

# Testing arthritis gloves in rheumatoid /inflammatory arthritis

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| <b>Submission date</b><br>05/09/2016   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>05/09/2016 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>01/12/2025       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> 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, including 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 RA and early inflammatory arthritis (EIA). Gloves provide pressure and warmth to relieve (night and/or day) hand pain, stiffness and improve the hands for 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 and Care Research (UK)

Who is the main contact?

Prof Yeliz Prior, y.prior@salford.ac.uk

## Contact information

### Type(s)

Public, Principal investigator, Scientific

### Contact name

Dr Yeliz Prior

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **Completion date**

02/03/2018

# Eligibility

## Key inclusion criteria

1. Adults (i.e. aged  $\geq 18$  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

## Healthy volunteers allowed

No

## Age group

Mixed

## Lower age limit

18 years

## Upper age limit

120 years

## Sex

All

## 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, as 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**

United Kingdom

England

Scotland

**Study participating centre**

**Leighton Hospital**

Middlewich Road

Crewe

England

CW1 4QJ

**Study participating centre**

**Victoria Infirmary**

Winnington Hill

Northwich

England

CW8 1AW

**Study participating centre**

**Macclesfield District General Hospital**

Victoria Road

Macclesfield

England

SK10 3BL

**Study participating centre**

**St Helens Hospital**

Marshalls Cross Road  
St Helens  
England  
WA10 3DA

**Study participating centre**

**Pennine MSK Partnership Ltd**

Integrated Care Centre  
New Radcliffe Street  
Oldham  
England  
OL1 1NL

**Study participating centre**

**Southport & Ormskirk District General Hospital**

Town Lane  
Southport  
England  
PR8 6PN

**Study participating centre**

**Hexham General Hospital**

Corbridge Road  
Hexham  
England  
NE46 1QJ

**Study participating centre**

**North Devon District Hospital**

Raleigh Park  
Barnstaple  
England  
EX31 4JB

**Study participating centre**

**Trafford General Hospital**  
Moorside Road  
Trafford  
England  
M41 5SL

**Study participating centre**  
**Royal Hallamshire Hospital**  
Glossop Road  
Sheffield  
England  
S10 2JF

**Study participating centre**  
**Cannock Chase Hospital**  
Brunswick Road  
Cannock  
England  
WS11 5XY

**Study participating centre**  
**New Victoria Hospital**  
55 Grange Road  
Glasgow  
Scotland  
G42 9TY

**Study participating centre**  
**Gartnavel General Hospital**  
1053 Great Western Road  
Glasgow  
Scotland  
G12 0YN

**Study participating centre**  
**Stobhill Hospital**  
133 Balornock Road  
Glasgow  
Scotland  
G21 3UW



**Study participating centre**  
**Scunthorpe General Hospital**  
Cliff Gardens  
Scunthorpe  
England  
DN15 7BH

**Study participating centre**  
**Diana Princess Of Wales Hospital**  
Scarcho Road  
Grimsby  
England  
DN33 2BA

**Study participating centre**  
**Kings Mill Hospital**  
Mansfield Road  
Sutton-in-Ashfield  
England  
NG17 4JL

**Study participating centre**  
**North Manchester General Hospital**  
Delaunays Road  
Manchester  
England  
M8 5RB

**Study participating centre**  
**Rochdale Infirmary**  
Whitehall Street  
Rochdale  
England  
OL12 0NB

**Study participating centre**  
**St Albans City Hospital**  
Waverley Road  
St Albans

England  
AL3 5PN

**Study participating centre**

**Haywood Hospital**

High Lane

Burslem

Stoke-on-Trent

England

ST6 7AG

**Study participating centre**

**Chapel Allerton Hospital**

Chapeltown Road

Leeds

England

LS7 4SA

## **Sponsor information**

**Organisation**

University of Salford

**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

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Yeliz Prior, y.prior@salford.ac.uk.

**IPD sharing plan summary**

Available on request

**Study outputs**

| Output type                                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 08/01/2021   | 11/01/2021 | Yes            | No              |
| <a href="#">Protocol article</a>              | protocol                      | 30/05/2017   |            | Yes            | No              |
| <a href="#">HRA research summary</a>          |                               |              | 28/06/2023 | No             | No              |
| <a href="#">Other publications</a>            | qualitative results           | 12/02/2022   | 10/10/2023 | Yes            | No              |
| <a href="#">Other publications</a>            | questionnaire study results   | 31/10/2022   | 10/10/2023 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |