



OCCUPATIONAL THERAPY

GLOVE PROVISION MANUAL V.2



This A-GLOVES: Occupational Therapy Glove Provision manual is provided as part of the NIHR Research for Patient Benefit Programme Grant Reference: **PB-PG-0214-33010**:

“The effects of compression gloves on people with Rheumatoid Arthritis or Early Inflammatory Arthritis with hand pain: a multi-centre randomised placebo-controlled trial.”

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The information within this manual is applicable for interventions provided within the A-GLOVES trial.

Any queries should be addressed to:

Prof Alison Hammond (Chief Investigator): a.hammond@salford.ac.uk

Dr Yeliz Prior (Trial Manager): y.prior@salford.ac.uk

Address for both: Centre for Health Sciences Research (OT), L701 Allerton, University of Salford, Frederick Road, Salford M6 6PU

© A. Hammond¹, A Jacklin², Y Hough³, J Adams⁴, Y Prior¹ 2016

¹ Centre for Health Sciences Research, University of Salford, UK; ² Occupational Therapy, Macclesfield General Hospital, Macclesfield, UK; ³ Occupational Therapy, St Helens Hospital, St Helens, UK; ⁴ School of Health professions, University of Southampton, Southampton, UK.

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a.hammond@salford.ac.uk or profalisonhammond@btinternet.com

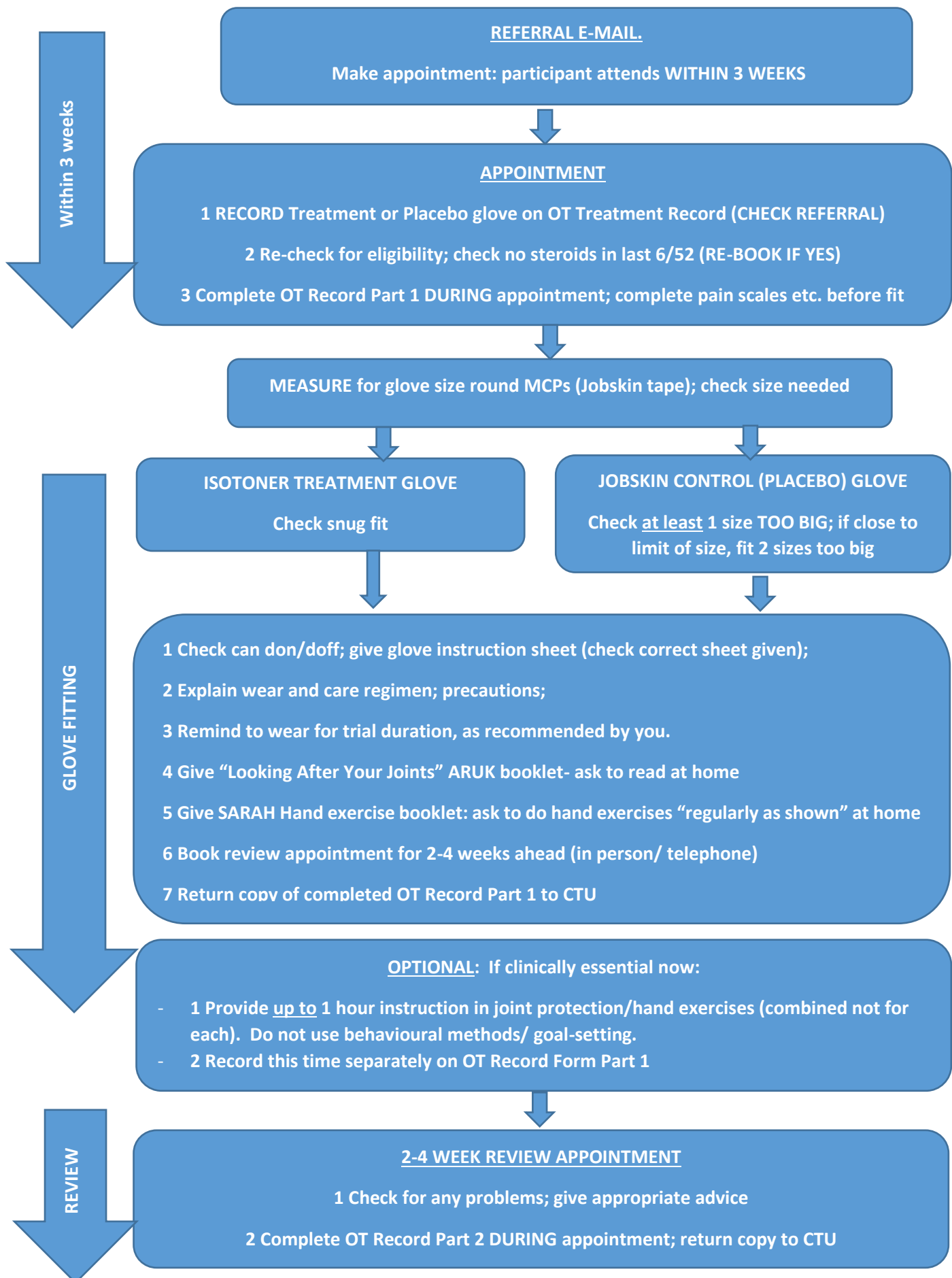
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INTRODUCTION:

This manual describes the Occupational Therapy (OT) protocol for the A-GLOVES trial, including glove-fitting (treatment and placebo); instructions and therapy assessments (but not trial assessments). The intervention group receive Isotoner gloves, applying warmth and pressure. The control (alternate or placebo) group receive Jobskin gloves purposefully fitted one-size too large, applying warmth only, with very minimal pressure. We do not know if arthritis gloves are effective or not. It is unclear whether gloves may have an effect through applying pressure or warmth (or both). The alternate (placebo) gloves therefore provide control for the effects of warmth (Hammond et al, 2015).

A-GLOVES OT PROTOCOL FLOWCHART





A-GLOVES TRIAL: OT GLOVE PROVISION PROTOCOL

A TRIAL REFERRAL

You will receive an encrypted e-mail(s) from Lancashire Clinical Trials Unit (CTU), with the participant's contact details, unique Participant Identification Number (PIN) and group allocation (treatment or placebo glove). The trial referral is sent to the **designated e-mail address** you provide to the Trial Manager.

Trial standard: all participants **must** attend for glove provision within 3 weeks of referral.

- As soon as possible, please make the appointment with the participant. **Check they can come** on that day/ time.
- If you are on annual or sick leave for more than 1 week ensure someone else can access the trial referral(s) and make trial appointments for participants on your behalf ready for your return.
- If this is not possible, ensure the Trial Manager is notified as far in advance as you can of your absence so that actions can be taken, if feasible, to delay referral.
- If a participant UTA/DNA's their appointment, see them **as soon as possible**. Record UTA/DNA on the OT Record Form Part 1.

Note: delays in receiving gloves mean participants will be wearing gloves for a shorter time before completing the 12 week follow-up questionnaire. This may be insufficient time to identify any glove effects.

Check you have the range of the correct glove sizes in stock for the appointment.

- Isotoner gloves must be supplied by your department. **Any problems** contact the Trial Manager (Dr Yeliz Prior) as soon as possible so that we can help
- Jobskin oedema gloves – we provide a stock of gloves (Small/ Medium/ Large) for use **ONLY** in the trial.

IF YOUR DEPARTMENT HAS E-BOOKING OR ADMINISTRATOR BOOKING OF APPOINTMENTS:

In advance of trial recruitment: establish a mechanism for your approx. 12+ trial participants (i.e. on average **ONLY** 1 per month) to attend:

- The trial glove appointment within 3 weeks of referral;
- Review appointment within 2-4 weeks of glove provision [if you normally do these in person].

It is important participants are not entered onto your waiting list of, for example, 8-12 weeks or longer. There is a risk they will not receive gloves before their 12 week assessment.

Suggested method:

We recommend you have at least 4 appointments available each month on different days of the week/times for new participant(s), allowing some flexibility for them to attend. (If only one is kept free, the participant may not be able to attend at that one time e.g. due to work commitments).

Please arrange by telephone with the participant which appointment they can attend and confirm in writing. Emphasise the gloves need to be fitted as soon as possible. Once a participant(s) is booked into one of these “free” appointments, the rest can be released ASAP.

B GLOVE FITTING APPOINTMENT

a) Before the participant arrives::

Check which gloves you are providing to the participant today. Check this on the A-Gloves referral e-mail from Lancashire CTU.

- Intervention Group: Isotoner gloves.
- Control (placebo) group: Jobskin gloves

Get the size range of the allocated glove model out ready. The appointment will last 30-45 minutes.

b) During the appointment:

1. Welcome:

- Complete your usual departmental documentation.
- Thank the participant for agreeing to be in the A-GLOVES trial and check they are willing to continue in the study. Always refer to the gloves as “arthritis gloves.” For example,
 - *“Many thanks for helping us with this study testing whether arthritis gloves work. You have already completed the study consent form and the first questionnaire. Can I just check.... Are you happy to continue with the study today?”*
This confirms the participant is willing to continue with their trial consent.
- Record study consent was confirmed in your OT notes and the A-GLOVES OT Record.
- The participant should say **yes.... Continue with step 2.**

If they say NO: [this will be very unusual at this stage...]

“Thank you for being willing to help with the study so far. I will let the study Trial Manager know you no longer wish to take part.

If you do not mind doing so, can you tell me why you no longer wish to do so? You do not have to tell me if you prefer not to...”

[Record the reason on the OT Record Form]

“Thanks very much for your time. Just to confirm, I can’t therefore provide you with the gloves as part of the trial today”

[Complete the OT Record Part 1 and return to Lancashire CTU].

2. Complete the **A-Gloves Trial OT Record: Part 1 Glove Fitting during the appointment.**

- Do not let the patient see this Record, apart from page 2 when completing the pain scales.
- Keep a copy of the A-Gloves Trial Record: Part 1 in your records.

3. Explain the purpose of "arthritis gloves" to the patient. Take care not to indicate whether one or other type of glove being tested may be better or worse than the other.

- Show them the gloves you will be fitting them with today

Explain, for example: "We are testing whether or not these arthritis gloves help reduce pain, stiffness, and any swelling in your fingers or hands during the day and/ or at night. We are also testing whether they have any effect on how you can use your hands. We don't have any good information about whether arthritis gloves work or which type of glove is best to use if they do.

- *You have been randomly allocated to wear the XXXXXX gloves [state which type of glove allocated, i.e. Isotoner arthritis gloves or Jobskin arthritis gloves].*

4. Take verbal consent for provision of gloves and record this in the patient's notes. [NB. Trial consent has already been completed]. For example:

- *"Is it OK for me to provide you with these gloves today?"*
- *Just to remind you, any travel costs you have from attending today and for the review appointment [nb if your department normally asks patients to attend for review in person] will be paid back to you. I can provide you with a claim form and Freepost envelope to send back to the researchers at the University of Salford.*
- **[PROVIDE THE PARTICIPANT WITH CLAIM FORM AND FREEPOST ENVELOPE NOW].**
- *Please just keep any receipts you have and attach these to the form and make sure you sign it here [Mark with an X where the participant has to sign]. If you have any queries about the form, please do contact the Trial Manager, Dr Prior, whose contact details are on the study information sheet you already have.*

c) A-GLOVES OT Record:

5. Complete the two pain scales on the A-GLOVES OT Record with the participant. For example:

- *"Please can you complete these two pain scales. They ask you: **In your RIGHT hand:** during the **daytime**, when doing moderate hand activities, e.g. housework, cooking, DIY, gardening: how is your pain on a scale of 0 (none) to 10 severe pain.?"*
- *[Repeat for left hand.....]"*

6. **Check the patient's eligibility for glove provision** using the criteria on the A-Gloves Trial OT Record: Part 1.

This was already checked at the time of screening/ consent. However, it is possible that some participants' hand status may have changed between consent and their glove appointment. This is an additional clinical check. For example:

Hand status:

- “First, I will just check it is OK for you to still receive the gloves.
- Do you have any problems with circulation in your hands? [Check: if they now report **severe** Raynaud’s they are ineligible]
- Do you have any problems with sensation in your hands? [Check: if they now report **severe** carpal tunnel syndrome or other neurological symptoms, they are ineligible]

If the patient has mild–moderate Raynaud's disease/ neuropathy, they can be provided with the gloves.

- **Give additional instructions to regularly: check the circulation/ sensation in their hands; and remove gloves.**

PARTICIPANT REPORTS SEVERE CIRCULATORY OR NEUROLOGICAL HAND PROBLEMS TODAY:

Please use your clinical judgement if it is appropriate to provide the gloves. If you do **not** consider they should wear gloves applying compression, do not provide gloves (even if they are in the Jobskin glove group).

“Many thanks for being willing to take part. However, your circulation [or nerve] hand problems today mean it isn’t appropriate to fit you with the gloves. The researchers will still send you a follow-up questionnaire. I can give you some advice today on how to manage your hand problems.”

Please provide the participant with the ARUK Looking After Your Joints booklet and the Hand Exercise booklet. (See later)

Report the reason for not supplying gloves on the OT Record Part 1.

Medication status

Check also for any recent changes in steroid medication:

- Have you had a steroid injection or started oral steroids (eg prednisolone) in the last 6 weeks?
- **If yes:** [this should be an unusual occurrence as people were screened for this at trial entry] “When did you have this?”
- Ask the participant the date the steroid injection was given or drug started. Check whether it **is** in the last 6 weeks.
- If longer: than 6 weeks/ almost 6 weeks: continue with appointment
- If less than 6 weeks: apologise and explain, for example:

- *“In this study, we need to make sure people taking part have not had a steroid injection or started steroids within the last 6 weeks. Unfortunately, because you did have this XXX weeks ago, we will have to put off fitting the gloves to another day - in XXX week’s time”*
- Re-arrange the appointment – and apologise again; explain their travel costs are still paid for.

5. Hand assessment:

- Complete either your department’s usual hand assessment or the form provided at the end of this protocol. (Your choice).
- Record the information related to glove provision as you normally would in your OT records/ medical notes.
- Please note, data you collect in this hand assessment is not used within the trial.

C SIZING AND FITTING THE GLOVES

6. **Apply alcohol gel** (or ensure you and the patient wash hands thoroughly) to both your and participant’s hands for infection control purposes prior to sizing for, trying out and fitting gloves. Leave the gel to dry for 1-2 minutes.
7. If not already identified during your hand assessment, ask the participant about their hand problems:
 - Pain, stiffness, swelling, hand function
 - Time of day they have problems
 - Discuss with the participant when will be the most appropriate times for them to wear the gloves being provided today.
 - Record your glove provision on the A-GLOVES Record [glove model, which hand(s); and **wear regimen** as you complete glove provision]
 - It is your clinical judgement what the best wear regimen is to negotiate with the participant. Only you can determine this based on your assessment and discussion with the participant on the day. For example, you may recommend day-time wear, but the person works and is unwilling to wear the gloves at work (e.g. because they have not informed their manager they have arthritis). Negotiate what is a feasible wear regimen in the morning before work/ after work and on non-work days. Record this, and your reasons, on the OT Record.

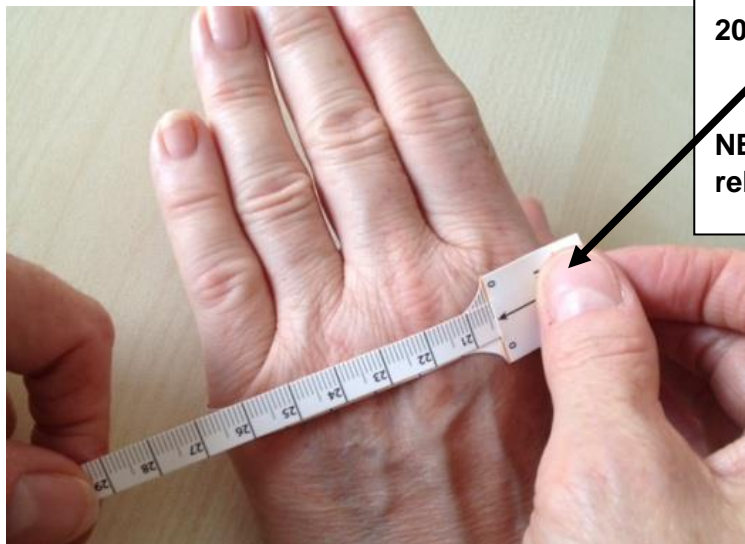
8. Glove Sizing:

Determine the correct glove size for the arthritis gloves:

Measure circumferentially around the 2nd to 4th MCPs using a Jobskin measuring tape. This is made of paper and can be discarded after using with one participant for hygiene reasons.

Ask the participant to almost extend the fingers and MCP joints – **keep slightly relaxed**. Pull the tape so that it fits snugly but not too tightly across the MCP joints and read the figure next to the arrow head on the tape.

Take the reading at the widest point of the MCPs. Be careful when reading the tape – lift the flap to check you get the right centimetre size.



**Example of how to read
Jobskin tape:**

20.4 cms - NOT 21.6 cms

**NB MCPs should be slightly
relaxed.**

PLEASE NOTE:

When fitting the gloves, **IF** the person's hand size measures as:

- TOO SMALL to correctly fit an XS Isotoner (i.e less than 14cms) or
- TOO LARGE to fit a LARGE Jobskin glove **and** it still be a bit loose (i.e. greater than **23.5cms**);

Whichever group they are allocated to, **DO NOT FIT** an arthritis glove.

Please clearly record on the A-GLOVES OT Record that the person's hand was too small or too large for you to fit a glove. PLEASE STATE THE MCP SIZE AS MEASURED USING THE JOBSKIN TAPE.

For information: please note the size ranges in centimetres of Isotoner and Jobskin classic oedema gloves are not the same. Always use the appropriate sizing chart.

For ISOTONER Gloves:

To determine the correct glove size:

- Refer to the sizing chart below; and to the manufacturers' glove packaging for glove sizing (extra small, small, medium, large on the packet)
- ALWAYS use clinical judgement re correct fit. Don't rely solely on the measurement. The person MAY apparently fit a medium but a small size may provide better support. ALWAYS check sizing. If they appear loose, try a smaller size.
- Ask the participant for feedback about comfort and how tight or loose the gloves feel. Try a smaller size if the participant feels they are not a snug enough fit.

Good snug fit (In this example, a Small)



Too loose fit. (In this example a Medium)



18cms

See Isotoner sizing chart:

For this example, the size to try is
Isotoner = **SMALL**

ISOTONER SIZE ON PACK	ISOTONER GLOVE SIZE RANGE	SIZE to FIT
XS	14-16.5cms	XS
S	16.5-19cms	S
M	19-21.5cms	M
L	21.5-24cms	L

9. Assist the patient initially with donning the glove over their fingers, then instruct them on how to continue to pull these over the hand/s. Emphasise that these should be:
- a snug, not tight, fit
 - fit at the base of the fingers
 - fit comfortably over the extended thumb and at base of the thumb
 - not become baggy when the hand is flexed
 - Check the patient's response about the fit and comfort of the gloves throughout.



10. Test manually for the appropriate fit by:
- Checking there is **slight** give in the material over the hand and fingers, to allow for adequate expansion should the participant experience any increase in hand swelling (e.g. due to a flare of their RA).
 - To do this, the glove seams are pinched simultaneously either side of a) the MCP joints and then b) the 2nd to 5th PIP joints.
11. Check:
- Press each finger pad until it blanches. On release, does the blood flow return quickly to the finger end? If not, the gloves may be too tight.



- With the hand slightly flexed, there is a “bounce” in the glove as it stretches across the palm and it is not too loose



12. Re-size the glove if necessary and perform the fit procedure again

Q: What do I say if people ask about the snug fit?

For example:

- *“We don’t know how arthritis gloves work. Some types of glove give gentle support and warmth and others apply warmth. These gloves help us see if the effect of support and warmth are helpful*
- *They need to be a snug fit to do this. They should provide a gentle support for the hands. Gloves may make it easier to move your hands. “*

IF THE PARTICIPANT’S HAND IS LARGER at the MCP CIRCUMFERENCE THAN 23.5cms:

and the Isotoner glove is too tight, please do not supply the gloves.

State on the OT Treatment Record that:

- a treatment (Isotoner) glove could not be fitted as the hand was too large.
- record the size of the hand in cms (measured using the Jobskin tape with MCPs in slight flexion) or other reason (e.g enlarged PIP joint(s); finger/ thumb size too large. Please provide as much detail as possible
- Explain to the participant that; a glove cannot be fitted because of size; we still need them to stay in the study; and it is important they still complete the 12 week questionnaire.

For Jobskin Gloves

These should be “**at least one size too big.**”

Check the JOBSKIN CLASSIC sizing chart below to help you determine what this is:
The gloves should appear loose, but not so loose they can fall off.



The pictures in this section show a 18cm wide hand wearing a **MEDIUM** Jobskin glove, which is “**one size too big**”.

- The correctly fitted Isotoner glove for this hand would be a Small.
- A correctly fitted Jobskin glove would normally be a Small (ie. fitting between a 17.9 – 20.3cm hand).
- [If this glove was being correctly fitted, an Extra Small Jobskin glove might be the best fit as the person is close to the boundary between XS and S sizes].
- Always err on choosing the largest size that looks acceptable.

JOBSKIN CLASSIC GLOVE SIZE: fits up to ...		FIT AT LEAST “ONE SIZE TOO BIG”
XS	17.8 cm	FIT A MEDIUM FIRST, TRY SMALL IF TOO BIG
S	20.3 cm	FIT A LARGE FIRST, TRY MEDIUM IF TOO BIG
M	22.9 cm	FIT A LARGE SIZE
L	25.4 cm	FIT A LARGE SIZE** ONLY if hand up to 23.5cm

**NOTE: If the participant’s hand is up to 23.5cm at the MCPs , they can still be fitted with a LARGE Jobskin glove.

Start by trying two sizes too big at first (if the participants’ hand size allows this). Then move down a size, if 2 sizes larger looks TOO big.

9. Assist the patient initially with donning the glove over their fingers, then instruct them on how to continue to pull these over the hand/s. IF THEY FEEL TOO TIGHT ROUND THE CUFF: you can gently pull the stitching to make it easier to get on. Emphasise that these gloves should:

- *“feel a little loose. It is important the gloves do not feel too tight on your hand.”*
- Start by fitting two sizes too big if the glove sizing allows. You can then try one-size too big if 2 sizes up seems too loose. The final size selected depends on the patient’s hand size.

10. Test manually for the appropriate fit by:

- Ensuring the at least a “one size larger” Jobskin classic oedema glove is not a “snug fit” applying compression.
- Test by pinching the material either side of the MCPS and then at the PIPs. Ensure it feels loose. Check the material can be pinched up on the dorsum of the hand.



11. Check:

- Press each finger pad until it blanches. On release, does the blood flow return quickly to the finger end? If not, the gloves may be too tight.
- The fingers are loose at the PIPs by inserting your finger tip



- With the hand slightly flexed, there is no “bounce” in the glove as it stretches across the palm. It should feel loose and easily pressed against the palm. *Please note: for larger hands (up to 23.5cms) in a LARGE glove, there will still be some bounce, because the person will be near the limit of what is a “loose enough” glove. (No XL sizes are available). However, wearers **do** report the pressure is noticeably less than that of Isotoners.*
- NB: If the hand is up to 23.5cm, even if the fit does not appear as loose as the gloves in the photos, **still fit placebo gloves.**



- the patient's response about the fit and comfort of the gloves.

12. Re-size the glove if necessary and perform the fit procedure again

IF THE PARTICIPANT'S HAND IS LARGER THAN 23.5cms MCP circumference:

or the glove does not fit for other reasons e.g. enlarged PIP joints and the Jobskin glove is not therefore sufficiently loose, please do not supply the gloves. State on the OT Treatment Record that:

- a placebo Jobskin glove could not be fitted as the hand was too large.
- Record: the size of the hand in cms (measured using the Jobskin tape with MCPs in slight flexion); or other reason the hand was too large
- Explain to the participant that; a glove cannot be fitted because of size; we still need them to stay in the study; and it is important they still complete the 12 week questionnaire.

Q: What do I say if people ask if the glove is too loose? For example,

- *“We don't know how arthritis gloves work: some types of glove apply gentle support and others apply warmth. These gloves are helping us to see if it is the effect of warmth.*
- *They need to be a little loose.*
- *We don't want them to be too tight and restrictive.*
- *The warmth may make it easier to move your hands”*

SEE PAGES 22-24: Responding to Participants Queries about the Control (Placebo) gloves for more ideas.

D WEAR AND CARE FOR BOTH GLOVES:

13. Check the patient can doff and re-don the glove independently.
14. The patient continues to wear the glove(s) during the remainder of the appointment. Check for any short-term problems arising and the patient's response to wear.
15. Provide the appropriate NWCOTSS-R agreed glove instruction sheet to the patient (see Appendix 3), i.e. either the Isotoner Glove (intervention group) or Jobskin Glove (placebo group). The A-Gloves Trial Manager will provide a stock of both information sheets.
16. Explain the wear regimen appropriate for the patient, tick this is on the relevant Glove Instruction Sheet and A-Gloves Trial Record: Part 1.
17. Explain precautions and glove care (see the Glove Information Sheets).
18. Inform the participant to wear the gloves as advised by you until they receive a letter with further instructions from the Trial Manager after they complete the A-Gloves Trial. This will be in 2-3 months, when they have completed and returned the second questionnaire; and interview (if they chose to participate in this).

E PROVIDING THE HAND EXERCISE AND JOINT PROTECTION BOOKLETS

19. Provide the ARUK booklet "Looking after your joints when you have arthritis" to the participant. Even if they have had the ARUK booklet before, please give and ask them to read again.
20. Provide the hand exercise booklet (based on the SARAH Trial) to the participant [Heine et al, 2012]. This additionally includes thumb exercises. If they have recently received a hand exercise programme from OT or PT and are currently doing these, you can omit providing the hand exercise booklet (to avoid confusing the person about which exercises to do).

Hand exercises:

- **Preferably, just give out the hand exercise booklet.**
- **ONLY IF** you consider it important to demonstrate the exercises, then do so. Ask the participant to wear a pair of disposable gloves and practice **once** during the appointment with the department's TheraPutty or Play Doh. Do **not** use behavioural contracting or goal-setting. **No more than 15 minutes** should be spent in teaching these. *Note: amongst North-West Rheumatology OTs the median time reported spent on teaching hand exercises to patients being provided with gloves was 12.5 (IQR 10-15) minutes). Thus this reflects clinical practice.*

- ONLY IF YOU NORMALLY do so, give the participant a piece of TheraPutty. If not, recommend the participant uses Play-Doh to do the exercises with.
- For wrist exercises: only if you are teaching these, demonstrate with a piece of 70cm piece of Theraband (tied into a loop). ONLY IF YOU NORMALLY DO SO, give participant a length of Theraband, otherwise ask them to use a 70cm length of tights, or length of 1.5-3cm wide elastic, tied into a loop.

Joint Protection:

- Preferably, just give out the Looking After Your Joints booklet.
- IF YOU consider it is important to teach joint protection now, provide your usual advice. No more than 45 minutes should be spent on teaching this. Note: this reflects the average time spent on teaching joint protection. Do not use cognitive-behavioural methods or goal-setting.
- If the participant has already received joint protection education previously, do not provide further information at this time (apart from the booklet).

For both joint protection and hand exercises:

21. **ONLY** if you consider it clinically relevant, should you spend up to one hour discussing the joint protection and hand exercise information (combined). Please record the intervention/s and time spent on each on the A-Gloves Trial OT Record: Part 1. Do NOT provide more than 1 hour of education during the 12 weeks the participant is in the trial.
22. You should **not** provide any cognitive- behaviourally based education in joint protection or hand exercises until **after** the patient completes the study. [The Trial Manager will inform you when this is]. This is because if participants increase markedly their use of hand exercises and joint protection, we will not be able to identify whether any benefits result from the gloves or other hand interventions.
23. You can provide other forms of therapy that will not directly affect hand function, **if** essential, for example counselling, relaxation, ADL training, work advice. Please record this, and the duration, on the OT Record.

Next:

24. Make a date for the review appointment with the patient and record this on the A-Gloves Trial OT Record.
25. If the OT department's review policy is NOT to review in person/ by telephone but to ask the patient to contact OT if they have any problems: tick this box on the A-Gloves Trial OT Record: Part 1. If a patient subsequently contacts OT with problems, complete the A-Gloves Trial OT Record Part 2 Review.

26. Complete and then return a copy of the **A-Gloves Trial OT Record Part 1** (Glove Fitting) to the Lancashire CTU as soon as possible. File the original in the A-Gloves Trial Site File.

F REVIEW APPOINTMENT(S):

27. Conduct the glove review 2 to 4 weeks after glove fitting, either in person or by telephone, as per departmental policy. Where possible, the same therapist should conduct the review who provided the gloves. The appointment will last 10-15 minutes.
28. Complete the **A-Gloves Trial OT Record: Part 2 Review** during the appointment/telephone review. Do not let the patient see this Record, apart from page 2 when completing the pain scales. If the review is conducted by telephone, then ask the pain scale questions and ask for/ record the numbers that best describe their pain.
- Complete the two pain scales on the A-GLOVES OT Record Part 2 with the participant. For example:
 - “Please *can you complete these two pain scales. They ask you: **In your RIGHT hand: during the **daytime**, when doing moderate hand activities, e.g. housework, cooking, DIY, gardening: how is your pain on a scale of 0 (none) to 10 severe pain.?***
 - [Repeat for left hand.....”]
29. Re-assess the patient using your OT department’s usual glove assessment (if this is standard procedure in your OT’s department); or use the hand assessment form in the appendix of this manual if you wish to. Record the information related to glove review as usual in your OT records/ medical notes.
30. Ask the patient’s opinion about the fit of the gloves and any problems. Record these (e.g. red areas of skin, numbness or tingling). If the patient reports problems, take the actions you consider clinically appropriate, for example:
- if minor - reinforce precautions and recommend regular glove removal;
 - or if severe - stop the patient wearing gloves. If the problem is arising from the Isotoner gloves now being too tight, fit a larger size if this is applicable.
 - Always ensure the Jobskin gloves are at least one size too large; If the participant’s hand has swollen since glove fitting, provide one size larger now. Never provide a Jobskin (control) glove which is a snug fit.
 - If the Isotoner gloves now seem **too** large (e.g. hand swelling has reduced after 2-4 weeks wear), you **CAN** provide a smaller size glove, as this ensures the participant is wearing a “correctly fitting” arthritis glove.
 - Record frequency of glove wear and any benefits obtained.
 - Inform the participant to contact the OT department if they experience any problems arising from wearing the gloves in future.
31. **Remind the participant to continue to wear the gloves as advised by you** until they receive a letter with instructions from the Trial Manager about wearing the gloves after

their completion of the A-Gloves Trial. This will be in 1-2 months, when they have completed and returned the second questionnaire; and interview (if they chose to participate in this).

Q: What do I say if people ask me about wearing the gloves after the trial?

- *When you have completed and returned the second questionnaire, the researchers will send a letter explaining what to do with the gloves after the trial. Meanwhile, if you have any queries about the gloves, please do get in touch with me. Please refer to the information sheet about wearing the gloves. [see step 15].*

32. Complete and return a copy of the **A-Gloves Trial OT Record: Part 2 Review** as soon as possible to the Lancashire CTU. File the original in the A-Gloves Trial Site File.

33. If the patient subsequently contacts the OT department with problems resulting from glove wear, prior to their completion of the trial, a further A-Gloves Trial OT Record: Part 2 Review must be completed about adverse events and actions taken. Return a copy of this second review form to the Lancashire CTU as soon as possible.

G AT THE END OF THE PARTICIPANT'S 12 WEEK INVOLVEMENT:

The participant is sent a letter including the following:

[Intervention group:]* You may continue to wear the gloves, if you wish to do so, for as long as you feel these are of benefit. Please contact the OT department which provided the gloves if you have any problems with them in future or you want to ask about replacement gloves. The OT contact details are on the Glove Information Sheet provided by the OT. If you no longer wish to wear them, then just put them in your household waste, as they are not re-usable.

[Control/Placebo group:]* Please stop wearing the arthritis gloves now. Just put them in your household waste, as they are not re-usable. If you still have hand pain and would like to try another type of arthritis glove, please contact the OT department which provided the gloves. Discuss this with the OT. The OT contact details are on the Glove Information Sheet provided by the OT.

34. The A-Gloves Trial Manager will inform you when the patient has completed the trial. After this date, you can provide any other hand treatment you consider applicable.

H RESPONDING TO QUERIES ABOUT THE CONTROL (PLACEBO) GLOVES

“The Placebo effect: Also called the placebo response. A remarkable phenomenon in which a placebo - an inactive substance - can sometimes improve a patient's condition simply because the person has the expectation that it will be helpful. Expectation to plays a potent role in the placebo effect. The more a person believes they are going to benefit from a treatment, the more likely it is that they will experience a benefit”
www.Medicinenet.com (accessed 30.9.2015).

Before you start, remind yourself that the placebo effect is a real therapeutic effect for people. Some estimates have shown that for people with OA placebos can have a moderate effect in reducing pain and stiffness and this can rise to a large treatment effect when treatments for the hand are isolated (Zhang et al, 2008). This may be the same for RA. (We don't yet know).

Different types of intervention can produce different placebo or 'non-specific' effects (Kaptchuk, 2000). Trials that administer placebo via needles or injections are reported as having the greatest placebo effect. However, other relevant components such as branding, colour, “newness”, practitioner interaction and optimism, alongside the opportunity for follow up appointments, can also have an impact (Doherty and Dieppe 2009; White et al, 2012). You may also like to know that in a recent pilot OT trial that considered thumb base OA placebo splints, the placebos were more effective than the verum trial splints (Adams et al, 2014).

It is therefore important to **be optimistic** in your responses to trial patients. However, we **cannot lie** to patients **nor** should we give them responses that suggest that we think that they have been allocated to a worse treatment arm. You will know that you are delivering a control (placebo) glove but, hopefully, the patient will not. Your responses to their questions are important to practice and get right.

Remember, we do not know if gloves work or the mechanism by which they work if they do. The treatment gloves provide pressure and warmth and the control (placebo) gloves warmth only. It is quite possible that warmth is helpful.

Below are some examples of how to respond to queries about the placebo glove.

The main principles are:

- 1 Acknowledge that gloves can work in many ways and that we do not yet know what these ways are
- 2 Divert the topic of conversation
- 3 Provide general reassurances
- 4 Be non-specific in response
- 5 Distract the response onto other areas

So possible responses could be ...

Q: So how does this glove work then?

Well, we know that gloves can work in many ways and we don't yet know what all those ways are – this is why we are conducting the trial. If you look at the glove you'll see it covers from your finger tips to the start of your forearm. We think that this is an important part of how these gloves work.

Q: But this glove doesn't seem to be doing anything – I can't see this as being able to do much good. How can this help me?

We are testing different gloves for this study and we don't know yet which glove is the most effective. At the moment we don't have evidence that any one type of design or fit works better than another. This is why we have been asked to do this study.

Q: I have pain mostly around my wrist but this glove is loose and sloppy around my wrist. Can I not have a tighter one please that feels more supportive?

This glove will provide some warmth around your wrist and if you look at the finger portions these are nicely supported too and kept warm too. Your wrist and hand work as a unit so we hope that if we treat your hand as a unit then this may have an effect.

Q: Can I have another type of glove – or the other type of glove you are testing - as I don't think this one will work

These gloves are all professionally manufactured and you have been measured very carefully to make sure we prescribe the correct fit for you. Please try this glove out for the time you are in the Study, so you give it a proper test, and then we can see if you would like another glove at the end of the study.

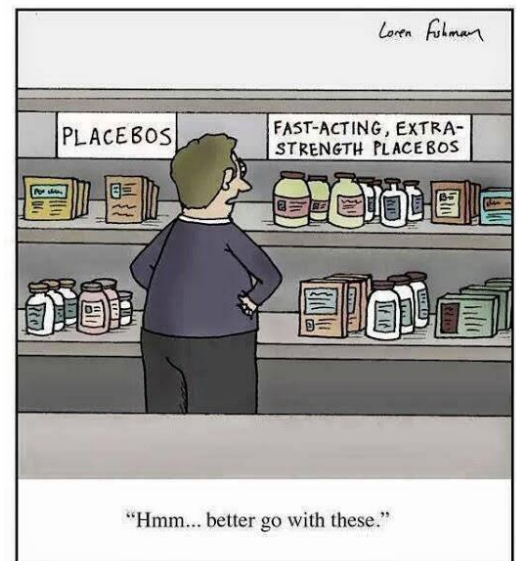
Q: I'm really not convinced that this will do anything to help at all!

The gloves are part of a large national trial that the government department that funds research in the NHS has decided should be funded. So it's a large trial across the UK. We have nearly 30 therapists taking part at 17 hospitals. Our aim is to find out the effects of these gloves.

Remember you will play a key part in how well the control (placebo) glove will be accepted.

Practise role play questions

- 1 I can't see how these will work at all – how do these gloves work?
- 2 But I get really sore hands and these don't seem to be giving any support at all ... I'm not sure I'll get on with these. Do you think they're right for me?
- 3 How will these gloves help my swelling in the morning? That's what I'm really concerned about!
- 4 Would you wear these if you had hands like mine?
- 5 Do you think they'll work for me?



References:

- Doherty M, Dieppe P. The placebo response in osteoarthritis and its implications for clinical practice. *Osteoarthritis and Cartilage*. 2009.
- Hammond A, Jones V, Prior Y The effects of compression gloves on hand symptoms and hand function in rheumatoid arthritis and hand osteoarthritis: a systematic review. *Clin Rehabil*. 2015; 30(3): 213:224.
- Heine PJ, Williams MA, Williamson E, Bridle C, Adams J, O'Brien A, Evans D, Lamb SE, and SARAH Team.. Development and delivery of an exercise intervention for rheumatoid arthritis: strengthening and stretching for rheumatoid arthritis of the hand (SARAH) trial. *Physiotherapy* 2012;98: 121-130
- Kaptchuk TJ. The double-blind randomised controlled placebo-controlled trial: gold standard or golden calf? *Journal of Clinical Epidemiology*. 2001; 54:541-549.
- White P, Bishop F, Prescott P, Scott C, Little P, Lewith G. Practice, practitioner, or placebo? A multifactorial, mixed-methods randomized controlled trial of acupuncture *Pain* 2012; 153(2):455-462.
- Zhang W, Robertson J, Jones A, Dieppe P, Doherty M. The placebo effect and its determinants in osteoarthritis: meta-analysis of randomised controlled trials. *Annals of the Rheumatic Diseases*. 2008; 67:1716-1723.

APPENDICES



A-GLOVES TRIAL OT RECORD: PART 1 GLOVE FITTING

Date referral received: ____/____/_____ (dd/mm/yyyy)	PIN: (as on A-GLOVES OT Referral e-mail)
Participant Name :	DOB:
Gender: Male / Female (Please circle)	Group allocation: Intervention / Placebo (Please circle)
Hospital:	OT Name:
Date patient contacted to make appointment: ____/____/____ (dd/mm/yyyy)	Date OT appointment for glove provision: ____/____/____ (dd/mm/yyyy)
Did the patient (please circle): Unable to Attend (UTA) Did Not Attend (DNA)	Date of re-scheduled appointment if UTA/DNA: ____/____/____ (dd/mm/yyyy)

GLOVE FITTING:

Start time:(e.g. 10:30am) End time:(e.g. 11.30am)

- Please state the time taken to fit the gloves and provide the ARUK Looking After Your Joints and the hand exercise leaflets.
- If you provide any other interventions, e.g. joint protection education, hand exercise training etc. today (or at another appointment) please list this separately on page 4.

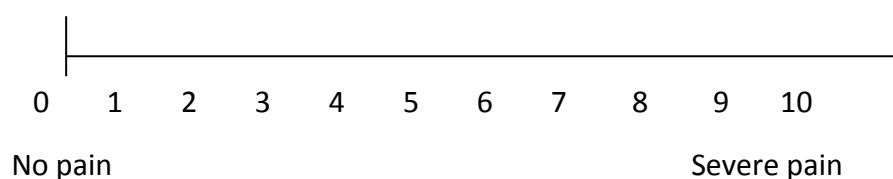
Please describe your hand pain:

For the following questions please **CIRCLE** the number below the line which best reflects your situation **on a typical day in the last week:**

1. In your **RIGHT** hand: during the **daytime**, when doing moderate hand activities, e.g. housework, cooking, DIY, gardening:



2. In your **LEFT** hand: during the **daytime**, when doing moderate hand activities, e.g. housework, cooking, DIY, gardening:



Is the patient still willing to participate? (please tick)

Yes ☐ No ☐

Eligibility check: answers must be **no** to all items to be provided with gloves today (please tick)

- | | | |
|--|------------------------------|-----------------------------|
| a) Does the participant have severe Raynaud's disease or other severe circulatory disturbances in the hand? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| b) Does the participant have severe neuropathies (nerve damage) in the hand (e.g. severe carpal tunnel syndrome)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| c) Does the participant have any contraindication(s) preventing glove wear (e.g. eczema, infections, broken skin)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

If the patient is unwilling or ineligible: please return this form ASAP to the Lancashire CTU.

Please explain to the participant why they are ineligible for trial participation.

Medication:

Have you had an intramuscular or intra-articular steroid injection in the last **6 weeks**?

Yes ☐No ☐

Or started on oral steroids, in the **last 6 weeks**?

Yes ☐No ☐**Steroids: If answer is yes:**

Date of injection/ oral steroids started: ____/____/____ (e.g. dd/mm/yyyy)

Actions:

- a) Re-book an appointment to be AT LEAST 6 weeks after the date when steroid started/ given.
- b) Inform the CTU you have postponed the appointment because of steroid start in the last 6 weeks

IF TREATMENT IS RE-BOOKED DUE TO STEROIDS:

Date of re-scheduled appointment for glove provision post- steroid: ____/____/____ (dd/mm/yyyy)

Treatment Start time: (e.g. 10:30am) End time: (e.g. 11.30am)

Were gloves provided today? (please tick)

Yes ☐No ☐

If no, please state fully the reasons for not providing gloves:

Your reasons:

If the participant declined to wear gloves, please state reasons given:

If yes, gloves were provided today (please tick as appropriate):

Which gloves?: Isotoner ☐ Jobskin oedema ☐

Which size fitted?: XSmall ☐ Small ☐ Medium ☐ Large ☐ XLarge ☐

Which hand(s)?: Right ☐ Left ☐ Both ☐

Jobskin oedema glove only: Was the glove fitted (at least) one size too large?(*please tick*)

Yes ☐ No ☐

If no: please state fully your reasons for **not** fitting the Jobskin oedema glove as per protocol:

Recommended wearing regimen:

Day time only ☐ Night-time only ☐ Both day and night ☐

Was the Looking After Your Joints booklet provided? Yes ☐ No ☐

Was the hand exercise information leaflet provided? Yes ☐ No ☐

Was the relevant glove information sheet provided? Yes ☐ No ☐

Have you provided any other OT interventions to the participant today/ since glove fitting?

(*Please tick*)

Yes ☐ No ☐

If yes, please state the date, duration of appointment and intervention type(s) (*e.g. hand exercises; joint protection, ADL training, wrist splint, relaxation*). **Note:** participants should receive no more than **1 hour** of joint protection/ hand exercise intervention (combined) **during** their trial participation.

Date	Duration of intervention(s)	Intervention(s) given

Review appointment date made for: ____ / ____ / ____ (dd/mm/yyyy)

(*please tick if appropriate*): **No glove review date set as per department policy*** ☐

On completion of glove fitting/ associated treatment: please check all items/ dates/ times are completed on this Record. Return this completed A-Gloves Trial OT Record: Part 1 as soon as possible in the Pre-Paid envelope to:

Alison Hadley
A-Gloves Trial Data Co-ordinator
Lancashire Clinical Trials Unit
Brook Building, Room BB418
University of Central Lancashire
Preston
PR1 2HE.



A-GLOVES TRIAL OT RECORD: PART 2 REVIEW

Date of glove review appointment: (dd/mm/yyyy) __/__/____	PIN: (as on A-GLOVES OT Referral e-mail)
Participant Name :	DoB:
Gender: Male / Female (Please circle)	Group allocation: Intervention / Placebo (Please circle)
Hospital:	OT Name:
Did the patient (please circle): Unable to Attend (UTA) Did Not Attend (DNA)	Date of re-scheduled appointment if UTA/DNA: ____/____/____ (dd/mm/yyyy)

GLOVE REVIEW:

Was this conducted (please tick as appropriate):

in person ☐ telephone ☐

no review as per department policy, patient contacted OT because experiencing problems * ☐

*[*If your departmental policy ins not to conduct Glove reviews; but the participant has later telephoned you with problems, please complete this OT Record: Part 2 Review].*

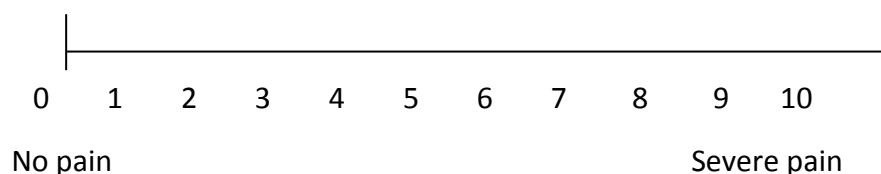
Review Start time: (e.g. 10:30am) **End time:** (e.g. 11.30am)

- Please state the time taken to review the gloves.
- If you provide any other interventions, e.g. joint protection education, hand exercise training etc. today (or at another later appointment) please list this separately on page 4.

Please describe your hand pain:

For the following questions please **CIRCLE** the number below the line which best reflects your situation **on a typical day in the last week:**

1. In your **RIGHT** hand: during the **daytime**, when doing moderate hand activities, e.g. housework, cooking, DIY, gardening:



2. In your **LEFT** hand: during the **daytime**, when doing moderate hand activities, e.g. housework, cooking, DIY, gardening:



3. **In the last week, during the day** on average, how many days a week have you worn your arthritis gloves? *If a glove not provided for right/ left hand, please circle "Not Given"*

RIGHT GLOVE	<i>Not given</i>	0	1	2	3	4	5	6	7
LEFT GLOVE	<i>Not given</i>	0	1	2	3	4	5	6	7

4. **In the last week, during the night**, on average, how many nights a week have you worn your arthritis gloves? *If a glove not provided for right/ left hand, please circle "Not Given"*

RIGHT GLOVE	<i>Not given</i>	0	1	2	3	4	5	6	7
LEFT GLOVE	<i>Not given</i>	0	1	2	3	4	5	6	7

Note: If the patient is not wearing gloves as recommended, remind them of their wear regimen

Did the patient report any benefits from glove wear?

--

Did the patient report any adverse reactions resulting from glove wear? (please tick)

Numbness: Yes ☐ No ☐

Pins and needles: Yes ☐ No ☐

Fingertips becoming discoloured (i.e. they go red, white or blue): Yes ☐ No ☐

Allergic reaction or irritation to skin: Yes ☐ No ☐

Sleep disturbance at night: Yes ☐ No ☐

Other (please state) _____

If adverse reaction(s) occurred: action recommended to patient (please tick)

Reduce time glove(s) worn at night: Yes ☐ No ☐

Reduce time glove(s) worn in the day: Yes ☐ No ☐

Stop glove(s) wear at night: Yes ☐ No ☐

Stop glove(s) wear in the day: Yes ☐ No ☐

Other (please state): _____

If you changed when the gloves should be worn: please tick as appropriate

Day time only ☐ Night-time only ☐ Both day and night ☐ Not applicable ☐

If you told the patient to stop wearing the gloves completely (day and/or night), please state fully your reasons for this:

Day-time:
Night-time:

Did you have to fit a new size of glove(s) today? Yes ☐ No ☐

If yes:

Which size fitted?: XSmall ☐ Small ☐ Medium ☐ Large ☐ XLarge ☐

Which hand(s)?: Right ☐ Left ☐ Both ☐

[Note: Jobskin gloves must continue to be at least one size too large].

If the patient chose to discontinue wearing gloves, please state their reason(s) why:

--

Have you provided any other OT interventions to the participant today/ since glove review?

(Please tick)

Yes ☐ No ☐

If yes, please state the date, duration of appointment and intervention type(s) (e.g. hand exercises; joint protection, ADL training, wrist splint, relaxation. Note: participants should receive no more than 1 hour of joint protection/ hand exercise intervention (combined) *during* their trial participation

Date	Duration of intervention(s)	Intervention(s) given

Any other comments:

If a further OT appointment is required (e.g. following telephone review):

Date next review scheduled : __/__/__ (dd/mm/yyyy)

Please complete a second review form when the patient attends for this Glove review

On completion of review appointment/ any associated treatment:

Please check all items/ dates/ times are completed. Return this completed A-Gloves Trial OT Record as soon as possible in the Pre-Paid envelope to:

Alison Hadley
A-Gloves Trial Data Co-ordinator
Lancashire Clinical Trials Unit
Brook Building, Room BB418
University of Central Lancashire
Preston
PR1 2HE



A-GLOVES TRIAL: ISOTONER ARTHRITIS GLOVES INSTRUCTION SHEET

DESCRIPTION

These gloves are made of a combination of nylon and spandex/ Lycra material that stretches round the hands and provides gentle pressure and warmth. This may ease the pain and stiffness due to arthritis.

USE OF GLOVES

- The glove(s) should feel snug but not too tight (i.e. it feels comfortable)
- Gloves should be worn with the seams on the outside
- Use for short periods during the day initially to get used to them.
- Do not wear the gloves continuously for 24 hours a day.
- Remove gloves for hand hygiene purposes and make sure hands are washed and dried thoroughly.
- Gloves can be worn all night.
- The gloves should only be worn on the hand (s) prescribed as stated below:

Right hand ☐

Left hand ☐

During daily activities ☐

At night ☐

CAUTION

Stop using the gloves and contact the therapist if you experience any of the following effects:

- Numbness
- Pins and needles
- They feel too tight. Remove the glove if the fingertip(s) become discoloured (i.e. go red, white or blue) or if you experience numbness or tingling in the tip of the finger.
- Allergic reaction
- Irritation to skin
- The gloves should not disturb your sleep. If they do then remove them.

CLEANING

Machine wash on a cold delicate cycle or hand wash using non-bio detergent. Do not use fabric softener. Lie flat to dry. **Do not** tumble dry or dry on direct heat (e.g. a radiator).

DRIVING

- Arthritis gloves have a slippery surface which can affect gripping the steering wheel. If you do wear them when driving, you must feel confident that you can safely control the vehicle.
- Discuss with your doctor if necessary.
- You should inform your insurance company if you are wearing the gloves for driving. This should not affect your insurance payments.

If you have any queries about the gloves please contact:

Relevant OT department's contact details.

North West COT Specialist: Section Rheumatology Group 18.10.14



A-GLOVES TRIAL: JOBSKIN ARTHRITIS GLOVES INSTRUCTION SHEET

DESCRIPTION

These gloves are made of a combination of nylon and spandex/ Lycra material that stretches round the hands and provides gentle warmth. This may ease the pain and stiffness due to arthritis.

USE OF GLOVES

- The glove(s) should feel slightly loose.
- Gloves should be worn with the seams on the outside
- Use for short periods during the day initially to get used to them.
- Do not wear the gloves continuously for 24 hours a day.
- Remove gloves for hand hygiene purposes and make sure hands are washed and dried thoroughly.
- Gloves can be worn all night.
- The gloves should only be worn on the hand (s) prescribed as stated below:

Right hand ☐

Left hand ☐

During daily activities ☐

At night ☐

CAUTION

Stop using the gloves and contact the therapist if you experience any of the following effects:

- Numbness
- Pins and needles
- They feel too tight. Remove the glove if the fingertip(s) become discoloured (i.e. go red, white or blue) or if you experience numbness or tingling in the tip of the finger.
- Allergic reaction
- Irritation to skin
- The gloves should not disturb your sleep. If they do then remove them.

CLEANING

Machine wash on a cold delicate cycle or hand wash using non-bio detergent. Do not use fabric softener. Lie flat to dry. **Do not** tumble dry or dry on direct heat (e.g. a radiator).

DRIVING

- Arthritis gloves have a slippery surface which can affect gripping the steering wheel. If you do wear them when driving, you must feel confident that you can safely control the vehicle.
- Discuss with your doctor if necessary.
- You should inform your insurance company if you are wearing the gloves for driving. This should not affect your insurance payments.

If you have any queries about the gloves please contact:

Relevant OT department's contact details.

Adapted from: North West COT Specialist: Section Rheumatology Group 18.10.14

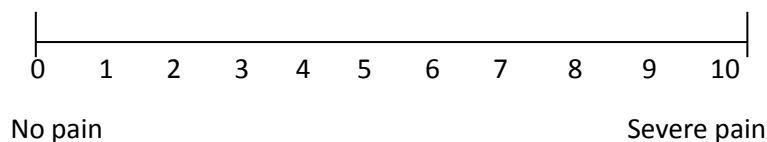
A-GLOVES TRIAL: HAND ASSESSMENT FORM (FOR DEPARTMENT USE ONLY)

Participant Name :	PIN: (as on A-GLOVES OT Referral e-mail)
DoB:	Date of Assessment:
Hospital:	OT Name:

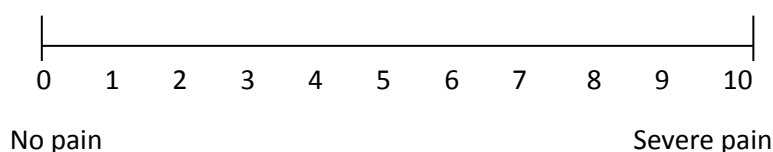
Hand symptoms:

RIGHT HAND: "On a scale of 0 to 10, over the last day, how do the following affect you? Please **circle the number**":

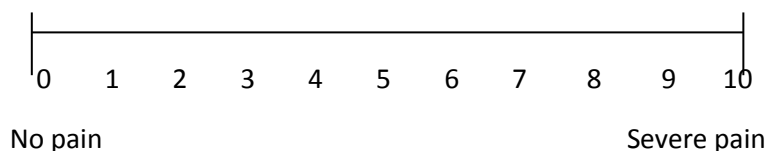
Pain during day at rest



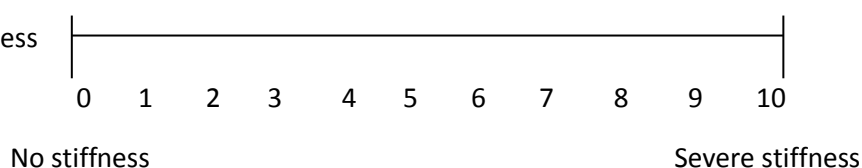
Pain during day whilst doing moderate hand activities e.g. work, cooking, gardening, DIY



Pain at night when resting

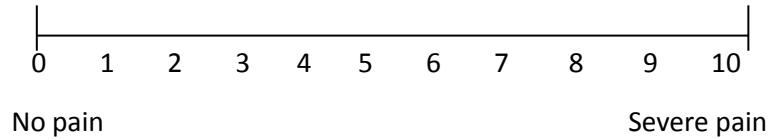


General hand stiffness

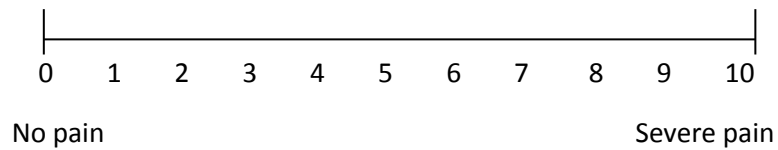


LEFT HAND: “On a scale of 0 to 10, over the last day, how do the following affect you? Please circle the number”:

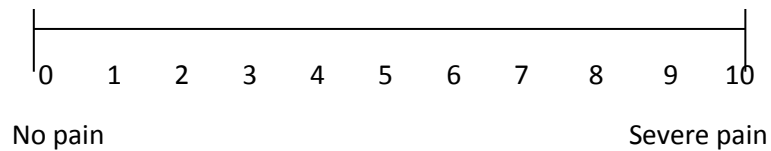
Pain during day at rest



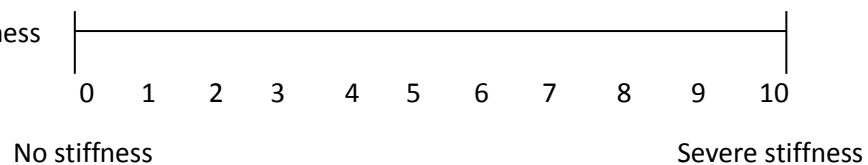
Pain during day whilst doing moderate hand activities e.g. work, cooking, gardening, DIY



Pain at night when resting



General hand stiffness



Swelling (assess hand for which you are supplying the glove. If two gloves, assess both hands).

Wrist circumference:

Use Jobskin® paper tape measure. Measure with palm facing upwards.

e.g. 38.4 cms

3	8
---	---

 .

4

Right

--	--

 .

--

 cms **Left**

--	--

 .

--

 cms

MCP circumference: use Jobskin® paper tape measure. MCPs in extension, palm facing downwards

Right

--	--

 .

--

 cms **Left**

--	--

 .

--

 cms

PIP joint circumference: use Jobskin paper tape measure. PIPs in extension, palm facing downwards

Right

Index

--

 .

--

 cms

Middle

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 .

--

 cms

Ring

--

 .

--

 cms

Little

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 .

--

 cms

Left

Index

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 cms

Middle

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 cms

Ring

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 cms

Little

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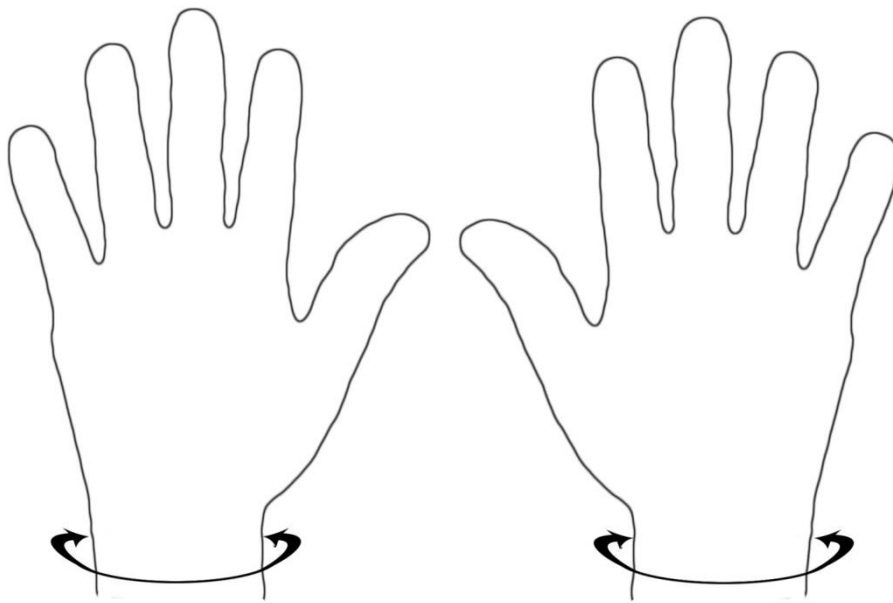
 .

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 cms

Hand Outlines:

- please record any comments about swelling, deformity, sensation, temperature (as applicable)

LEFT DORSAL**RIGHT DORSAL****Other Notes:**

Please note: this assessment form is for department use only. Please use your own hand assessment procedure if you prefer to. Please keep a copy of this form in your own records. Do not return to the CTU or Trial Manager.

