Scottish Government Health Directorates Chief Scientist Office

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Dynamic Lycra Orthoses (DLO) as an adjunct to upper limb rehabilitation after stroke: A feasibility study and trial.

Researchers
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Aims To:

- Examine feasibility, acceptability, and usefulness of the DLO
- Model the DLO intervention for use in a feasibility randomised controlled trial (RCT)
- Assess potential impact of the DLO on arm recovery outcomes after stroke
- Assess feasibility of conducting an RCT of the DLO in rehabilitation

Project Outline/Methodology

Phase 1: DLO are commercially available lycra sleeves designed to improve control of movement in the arm after stroke. After eight weeks of DLO wear we conducted semi-structured interviews with stroke survivors, their carers and rehabilitation professionals to examine feasibility and acceptability of the DLO. This allowed us to model the intervention for Phase 2, a two arm, single blind randomised controlled feasibility trial with blinded outcome assessment at baseline (T1) after 8 weeks DLO wear (T2) and at 16 week follow-up (T3).

Key Result

Phase 1: 17 stroke survivors wore the DLO as an adjunct to rehabilitation. Of those, five withdrew because of problems with DLO wear. Semi-structured interviews with 12 stroke survivors, six carers and nine rehabilitation staff suggested that using the DLO in rehabilitation was feasible with training, careful fitting and adjustment, gradual increase in time worn and with infection control procedures. However the onset of post-stroke swelling of the hand and fingers, sometimes led to discontinued use. Stroke survivors and staff suggested that improved control of movement, function, positioning and sensory awareness were important potential benefits, however good fit and comfort were vital. To address these issues for Phase 2, we adjusted the intervention design and prescription in collaboration with the manufacturers.

Phase 2:Our recruitment target was 51, we recruited 43 particpants, of whom 27 were randomised to receive the DLO, which was worn for 8 hours daily for 8 weeks. 15 particpants in the control group received usual care. Study retention, was 22 (81.5%) and 12 (75%) for intervention and control groups respectively at T2, and 15 (55.6%) and 9 (56.3%) at T3. Most withdrawals before T2 occurred because of unrelated ill-health, but three were because of DLO discomfort. We did not undertake definitive hypothesis testing, but mean differences in change from T1 in arm impairment and functional outcomes all favoured the control group. Interviews with staff at the end of the trial suggested the DLO was coherent with rehabilitation aims, despite uncertainty about how it worked and its potential effects. Staff considered trial processes as feasible, however consistently prioritising the trial was challenging.

Conclusions

Although study processes were feasible and staff and patient engagement in the study was high, recruitment and retention rates were lower than anticipated. There was no indication of benefit and adverse responses were common, suggesting progression to full trial is not warranted without substantial intervention refinement

What does this study add to the field?

The study suggests that the DLO may not be beneficial for recovery of arm function in stroke survivors receiving rehabilitation, and may restrict rather than facilitate movement. Fundamental intervention refinement is required before progression to a full trial.

Implications for Practice or Policy

DLO should not be used in rehabilitation with stroke survivors without further refinement and testing.

Where to next?

We will work with bioengineers and the manufacturers to evaluate and refine the intervention prior to seeking further funding.

Further details from:

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The LOTUS Study