Research in Developmental Disabilities 53-54 (2016) 267–278

Contents lists available at ScienceDirect

Research in Developmental Disabilities

Evaluation of group versus individual physiotherapy following lower limb intra-muscular Botulinum Toxin-Type A injections for ambulant children with cerebral palsy: A single-blind randomized comparison trial☆

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ARTICLE INFO

Article history:
Received 9 March 2015
Received in revised form 23 February 2016
Accepted 24 February 2016
Available online 5 March 2016

Keywords:
Cerebral palsy
Physiotherapy
Botulinum Toxin-A
Lower limb
Model of care

ABSTRACT

This study aimed to evaluate efficacy of group (GRP) versus individual (IND) physiotherapy rehabilitation following lower limb intramuscular injections of Botulinum Toxin-Type A (BoNT-A) for ambulant children with cerebral palsy (CP). Following lower limb BoNT-A injections, 34 children were randomly allocated to GRP ($n = 17$; mean age 7y8m SD 2.0; 13 males; Gross Motor Function Classification System (GMFCS) I = 5, II = 8, III = 4) or IND physiotherapy ($n = 17$; mean age 8y7m SD 2.0; 11 males; GMFCS I = 9, II = 5, III = 3). Primary outcomes were the Canadian Occupational Performance Measure (COPM) and Edinburgh Visual Gait Score (EVGS) assessed at baseline, 10 and 26 weeks post intervention. There were no baseline differences between groups. GRP intervention had greater, but not clinically meaningful, improvement in COPM satisfaction (estimated mean difference EMD 1.7, 95% CI 0.4–3.1; $p < 0.01$) at 26 weeks. Both groups demonstrated clinically significant improvements in COPM performance and satisfaction, but minimal change in quality of gait (EVGS). Six hours of direct physiotherapy (either GRP or IND) with an additional indirect dose (median 16 episodes) of individualized home programme activities following lower limb BoNT-A injections, however, was inadequate to drive clinically meaningful changes in lower limb motor outcomes.

What this paper adds

- This pragmatic randomized comparison trial is the first to evaluate efficacy of group (GRP) versus individual (IND) goal-directed physiotherapy following lower limb intramuscular injections of Botulinum Toxin-Type A (BoNT-A) for ambulant

☆ Trial Registration: ACTRN12611000454976.

Abbreviations: BoNT-A, Botulinum Toxin-Type A; COPM, Canadian Occupational Performance Measure; CP, cerebral palsy; CP Health, Queensland Cerebral Palsy Health Service, Royal Children's Hospital, Brisbane, Queensland; CPQOL-child, Cerebral Palsy Quality of Life Questionnaire-child: primary caregiver proxy version; EVGS, Edinburgh Visual Gait Score for Cerebral Palsy; GMFCS-E&R, Gross Motor Function Classification System-Expanded and Revised; GMFM-88, Gross Motor Function Measure-88; GRP, group; IND, individual; 1MFWT, One Minute Fast Walk Test; PRT, Paediatric Reach Test.

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http://dx.doi.org/10.1016/j.ridd.2016.02.014
0891-4222/

children with cerebral palsy. Results demonstrated no clinically meaningful differences between groups on any primary or secondary outcomes. Both groups demonstrated clinically meaningful improvement in caregiver/s perception of and satisfaction with their child's goal-related occupational performance. This study suggests that a distributed "block model" of weekly therapy over a six week period, augmented by a home programme, is sufficient to improve occupational performance but not lower limb motor outcomes. The results and potential limitations of this study are discussed in relation to the evidence for optimal direct and indirect rehabilitation dose and model of therapy delivery following lower limb BoNT-A injections, with recommendations for future research highlighted. Qualitative feedback reflected that group therapy was feasible and an acceptable model of therapy delivery for this population and merits further research regarding optimal dose and model of delivery to drive functional change.

1. Introduction

Cerebral palsy (CP) describes a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing foetal or infant brain (Rosenbaum et al., 2007). Incidence of CP is 2.11 per 1000 live births (Oskoui, Coutinho, Dykeman, Jette, & Pringsheim, 2013), and in Australia 71% of children with CP are ambulant with spasticity the most common motor type (Australian Cerebral Palsy Register, 2013). Spasticity, in combination with muscle tightness, weakness, decreased selectivity and reduced motor control, contributes to limitations in ambulation, functional ability, balance, physical fitness and participation (Verschuren, Darrah, Novak, Ketelaar, & Wiart, 2014). Therapeutic management focuses on minimizing impairments and maximizing goal-related functional performance and participation.

For ambulant children with CP, focal intramuscular injections of BoNT-A are efficacious (Heinen et al., 2010; Strobl et al., 2015), safe (Papavasiliou et al., 2013) and routinely used in clinical practice to manage lower limb spasticity (Heinen et al., 2010; Love et al., 2010; Strobl et al., 2015). To capitalize on the temporary reduction in spasticity, expert consensus recommends accompanying intensive rehabilitation (physiotherapy including goal-related motor training in combination with serial casting, stretching, strengthening and/or orthoses) to optimize functional performance and goal attainment (Heinen et al., 2010; Love et al., 2010; Molenaers, Fagard, Van Campenhout, & Desloovere, 2013; Strobl et al., 2015). The combination of intramuscular lower limb BoNT-A injections and physiotherapy has been compared to physiotherapy alone or with placebo injections in a number of randomized controlled trials (RCTs) demonstrating the supplementary effects of BoNT-A to improve gross motor function (Bjornson et al., 2007; Love et al., 2001; Scholtes et al., 2006; Ubhi, Bhakta, Ives, Allgar, & Roussounis, 2000), quality of gait (Park, Park, Chang, Park, & Lee, 2006; Scholtes et al., 2007; Ubhi et al., 2000) and goal attainment (Molenaers et al., 2013; Scholtes et al., 2006; Williams et al., 2013). There are a number of studies, however, that report limited between group differences in functional improvement (Ackman et al., 2005; Chaturvedi et al., 2013; Mall et al., 2000; Reddihough et al., 2002). The efficacy of combined multi-level BoNT-A injections and rehabilitation on gross motor function remains controversial. A number of studies have evaluated additional parameters around therapy following BoNT-A injections including comparison of therapy dose (Liu et al., 2013; Molenaers et al., 2013), model of distribution (Brunner, Rutz, Juenemann, & Brunner, 2014), and content of therapy (Desloovere et al., 2012; Franki et al., 2015). Due to methodological quality limitations, poor reporting and variability, the optimal content and critical dose of intervention to yield sustained changes in functional performance remains unclear (Garcia Salazar, dos Santos, Pavao, Rocha, & de Russo, 2015; Ryll, Bastiaenen, De Bie, & Staal, 2011).

Whilst parameters around dose and content have been minimally explored, models of therapy provision have not, with all studies delivering post BoNT-A therapy individually. Group physiotherapy may provide an effective alternative to individually delivered therapy, as demonstrated in a number of RCTs comparing a group model to standard care in ambulant children who have not received BoNT-A (Lowing, Bexelius, & Brogren Carlberg, 2009; Scholtes et al., 2010; Verschuren et al., 2007). Additionally, group therapy has been reported to positively impact motivation, engagement and participation (Gilmore, Ziviani, Sakzewski, Shields, & Boyd, 2010). Despite its potential, group physiotherapy following lower limb BoNT-A injections has not been investigated.

The aim of this study was to evaluate efficacy of a group versus individual model of goal-directed physiotherapy following BoNT-A injections to the lower limbs for ambulant children with CP, with standardized therapy content and dose. We hypothesized that group physiotherapy would result in greater improvement in caregivers' perception and satisfaction of their child's goal-related performance and improvement in quality of life whilst outcomes at the body function and structure (quality of walking, functional balance) and activity levels (walking efficiency, gross motor ability) would improve more in the individual model with potential for greater specificity of training and repetition of skill practise in a one-on-one format. Secondary aims were to qualitatively explore acceptability and feasibility of both models.

2. Method

2.1. Participants

Children were recruited prospectively through the Queensland Cerebral Palsy Health Service, Australia (CP Health). Children were eligible for inclusion if they: (1) were aged four to 14 years at study entry; (2) had a diagnosis of CP with