Hammond A, Prior Y. Compression gloves for patients with hand arthritis (C-GLOVES): a feasibility study. Hand Therapy. Accepted 16/12/2020. Published January 2021

Supplementary File I: C-GLOVES Phase 1: Feasibility study planning

The study was planned based on findings of a systematic review [6] and through discussions with participating therapists (members of the North-West Alliance of Rheumatology Occupational Therapists) and two patient research partners. Three meetings were held in which we developed the trial protocol and agreed:

1. **Trial Design:** The benefits of conducting randomised controlled feasibility trials and the procedures associated with these, were discussed, including testing willingness for therapists to recruit patients into a randomised controlled trial and patients to give consent to be randomised. Although there is limited evidence of compression glove effectiveness, gloves are already part of NHS usual care. Therapists expressed concerns about randomising in a feasibility study, given that participants would not be provided with "usual care." Therapists emphasised finalising procedures should be tested first. Feasibility studies do not need to be randomised [31,32]. We therefore decided not to randomise to a control group as most feasibility trial objectives could be met.
2. **Trial procedures** including: the make and model of compression glove to test, i.e. Isotoner™ open finger gloves, as therapists most often prescribed these [5]; follow-up at four-weeks, as any effects of glove-wear are normally reported within one to two weeks. A one-week margin before and after follow-up assessment was allowed, in case participants or therapists could not attend/conduct this at four weeks. Therapists also decided: which rheumatological conditions to test gloves in (i.e. these were the commonest conditions gloves were provided for clinically); and to assess outcomes of the two main patient groups separately: i.e. inflammatory (rheumatoid and undifferentiated inflammatory arthritis) and regenerative arthritis (osteoarthritis). This was because glove provision in inflammatory conditions is primarily to relive pain and swelling; and in osteoarthritis to relieve pain.

3. **Inclusion and exclusion criteria**: based on therapists' a) clinical decision-making for glove provision and glove contraindications and b) trial criteria regarding diagnoses, and medication.
4. **The standardised hand assessment protocol**: therapists identified their treatment aims when providing gloves to patients with inflammatory arthritis and osteoarthritis. From this, the group decided the types of outcome measures to include. The research team then identified potential measures, with good reliability and validity, to match these aims and outcome types. The group discussed the feasibility of potential outcomes to finalise the protocol. For example, objective hand function measures included: the Southampton Hand Assessment Procedure (too costly to provide); Serial Occupational Dexterity Assessment, Arthritis Hand Function Test and Jebsen Hand Function Test (all would need making/developing for departments; and take 15 (or more) minutes to complete- considered as too long); and the Grip Ability Test (selected - as requires simple equipment and takes 5 minutes). The group also agreed relevant demographic and hand/disease status information to record. We initially aimed to have independent assessors at each site. However, during the planning phase it became apparent this would not be feasible as sites with two therapists could not guarantee the other would be available to schedule to complete an independent assessment and single-handed therapists could not identify another staff member available to assess.
5. **Glove provision and review**: therapists discussed their existing methods of fitting gloves and agreed best practice for: provision (including measuring and sizing, correct fitting, verbal instructions for patients); and glove review at 4 weeks in person.
6. **The patient glove instruction sheet**: therapists provided their existing glove instruction sheets. The research team collated content from these. The group then discussed and agreed final content.
7. **The C-GLOVES Therapist Manual** was developed, including the assessment and treatment protocols, reviewed by the group and agreed (See Supplementary File 2).

A pilot training workshop with three therapists was conducted to practice assessment and treatment protocols. We changed the planned method of measuring composite finger flexion (i.e. finger pulp to palmar wrist crease [29]) as therapists had difficulty performing this, instead using nail fold to distal wrist crease [12]. A one-day therapist training workshop was held with all 14 participating therapists to

practice trial procedures, assessment and treatment protocols. Patient research partners attended. We conducted an intra-rater reliability study of joint swelling, finger flexion and the Grip Ability Test, with acceptable levels identified [11]. Therapists practised grip strength measurement [13]. Therapists' ability to fit gloves correctly following the agreed treatment protocols was observed by the research team, and therapists were given feedback by both the researchers and patient research partners on their technique and fit. The therapist manual was updated following therapist and patient research partner feedback (Supplementary File 2). Therapists instituted the assessment and treatment protocols within their usual care to standardise best clinical practice across departments.

References:

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 30.09.20.
32. Eldridge SM, Lancaster GA, Campbell MJ, Thabane L, Hopewell S, Coleman CL, Bond CM. Defining feasibility and pilot studies in preparation for randomised controlled trial: development of a conceptual framework. PLOS One 2016: https://doi.org/10.1371/journal.pone.0150205. Accessed 30.09.20