

Appraisal

Critically appraised paper: Additional rehabilitation following botulinum toxin-A does not improve goal attainment and upper limb activity in chronic stroke survivors

Synopsis

Summary of: Lannin NA, Ada L, English C, Ratcliffe J, Fauz SG, Palit M, et al on behalf of the InTENSE Trial Group. Effect of additional rehabilitation after botulinum toxin-A on upper limb activity in chronic stroke: The InTENSE Trial. *Stroke*. 2020;51:556–562.

Question: In chronic stroke survivors who receive botulinum toxin-A in muscles that cross the wrist, does the addition of 3 months of evidence-based movement training compared with usual care change goal attainment and upper limb activity? **Design:** Randomised controlled trial with concealed allocation and blinded outcome assessment. **Setting:** Seven spasticity clinics across three states in Australia. **Participants:** Adults who were > 3 months post-stroke, scheduled to receive botulinum toxin-A injection to any muscle that crosses the wrist and not currently receiving upper limb rehabilitation. Key exclusion criteria were botulinum toxin-A and casting in the past 6 months and/or cognitive impairment. Randomisation of 140 participants allocated 69 to the experimental group and 71 to the control group. **Interventions:** Both groups received botulinum toxin-A to one or more muscle(s) that crossed the wrist. In addition, the experimental group received up to three serial casts to maximise wrist extension for 2 weeks, followed by 10 weeks of movement training, including electrical stimulation and progressive resistance exercises aimed at decreasing weakness and improving active movement. Participants were recommended to practise for 60 minutes/day on 7 days/week and were supported by clinic-based sessions, home visits and phone calls by physiotherapists or occupational therapists. The control group

received a handout with stretching and arm and hand exercises; they also received one follow-up telephone call. **Outcome measures:** The primary outcome was the Goal Attainment Scale T-score and upper limb activity measured using the Box and Block test (number of blocks) immediately post intervention at 3 months. Secondary outcome measures were spasticity, wrist extension range of motion, grip strength, pain, burden of care and quality of life. **Results:** A total of 138 (99%) participants completed the study. At the end of the 3-month intervention period there was no difference in Goal Attainment Scale T-scores (MD 2, 95% -2 to 7) or upper limb activity (MD 0.00 blocks, 95% CI -0.02 to 0.01). The experimental group had greater grip strength compared with the control group (MD 1.4 kg, 95% CI 0.2 to 2.7). No other between-group differences were demonstrated. **Conclusion:** In chronic stroke survivors who received botulinum toxin-A to muscles that cross the wrist, the addition of 3 months of movement training was no more effective than a handout in changing goal attainment and upper limb activity. Greater increases in grip strength were seen in the experimental group.

Provenance: Invited. Not peer reviewed.

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<https://doi.org/10.1016/j.jphys.2021.05.005>

Commentary

Botulinum toxin-A for the treatment of post-stroke upper limb spasticity is commonly administered in combination with rehabilitation therapies, and supported by clinical guideline recommendations.¹ Whilst the effectiveness of botulinum toxin-A to reduce resistance to passive movement is strongly supported, the evidence for functional improvements remains equivocal.^{2,3} Research in this area has been complicated by variations in injection protocols, goals, concurrent therapy and outcome measurements. It is particularly difficult to isolate the effect of adjunctive therapy compared to botulinum toxin-A itself.

The InTENSE trial protocol was rigorous and interventions were evidence based. Exercise adherence in the experimental group was high. Outcome measures spanned multiple domains and included the primary outcomes of the Goal Attainment Scale, appropriate for heterogeneous goals, and the Box and Block Test, a measure of manual dexterity.

The intensive upper limb rehabilitation program was not effective in this study, with no between-group differences in the primary outcomes and only grip strength significantly favouring the intervention group. Changes over time in outcomes were non-significant or of small magnitude. However, it is important to highlight that participants were on average 3 years post stroke and 78% were unable to move at least one block on the Box and Block Test at baseline. This may indicate very limited potential for improvement. Clinically, this study implies that intensive

therapy is not warranted following botulinum toxin-A in those with both greater stroke severity and chronicity. Furthermore, the trial suggests caution using botulinum toxin-A itself for this population, given the small amount of change seen across outcomes. An intensive therapy regimen after injection may be beneficial earlier after stroke in those with some active movement,⁴ and this should be explored in future trials. The use of botulinum toxin-A for upper limb spasticity should continue to be person-centred, with careful consideration of appropriate goals, adjunctive therapy approaches and outcome measurements.

Provenance: Invited. Not peer reviewed.

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<https://doi.org/10.1016/j.jphys.2021.05.004>

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