

Rehabilitation after botulinum toxin injections: A randomised controlled trial protocol.

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Background: Current treatment for spasticity includes botulinum toxin-A (BoNT-A) injection. Some evidence exists to support the use of BoNT-A, but all studies recommend that BoNT-A be provided in conjunction with rehabilitation. However, little direct evidence exists for optimum type, dosage and timing of rehabilitation therapy. Since severe spasticity significantly reduces a person's ability to participate in their daily occupations, more effective methods for its treatment are necessary.

Aim: To evaluate the effectiveness and cost benefit of providing rehabilitation after BoNT-A injections for spasticity management.

Method: A randomised, assessor-blinded controlled study was established. Participants allocated to the BoNT-A injection only group receive one dose of BoNT-A plus a handout and explanation of rehabilitation exercises to continue in their own home. Participants allocated to the Therapy only group receive serial casting plus movement training by occupational therapists and physiotherapists. Participants allocated to the BoNT-A plus Therapy group receive one dose of BoNT-A plus the therapy. Outcomes will be assessed at baseline, post-intervention, and at 3 months following the conclusion of intervention and will include assessment of functional movement, quality of life, and cost. All statistical analyses will be performed using intention to treat.

Discussion: The results of this trial will be used as a basis for clarifying the efficacy of spasticity interventions. Results will provide urgently needed information to meet the National Stroke Foundation research priority for understanding the relative efficacy of spasticity treatment.