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Research paper

The effectiveness of Baby-CIMT in infants younger than 12 months with clinical signs of unilateral-cerebral palsy; an explorative study with randomized design

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ABSTRACT

Aim: To explore the effectiveness of baby-CIMT (constraint-induced movement therapy) and baby-massage for improving the manual ability of infants younger than 12 months with unilateral cerebral palsy (CP).

Method: Infants eligible for inclusion were 3–8 months old with asymmetric hand function and at high risk of developing unilateral CP. Thirty-seven infants were assigned randomly to receive baby-CIMT or baby-massage. At one year of age 31 children were diagnosed with unilateral CP, 18 (8 boys, 6.1 ± 1.7 months) of these had received baby-CIMT and 13 (8 boys, 5.0 ± 1.6 months) baby-massage. There were two 6-week training periods separated by a 6-week pause. The Hand Assessment for Infants (HAI), Assisting Hand Assessment (AHA), the Parenting Sense of Competence Scale (PSCS) and a questionnaire concerning feasibility were applied.

Results: There was improvement in the "Affected hand score" of HAI from median 10 (6;13 IQR) to 13 (7;17 IQR) raw score in the baby-CIMT group and from 5 (4;11 IQR) to 6 (3;12 IQR) for baby-massage with a significant between group difference ($p = 0.041$). At 18-month of age, the median AHA score were 51 (38;72 IQR) after baby-CIMT ($n = 18$) compared to 24 (19;43 IQR) baby-massage ($n = 9$). The PSCS revealed an enhanced sense of competence of being a parent among fathers in the baby-CIMT group compared to fathers in the baby-massage ($p = 0.002$). Parents considered both interventions to be feasible.

Conclusion: Baby-CIMT appears to improve the unimanual ability of young children with unilateral CP more than massage.

What this paper adds?

Baby-CIMT performed during the first year of life in children diagnosed with unilateral CP at one year of age appears to positively influence the early development of hand function. Parents found both programs feasible.

Abbreviations: AIMS, Alberta Infant Motor Scale; Baby-CIMT, baby constraint-induced movement therapy; CP, cerebral palsy; CIMT, Constraint-induced movement therapy; HAI, Hand Assessment for Infants; MRI, Magnetic resonance imaging; PSCS, Parenting Sense of Competence scale; RCT, randomized controlled trial; WMDI, white matter damage of immaturity

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1. Introduction

Infants with unilateral brain lesions are at high risk of developing unilateral cerebral palsy (CP) and in the light of the considerable plasticity of the young brain, possible early interventions deserve exploration (Basu, Pearse, Kelly, Wisher, & Kisler, 2014; Martin, Chakrabarty, & Friel, 2011). Most early interventions to date have targeted the general motor and cognitive development of infants with CP but none have focused on improving hand function in infants at risk of developing unilateral CP (Orton, Spittle, Doyle, Anderson, & Boyd, 2009; Morgan, Darrah et al., 2016). However, constraint-induced movement therapy (CIMT), developed specially to improve the function of the affected hand of individuals with unilateral CP has proven effective for older children (Chiu & Ada, 2016) and shown promise for infants in a retrospective study (Nordstrand, Holmefur, Kits, & Eliasson, 2015) but has not yet been systematically used with infants. An obstacle to conducting early intervention studies with infants is the unclear diagnosis and lack of tools for measuring and evaluating the development of hand function at an early age (Krumlinde-Sundholm, Ek, & Eliasson, 2015). Now, baby-CIMT (Eliasson, Sjostrand, Ek, Krumlinde-Sundholm, & Tedroff, 2014), together with the new Hand Assessment for Infants (HAI) developed to measure how infants use their hands (Krumlinde-Sundholm et al., 2017) will make it possible to explore the effectiveness of early interventions with infants below 12 months with high risk of unilateral CP.

It is a challenge to perform an early intervention with infants with CP since this diagnosis is most often made at a later age. CP registers indicate the average age for a diagnosis of CP is 19 months, but the age range is wide (see McIntyre, Morgan, Walker, & Novak, 2011). Unilateral lesions do not necessarily lead to unilateral CP and indeed only approximately 30% of all children who suffer a neonatal stroke eventually develop unilateral CP (Husson et al., 2010). Hand asymmetries, the usual clinical signs of unilateral CP typically do not appear until 4–6 months of age. Furthermore, the available tools for assessment cannot detect or quantify potential asymmetries between the two hands (Greaves, Imms, Dodd, & Krumlinde-Sundholm, 2010; Krumlinde-Sundholm et al., 2015). The new assessment tool, HAI, which is designed for infants 3–12 months, makes it possible to measure hand function in infants at risk of unilateral CP (Krumlinde-Sundholm et al., 2017). HAI has been developed to measure how the infant uses their hands both separately and together during play.

The primary objective of this exploratory study was to compare the effectiveness of baby-CIMT and baby-massage provided by parents in the home environment on the development of manual ability of infants with unilateral CP during the first year of life. Our first hypothesis was that baby-CIMT develops manual ability more rapidly even though baby-massage does promote general development (Bennett, Underdown, & Barlow, 2013). Our second hypothesis was that manual ability develops more rapidly during the training periods than during the pause between these periods. Moreover, we asked whether the effect was maintained at the follow-up at 18 months of age, if the intervention was feasible, and if the treatment protocols influenced self-rated parental competence.

2. Methods and design

2.1. Trial design

In this exploratory study, a randomised design was employed to allocate participants to different groups for the evaluator-blinded prospective parallel-group trial, conducted from 2009 to 2015 at the Astrid Lindgren Children's Hospital, a tertiary hospital in Stockholm, Sweden. The participants were assigned randomly to receive either baby-CIMT or baby-massage (Fig. 1) during two 6-week periods separated by 6-weeks with follow up at 18 months of age. There were five different time points for data collection (Fig. 1). Physiotherapy (about 1or 2 times each month) and other planned interventions continued as usual for both groups. The study was approved by the Stockholm Regional Ethical Review Board (no. 2009/1100-32). The trial registration number is SFO-V4072/2012, 05/22/2013 and further details are presented in the study protocol (Eliasson, Sjostrand et al., 2014).

2.2. Participants

The infants were recruited from various follow-up programs and other clinics at Astrid Lindgren Children's Hospital. Infants between 3 and 8 months of corrected age and a ≥15% difference between the two hands assessed by the HAI (Krumlinde-Sundholm et al., 2017) were eligible to participate. Infants also needed to be considered at high risk of developing unilateral CP, that is, had a known neonatal event that affected the brain, and/or clinical signs that had been identified by a child neurologist or physiotherapist using assessments such as the Alberta Infant Motor Scale (AIMS) or Hammersmith Infant Neurological Examination (HINE) (Novak et al., 2017, Darrah, Piper, & Watt, 1998; Dubowitz & Dubowitz 1981). The exclusion criteria were 1) severe visual impairment, 2) seizures that could not be controlled by antiepileptic drugs and 3) families who were not able to communicate in either English or Swedish. Infants were withdrawn from the study at one year of age if assessed by a paediatric neurologist as having no unilateral CP (see procedure). All parents received oral and written information concerning the study before providing the written informed consent.

2.3. Randomisation and blinding

Eligible children were randomized to the interventions. Randomisation was stratified by age (3–4, 5–6, and 7–8 months, corrected for prematurity) and neonatal event (neonatal arterial stroke at a gestational age ≥week 37, preterm birth at < week 37, and unknown/other) and performed after the first assessment when the consent form was completed. A list of random numbers associated with these stratification factors was generated before initiation of the intervention and was known only to the first author (ACE), who