

Is Cognitive Orientation to daily Occupational Performance (CO-OP) more effective to achieve personal goals than conventional habilitation services for children with cerebral palsy or spina bifida?

Submission date 04/02/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/02/2020	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2022	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Research shows that people with Cerebral Palsy (CP) and Spina Bifida (SP) have difficulties governing their own lives due to executive dysfunctions (problem-solving, planning, initiation). Cognitive Orientation in Daily Occupational Performance (CO-OP) has been shown to enhance self-efficacy and executive functions in young adults with CP or SB through the enablement of self-chosen goals by learning of strategy-use and metacognitive thinking. This study aims to investigate the efficacy of CO-OP for children and adolescents with CP or SB compared to conventional habilitation services.

Who can participate?

Children and adolescents 9 to 16 year olds with cerebral palsy (with fairly good ability to use their hands) or spina bifida (with and without hydrocephalus) who:

1. Have experienced problems performing or organizing activities due to difficulties with initiative, planning, problem-solving and decision-making process
2. Go to school in compulsory school in the mainstream curriculum and communicate in Swedish
3. Are capable of formulating their own goals

What does the study involve?

The children and adolescents are randomly allocated to either a 10-week intervention with CO-OP or a waitlist group with ordinary habilitation services (control group). After 10 weeks the groups switch so the children and adolescents in the waitlist group start a COOP intervention. Four goals are identified by each child both in the intervention group and the control group (one remains untrained to study generalization and transfer to other environments or new situations). Investigations are done before and directly after the intervention and 3 months after.

What are the possible benefits and risks of participation?

The goal of this project is partly to be able to achieve the goals participants set themselves to cope with everyday activities by learning/improving their problem-solving ability and learning to use strategies. If any of these treatment effects are achieved, it is likely to mean increased independence in various activities, less dependence on relatives and assistants, and increased participation in everyday life as well as increased self-efficacy. The risks of participating in the project are very small. There is a small risk that those who participate may experience a feeling of failure, but the method is based on finding ways to achieve their goals, so the responsible occupational therapist will try to prevent this.

Where is the study run from?

This study is a multicenter study in four different regions in Sweden:

1. Regional Rehabilitation Centre for Children and Adolescents, Queen Silvia Children's Hospital
2. Habilitering & Hälsa, Region Stockholm
3. Habilitering & Hälsa Västra Götalandsregion
4. Habiliteringen Halland
5. Region Gävleborg, Barn- och ungdomshabilitering

When is the study starting and how long is it expected to run for?

April 2015 to June 2020

Who is funding the study?

1. Vastra Gotaland regional research fund
2. Norrbacka-Eugenia Foundation
3. Sahlgrenska University Hospital ALF
4. The Foundation Sunnerdahl Handikapp Fund
5. Josef och Linnea Carlssons Foundation
6. Regional research fund Habitation & Health, Vastra Gotalandsregionen
7. Folke Bernadotte Foundation
8. RBU Research Foundation

Who is the main contact?

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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Is Cognitive Orientation to daily Occupational Performance (CO-OP) more effective to achieve personal goals than conventional habilitation services for children with cerebral palsy or spina bifida: a randomised control trial

Acronym
CO-OP in children with CP or Spina Bifida

Study objectives
The project is based on four hypotheses:
1. CO-OP is more effective than conventional habilitation services in order to reach self-identified activity goals
2. CO-OP intervention to a higher extent leads to the achievement of an untrained goal than conventional habilitation services (transfer effect)

3. With CO-OP intervention self-rated participation in society (estimated by the person himself) increases more than with conventional habilitation
4. CO-OP intervention increases executive ability to a greater extent than conventional habilitation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/05/2016, Regional Ethics Review Board in Gothenburg (Regionala etikprövningsnämnden i Göteborg, Box 401 405 30, Göteborg, Sweden; Tel: +46 (0)3178621), Dnr: 393-16, Ref. No. 393-16

Study design

Interventional multicentre randomized cross over trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cerebral palsy or spina bifida

Interventions

The children and adolescents will be allocated to either a 10-weeks intervention with CO-OP or waitlist group with ordinary habilitation services (control group). After 10 weeks the groups will switch so the children and adolescents in the waitlist group will start a COOP intervention. Four goals were identified by each child both in the intervention group and the control group (one remains untrained to study generalization and transfer to other environments or new situations). Investigations will be done before and directly after the intervention and 3 months after.

Intervention Type

Behavioural

Primary outcome(s)

1. Self-rated goal attainment measured with Canadian Occupational Performance Measure (COPM) in both groups (both treatment and waitlist-control) at goalsetting before the treatment /control period, and directly after the period. COPM also used as follow up at 3 months after the treatment period for the treatment group
2. Objective goal attainment measured with Performance Quality Rating Scale (PQRS). This is an observational method, the participants' (when in the treatment group) performance of the four activities they choose as goals is video-recorded at the first treatment session and at the last and 3 months after the treatment period. These videos are rated by an independent rater according to the PQRS method. For the waitlist- control group, the performance of their four activities/goals is video recorded at pre-assessment before and after the waiting/control period and rated according to the PQRS method by an independent rater.

Key secondary outcome(s)

1. Self-rated competence and value of everyday-activities are rated with The Child Occupational Self- Assessment-Swedish version (COSAS) by the participants (in both groups) before, directly after and for treatment group 3 months post-intervention
2. Executive function is rated by proxy with Behavior Rating Inventory of Executive Function (BRIEF) and self-rated by participant > 11 years of age, before and directly after for both groups and at follow up after 3 months for the treatment group
3. Executive function is also measured with part of the Delis-Kaplan Executive Function System (D-KEFS, Trail Making Test, Tower test, Verbal Fluency Test) before and directly after for both groups and at follow up at 3 months for the treatment group

Completion date

13/06/2020

Eligibility

Key inclusion criteria

Children and adolescents with cerebral palsy (MACS I-III GMFCS I-IV) or spina bifida (with or without hydrocephalus), aged 9-16 years (in the year of enrolment) who have:

1. Experienced problems (self-perceived or experienced by parents) to perform or organize activities due to difficulties with initiative, planning, problem-solving and decision-making process
2. Goes to school in compulsory school in the mainstream curriculum and communicates in Swedish
3. Capability to formulate own goals

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

9 years

Upper age limit

16 years

Sex

All

Total final enrolment

46

Key exclusion criteria

1. Children who communicate with Augmentative and Alternative Communication (ACC) or are unable to communicate in Swedish
2. Going to compulsory school in special education for intellectual disability curriculum in time of enrolment

Date of first enrolment

01/06/2017

Date of final enrolment

30/08/2019

Locations

Countries of recruitment

Sweden

Study participating centre

Regional Rehabilitation Centre for Children and Adolescents, Queen Silvia Children's Hospital

Box 210 62

Göteborg

Sweden

418 04

Study participating centre

Habilitering & Hälsa, Region Stockholm

Box 45436

Stockholm

Sweden

104 31

Study participating centre

Habilitering & Hälsa Västra Götalandsregion

Ekelundsgatan 8,

Göteborg

Sweden

411 18

Study participating centre

Habiliteringen Halland

Hallands sjukhus

Halmstad
Sweden
30185

Study participating centre
Region Gävleborg, Barn- och ungdomshabilitering
Folkparksvägen 5
Gävle
Sweden
806 33

Sponsor information

Organisation
Queen Silvia Children's Hospital (Sweden)

ROR
<https://ror.org/00yqpgp96>

Organisation
Habilitering och Hälsa VG-region

Organisation
Habiliteringen Halland

Organisation
Habilitering & Hälsa

Funder(s)

Funder type
Research organisation

Funder Name
Vastra Gotaland regional research fund

Funder Name

Norrbacka-Eugeniastiftelsen

Alternative Name(s)

Norrbacka-Eugenia Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

Funder Name

Sahlgrenska University Hospital ALF

Funder Name

The Foundation Sunnerdahl Handikapp Fund

Funder Name

Josef och Linnea Carlssons Foundation

Funder Name

Regional research fund Habitation & Health, Vastra Gotalandsregionen

Funder Name

Folke Bernadotte Foundation

Funder Name

RBU Research Foundation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Marie Peny-Dahlstrand (marie.peny-dahlstrand@vgregion.se).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/03/2022	10/06/2022	Yes	No