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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

Registration date
12/02/2020

Overall study status
Completed

Last Edited
10/06/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use the contact details to request a patient information sheet

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 measure

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.

Secondary outcome measures
1. Self-rated competence and value of everyday-activities are rated with The Child Occupational Self- Assessment-Swedish version (COSA-S) 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

Overall study start date
30/04/2015

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

Age group
Child

Lower age limit
9 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
60

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
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Sponsor information

Organisation
Queen Silvia Children's Hospital (Sweden)

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Sponsor type
Hospital/treatment centre

Website
https://www2.sahlgrenska.se/en/SU/In-English/

ROR
https://ror.org/00yqpgp96

Organisation
Habilitering och Hälsa VG-region

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Sponsor type
Hospital/treatment centre

Organisation
Habiliteringen Halland

Sponsor details
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Sponsor type
Hospital/treatment centre

Organisation
Habilitering & Hälsa

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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Data is planned to be analysed during April-May 2020 and manuscript to be written and submitted in autumn 2020.

Intention to publish date
30/06/2022

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