Feasibility of a randomized controlled trial of Lycra sleeve for management of glenohumeral subluxation in people with stroke

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Background: Glenohumeral subluxation (GHS) is a common secondary complication reported in up to 81% of people with stroke. The aims of this study were to evaluate the feasibility of conducting a fully powered randomized controlled trial of the Lycra sleeve for the management of GHS.

Method: Stroke survivors over 18 years with hemiplegia, muscle strength of ⩽3 on Medical Research Council scale, able to provide informed written consent were recruited from acute settings. Evaluation points were at baseline and at three months. Patients were randomized to immediate (IG) or delayed (received sleeve at three months) groups (DG). Staff, patients and carers received training on application of sleeve. Recruitment, retention, adverse events and completeness of data collection were explored at three months using descriptive statistics: GHS (ultrasound method), passive range of movement, muscle strength, spasticity, upper limb function and quality of life. Questionnaires explored acceptability.

Results/findings: Of 257 stroke survivors screened, 31 (12%) were recruited (*N* = 19 IG). Retention was 87% (*N* = 27) and all patients tolerated clinical outcome measures. Average days the sleeve was worn: 50/90 days (mean 10 hours/day). Seven (41%) participants from IG and two (22%) from DG showed reduction in GHS. Swelling in the hand was reported by 2/27. A further three participants were unsure of adverse effect due to preexisting medical condition(s). Patients reported the sleeve was comfortable to wear (100% *N* = 27) and was acceptable in their daily life (96% *N* = 27).

Conclusion: Recruitment was low but retention was good. This study found that a subsequent clinical trial was feasible, with modifications to the recruitment strategy.