisation

Medical University of Vienna (Austria)

Sponsor details

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Sponsor type

University/education

ROR

https://ror.org/05n3x4p02

Funder(s)

Funder type

Industry

Funder Name

Physio Austria (Austria)

Funder Name

Ergo Austria (Austria)

Funder Name

FH Campus Wien, University of Applied Sciences (Austria)

Funder Name

Medical University Vienna, Department of Rheumatology (Austria)

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	09/11/2018		Yes	No