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Rheumatology occupational therapists' views of participating in a randomised controlled trial of arthritis gloves

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Background: Arthritis gloves are provided by NHS rheumatology occupational therapists (OTs) to people with inflammatory arthritis (IA) to reduce hand pain and stiffness and improve hand function. However, there is little evidence to support their effectiveness or efficacy. We are conducting a NIHR Research for Patient Benefit (PB-PG-0214-33010) funded multi-centre national randomized controlled trial (RCT) testing the efficacy of arthritis gloves in people with IA. Twenty-seven Rheumatology OTs from (Band 6) from 17 NHS Trusts across the UK are treating trial participants. As part of their trial training, we explored OTs' views about contributing to the RCT, to identify any concerns and ongoing training needs in trial delivery.

Methods: Three focus groups (FGs), using a semi-structured interview schedule were conducted. The Rheumatology OTs collaborating in the trial attended a one-day clinical trial training programme which included trial background, key study procedures and practice providing the intervention and placebo gloves in a standardized manner using the OT Glove Provision Manual. Informed written consent was obtained from all participants and FGs were audio recorded, transcribed verbatim and analysed by two researchers independently using Thematic Analysis to increase the confirmability of the findings.

Results: The main challenges identified by OTs were themed around Personal, Service and Research Methodology Factors. Personal Factors included: trepidations about being involved in a RCT; and concerns around delivering a placebo treatment to patients with hand pain and stiffness. Service Factors included: being able to recruit to target within service constraints; receiving support from their consultants and research staff; and whether they could treat participants within the given time frame. Research Methodology Factors included: risk of introducing bias when delivering a placebo treatment, due to concerns about going against participants' best interests, or lack of experience addressing participants' queries without revealing treatment allocation. However, they also perceived opportunities from being involved in a multi-centred RCT. These were Professional Development and evidence-based practice opportunities such as; potential to improve relationships within their multi-disciplinary teams, widen their professional networks, and raise the profile of OT by contributing to evidence-based practice. Most OTs acknowledged that their trepidations were related to inexperience and expected to become more confident following training, familiarization with study protocols and delivery of their first placebo treatment.

Conclusion: This trial is one of the few UK-funded placebo-controlled trials examining the clinical efficacy of OT intervention in rheumatology services. This introduces new issues for clinicians in knowingly delivering placebo interventions as part of a RCT. Our OTs identify personal, service and research factors that cause them trepidation in taking part but also recognize clear professional development opportunities in contributing to evidence-based practice