# Compression gloves for patients with hand arthritis (C-GLOVES) : a feasibility study

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# Compression gloves for patients with hand arthritis (C-GLOVES): A feasibility study

**Alison Hammond and Yeliz Prior**

## Abstract

**Introduction:** Compression gloves are frequently provided to patients with hand arthritis. Evidence for effectiveness is limited. The aim of this study was to determine feasibility of recruitment, assessment and treatment procedures, in preparation for a future compression glove trial.

**Methods:** A non-randomised feasibility study with out-patients with either undifferentiated inflammatory arthritis, rheumatoid arthritis or hand osteoarthritis, with moderate to severe hand pain. All received Isotoner$^{TM}$ compression gloves provided by rheumatology occupational therapists. The main outcomes were feasibility of recruitment, assessment and treatment procedures, trial outcome selection and sample size calculation. Participants were assessed at baseline and four weeks. Assessments included: numeric rating scales (0–10) of hand pain (on activity, at rest, at night) and stiffness; hand joint swelling; finger flexion; and hand function (Grip Ability Test).

**Results:** Of 318 patients screened, 86/204 (42%) of inflammatory and 68/114 (60%) of hand osteoarthritis patients were eligible. Of these, 41 (48%: age: 59.10 (SD 12.54) years) and 32 (47%: age: 60.75 (SD 8.64) years) respectively, consented. All completed four-week follow-up. Assessment and treatment protocols were feasible. Hand pain on activity and at night, stiffness, joint swelling, finger flexion and hand function improved: e.g. hand pain on activity: inflammatory arthritis change = −0.95 (SD 2.26; p = 0.01); osteoarthritis −1.57 (SD 1.78; p = 0.001). Participants reported improved hand pain, stiffness and hand function as main benefits.

**Conclusion:** Procedures tested were feasible. The most relevant primary outcome was hand pain on activity. Future trials would need 161 participants (Inflammatory arthritis) and 151 (hand osteoarthritis).

**Trial registration:** Clinical Trials.Gov: NCT01874067

## Keywords

Rheumatology, quantitative research, outcome measures

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## Introduction

Compression gloves are provided to people with hand arthritis, with persistent moderate to severe hand pain, stiffness and/or swelling, in order to improve hand symptoms and hand function.[1–4] Gloves are usually made of nylon and elastane. The amount of elastane, combined with glove fit, affects the amount of pressure applied. Gloves' mechanism of action is thought to be that applying pressure: reduces articular and peri-articular swelling; and increases blood flow, so increasing hand temperature.[1–4]

Rheumatology occupational therapists in the United Kingdom National Health Service prescribe compression gloves to about a third of their patient caseload with: undifferentiated inflammatory arthritis, rheumatoid arthritis or hand osteoarthritis.[5] Isotoner$^{TM}$ gloves are the most common make provided (Figure 1). Gloves can be prescribed for day- and/or

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**Figure 1.** Isotoner™ compression glove.

night-time wear. Concomitant hand therapy can include hand exercises and joint protection education.[5]

A systematic review of compression glove randomised controlled trials[6] identified four with moderate to high risk of bias.[1,7–9] These tested closed finger gloves (i.e. enclosing fingertips) worn at night for one to four weeks in people with rheumatoid arthritis (n = 8 to 24). Trials were inconclusive about effects on hand pain, stiffness, grip and pinch strength, finger range of motion and dexterity. None evaluated open finger gloves (i.e. fingertips exposed) or day-time wear regimens, which reflect modern-day practice.[5] There is a need for trials to evaluate the effects of compression gloves in hand arthritis.

The aim of this study was to determine the feasibility of recruiting to, assessing and delivering a standardised compression glove intervention for people with hand arthritis, to assist planning future trials in inflammatory arthritis (specifically undifferentiated inflammatory, early and established rheumatoid arthritis); and in hand osteoarthritis. The objectives were to: develop standardised assessment and treatment protocols for compression gloves; assess feasibility of recruitment, assessment and treatment procedures and planned outcome measures; investigate recruitment and attrition rates; explore the effects of compression gloves on hand symptoms and function; investigate participants' views of glove-wear; and estimate sample sizes for future trials.

## Methods

### Study design

We conducted a non-randomised, prospective feasibility study: in people with either inflammatory arthritis or hand osteoarthritis. Favourable ethical opinion was provided by the East Midlands-Northampton Research Ethics Committee (13/EM/0253). The trial is registered with Clinical Trials.Gov: NCT01874067. All participants provided informed written consent. Recruitment opened on 1st September 2013 and closed 31st May 2014, with data collection completed by August 2014. The study design and procedures were planned with participating therapists and patient research partners (Supplementary File I).

### Setting

The setting was 10 rheumatology occupational therapy departments: in five NHS district general hospitals, three teaching hospitals and two community health care centres in the United Kingdom. Treatment was provided by 14 rheumatology occupational therapists.

### Participants

Trial participant inclusion criteria were: aged 18 years or over; diagnosed with either: inflammatory arthritis (specifically: undifferentiated inflammatory arthritis, (i.e. with persistent hand synovitis which cannot be classified as a specific rheumatological disorder) or rheumatoid arthritis) diagnosed by a Rheumatology Consultant, or hand osteoarthritis (affecting the fingers/hand and not solely the carpometacarpal phalangeal joint) diagnosed by a General Practitioner, Consultant or Advanced Therapy Practitioner.

As per therapists' usual care pathway, patients should be experiencing persistent moderate to severe hand pain, stiffness and/or swelling causing at least one of:

- difficulty using the hands during the day (for day wear), if the patient's main problems are proximal interphalangeal joint and/or metacarpophalangeal joint involvement (rather than solely wrist and/or thumb involvement, for which wrist working and/or thumb spica splints are applicable);
- disturbed sleep (for night wear);
- and limited ability to use the hands in the morning, if symptoms and hand function are not readily improved by using warm water or exercise (for night wear).

Participants should: be willing to wear the compression gloves as recommended; have enough hand

function to be able to don and doff gloves (unless help available); and understand English enough to complete self-report measures and understand glove wear instructions. Additionally, eligible participants should be able to attend a glove review and assessment appointment four-weeks later.

We excluded patients diagnosed with: other inflammatory forms of arthritis affecting the hands (e.g. psoriatic arthritis, gout, ankylosing spondylitis); severe: hand neuropathies, Raynaud's disease and/or hand circulatory disturbances (as these could be exacerbated by compression glove wear); severe hand deformities preventing glove-fitting; other medical conditions which could alter hand function between assessments (e.g. neurological conditions); and any contraindications to glove-wear (e.g. eczema, broken skin).

Additional exclusion criteria were: patients should not have received intra-articular or intra-muscular steroid injections or started/changed oral steroids or anti-inflammatory non-steroidal drugs within the last four weeks; or started/changed disease modifying anti-rheumatic drugs or biologic drugs within the last 12 weeks. This was because drug changes could be a confounding factor affecting outcomes. However, participants with undifferentiated inflammatory arthritis or rheumatoid arthritis, if newly diagnosed and recently started their drug regimen, could have such changes, which were recorded at baseline. We also excluded those who had previously worn compression gloves and required replacements. Participants were not excluded who previously received any other type of hand splint.

### Recruitment procedures

Participants were recruited by therapists from amongst their caseload. They approached those with inflammatory arthritis or hand osteoarthritis and persistent hand symptoms only. Participants were provided with a study explanation and that they were consenting to allow their anonymised hand assessment data to be forwarded to the researchers. Participants would still be provided with gloves, as per the usual care pathway, if clinically appropriate. If interested, participants were screened. If eligible, they were given a fuller study explanation and participant information sheet to ensure written informed consent was received.

### Intervention

All participants were fitted with Isotoner$^{TM}$ open finger gloves (Figure 1), following the agreed treatment protocol as specified in the therapist manual (Supplementary File II). Isotoner$^{TM}$ gloves are made of nylon containing 20% elastane and apply 23 to 32 mm Hg pressure, according to the manufacturer's information.[10] This is the highest amount of pressure applied amongst compression glove makes available. Therapists determined if gloves were prescribed for one or both hands, and to be worn day and/or night, based on clinical need. All participants continued to receive usual care.

### Outcome measures

Prior to glove fitting, therapists completed the agreed assessment protocol as specified in the therapist manual (Supplementary File II). A study box was provided to each site containing the therapist manual, hand assessment record forms, Jobskin tape measures, 15-centimetre ruler, Grip Ability Test and a stopwatch, to ensure standardised equipment and procedures. Outcomes were:

- pain: three 0 to10 numeric rating scales of no to severe hand pain when performing moderate hand activities (such as cooking, housework or gardening), when resting and at night.
- stiffness: duration of early morning stiffness in minutes; and a 0 to 10 numeric rating scale of no to severe hand stiffness.
- self-reported hand condition status: a five-point scale of very severe (1)/severe/moderate/good/very good (5).
- swelling of each of the 2nd to 5th proximal interphalangeal joint and combined 2nd to 5th metacarpophalangeal joints (except in HOA): using a single-use Jobskin paper tape measure in centimetres.[11]
- composite finger flexion for each of the 2nd to 5th digits measured using a 15-centimetre ruler.[11,12]
- Grip strength: using a Jamar dynamometer measured in kilograms.[13] Only six sites owned a dynamometer and, due to budget restrictions, we could not provide these to the other four.
- Grip Ability Test: a timed test performing three hand activities.[14]
- The Measure of Activity Performance Hand: a bilateral self-report measure of performing 18 hand activities (0 to 3 scale).[15,16]

At four-week follow-up, therapists again assessed the above and recorded any drug regimen changes and other hand therapy since glove fitting. Participants reported if they discontinued glove wear and why. Therapists asked participants: what effects, if any, the gloves had; if they considered gloves beneficial, what the most important benefit was; and any problems with wearing gloves. Therapists recorded key points of responses (or verbatim if possible) on the hand assessment record.

### Analysis

As this was a feasibility study, sample sizes were not calculated. We aimed to recruit 40 participants with inflammatory arthritis, and 40 with hand osteoarthritis, as feasibility trial sample sizes are recommended as 20 to 40 participants.[17,18] Results for the two patient groups were reported separately. Recruitment and retention rates were summarised descriptively. Analyses aimed to determine if: future trials are feasible in inflammatory arthritis or hand osteoarthritis and assist in outcome selection, and not to evaluate effectiveness. For each outcome, baseline and four-week follow-up data were summarised using means and standard deviations, if normally distributed, and tested using paired samples t-tests, with effect sizes calculated using eta-squared: $t^2/t^2+(n-1)$. Guidelines for interpreting this are 0.01 = small effect; 0.06 = moderate effect and 0.14 = large effect.[19,20] Ordinal or not normally distributed data was summarised using medians and interquartile ranges and tested using Wilcoxon tests, with effect sizes calculated as $z/\sqrt{n}$ and interpreted as 0.1 = small effect; 0.3 = medium effect and 0.5 = large effect.[19,20] Outcomes were analysed for dominant and non-dominant hands. For pain outcomes, data were also analysed per wear regimen, i.e. daytime pain on activity and at rest were analysed for those recommended to wear gloves in the daytime; and night pain for those recommended to wear gloves at night.

Participants' qualitative responses were content analysed, as responses were brief.[21] Data were read, coded and categorised by two researchers to ensure confirmability. Frequencies and types of problems, positive and negative effects and most important benefits were reported.

## Results

### Recruitment and participant flow

Figure 2 shows recruitment and participant flow. Seven sites opened as planned. However, three of these had unexpected trouble purchasing gloves through their NHS supply system, delaying recruitment by one to four months. Research and Development department approvals took longer than expected at the three other sites: with one open for 7.5 and two for six months. During the recruitment period, 42% of the inflammatory arthritis and 60% of the hand osteoarthritis patients screened were eligible. Of those eligible, 48% and 47% respectively consented. Of those not consenting, 32 (37% of those eligible) with inflammatory and 22 (32% of those eligible) with hand osteoarthritis were either unable/unwilling to attend for the follow-up appointment or the therapist was unable to provide this to schedule (Figure 2). All participants received gloves and no participants were lost to follow-up.

### Participants

Demographic and clinical characteristics are shown in Table 1. As the demographic characteristics and baseline measures were similar between groups, apart from symptom and diagnosis duration (Table 1).

### Feasibility of recruitment, assessment and treatment

Per site, screening numbers varied between six and 61 patients. Recruitment rates also varied considerably: between 0 and 16 participants per site, i.e. between 0 to 58% of those screened.

Four sites had two occupational therapists able to treat and/or assess. However, it was usually not feasible for them to act as independent assessor for the other's participants, due to workload constraints. Six sites were unable to identify an independent assessor for training, as the therapists were singe-handed Rheumatology occupational therapists. Prior to the study, at the training day (Supplementary File I), all therapists demonstrated they could conduct the assessments and fit compression gloves correctly. In both groups, five participants were assessed after the planned maximum five-week follow-up.

### Glove wear and concomitant treatment

In both groups, most participants were issued gloves for both hands (with almost all for their dominant hand). Similar numbers were recommended day- and night-time wear regimens, with about half recommended a combined day and night wear regimen (Table 1). A third (n = 14) with inflammatory arthritis discontinued glove-wear either in the day- or night-time, 10 of whom were prescribed gloves for both day and night wear and continued wearing gloves part of the time. Four with hand osteoarthritis also discontinued glove wear part of the time. Reasons for discontinuation are listed in Figure 2. By four-week follow-up, 11 with inflammatory arthritis had drug regimen changes (five disease modifying drugs; six steroid injections), no participants with hand osteoarthritis had drug changes. Six people with inflammatory arthritis received hand exercise and three joint protection education; three with hand osteoarthritis received hand exercise and joint protection education.

### Outcomes

Outcomes are reported in Tables 2 and 3 for the dominant hand only. At four-weeks, participants with inflammatory arthritis or hand osteoarthritis both

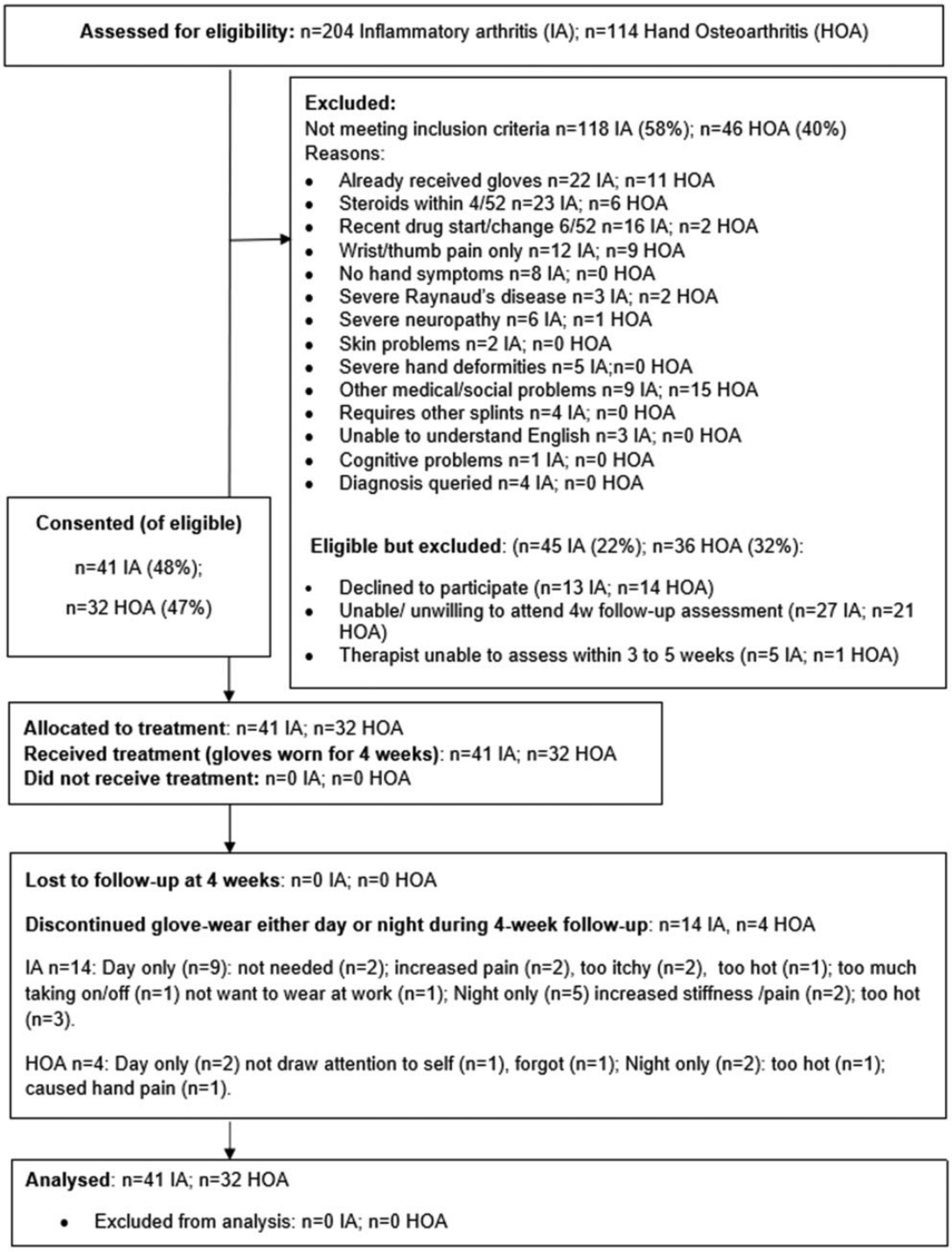


**Figure 2.** Recruitment and participant flow in inflammatory arthritis (IA: includes undifferentiated inflammatory and rheumatoid arthritis) and hand osteoarthritis (HOA) participants.

reported significantly less pain during moderate activities and at night (but not at rest during the day), as well as less stiffness, with large effect sizes. In terms of joint swelling, in the inflammatory arthritis group, there were significant reductions in metacarpophalangeal joints and 3rd to 5th proximal interphalangeal joints circumferences. These were small differences, around 2 mm or less, and it is unclear if these would be clinically significant, even if statistically significant. There were no significant changes in hand osteoarthritis proximal interphalangeal joint circumferences. Finger flexion improved significantly with moderate

**Table 1.** Baseline demographic characteristics of participants with undifferentiated inflammatory arthritis, rheumatoid arthritis and hand osteoarthritis.

| | UIA (n = 14) | | RA (n = 27) | | Inflammatory Arthritis (n = 41) | | Hand Osteoarthritis (n = 32) | |
|---|---|---|---|---|---|---|---|---|
| **Age** (years): mean (SD) | 60.64 (15.34) | | 58.30 (11.05) | | 59.10 (12.54) | | 60.75 (8.64) | |
| **Gender** (n) (men: women) | 3:11 | | 5:22 | | 8:33 | | 2:30 | |
| **Symptom duration** (years: median, IQR) | 0.75 (0.25–1.63) | | 8 (2-12) | | 3.58 (0.5–10) | | 4 (1.75–10) | |
| **Time since diagnosis** (years: median, IQR) | 0.16 (0.08–0.33) | | 6 (2.33–11) | | 2.33 (0.23–8.5) | | 1.75 (0.19–8) | |
| **Current Medication (n):** | | | | | | | | |
| -DMARDS | 11 | | 21 | | 32 | | n/a | |
| -oral steroids | 3 | | 3 | | 6 | | n/a | |
| -biologic drugs | 0 | | 5 | | 5 | | n/a | |
| -recent drug changes | 5 | | – | | – | | – | |
| **Hand dominance (n)** (right: left) | 13:1 | | 24:3 | | 37:4 | | 28:4 | |
| **Hand deformities** (n): dominant hand | 4 | | 11 | | 17 | | 2 | |
| **Gloves fitted to (n):** Both; dominant only: non-dominant only hands | 10: 3: 1 | | 23: 3: 1 | | 33: 6: 2 | | 25: 5: 2 | |
| **Glove wear regimen:** | **D** n = 13 | **ND** n = 11 | **D** n = 26 | **ND** n = 24 | **D** n = 39 | **ND** n = 35 | **D** n = 30 | **ND** n = 27 |
| -day only | 4 | 3 | 5 | 6 | 9 | 9 | 6 | 5 |
| -night only | 1 | 1 | 8 | 7 | 9 | 8 | 6 | 5 |
| -day and night | 6 | 7 | 13 | 11 | 21 | 18 | 18 | 17 |
| No. days between assessments: mean (SD) | | | | | | 29.76 (4.03) | | 31.16 (6.37) |

UIA: undifferentiated inflammatory arthritis; RA: rheumatoid arthritis; DMARDS: disease modifying anti-rheumatic drugs; D: dominant hand; ND: non-dominant hand.
Footnote: Inflammatory Arthritis group is the combined undifferentiated inflammatory arthritis and rheumatoid arthritis group.

to large effect sizes in some fingers in both the inflammatory arthritis and hand osteoarthritis groups. Hand function improved significantly in both groups with moderate effect sizes. Results were similar for non-dominant hands (data not shown).

## *Participants' views*

Most participants reported benefits from wearing compression gloves, although about a third also noted negative effects, reducing glove-wear as a result (Figure 2, Table 4). The most common effects and important benefits were reported as: hand symptom reduction (particularly pain); positive sensations from glove-wear (particularly hands feeling supported or comforted); and improved hand function (particularly activities being easier) (Table 4). The benefits reported varied, for example:

> *"They reduce stiffness… use them for short periods in the morning…. pain relief using them after activities…. can't use them during household jobs as they reduce grip. Beneficial if using a computer mouse…. Gloves stop fingers bending up in the morning, Help relax the hands and give comfort."* [53-year old woman with RA].
>
> *"Eased the pain and stiffness...some reduction in swelling (but might be due to the steroids)… easier to complete things…comfortable and not restrictive."* [56-year old woman with RA].
>
> *"Supportive, warming, they increase flexibility…..some reduction in the time taken to 'get going' in the morning."* [48-year old woman with HOA].
>
> "*There's no pain in the morning. It's easier to move [my hands] during the day. There's no 'locking' of my middle fingers now."* [72-year old man with HOA].

## *Sample size*

We used the hand pain on activity numeric rating scale to calculate sample sizes needed for definitive superiority randomised controlled trials of compression gloves

**Table 2.** Outcome measures at baseline and four weeks for the combined undifferentiated inflammatory and rheumatoid arthritis group: Dominant hand (n = 39).

| Measures | n | 0 weeks (mean, SD) | 4 weeks (mean, SD) | Mean difference (SD) | t and p values: t | p | Effect size |
|---|---|---|---|---|---|---|---|
| **Dominant Hand**: | | | | | | | |
| Pain (0–10 NRS): | | | | | | | |
| - during activity[a] | 39 | 5.56 (2.28) | 4.62 (2.31) | 0.95 (2.26) | 2.62 | 0.01 | 0.15 |
| - at rest (day)[a] | 39 | 4.10 (2.47) | 3.67 (2.31) | 0.44 (2.36) | 1.15 | 0.26 | 0.03 |
| - at night[a] | 39 | 4.41 (2.33) | 3.44 (2.35) | 0.97 (2.12) | 2.87 | 0.01 | 0.18 |
| Pain (0–10 NRS): | | | | | | | |
| - during activity[b] | 30 | 6.03 (1.73) | 4.70 (2.34) | 1.33 (2.19) | 3.34 | 0.002 | 0.28 |
| - at rest (day)[b] | 30 | 4.60 (2.28) | 3.80 (2.38) | 0.80 (2.44) | 1.79 | 0.08 | 0.10 |
| - at night[c] | 30 | 3.90 (2.22) | 2.87 (2.26) | 1.03 (2.06) | 2.75 | 0.01 | 0.21 |
| Stiffness (0–10 NRS) | 39 | 5.49 (2.62) | 3.97 (2.33) | 1.57 (2.27) | 4.16 | 0.001 | 0.31 |
| Joint circumference (cm.) | | | | | | | |
| - 2nd PIPJ | 38 | 6.67 (0.59) | 6.60 (0.57) | 0.07 (0.23) | 1.91 | 0.06 | 0.09 |
| - 3rd PIPJ | 38 | 6.74 (0.59) | 6.66 (0.55) | 0.09 (0.23) | 2.54 | 0.02 | 0.15 |
| - 4th PIPJ | 38 | 6.25 (0.56) | 6.16 (0.53) | 0.09 (0.20) | 2.87 | 0.01 | 0.18 |
| - 5th PIPJ | 32 | 5.66 (0.61) | 5.43 (0.57) | 0.22 (0.41) | 3.08 | 0.004 | 0.23 |
| - 2nd to 5th MCPJs | 38 | 19.87 (1.69) | 19.70 (1.66) | 0.17 (0.41) | 2.54 | 0.02 | 0.15 |
| Finger flexion (cm.) | | | | | | | |
| - 2nd digit | 38 | 6.33 (1.58) | 6.10 (1.51) | 0.22 (1.12) | 1.23 | 0.23 | 0.05 |
| - 3rd digit | 37 | 5.48 (1.63) | 4.93 (1.44) | 0.55 (1.10) | 3.12 | 0.004 | 0.21 |
| - 4th digit | 38 | 4.47 (1.51) | 4.07 (1.26) | 0.40 (1.16) | 2.11 | 0.04 | 0.10 |
| - 5th digit | 38 | 4.47 (1.60) | 4.04 (1.30) | 0.43 (1.26) | 2.14 | 0.04 | 0.11 |
| Grip Ability Test (max.score 180) | 37 | 43.11 (32.20) | 37.47 (29.41) | 5.64 (23.13) | 1.48 | 0.15 | 0.06 |
| Grip strength (kg.) | 12 | 10.56 (8.58) | 13.67 (6.93) | 3.11 (5.46) | 1.98 | 0.07 | 0.26 |
| | | | | | z and p values: z | p | |
| | | Median (IQR) | Median (IQR) | | | | |
| Perceived Hand severity (1–5) | 38 | 2.5 (2–3) | 3 (3–3) | | 3.38 | 0.001 | 0.55 |
| MAP-HAND (bilateral:0-54) | 41 | 21 (16–28) | 20 (15–23) | | −2.14 | 0.03 | 0.33 |
| Hand early morning stiffness (bilateral; minutes) | 38 | 60 (30–152.5) | 35 (15–60) | | 3.98 | <0.01 | 0.64 |

MAP-HAND: Measure of Activity Performance Hand; NRS: numeric rating scale; MCPJ: metacarpophalangeal joints; PIPJ: proximal interphalangeal joint; IQR: inter-quartile range; SD: standard deviation;[a] all participants prescribed a glove for their dominant hand;[b] participants prescribed gloves for daytime wear on dominant hand;[c] participants prescribed gloves for night-time wear on dominant hand.

in inflammatory arthritis and in hand osteoarthritis. The minimal clinically important difference for pain in rheumatoid arthritis is 1.1 points on a 0 to 10 scale.[22,23] There is no predefined minimal clinically important difference for pain scales in hand osteoarthritis, but this was considered as a $\geq$0.5 standard deviation of the mean baseline score.[24] Baseline standard deviations for hand pain on activity were 2.28 and 1.70 respectively. At a 5% significance level and 80% power: for inflammatory arthritis, 67 participants would be needed in each group, allowing for a 20% drop-out rate, this would be 161 in total; in hand osteoarthritis, 63 would be needed in each group, with a 20% drop-out rate this would be 151 in total.[25]

## Discussion

Most objectives of this feasibility study were met. Standardised compression glove assessment and treatment protocols were developed and could be successfully delivered by therapists. We achieved our recruitment target of 40 participants with inflammatory arthritis, but not for hand osteoarthritis. Outcomes improved sufficiently to indicate definitive trials in inflammatory arthritis and hand osteoarthritis are warranted. This is a feasibility study and cannot identify if gloves are effective. There were moderate to large effect sizes in hand pain, stiffness and hand function (and joint swelling in inflammatory arthritis). Reduced hand pain was the most important glove-wear benefit

**Table 3.** Outcome measures at baseline and four weeks for the hand osteoarthritis group: Dominant hand (n = 30).

| Measures | n | 0 weeks (mean, SD) | 4 weeks (mean, SD) | Mean difference (SD) | t and p values: t | p | Effect size |
|---|---|---|---|---|---|---|---|
| **Dominant Hand:** | | | | | | | |
| Pain (0–10 NRS): | | | | | | | |
| - during activity[a] | 30 | 7.27 (1.70) | 5.70 (2.34) | 1.57 (1.78) | 4.83 | 0.001 | 0.44 |
| - at rest (day)[a] | 30 | 4.70 (2.18) | 4.07 (1.99) | 0.63 (1.88) | 1.84 | 0.08 | 0.10 |
| - at night[a] | 30 | 6.13 (2.43) | 3.90 (2.50) | 2.33 (2.62) | 4.67 | 0.001 | 0.43 |
| Pain (0–10 NRS): | | | | | | | |
| - during activity[b] | 24 | 7.38 (1.81) | 5.79 (2.21) | 1.58 (1.74) | 4.45 | 0.001 | 0.46 |
| - at rest (day)[b] | 24 | 4.92 (2.15) | 4.29 (2.01) | 0.63 (2.02) | 1.52 | 0.14 | 0.09 |
| - at night[c] | 24 | 5.63 (2.45) | 3.46 (2.28) | 2.17 (2.60) | 4.08 | 0.001 | 0.42 |
| Stiffness (0–10 NRS) | 30 | 7.00 (1.60) | 5.53 (2.37) | 1.47 (2.45) | 3.29 | 0.003 | 0.27 |
| Joint circumference (cm.) | | | | | | | |
| - 2nd PIPJ | 30 | 6.57 (0.45) | 6.51 (0.52) | 0.06 (0.19) | 1.82 | 0.08 | 0.10 |
| - 3rd PIPJ | 30 | 6.62 (0.51) | 6.63 (0.91) | 0.01 (0.25) | −0.22 | 0.83 | <0.01 |
| - 4th PIPJ | 30 | 6.30 (0.93) | 6.23 (0.55) | 0.08 (0.22) | 1.88 | 0.07 | 0.11 |
| - 5th PIPJ | 30 | 5.34 (0.56) | 5.39 (0.42) | 0.01 (0.45) | 0.08 | 0.94 | <0.01 |
| Grip strength (kg.) | 11 | 13.06 (8.85) | 15.18 (10.21) | 2.12 (4.76) | 1.48 | 0.17 | 0.17 |
| | | | | | z and p values: z | p | |
| | | Median (IQR) | Median (IQR) | | | | |
| Finger flexion (cm..) | | | | | | | |
| - 2nd digit | 30 | 6.80 (5.06–7.65) | 5.65 (5.15–7.03) | | −2.34 | 0.02 | 0.43 |
| - 3rd digit | 30 | 5.15 (4.38–6.60) | 4.50 (3.88–5.53) | | −2.08 | 0.04 | 0.38 |
| - 4th digit | 30 | 4.75 (3.38–6.30) | 3.50 (3.23–5.73) | | −2.29 | 0.02 | 0.42 |
| - 5th digit | 30 | 4.20 (3.25–5.35) | 3.65 (3.08–5.00) | | −1.22 | 0.22 | 0.06 |
| Grip Ability Test (max. score 180) | 30 | 35.71 (29.02–48.04) | 30.08 (26.08–40.09) | | −2.89 | 0.004 | 0.53 |
| Perceived Hand severity (1–5) | 28 | 2 (2–3) | 3 (2–3) | | −2.52 | 0.01 | 0.31 |
| MAP-HAND (bilateral:0-54) | 32 | 24.50 (18.50–32.50) | 23.50 (16.50–26.75) | | −1.77 | 0.08 | 0.31 |
| Early morning stiffness (minutes) | 31 | 60 (30–120) | 60 (15–90) | | −0.71 | 0.48 | 0.13 |

MAP-HAND: Measure of Activity Performance Hand; NRS: numeric rating scale; PIPJ: proximal interphalangeal joint; IQR: inter-quartile range; SD: standard deviation;[a] all participants prescribed a glove for their dominant hand;[b] participants prescribed gloves for daytime wear on dominant hand;[c] participants prescribed gloves for night-time wear on dominant hand.

reported by participants. Effects were seen in both daytime hand pain on activity and night-time pain. We therefore selected the former as a primary outcome for future trials, as participants more often reported hand function benefits than sleep improvement. Sample sizes were then estimated. Although we identified recruitment, assessment and treatment procedures were feasible, we identified several issues in relation to conducting a future trial.

Recruitment was problematic. There were delays in starting recruitment, and numbers screened and consented were lower than anticipated, particularly in hand osteoarthritis. Delayed recruitment occurred at three sites due to difficulties purchasing compression gloves, which are normally provided as part of usual care. In future trials, providing compression gloves to sites would avoid this delay. Therapists could recruit from amongst their caseloads but numbers screened and recruited varied considerably between sites. Average recruitment was five inflammatory and four hand osteoarthritis participants/month. At this rate, with these 10 sites, achieving the proposed sample size in inflammatory arthritis would take 32-months and 38-months in hand osteoarthritis. To recruit within a feasible time frame, e.g. around 16 to 18 months within a typical three-year trial, will require more sites and increasing screening and consenting rates at each.

Increasing screening rates is feasible in inflammatory arthritis. Patients are referred to occupational therapy from rheumatology out-patient clinics. There are likely to be more patients with moderate to severe hand pain attending clinics but not being referred. Expanding recruitment into rheumatology out-patient

**Table 4.** Frequency of self-reported compression glove effects and most important benefits from glove-wear.

| | Perceived effects of compression gloves (n) | | Most important benefit of compression gloves (n) | |
|---|---|---|---|---|
| Category and code | IA (n = 41) | HOA (n = 32) | IA (n = 35) | HOA (n = 30) |
| **Positive effects:** | **35** | **30** | | |
| **Type of positive effects:** | | | | |
| **1 Hand symptom reduction:** | **21** | **22** | – | – |
| - pain/aching | 15 | 16 | 14 | 7 |
| - stiffness | 9 | 11 | 3 | 5 |
| - swelling | 7 | 5 | 0 | 2 |
| - pins and needles/numbness | 0 | 3 | 0 | 0 |
| **2 Positive hand sensations** | **19** | **16** | – | – |
| - supportive | 11 | 11 | 8 | 4 |
| - comforting/comfortable | 9 | 7 | 2 | 2 |
| - warmth | 4 | 3 | 0 | 1 |
| **3 Improved hand movement and function:** | **12** | **10** | – | – |
| - activities easier | 7 | 7 | 1 | 5 |
| - fingers more flexible | 6 | 4 | 3 | 2 |
| - grip stronger | 3 | 0 | 3 | 0 |
| - fingers less curled in the morning | 3 | 2 | 0 | 0 |
| **4 Improved sleep** | 2 | 3 | 1 | 2 |
| **No effects** | **6** | **2** | – | – |
| **Negative effects:** | **12** | **10** | – | – |
| - itching/ irritating/ too hot | 4 | 4 | – | – |
| - increased aches/pain | 4 | 4 | | |
| - limiting hand function/ finger flexion | 3 | 1 | – | – |
| - get dirty/scruffy quickly | 2 | 1 | | |
| - increased stiffness | 0 | 2 | – | – |
| - pressure making finger nodes sore | 0 | 1 | – | – |
| - uncomfortable | 1 | 0 | – | – |
| - problem taking on/off for toilet at night | 0 | 1 | | |

IA: inflammatory arthritis; HOA: hand osteoarthritis. Participants could experience both of and more than one positive or negative effect in each category.

clinics should increase numbers screened. Fewer hand osteoarthritis patients were screened, meaning trial recruitment could be more problematic. Referrals typically come from General Practitioners. However, many with hand osteoarthritis may not seek help, even when in severe pain, feeling that nothing can be done.[26] Only 3% of those with severe hand osteoarthritis reported being referred to an occupational therapist within the last year.[27] A trial in hand osteoarthritis would therefore require identifying sites receiving high numbers of primary care referrals and/or with effective primary care research recruitment pathways.

Increasing consenting rates is also required. Of those screened, 16% with inflammatory arthritis, and 19% of those with hand osteoarthritis, were eligible but unable to attend for the four-week follow-up glove review and assessment or the therapist was unable to provide a suitably timed appointment (e.g. due to annual leave), meaning these patients could not be recruited. Conducting telephone glove reviews and collecting data via mailed self-report questionnaires would avoid the need for this second visit, as well as reducing participant burden. Remote reviews also normally occur in usual care and are therefore a feasible alternative.[5]

Whilst therapists were able to conduct hand assessments, including the objective outcomes (i.e. finger flexion, joint circumferences, Grip Ability Test and grip strength), it was not feasible to have independent assessors, as other staff within participating departments did not have sufficient time or availability to conduct assessments to schedule. Future trials would therefore need to fund independent assessors, increasing trial costs considerably, and ensure they are available to meet the assessment schedule. Logistically, this is likely to prove difficult. If a trial is portfolio adopted by the UK Clinical Research Networks, NHS research facilitators (i.e. usually research nurses or clinical trials assistants) also can conduct assessments in trials, as well as recruiting.[28] However, in practice it can be difficult to get the additional and sustained commitment to conduct assessments within rehabilitation trials.

Participants reported the main benefits were improved hand pain, stiffness and hand function. As these can be validly and reliably collected using patient reported outcome measures, we recommend self-report questionnaires are used for data collection in future trials, in order to contain trial costs.

The results should not be considered as indicating compression gloves improve hand symptoms and function, as participants were not randomised to a control group nor were there independent assessors. A quarter of inflammatory arthritis participants had steroid injections or drug changes during the trial, which could contribute to improvements. Only a randomised controlled trial with independent or self-report outcome assessment can answer if compression gloves are effective.

The strengths of this study were that we developed the recruitment, assessment and treatment procedures through expert consensus with therapists from the 10 participating sites and patient research partners to ensure these were feasible in clinical practice and acceptable to patients. This means that protocols were likely to be acceptable in a future trial. We ensured therapists were able to: provide and fit gloves correctly, through observation and feedback from researchers and patient research partners; and conduct assessments correctly through a reliability study of objective measures. Best usual care practice was agreed across sites. We assessed open finger Isotoner ™ compression gloves, which are the most common gloves used in clinical practice[5] and have not previously been evaluated.[6] Participants comments provided insights into perceived benefits of glove wear, influencing planning for future trial outcome choices and data collection methods. This was also the first study exploring effects of daytime compression glove-wear and in hand osteoarthritis.

The limitations were that there was no control group and therefore we do not know if participants would accept randomisation to a control group. Further consensus is required with clinical therapists and patient research partners as to what should constitute a control group: e.g. receiving either hand exercise and joint protection education as "usual care"; an attention-control intervention of similar duration; or placebo gloves. If placebo gloves are used, then a suitable placebo glove needs identifying. For example, previous studies have used: loose-fitting compression gloves;[7] non-stretch cotton gloves[8] or thermal gloves.[1] We also do not know if therapists would be willing to recruit into a randomised controlled trial. Therapists provide gloves to about a third of their caseload. It will therefore be essential when recruiting therapists, and during training, to discuss the very limited evidence for compression glove effectiveness. For example, if the control group receives placebo gloves, therapists will need to be willing to accept that there is clinical equipoise between compression and placebo gloves. Therapists will therefore need to consider their current beliefs about glove effectiveness in order to be willing to recruit and accept randomisation. Additionally, they would need training in how to deliver placebo gloves convincingly.[29] Further work with patient research partners is needed to discuss how best to describe to patients the current lack of evidence for compression gloves, and the need for a trial to test these, in order for patients to be willing to be randomised into a trial. We did not have independent assessors or interviewers, which could have introduced bias.

In a future trial, provision of concomitant hand therapy should be standardised, as participants had varying amounts of this. Participants' perceptions of compression gloves highlighted adverse effects and why some stopped wearing these as recommended. In a future trial, self-reported glove-wear and in-depth interviews by an independent interviewer would provide better insights into participants' use of and perceptions of compression gloves. Further assessment of treatment fidelity is also recommended, e.g. through observation of treatment sessions, which may now be more feasible remotely with increased access to video meeting facilities. There was a high level of adverse events. This led to some stopping glove wear and others reducing glove wear during the day or night. In a future trial, the effects of glove provision (as opposed to glove wear) need to be tested, as this reflects the reality of clinical practice. An intent-to-treat analysis should therefore be conducted, with a per protocol analysis excluding those not receiving gloves for any reason.

In conclusion, a trial of compression gloves is warranted and procedures are feasible in inflammatory arthritis. This study identified issues to be addressed. It also provides an example of how expert clinical therapist and patient research partners consensus can be obtained to develop trial and treatment protocols, in both research and for clinical practice. A mixed method randomised controlled trial, with a nested qualitative study and independent interviewer, was planned at 16 sites in the United Kingdom, additionally recruiting from rheumatology clinics.[30] The trial includes standardised concomitant hand therapy, telephone or in-person glove review, and data collection with mailed self-report questionnaires. Outcomes are hand pain on activity and at night, hand stiffness, hand function and an economic analysis comparing the costs and health benefits of compression gloves from a health and social care perspective. A future trial in hand osteoarthritis is warranted but requires a clear primary care and

community recruitment pathway to ensure enough recruitment.

Online supplementary file I: C-Gloves Phase 1 feasibility study planning

Online supplementary file II: C-GLOVES: Therapist Compression Glove Hand Assessment and Treatment Manual.

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## Informed consent

Written informed consent was obtained from the patient(s) for their anonymized information to be published in this article.

## Ethical approval

Ethical approval for this study was provided by the East Midlands-Northampton Research Ethics Committee (13/EM/0253), Health Research Authority (HRA) and research and development approvals were obtained as necessary. Ethical approval was also provided by the School of Health Sciences Ethics Panel, University of Salford.

## Guarantor

AH

## Contributorship

AH and YP conceived the study. AH, YP and Vivienne Jones (VJ) designed the study. AH was the grant holder and Chief Investigator. AH completed the statistical analysis, with advice from the North West Research Design Service; AH and VJ analysed the participants' verbatim responses. AH and YP contributed to the interpretation of data, completed the manuscript and read and approved the final version.

## Availability of data

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

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## References

1. Oosterveld FJG and Rasker JJ. The effect of pressure gradient and thermolactyl control gloves in arthritis patients with swollen hands. *Br J Rheumatol* 1990; 29: 197–200.
2. McKnight PT and Kwoh CK. Randomised controlled trial of pressure gloves in rheumatoid arthritis. *Arthritis Care Res* 1992; 5: 223–227.
3. Murphy D. Lycra working splint for the rheumatoid arthritic hand with MCP ulnar deviation. *Aust J Rural Health* 1996; 4: 217–220.
4. Barbarioli M. A lycra glove working splint for rheumatoid arthritis: a case study. *Br J Occup Ther* 2001; 64: 364–366.
5. Prior Y and Hammond A. The survey of rheumatology occupational therapy compression glove practice and provision in the UK. *Rheumatology* 2015; 54: i101–i102.
6. Hammond A, Jones V and Prior Y. The effects of compression gloves on hand symptoms and hand function in rheumatoid arthritis and hand osteoarthritis: a systematic review. *Clin Rehabil* 2016; 30: 213–224.
7. Culic DD, Battaglia MC, Wichman C, et al. Efficacy of compression gloves in rheumatoid arthritis. *Am J Phys Med* 1979; 58: 278–284.
8. Swezey RL, Spiegel TM, Cretin S, et al. Arthritis hand response to pressure gradient gloves. *Arch Phys Med Rehabil* 1979; 60: 375–377.
9. Dixon AS and Harrison RA Trial for isotoner™ gloves for morning stiffness and pain in rheumatoid arthritis. *Br J Clin Pract* 1986; 40: 271–272.
10. Isotoner™ Gloves information from Isotoner™ website, https://www.Isotoner.com/p/Isotoner-fingerless-therapeutic-gloves-25830 (accessed 30 September 2020).

11. Hammond A, Jones V and Prior Y. Reliability of three objective hand measures in rheumatoid arthritis: joint circumference, composite finger flexion and the grip ability test. *Rheumatology* 2014; 53i: i124–i124.
12. Melvin JL. Evaluation of range of motion. In: Melvin JL (ed.) *Rheumatic disease: occupational therapy and rehabilitation*. 2nd Ed. FA Davis Company: Philadelphia, 1989, pp. 281–290.
13. Gilbertson L and Barber-Lomax S. Power and pinch grip strength recorded using the hand-held jamar dynamometer and B+L hydraulic pinch gauge: British normative data for adults. *Br J Occup Ther* 1994; 57: 483–488.
14. Dellhag B and Bjelle A. A grip ability test for use in rheumatology practice. *J Rheumatol* 1995; 22: 1559–1565.
15. Paulsen T, Grotle M, Garratt A, et al. Development and psychometric testing of the patient-reported measure of activity performance of the hand (MAP-HAND) in rheumatoid arthritis. *J Rehabil Med* 2010; 42: 636–644.
16. Fernandes L, Grotle M, Darre S, et al. Validity and responsiveness of the measure of activity performance of the hand (MAP-HAND) in patients with hand osteoarthritis. *J Rehabil Med* 2012; 44: 869–876.
17. Browne RH. On the use of a pilot sample for sample size determination. *Stat Med* 1995; 14: 1933–1940.
18. Kieser M and Wassmer G. On the use of the upper confidence limit for the variance from a pilot sample for sample size determination. *Biom J* 1996; 38: 941–949.
19. Pallant J. *SPSS survival manual*. 4th Ed. Maidenhead: McGraw-Hill, 2010.
20. Cohen J. *Statistical power analysis for the behavioural sciences*. 2nd ed. Hillsdale, NJ: Lawrence Earlbaum Associates, 1988.
21. Bengtsson M. How to plan and perform a qualitative study using content analysis. *Nursing Plus Open* 2016; 2: 8–14.
22. Hawker GA, Mian S, Kendzerska T, et al. Measures of adult pain. *Arthritis Care Res* 2011; 63(Suppl 11): S240–252.
23. Wolfe F and Michaud K. Assessment of pain in rheumatoid arthritis: minimal clinically significant difference, predictors, and the effect of anti-tumor necrosis factor therapy. *J Rheumatol* 2007; 34: 1674–1678.
24. Strand V, Boers M, Idzerda L, et al. It's good to feel better but it's better to feel good and even better to feel good as soon as possible for as long as possible. Response criteria and the importance of change at OMERACT 10. *J Rheumatol* 2011; 38: 1720–1727.
25. PS: Power and Sample Size Calculator 3.1, https://ps-power-and-sample-size-calculation.software.informer.com/versions/ (accessed 30 September 2020).
26. Hill S, Dziedzic KS and Ong BN. The functional and psychological impact of hand osteoarthritis. *Chronic Illn* 2010; 6: 101–110.
27. Dziedzic K, Thomas E, Hill S, et al. MRC hand programme-prevalence of hand problems and hand pain in older people: a survey of the general population in North Staffordshire. *Rheumatology* 2004; 43: 88.
28. NIHR Clinical Trial Research Networks, https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm (accessed 13 December 2020).
29. Jones LE, White P, Donovan-Hall M, et al. The thoughts and feelings held by clinicians about the delivery of a placebo thumb splint in an osteoarthritis rehabilitation trial. *Hand Ther* 2013; 18: 77–83.
30. Prior Y, Sutton C, Cotterill S, et al. The effects of arthritis gloves on people with rheumatoid arthritis or inflammatory arthritis with hand pain: a study protocol for a multi-Centre randomized controlled trial (the A-GLOVES trial.). *BMC Musculoskelet Disord* 2017; 18: 224.
31. National Institute of Health Research. Definition of feasibility vs. pilot studies, https://www.nihr.ac.uk/documents/nihr-research-for-patient-benefit-rfpb-programme-guidance-%20%20on-applying-for-feasibility-studies/20474 (accessed 30 September 2020).
32. Eldridge SM, Lancaster GA, Campbell MJ, et al. Defining feasibility and pilot studies in preparation for randomised controlled trial: development of a conceptual framework. *PLoS One* 2016; 11: e0150205.