

BMJ Open Effectiveness of CO-OP group intervention for children with developmental coordination disorder: single-case experimental design study protocol

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ABSTRACT

Introduction With the Cognitive Orientation to daily Occupational Performance (CO-OP) approach, children with developmental coordination disorder learn to use a problem-solving strategy to deal with their motor difficulties and perform daily activities of their choice. Therapists use guided discovery to enable children to find their own solutions. Although CO-OP is recommended in a group setting, studies are needed to support its effectiveness.

Methods and analysis A single-case study design with multiple baselines across participants and four systematic replications will be used. In each of the five groups, four children (aged 8–12 years) will be randomly included at the baseline. The baseline includes 5–8 measurements, and the CO-OP intervention stage is comprised of 10 sessions. The follow-up stage includes five measurements. Prior to baseline, each child in each of the five groups will choose five activities of which three will be carried out during the intervention sessions. Children's performance in each of these activities will be scored using the Performance Quality Rating Scale (PQRS) as the main measure. Three secondary measures will be collected: perceived activity performance using the Canadian Occupational Performance Measure, quality of life using the Kidscreen-27 and spontaneous motor rhythm using a computerised typing task. Graphed data will be analysed visually at the individual level with the Visual Aid Implying an Objective Rule (VAIOR) protocol which provides a colour code based on the level and trend of two consecutive phases, facilitating an objective visual analysis. Statistics will be performed for PQRS scores at the individual level and at the group level.

Ethics and dissemination The protocol has been approved by the Comité de protection des personnes Sud-Est I (CPP 2021070) and the Comité d'éthique de la recherche avec les êtres humains de l'Université du Québec à Trois-Rivières (CER-22-294-07.03). Results will be published in a peer-reviewed scientific journal.

Trial registration number NCT05231486.

BACKGROUND

Developmental coordination disorder (DCD), a chronic and usually permanent

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The single-case multiple-baseline experimental design (SCED) is adapted to take into account the heterogeneity characteristic of children with developmental coordination disorder.
- ⇒ SCED allows for both individual and grouped rigorous analyses to support a research-informed practice.
- ⇒ The use of four systematic replications across participants and activities increases the internal and external validity of the results.
- ⇒ Replications performed by the same research team limit the external validity of the study.

condition commonly diagnosed during childhood, is characterised by motor impairment that interferes with the child's activities of daily living and academic achievement,¹ ranging from slowness to severe difficulties in daily skills such as tying one's shoelaces, bicycle riding or writing. DCD includes difficulty learning new gestures or motor activities and performing them correctly in everyday life.¹

The current prevalence of DCD is estimated to be 5%–6% of school-aged children.^{1–4} In 50%–70% of cases, DCD continues through adolescence and adulthood.¹ In addition, DCD has been shown to affect children's self-esteem and mental health.⁵ Consequently, international DCD practice guidelines recommend early and effective intervention for children with DCD.⁶

The DCD practice guidelines highlight the need for effective interventions that target daily living skills,⁶ such as the Cognitive Orientation to daily Occupational Performance (CO-OP) approach.^{7–9} CO-OP is a task-oriented approach that teaches children to use a simplified problem-solving strategy.



Therapists guide children to learn new strategies to overcome their daily challenges and perform activities of their choice (eg, changing body position or paying attention to a particular moment of the activity). Over the course of the sessions, children gradually discover elements to modify in their motor execution procedures for selected activities. As children become aware of these modifications, they can more easily reproduce them in various contexts (eg, school or family). Indeed, motor repetition of gestures unrelated to activity or on process approach (eg, sensory integration and kinaesthetic training) does not show improvement in prior literature.^{8,9} Past research has demonstrated that the CO-OP approach is effective for improving children's functioning in the targeted activities and that increased functioning also generalises to other activities.¹⁰

The practice guidelines also emphasise that group-based intervention is to be preferred over individual intervention⁶ because it answers a number of psychosocial needs of children with DCD related to self-esteem and sense of belonging,¹¹ while reducing healthcare costs.¹² However, there is limited literature on the effectiveness of a group-based CO-OP approach for children with DCD,^{13–15} and the methodological rigour of published studies is limited.^{15,16}

Study objectives

The main objectives are to determine whether a group-based CO-OP approach for children with DCD improves their activity performance in a given activity and whether this improvement is generalisable in different contexts of use than that of intervention (eg, school or family). A secondary objective is to study the impact of the approach on children's quality of life, performance and satisfaction self-evaluation in targeted activities and on body functions (eg, spontaneous motor rhythm).

METHODS

Study design

This study is a series of single-case experimental designs (SCEDs) with multiple baselines across subjects. The study design was selected to take into account the clinical heterogeneity characteristic of children with DCD^{2,4,17} and the CO-OP intervention patterns.¹⁸ Indeed, there is a wide range of impairments and disabilities associated with DCD.¹ The main impairment in DCD can be related to fine motor skills, gross motor skills or both⁶ involving the need for a wide range of complex and multidimensional interventions.¹⁹ The Medical Research Council guidelines for the development of complex interventions recommend the use of an initial SCED study design to ascertain the effectiveness of such complex interventions.¹⁹ SCED involves repeated and prospective measurement of the same subject, each subject being his own control. SCED studies allow to demonstrate the effectiveness of an intervention by replicating its effects on at least three participants in the same research.^{20,21} It is

concluded that an intervention is effective when the same effect is found at least three times, which corresponds to at least three subjects in parallel groups.²² SCED allows inferences about an individual's specific behaviour change in response to the specific timing and type of an intervention.²³

Participants

Participants are children between the ages of 8 and 12 years with a confirmed diagnosis of DCD at the child and adolescent psychiatry department of the Montpellier University Hospital. The age limits of the study, 8–12 years, were chosen based on one of the measurement tools (Kidscreen-27) which has standards from 8 years as well as the most representation of 8–12 years on the waiting list for a CO-OP group at the Montpellier Hospital Centre (France). The DCD diagnosis must meet the Diagnostic and Statistical Manual of mental Disorders, Fifth Edition (DSM-5) criteria (validation of A, B, C and criteria D). Inclusion criteria are as follows: (1) to be aged between 8 and 12 years at the time of inclusion, (2) to have been placed on the waiting list to benefit from the CO-OP group by the doctor coordinating the treatment pathway at the Montpellier University Hospital (France) and (3) to have a confirmed diagnosis of DCD according to a multidisciplinary assessment and resulting in an overall score ≤ 16 percentile on the Movement Assessment Battery for Children, Second Edition,^{6,24} and an IQ ≥ 70 points on the Wechsler Intelligence Scale for Children, Fifth Edition.²⁵ Eligible families will be informed by child psychiatrists on the goals and implications of the research. If families agree to participate, their written consents (parents and children) will be required.

Exclusion criteria are as follows: (1) moderate or severe language disorder, (2) moderate or severe anxiety disorder and (3) occupational therapy at the time of inclusion until the end of the group study procedure. Children on the waiting list for CO-OP group have been assessed by a multidisciplinary team, which clinically evaluated or used standardised assessments to assess severe or moderate language disorders, as well as the presence of anxiety.

Sample size calculation

While few participants are sufficient to provide evidence of intervention effectiveness (typically one to three), international recommendations advocate replicating the effects on 20 patients across multiple articles by 3 different research teams to obtain maximum evidence of effectiveness.²³ For the multiple-baseline design, it is necessary to replicate the entire experiment over three or more replicates to ensure validity.²¹ Many authors^{23,26} suggest that there is evidence from SCED that an intervention is effective when examined through 5 replications and a total number of 20 participants.^{23,27} The research involves five replications, corresponding to five experimental groups.

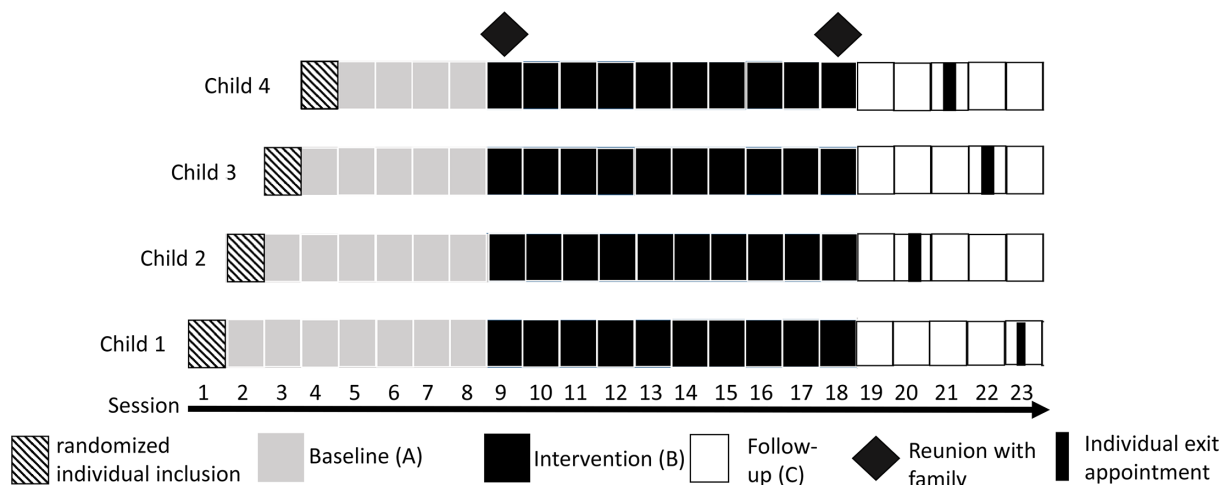


Figure 1 Procedure for one experimental group.

Procedure

For each group, three stages will be evaluated: the baseline, before intervention (A), the intervention (B) and the follow-up (C) after the intervention (figure 1). Our protocol uses the extension of Standard Protocol Items: Recommendations for Interventional Trials,²⁸ specially designed for SCED.²⁹

The study uses the Wampold-Worsham random sequential introduction procedure.³⁰ In all groups, each of the four children will be randomly included in the study at one of the four possible protocol starting points, determining the sessions' number completed during the baseline (5–8 baseline assessment points). The Wampold-Worsham random sequential introduction procedure³⁰ will be generated by the computer program Excel Package of Randomization Tests. Only the baseline stage will vary from five to eight sessions depending on the respective place of each child in a randomly chosen intervention group before being grouped together for the intervention stage B. Stage B begins at the ninth session. This session includes an initial meeting (around 30 min) with all the families and children participating in the study. This meeting will be used to inform participants on the course of the following sessions (sessions 9–18, stage B), as well as the choice of three target activities that will be practised during the CO-OP intervention and two other

activities that will not be practised during the sessions. The CO-OP intervention sessions will be carried out during stage B by two certified therapists. Stage B exit meeting with all families and children will be offered immediately after session 18. Finally, from sessions 19 to 23 (stage C), the measures will be continued. During stage C, a new individual meeting will be randomly offered to each child and his family. The design of the SCED estimate for this study is carried out in accordance with the scale risk of bias scale in N-of-1 trials.^{21 31}

Intervention

The CO-OP approach has four objectives: (1) activity acquisition, (2) development of cognitive strategies, (3) generalisation of the achievement of targeted activities in daily life and strategies and (4) transfer to new activities and contexts. Ten 1-hour sessions will be undertaken to practice three targeted motor activities. A four-step problem-solving strategy (goal-plan-do-check), called the global cognitive strategy,⁷ will be used. Throughout the sessions, therapists guide children verbally in an individualised way by promoting the exchange of ideas with all the children. Children discover new strategies and succeed in their chosen goals (table 1). At each session, time spent on each of the three activities will last no longer than 15 min.

Table 1 Description of the 10 Cognitive Orientation to daily Occupational Performance (CO-OP) intervention sessions

Study session	Key feature used	Description
9	Introduction of global strategy (goal-plan-do-check) Children use global strategy in order to identify activity goal, describe plan elements, perform plan, identify what element of plan worked and keep or abandon it. Global strategy is used to coordinate other strategies	This session has four steps to teaching global strategy: (1) description of goal-plan-do-check by therapist with active participation of children, (2) appropriation of terms by children, (3) use of global strategy by children on therapist for a neutral task and (4) each child uses global strategy for their own on another neutral task
10–18	Global strategy Guided discovery Each activity worked for 15 min maximum	Use of global strategy by children in their targeted activities Therapists use guided discovery with each child to help him discover plans and other strategies by himself

Procedural fidelity related to the CO-OP approach will be measured through three recorded sessions randomly chosen from the 10 sessions carried out during the stage B intervention (30% of the sessions).²⁰ All therapists were trained by a certified CO-OP instructor and will follow the CO-OP manualised procedure.⁷ The therapists involved in the group-based intervention have been certified as CO-OP therapists by the International Cognitive Approaches Network beforehand to ensure the procedural fidelity of the CO-OP intervention. Two external evaluators will assess procedural fidelity using the CO-OP approach fidelity grids.¹⁸ A fidelity rate of 80% or more is expected. Indeed, procedural fidelity improves both internal validity (the intervention is delivered as intended) and external validity (the intervention can be replicated and applied in real-world settings).²⁵ SCED standards include the need to assess procedural fidelity.^{26–29}

Patient and public involvement

Children and their parents were not involved in the design, or conduct, or reporting of our research. A simplified version of the scientific articles will be made available to children and their families.

Outcome measures

Activity performance (primary outcome measure)

PQRS, developed specifically for research on the CO-OP approach, is the primary outcome measure used to quantify activity performance at each of the five activities chosen by each child.³² The PQRS is a 10-point observation-based rating scale ranging from 1 (performance not at all successful) to 10 (performance completely successful), with higher scores indicating better performances. The PQRS has a significant inter-rater reliability (ICC) of 0.83–0.93.³²

All activities performed by children will be video-recorded for later PQRS rating by two trained independent evaluators, blinded to the timing of the evaluation of each of the three stages of the study. The order of the video clips will be randomly shuffled. Metadata will be stripped from videos to maintain blinding. Each child will be attributed a code to preserve their anonymity. ICC will be sampled in all stages for 20% of PQRS score.²¹ ICC will be calculated for the PQRS primary endpoint between the assessment performed by the primary examiner and the one performed by the independent assessors. The interpretation of ICC values will be done using the following threshold values: acceptable starting from 0.70, good at 0.80 and very good at 0.90.³³

Secondary outcome measures

The secondary outcomes are performance and satisfaction self-evaluation in targeted activities respectively rated by children and their parents. It will be measured using the Canadian Occupational Performance Measure (COPM) administered by therapists using the CO-OP approach.³⁴ The COPM is a semistructured interview conducted by

Table 2 Potential activities chosen for each child according to Canadian Occupational Performance Measure (COPM)

Home activities	School activities	Leisure activities
Cutting	Using compass	Soccer (shoot)
Tying shoelaces	Drawing line with ruler	Using a racket
Unscrew a bottle	Colour without going over	Catching a ball
Spread butter	Cut with scissors	Throw a ball
Snap a zipper	Drawing line with ruler	Hold playing cards fanned out
Unscrew a bottle	Store in plastic sheet	To distribute playing cards
Carry a pile of clothes		To dribble
To serve water in a glass		
To tie one's hair		
To button		
To brush teeth		

therapists with both children and parents. The measure enables therapists to target functional improvement objectives (ie, motor activities) and captures changes in performance and satisfaction over time as perceived by participants. Table 2 compiles the activities individually selected by the children from the five experimental groups. Participants are asked to rate their performance and satisfaction on a 10-point Likert scale, from 1 to 10. Test-retest reliability is estimated between 0.84 and 0.92.³⁵ A difference of two points between pretest and post-test measurements is considered clinically significant.³⁶

Another secondary outcome is children's QoL assessed with the Kidscreen-27 (self-questionnaire and parent-proxy version).³⁷ The Kidscreen-27 measures children's QoL through five dimensions: (a) physical well-being, (b) psychological well-being, (c) autonomy and parents, (d) peer relationships and social support and (e) school environment. This self-report measure can be used for children and adolescents with chronic conditions, aged 8–18 years. Two forms are available: self-questionnaire for children and parent-proxy questionnaire. Parents and their child are asked to rate their QoL during the last week from 'not at all' to 'extremely' to questions. Cronbach's internal consistency reliability is rated as good to excellent for the Kidscreen-27 subscales with α between 0.74 and 0.95.³⁷ COPM and Kidscreen-27 (child and parent version) will be administered during individual meeting during stages A and C.

The last secondary outcome is the spontaneous motor rhythm, commonly used to assess sensorimotor patterns in children with neurodevelopmental disorders.^{38–40} While the PQRS is a direct measurement of the performance of daily activities, this measure assesses the basic sensorimotor functions.³⁸ At each of the 23 sessions, children will be required to complete a computerised typing task. In this task, children must produce 80 keystrokes

on the space bar of a keyboard at their own pace, in a comfortable way, 'as if they had to do it for hours'. The average obtained for beats per minute over 80 keystrokes will be used. This average is calculated automatically.

Data analysis

Primary outcome measures

An analysis of the PQRS scores will be performed for each group and for all participants using visual analysis and statistical analysis (effect size estimation).

Visual analysis

A visual comparison of two contiguous stages (baseline vs intervention and intervention vs follow-up) will be performed using the Visual Aid Implying an Objective Rule protocol (VAIOR protocol),⁴¹ including analyses of level, trend, variability and overlap of data between two contiguous stages. The VAIOR protocol allows for the creation of graphs where the difference in level with or without trend correction between two consecutive phases is represented by the colour of data points in the second phase: data points are red if they are strictly lower than those in the previous phase, yellow if they are at the same level and green if they are strictly higher. This facilitates visual analysis and makes it more objective.⁴¹ Conversely, certain interventions have an immediate effect on performance. The effects can then be analysed from the first intervention session. We have, however, the hypothesis of a delayed effect related to the nature of the CO-OP intervention. Indeed, improving performance with CO-OP intervention requires several sessions. Thus, we will use an analysis option that does not consider the first three measurement points of the intervention phase. According to the VAIOR protocol, an analysis will be performed for each participant for (1) baseline trend, using the Theil-Sen method^{42 43}; (2) the variability band, in other words, the variability around the baseline trend, using the median of the absolute deviations (ie, the median of the absolute deviations from the reference values according to the trend line adjusted with the Theil-Sen method); and (3) the percentage of data points in the intervention stage which was above the projection of the variability band. Finally, we answer the question, 'Does the group CO-OP intervention seem to improve activity performance?', on the basis of the overall effect of the group-based CO-OP, considering all data points from the intervention stage.⁴¹ To perform this visual analysis, we will refer to the website <https://manolov.shinyapps.io/TrendMAD>.

Statistical analyses and effect size estimation

At the individual level, comparisons between stages will be made using the τ measure, a version of Tarlow,⁴² in order to obtain an effect size. This version of τ was developed to overcome the influence of the baseline trend often found in time series data. Tarlow's version of τ is considered an improved effect size statistic over other methods in the field of SCEDs.^{42 44} The final size of the τ effect (ES) is between -1 and +1 and indicates the strength and

direction of the treatment effect on children's performance quality of chosen activities (PQRS score). τ values greater than zero indicate a positive association between the intervention (CO-OP group) and the PQRS score, regardless of the trend present in the baseline. Analyses will be performed using the website <http://www.ktarlow.com/stats/tau>.

At the group level, PQRS scores will be aggregated by group and then for all by calculating the Between-Case Standardised Mean Difference (BC-SMD). BC-SMD calculates an effect size between several participants rather than for each participant.⁴³ Additionally, BC-SMD is particularly indicated in multiple-baseline SCEDs across subjects measuring a minimum of three participants.^{45 46} This measure is a counterpart to Cohen's *d*, often used as a measure of effect size in randomised controlled trials. The size of the BC-SMD effect can be interpreted according to the following scale⁴⁷: small (0.20–0.50), medium (0.50–0.80) and large (≥ 0.80). BC-SMD analyses will be performed using the website <https://jepusto.shinyapps.io/scdhlml/>.

Secondary outcome measures

The performance and satisfaction self-assessment (COPM scores), and children's QoL (Kidscreen-27), will be collected as preintervention and postintervention measures.

Statistics

A Wilcoxon test (non-parametric) will be used to determine the presence of a significant difference in both variables when comparing premeasure and postmeasure on COPM and Kidscreen-27 scores. Effect size estimates will be calculated from the Wilcoxon test with the software Statistica. Finally, the mean and SD of spontaneous motor rhythm will be compared between the three stages (baseline, intervention and follow-up) using repeated measures with analysis of variance (ANOVA) (or the non-parametric Friedman version, according to the normality of the distributions assessed by the Shapiro-Wilk test) with the software Statistica to determine if a significant difference is present.

DISCUSSION

The effectiveness of the CO-OP approach used on children with DCD has been widely validated.^{48–51} The effectiveness of a group-based CO-OP approach has been less studied and evidenced,¹⁶ although recommended by international practice guidelines.⁶ It is admitted that group-based design improves psychosocial dimensions, such as self-esteem and sense of belonging,¹¹ and also reduces healthcare costs.¹² The effectiveness study would help to enhance the value of CO-OP intervention groups for greater patient benefit, creating a new healthcare offering. Further research is needed to support the effectiveness of this approach and generalise its use.

DCD is a common neurodevelopmental disorder diagnosed in 5%–6% of the general population, but its strong heterogeneity¹ is a challenge for the recruitment of large samples required to conduct randomised controlled trials. A multiple-baseline SCED, repeated across subjects, is a rigorous and relevant alternative method to assess the effectiveness of complex interventions such as CO-OP.²² Additionally, SCED used will enable a more in-depth understanding of the various active principles at play during group interventions, potentially allowing for optimisation based on individual child characteristics.

Ethics and dissemination

The research was validated by the Comité de protection des personnes Sud-Est I, France (Reference CPP 2021-070) and registered with the Identifiant de la Recherche Biomédicale (ID RCB) (Project 2021070; 21.05.07.62358). Ethics approval was obtained from the Comité d'éthique de la recherche avec les êtres humains de l'Université du Québec à Trois-Rivières, Canada (CER-22-294-07.03). The clinical trial (second version, January 2023) is registered on ClinicalTrials.gov (ID: NCT05231486). The research start date is 11 January 2023. In accordance with authorisation from the French Commission Nationale de l'Informatique et des Libertés, directly identifying data will be processed and transmitted separately from health data and recorded in a separate database. Furthermore, only a strictly limited number of authorised persons subject to professional secrecy will be able to access directly identifying data. Video recordings will be kept for 4 years and then destroyed. Other data will be kept for 4 years in database active and 15 years in archiving. The results will be published in peer-reviewed journals. Communications will be submitted to conferences in the form of posters and oral communications.

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