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# Occupational therapy for children with cerebral palsy (Protocol)

STEULTJENS EMJ, DEKKER J, BOUTER LM, VAN DE NES JCM, LAMBREGTS BLM, VAN DEN ENDE CHM


## ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows: The object of our systematic review, therefore, was to determine whether OT interventions improve functional abilities and social participation in children with cerebral palsy.


## BACKGROUND

Cerebral palsy (CP) is a static encephalopathy that can be defined as a non-progressive disorder of posture and movement. It is often associated with epilepsy and abnormalities of speech, vision and intellect, resulting from a defect or lesion in the developmental brain. CP is a common disorder with an estimated prevalence of 2/1000 in the general population (Behrman 2000). A large variety of symptomatology is seen in children with CP (DeLisa 1998). It is also a condition that occurs early in life and is present throughout a person's lifetime. It can affect all aspects of a person's development throughout his/her life.

The management of a child with cerebral palsy, with the objective of optimizing the child's ability to function, typically includes the input of many disciplines, including occupational therapy (OT) (Rosen 1996). Occupational therapy focuses on the development of skills necessary for the performance of activities of daily living.

These activities include play, self-care activities such as dressing, grooming and feeding, and fine motor tasks such as writing and drawing. OT also addresses cognitive and perceptual disabilities, especially in the visual-motor area. Another aspect of OT is the adaptation of equipment and seating to allow better upper extremity use and to promote functional independence (Wilsdon 1996).

Furthermore, parent counseling is an important aspect of the OT treatment with regard to optimizing parental support for improving the functional abilities of the CP child. Different approaches to treatment are taken within OT, such as neuro-developmental treatment (NDT), the Vojta method, or sensory integration (SI).

One study (Koman 2002) reported that 50% of children with CP receive OT.

Five reviews (Brown 2001, Roxborough 1995, Gormley 1999, Hur 1995, Parette 1984) addressOT-related topics. Three of these were narrative in origin (Gormley 1999, Hur 1995, Parette 1984), while the two systematic reviews (Brown 2001, Roxborough 1995) focused on the efficacy of very specific interventions applied within OT, viz. NDT in general and adaptive seating respectively. Until now, no systematic summary has been produced of the evidence of the efficacy of various OT interventions in children with cerebral palsy.

## OBJECTIVES

The object of our systematic review, therefore, was to determine whether OT interventions improve functional abilities and social participation in children with cerebral palsy.

## CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

### types of studies

Studies with one of the following designs will be entered in the review.

1) Randomised controlled clinical trial (RCT): An experiment in which investigators randomly allocate eligible people into treatment and control groups. Cross-over trials will be considered as RCTs according to the Cochrane Collaboration Guidelines (Clarke 2000).

2) Controlled clinical trial (CCT): an experiment in which eligible people are in a non-randomized way allocated to the treatment and the control groups 3) Other than controlled designs (OD): patient series and prepost studies. Such ODs can only contribute in a limited way to the best evidence synthesis.

### Types of participants

Studies with children/adolescents aged .20 years with a clinical diagnosis of cerebral palsy will be included.

### Types of intervention

Occupational therapy interventions will be regarded as \comprehensive OT" (when all five intervention categories are part of the evaluated OT treatment) or will be classified into five specific intervention categories: 1) training of sensory-motor functions; 2) training of skills; 3) parental counselling; 4) advice or instruction regarding the use of assistive devices; and 5) provision of splints.

All studies with above specified interventions according to a group of four experienced occupational therapists and reviewer CHME (seeMethods of the review) are eligible for inclusion in this review.

### Types of outcome measures

Primary outcome measures: Functional ability and/or social participation.

Secondary outcome measures: Motor-function (either balance or arm-hand function) and/or muscle tone.

These secondary measures are regarded as process measures i.e., measures considered to be indicators of a successful treatment. As will be explained below, process measures can only contribute in a limited way to the best evidence synthesis.

## SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Movement Disorders Group methods used in reviews.

Only full length articles or full written reports will be considered for inclusion in the review.

1) The following search strategy, divided into two sections: A) cerebral palsy and B) occupational therapy, will be applied .

The strategy for Pubmed 1966 to date:

A) Cerebral palsy
#1 Cerebral palsy
B) Occupational therapy
#2 Occupational therapy
#3 Activities of daily living
#4 Exercise therapy
#5 Splints
#6 Self-help devices
#7 Early intervention

#8 Parents/education
#9 Parents/psychology
#10 Professional family relations
#11 Play and playthings
#12 #2-#11 or
#13 #1 and #12
#14 limits to human

The following databases will be searched:
a) MEDLINE (1966-....)
b) CINAHL (1982-.....)
c) Embase (1980-.....)
d) SCISEARCH (1974 -.....)
e) AMED (1985-.....)
f ) Cochrane Controlled Trials Register
g) The databases of the libraries of medical and rehabilitation literature of the Dutch National Institute Allied Health Professions (NPI) and of the Netherlands Institute for Health Services Research (Nivel)
h) The database of the Rehabilitation and Related Therapies (RRT) Field of the Cochrane Collaboration
i) The specialized trials register of the Cochrane Movement Disorders Group

The search strategy will be formulated in Pubmed and will be adapted by an experienced medical librarian to make it applicable for the other databases.

2) The same databases will be searched to identify reviews about the efficacy of occupational therapy in cerebral palsy.
3) The reference lists of the identified studies and reviews will be screened for additional references.
4) Authors of papers reporting trials about the effectiveness of occupational therapy in cerebral palsy patients will be contacted by mail and asked for any additional (un)published studies relevant for this systematic review. A list with so far identified trials will be enclosed.
5) Authors of abstracts of possible eligible studies will be asked for a full written report.

**METHODS OF THE REVIEW**

Selection for inclusion in the review, assessment of the methodological quality and data extraction will be performed in three separate steps. Three reviewers (EMJS, BL,CHME)will take part in these procedures. Prior to all steps, assessment procedures are tested in a sample of three articles eligible for this review by two reviewers. A standard form for each step will be made.

Selection for inclusion Because of the broad search strategy we expect to find a large number of ineligible articles. The procedure for inclusion of the studies will be based on the recommendations by Van Tulder et al (VanTulder 2002): The first selection, based on titles and abstracts, will independently be performed by two reviewers (EMJS and CHME). This first selection can result in probable inclusion of the study, exclusion of the study, or can be indecisive. The second step for inclusion (definite include or exclude) will independently be done by two reviewers (EMJS and CHME), using full reports and considering the criteria stated above. Disagreements regarding inclusion status will be resolved by discussion. If no consensus is met a third reviewer (BL) decides. Finally, a group of four occupational therapists will assess the criteria for 'type of intervention' and if appropriate classify the type of intervention into one of the five different interventions or combinations of interventions. Consensus will be reached by discussion.

Assessment of methodological quality The variety in study designs to be included in this systematic review necessitates the use of different quality assessment tools.

The methodological quality of RCTs and CCTs will be rated by a list recommended by Van Tulder (Van Tulder 1997). The list, containing all criteria proposed by Jadad (Jadad 1996) and Verhagen et al (Verhagen 1998), consists of 11 criteria for internal validity, 6 descriptive criteria and 2 statistical criteria (Appendix 1). One modification was made in the specification of the criterion 'eligibility': the 'condition of interest' (the impairment or disability that indicated referral to occupational therapy) is added as an eligibility criterion, as proposed byWells (Wells 2000). All criteria are scored as yes, no, or unclear. Equal weights will be applied to all items. Studies are considered to be of 'high quality' if at least 6 criteria for internal validity, 3 descriptive criteria and one statistical criterion are scored positively.

The methodological quality of ODs will be rated using an adapted version of the Van Tulder list. Some items (concerning randomization, similarity of patient groups, blinding of careprovider, blinding of patient) are considered to be inapplicable to ODsand are removed from the list. Some items are reformulated to make the item applicable to one patient group (for instance: \were co-interventions avoided or comparable?' is reformulated into "were co-interventions avoided>`) or to make the item applicable for the design of the study (for instance: "was the outcome assessor blinded to the intervention\ is reformulated into: "was the careprovider not involved in the outcome assessment>`) The final list of criteria used in OD consists of 7 criteria for internal validity, 4 descriptive criteria and 2 statistical criteria (Appendix 1). All criteria are scored as yes, no, or unclear. Equal weight will be applied to all items. Studies are considered to be of 'sufficient quality' if at least 4 out of 7 criteria for internal validity, 2 descriptive criteria and one statistical criterion are scored positively.

Of course, the distinction between ODs with a sufficient or nonsuf ficient quality is a relative one: the internal validity of ODs is substantially weaker than the internal validity of RCTs/CCTs.

The methodological quality of the included trials will be independently assessed by two reviewers (EMJS, BL).

Disagreements will be resolved by discussion. If no consensus is met a third reviewer (CHME) decides.

Data extraction The following information will be systematically extracted by EMJS 1. Study characteristics: number of participating patients, specified criteria for diagnosis of cerebral palsy, in- and exclusion criteria, type of experimental and control interventions, co-interventions, features of interventions (duration, frequency, setting), number of drop-outs.

2. Patient characteristics: sex, age, disease duration, disease severity.

3. Outcome and process measures assessed immediately after finishing the intervention, within six months follow up and after six or more months follow up.

Data synthesis For continuous variables standardized mean differences will be computed if possible. In cases of missing data standard deviations will be computed, if possible, from the available data.

For dichotomous variables odds ratios with corresponding 95% confidence interval will be computed.

Analysis of the results In this review five different intervention categories are distinguished: 1) training of motor functions; 2) training of skills; 3) parental counselling; 4) advice or instruction regarding the use of assistive devices and 5) provision of splints. Other categories can occur when combination of interventions (e.g. comprehensive OT) are evaluated. Analyses will be performed separately for each intervention category. In cross-over trials without a wash-out period between interventions data after the 'cross-over' will not be further analysed. The primary analysis will focus on comparisons of an occupational therapy intervention with a 'no treatment' control group. However, if studies compare the effect of more than two intervention groups, two reviewers (EMJS, CHME) will decide by

consensus, how these comparisons will be classified. In particular, if two interventions are compared, the predominant contrast needs to be the occupational therapy treatment provided.

We expect to find too much diversity among studies with regard to patients (severity of the disease), interventions (duration, frequency and setting) and outcome measures (diversity, presentation of the results) to make quantitative analysis (metaanalysis) appropriate. Instead, we will perform a best evidence synthesis by attributing various levels of evidence to the effectiveness of occupational therapy, taking into account the design of the studies, the methodological quality and the outcome of the original studies. The best-evidence synthesis is based upon the one proposed by Van Tulder (Van Tulder 2002) and adapted for the purpose of this review. If the amount of studies that show evidence is less than 50% of the total number of studies found within the same category of methodological quality and study design (RCT, CCT or OD) we will state no evidence.

Strong evidence provided by consistent, statistically significant findings in outcome measures in at least two high quality RCTs Moderate evidence provided by consistent, statistically significant findings in outcome measures in at least one high quality RCT and at least one low quality RCT or high quality CCT Limited evidence provided by statistically significant findings in outcome measures in at least one high quality RCT or: provided by consistent, statistically significant findings in outcome measures in at least two high quality CCTs ( in the absence of high quality RCTs) Indicative findings provided by statistically significant findings in outcome and/or process measures in at least one high quality CCTs or low quality RCTs ( in the absence of high quality RCTs) or: provided by consistent, statistically significant findings in outcome and/or process measures in at least two high quality ODs (in the absence of RCTs and CCTs) No or insufficient evidence in case of results of eligible studies do not meet the criteria for one of the above stated levels of evidence or: in case of conicting (statistical significant positive and statistical significant negative) results among RCTs and CCTs or: in case of no eligible studies Sensitivity analyses will be performed by attributing different levels of quality to the studies: 1) results will be re-analysed excluding low quality studies.

2) results will be re-analysed considering studies to be of "high quality\ if 4 or more criteria of internal validity are met.

Furthermore, if feasible, we will perform subgroup analysis on the efficacy of OT in different settings (at home, in hospital).

APPENDIX 1: CRITERIA OF METHODOLOGICAL QUALITY RCTs, CCTs Patient selection a) were the eligibility criteria specified? b) treatment allocation: 1)was a method of randomization performed? 2)was the treatment allocation concealed? c) were the groups similar at baseline regarding the most important prognostic indicators? Interventions d) were the index and control interventions explicitly described? e) was the care provider blinded for the intervention? f ) were co-interventions avoided or comparable? g) was the compliance acceptable in all groups? h) was the patient blinded to the intervention? Outcome measurement i) Was the outcome assessor blinded to the interventions? j) were the outcome measures relevant? k) were adverse effects described? l) was the withdrawal/drop out rate described and acceptable? m) timing follow-up measurements: 1)was a short-term follow-up measurement performed? 2)was a long-term follow-up measurement performed? n) was the timing of the outcome assessment in both groups comparable? Statistics o) was the sample size for each group described? p) did the analysis include an intention-to-treat analysis? q) were point estimates and measures or variability presented for the primary outcome measures? OD Patient selection a) were the eligibility criteria specified? Interventions d) was the intervention explicitly described? f ) were cointerventions avoided? g) was the compliance acceptable? Outcome measurement i) Was the outcome assessor not involved in the treatment? j) were the outcome measures relevant? k) were adverse effects described? l) was the withdrawal/drop out rate described and acceptable? m) timing follow-up measurements: 1)was a short-term follow-up measurement performed? 2)was a long-term follow-up measurement performed? n) was the timing of the outcome assessment in all

patients comparable? Statistics o) was the sample size of the patient group described? p) did the analysis include an intention-to-treat analysis? q) were point estimates and measures or variability presented for the primary outcome measures? Internal validity: b, e, f, g, h, i, j, l, n, p; descriptive criteria: a, c, d, k, m; statistical criteria: o, q.

## POTENTIAL CONFLICT OF INTEREST

None known.

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