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An ecological approach of Constraint Induced Movement Therapy for 2–3-year-old children: A randomized control trial

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ABSTRACT

The aim was to evaluate the effect of Eco-CIMT in young children with unilateral cerebral palsy in a randomized controlled crossover design. The training was implemented within the regular pediatric services, provided by the child's parents and/or preschool teacher and supervised by the child's regular therapist.

Methods: Twenty-five children (mean age 28.8 months [SD 11.2], 72% male) participated. Assisting Hand Assessment (AHA) was used as the outcome measure. The Eco-CIMT was provided for 2 h a day over a period of two months. Children were randomized into two groups and started either with Eco-CIMT or as controls with a four-month washout period before crossing over.

Result: A significant effect of Eco-CIMT was found when compared to the control period, and the estimated treatment effect was 5.47 (95% C.I. 2.93–8.02) (including both Group 1 and Group 2) ($p < 0.001$). The non-significant estimated carryover effect allowed us to collapse the two groups based on estimates from the ANOVA model. No clear relationship to hours of training, age or general attitudes of mastery was found.

Conclusion: Eco-CIMT influenced development more than ordinary treatment at this age when Eco-CIMT was performed by parents and preschool teachers supervised by the child's ordinary therapist.

1. Introduction

Most studies using Constraint Induced Movement Therapy (CIMT) as training for children with unilateral cerebral palsy (CP) have been performed in a research context with specially trained and experienced therapists. It is still unknown whether the CIMT method can be used with the same effect in regular pediatric rehabilitation services. During a controlled training situation CIMT seems to be an adequate method for training hand function in children with unilateral CP (Aarts, Jongerius, Geerdink, van Limbeek, & Geurts, 2010; Bonnier, Eliasson, & Krumlinde-Sundholm, 2006; Charles, Wolf, Schneider, & Gordon, 2006; Eliasson, Krumlinde-Sundholm, Shaw, & Wang, 2005; Eliasson, Shaw, Ponten, Boyd, & Krumlinde-Sundholm, 2009; Taub, Ramey, DeLuca, & Echols, 2004). A Cochrane review also indicated a somewhat positive effect, although based on small numbers of children and few randomized controlled trials (Hoare, Wasiak, Imms, & Carey, 2007). Training has commonly been compared to ordinary treatment (Charles et al., 2006; Eliasson et al., 2005; Sung et al., 2005; Taub et al., 2004), and recently to bimanual training and combined training approaches (Aarts et al., 2010; Charles & Gordon,

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2006; Sakzewski et al., 2011). It has been shown that CIMT can be provided successfully to children at different ages. Gordon and colleagues have shown no difference in training effect between children at 4–8 years of age and those at 9–13 years of age (Gordon, Charles, & Wolf, 2006). Eliasson and colleagues have demonstrated good effect from 18 months to four years of age, but have also done so for teenagers (Bonnier et al., 2006; Eliasson et al., 2005, 2009).

It seems, however, that the early preschool period is the most sensitive period for development of hand function. When the longitudinal development of the hemiplegic hand function was investigated in children between 18 months and eight years of age, it has been shown to improve with age (Holmefur, Krumlinde-Sundholm, Bergstrom, & Eliasson, 2010). Nevertheless, the children who at age 18 months spontaneously used their hand for grasping had more rapid development and reached a higher ability level compared to those who did not spontaneously use their hand at 18 months of age. The former, higher ability group reached 90% of their ability limit at the age of three years, while the children in the lower ability group reached 90% of their limit considerably later, at the age of seven years (Holmefur et al., 2010). Accordingly the early age might also be the time when intensive training should be provided.

We have previously described a model for modified CIMT, in which families and preschool teachers are responsible for the training on a daily basis with weekly supervision from a trained therapist (Eliasson et al., 2005). The suggested regime was 2 h of training per day for two months. The previously described model has been further developed in this study and theoretically more clearly connected to the Dynamic System Theory discussed by Thelen and Smith (1996), as well as to principles of motor learning (Smith & Wrisberg, 2001) and to Bronfenbrenner's ecological model of child development (Bronfenbrenner & Morris, 1998). We propose that the model used in this study can be called Eco-CIMT since it has an ecological approach. The theories included in Eco-CIMT are well known and commonly used in pediatric rehabilitation services. They influence, for example, functional and goal-oriented training as well as family center services (King, Teplicky, King, & Rosenbaum, 2004; Lowing, Bexelius, & Carlberg, 2010; Mastos, Miller, Eliasson, & Imms, 2007). Utilizing the Eco-CIMT model, we now wanted to take the implementation process further forward. Our hypothesis was that the same results could be replicated in a randomized controlled study where parents and preschool teachers are supervised by the child's ordinary therapist following a 10-step model (see Appendix A). The aim of this study was therefore to evaluate effects of Eco-CIMT in small children in which the training was provided by the child's parents and/or preschool teachers and supervised by the child's ordinary therapist, by applying a randomized controlled crossover design.

2. Methods

2.1. Participants and recruitment

Families with children with unilateral CP within pediatric services in Stockholm were invited to participate in this study. An invitation letter was distributed to potential participants by their occupational therapist and physiotherapist. Inclusion criteria for children were (a) age 18 months to five years, (b) any severity level of decreased hand function, (c) ability to cooperate in the testing procedure, and (d) parents willing to commit to the eight-week intervention procedure. Children were excluded if they (a) had visual and behavioral problems that would interfere with the treatment or testing procedure, (b) had had botulinum toxin injection in the last six months, (c) were included in another intensive training program, or (d) had undergone surgery or had an unstable medical situation during the study period. Informed consent was obtained from all families, and the study was approved by the Ethics Research Committee at Karolinska Institutet in Stockholm, Sweden.

2.2. Study design

A randomized crossover design with a "washout" period was used (Walter, 1997) to evaluate the effect of Eco-CIMT compared to ordinary treatment. A crossover design is efficient when a smaller sample is available and when there is a strong component of variation due to individual subjects. The precision of the estimated treatment effect can be increased when the child acts as its own control (Brown, Jr., 1980; Fleiss, 1986). All children were involved in the study for eight months. Group 1 started with 2-months of Eco-CIMT, and Group 2 started as controls for two months. After a 4-month "washout period", there was a crossover in which the control group (Group 2) received Late Eco-CIMT and the Eco-CIMT group (Group 1) served as controls. In a traditional crossover design it is assumed that the outcome of treatment is of relatively short duration and will return approximately to baseline level when the effect of therapy wears off after a suitable washout period has elapsed. In this case, we expected the Eco-CIMT effect to be persistent or continue to increase. Under these circumstances, some of the effect seen in the washout period may be due to a residual effect of the treatment in the first period (Walter, 1997). By examining the carryover bias effect it is possible to determine whether the order of treatment is insignificant or not. If insignificant, a fully effective estimate of treatment effect can be derived from both treatment periods and use the within-subject control feature of the design (Walter, 1997).

The randomization of the children was stratified according to age and level of hand function. There were two age groups: 18 months to four years and four to six years. Hand function was graded as mild (pincer grasp: isolated finger movements present), moderate (grasping with whole hand: no isolated finger movements) or severe (no grasping) (Claeys, Deonna, & Chrzanowski, 1983). The children were recruited consecutively. The randomization was produced by using a computer-generated list of random number after the consent form was filled in. The design is based on the consort statement for reporting randomized controlled trials (Schulz, Altman, & Moher, 2010).