ISRCTN25892131 https://doi.org/10.1186/ISRCTN25892131

Testing arthritis gloves in rheumatoid /inflammatory arthritis

Submission date
05/09/2016

Recruitment status
No longer recruiting

Registration date
05/09/2016

Overall study status
Completed

Last Edited
10/10/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Arthritis is a common condition affecting around 10 million people in the UK. There are various types of arthritis, including osteoarthritis and the less common inflammatory arthritis (IA). IA is a group of conditions, inkling rheumatoid arthritis (RA), in which a person's immune system starts to attack healthy joints, causing pain, swelling (inflammation) and stiffness in the joints. Arthritis Gloves are provided in the NHS to people with rheumatoid arthritis (RA) and early inflammatory arthritis (EIA). Gloves provide pressure and warmth to relieve (night and/or day) hand pain, stiffness and improve using hands in everyday activities and at work. Various arthritis gloves are also available from online and High Street stores (£5 – 35). The few small studies testing gloves' effects found they reduced finger swelling at night, but other effects were unclear. One study found they had similar benefits to a thermal glove (which gave warmth but not pressure). The aim of this study is to investigate the effect of gloves which provide warmth and pressure and gloves which provide warmth alone on hand pain, stiffness and function of people with RA or IA.

Who can participate?
Adults with IA who have difficulty using their hands during the day, disturbed sleep, or limited use of hands when they wake up.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are provided with correctly fitted mid-finger length Isotoner compression gloves, which give warmth and pressure. Those in the second group are given the same gloves but fitting one size too large so that they provide warmth but not pressure. Participants in both groups have their gloves fitted at a 45 minute appointment, where they also receive a wear and care glove information leaflet and a hand exercise booklet with photos of exercises (which they are encouraged to regularly perform). Within two to three weeks, the participant attends for a 15 minute glove review appointment to check fit of gloves and for advice if any problems have arisen. At the start of the study and after 12 weeks, participants in both groups complete a number of questionnaires in order to assess hand pain, stiffness and hand function. A small group of participants are also interviewed about their views on wearing the gloves.

What are the possible benefits and risks of participating?
If this study shows that arthritis gloves are effective, then participants may benefit from relief from hand pain, stiffness, and/or swelling; improved ability to sleep (by reducing night hand pain); and improved ability to use the hands in everyday activities and at work. There are no known severe risks involved with wearing arthritis gloves, but some participants may find the gloves feel hot and/or itchy after a few hours during hot weather or that they occasionally feel too tight (causing temporary pins and needles or numbness).

Where is the study run from?
22 NHS hospitals in England and Scotland (UK)

When is the study starting and how long is it expected to run for?
April 2015 to December 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr Yeliz Prior (public)
y.prior@salford.ac.uk
2. Prof. Alison Hammond (scientific)
a.hammond@salford.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Yeliz Prior

Contact details
Centre for Health Sciences Research
L701 Allerton Building
Frederic Road
University of Salford
Salford
United Kingdom
M6 6PU
+44 (0)161 295 0211
y.prior@salford.ac.uk

Type(s)
Scientific

Contact name
Prof Alison Hammond

ORCID ID
http://orcid.org/0000-0002-5266-9991

Contact details
Centre for Health Sciences Research
L701 Allerton Building
Frederic Road
University of Salford
Salfod
United Kingdom
M6 6PU
+44 (0)161 295 0038
a.hammond@salford.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 19528

Study information

Scientific Title
The effects of arthritis gloves on people with rheumatoid arthritis or early inflammatory arthritis with hand pain: a multicentre-randomised controlled trial

Study objectives
Hypothesis:
The intervention gloves (as delivered in routine clinical care by OTs) compared to alternate gloves, do not affect hand pain, stiffness and function of people with RA or IA.

Primary objective:
To assess whether there is a clinically important difference in self-reported dominant hand pain during activity during the day between patients with RA or IA receiving intervention gloves delivered by clinical rheumatology occupational therapists in addition to usual care; compared to patients receiving alternate gloves delivered by clinical rheumatology occupational therapists plus usual care, in order to assess their clinical benefit to the patient.

Secondary objectives:
1. Compare differences between these two groups for secondary outcomes of self-reported non- dominant hand pain during activity; dominant and non-dominant nocturnal hand pain, hand pain during the day at rest, hand stiffness, hand joint swelling, hand function, disability, adherence, and NHS costs, in order to assess their clinical benefit to the patient and cost-effectiveness to the NHS

2. Explore participants' views of: the effects of arthritis (intervention and placebo) gloves on hand symptoms, function, and their daily lives; acceptability of glove wear; and how and when they prefer to use these

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Committee 2, 05/08/2015, ref: 15/NS/0077

Study design
Randomized; Interventional; Design type: Treatment, Complementary Therapy

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Musculoskeletal disorders, Primary sub-specialty: Metabolic bone disease

Interventions
Participants will be randomised into two treatment arms following completion of the baseline questionnaire, using a web-based system managed by Lancashire Clinical Trials Unit.

Intervention group: Participants will receive correctly fitted mid-finger length Isotoner compression gloves.

Control group: Participants receive mid-finger length Jobskin classic oedema gloves fitted at least one size too large so that they provide warmth but not therapeutic levels of compression.

Intervention and alternate gloves will be fitted by Rheumatology occupational therapists who have attended the study training programme. Participants attend for one approximately 45 minute appointment in which gloves are fitted and provided, along with a standardised wear and care glove information leaflet.

Participants are advised to wear the gloves either during the day and/ or at night, dependent on their clinical needs and as determined by the occupational therapists (OTs) fitting the gloves. Gloves are not worn continuously.

Participants are also advised to regularly perform hand exercise and a hand exercise booklet with photos of exercises is provided. Additionally, they are given brief advice on joint protection and the Arthritis Research UK booklet "Looking After Your Joints when you have arthritis" is provided. Within two to three weeks, the participant attends for a 15 minute glove review appointment to check fit of gloves and for advice if any problems have arisen. If it is normal OT department policy for glove reviews, alternately a telephone review can be conducted or participants asked to contact the OT if problems arise.

Participants are followed up after 12 weeks of glove wear.

Intervention Type
Other

Primary outcome measure
Dominant Hand Pain during activity is measured using a 0-10 numerical rating scale (NRS) at baseline and 12 weeks. Anchor points used are No Pain to Severe Pain

Secondary outcome measures
1. Non-dominant hand pain during activity; dominant and non-dominant hand pain at rest in the day, at rest in the night measured using a 0-10 numerical rating scale at baseline and 12 weeks.
2. Hand stiffness is measured using a 0-10 numerical rating scale (NRS) at baseline and 12 weeks
3. Self-reported hand condition is measured using a five point rating scale of very severe/severe /moderate/good/very good at baseline and 12 weeks
4. Hand Function is measured using the Measure of Activity Performance of the Hand (MAPHAND) and the Michigan Hand Outcomes Questionnaire (MHQ) at baseline and 12 weeks
5. Disability is measured using the Health Assessment Questionnaire (20 items of daily function) at baseline and 12 weeks
6. Health economic analysis is undertaken using the EQ5D-3L and a health resource use questionnaire at 12 weeks
7. Glove wear is measured through:
7.1. Questionnaire items at 12 weeks about: frequency and duration of glove wear during the day and/ or at night in the last 4 weeks; any benefits and/or problems resulting from glove wear
7.2. Qualitative interviews conducted with sub-sample of participants to explore their' views on: benefits or negative effects of glove wear (including at work for those employed); glove appearance, quality, comfort, ease of applying; willingness to buy gloves in future at 12 weeks

Overall study start date
01/09/2013

Completion date
02/03/2018

Eligibility

Key inclusion criteria
1. Adults (i.e. aged ≥18 years) with Rheumatoid Arthritis (RA) or Inflammatory Arthritis (IA: i.e. persistent synovitis in the hands with no other known cause but not yet meeting criteria for RA) diagnosed by a Rheumatology Consultant. Participants can have other hand conditions resulting from RA/ IA, e.g. hand osteoarthritis, fibromyalgia, mild--moderate carpal tunnel syndrome.
2. Answering YES to the following agreed criteria for glove provision (devised by Rheumatology occupational therapists in North-West England):

Do you have persistent pain in the finger and/or knuckle joints causing you at least one of the following:
2.1. Difficulty using hands during the day
2.2. Disturbed sleep
2.3. Limited ability to use your hands on waking/in the morning
3. Willing to wear arthritis gloves
4. Able to read and understand English?
5. Able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 176; UK Sample Size: 176

Total final enrolment
206

Key exclusion criteria
1. Having any other diagnosed rheumatic conditions, such as gout, psoriatic arthritis, ankylosing spondylitis, connective tissue disorders (systemic lupus, systemic sclerosis), resulting in inflammatory arthritis in the hand/s
2. Severe Raynaud's disease or other circulatory disturbances in the hand
3. Severe neuropathies (nerve damage) in the hand
4. Severe hand deformities meaning putting gloves on and off is too difficult
5. Any contraindication (e.g. eczema, infections, broken skin) meaning glove wear could potentially pose an infection risk to the patient
6. Previously worn arthritis gloves (received either from occupational therapy, or bought themselves, as they will be aware the placebo gloves are insufficiently close fitting)
7. Not able to provide informed consent

DEFERRED ENTRY: If the participant has had an intramuscular (IM) or intra--articular (IA) steroid injection, or started on oral steroids, in the last 6 weeks; but are eligible in all other respects. Study entry will be deferred until 6 weeks after the IM or IA injection/ start of oral steroids, has steroids usually are effective within 6 weeks. (Steroids could be a confounding variable if the gloves are provided at the same time).

Date of first enrolment
01/02/2016

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Leighton Hospital
Middlewich Road
Crewe
United Kingdom
CW1 4QJ

Study participating centre
Victoria Infirmary
Winnington Hill
Northwich
United Kingdom
CW8 1AW

Study participating centre
Macclesfield District General Hospital
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
St Helens Hospital
Marshalls Cross Road
St Helens
United Kingdom
WA10 3DA

Study participating centre
Pennine MSK Partnership Ltd
ntegrated Care Centre

New Radcliffe Street
Oldham
United Kingdom
OL1 1NL

Study participating centre
Southport & Ormskirk District General Hospital
Town Lane
Southport
United Kingdom
PR8 6PN

Study participating centre
Hexham General Hospital
Corbridge Road
Hexham
United Kingdom
NE46 1QJ

Study participating centre
North Devon District Hospital
Raleigh Park
Barnstaple
United Kingdom
EX31 4JB

Study participating centre
Trafford General Hospital
Moorside Road
Trafford
United Kingdom
M41 5SL

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
United Kingdom
S10 2JF

Study participating centre
Cannock Chase Hospital
Brunswick Road
Cannock
United Kingdom
WS11 5XY

Study participating centre
New Victoria Hospital
55 Grange Road
Glasgow
United Kingdom
G42 9TY

Study participating centre
Gartnavel General Hopsital
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Study participating centre
Stobhill Hospital
133 Balornock Road
Glasgow
United Kingdom
G21 3UW

Study participating centre
Scunthorpe General Hospital
Cliff Gardens
Scunthorpe
United Kingdom
DN15 7BH

Study participating centre
Diana Princess Of Wales Hospital
Scartho Road

Grimsby
United Kingdom
DN33 2BA

Study participating centre
Kings Mill Hospital
Mansfield Road
Sutton-in-Ashfield
United Kingdom
NG17 4JL

Study participating centre
North Manchester General Hospital
Delaunays Road
Manchester
United Kingdom
M8 5RB

Study participating centre
Rochdale Infirmary
Whitehall Street
Rochdale
United Kingdom
OL12 0NB

Study participating centre
St Albans City Hospital
Waverley Road
St Albans
United Kingdom
AL3 5PN

Study participating centre
Haywood Hospital
High Lane
Burslem
Stoke-on-Trent
United Kingdom
ST6 7AG

Study participating centre
Chapel Allerton Hospital
Chapeltown Road
Leeds
United Kingdom
LS7 4SA

Sponsor information

Organisation
University of Salford

Sponsor details
Centre for Health Sciences Research
Allerton Building
Frederick Road
Salford
England
United Kingdom
M6 6PU

Sponsor type
Hospital/treatment centre

Website
http://www.salford.ac.uk/health-sciences/research/research-programmes/rehabilitation-research

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high -impact peer-reviewed journal in circa March 2019.

Intention to publish date
31/03/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/05/2017		Yes	No
Results article	results	08/01/2021	11/01/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	qualitative results	12/02/2022	10/10/2023	Yes	No
Other publications	questionnaire study results	31/10/2022	10/10/2023	Yes	No