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Efficacy of CO-OP Approach With and Without Parental Coaching: RCT Study Protocol

Efficacité de l'approche CO-OP avec et sans coaching parental : protocole d'essai clinique randomisé

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Key words: Activity; Children; Developmental coordination disorder; Motor skill disorders; Occupational therapy; Participation.

Mots clés : Activité; enfants; ergothérapie; participation; trouble développemental de la coordination; troubles de motricité.

Abstract

Background. Developmental coordination disorder (DCD) leads to decreased occupational performance and restricted participation. Cognitive Orientation to daily Occupational Performance Approach (CO-OP) is effective, and as parental support is a key element, it seems relevant to investigate. **Purpose.** To describe a study protocol that will compare CO-OP with and without Occupational Performance Coaching (OPC) on activity and participation of children with DCD. **Method.** Randomized controlled with seven to 12-year-olds, assigned to either experimental (CO-OP+OPC) or control (CO-OP) group, both receiving traditional CO-OP, with four additional parental group sessions for the experimental group. **Key Issues.** Actual and perceived occupational performance and satisfaction of children's chosen goals and participation, motor performance and executive function. Measures will be obtained at baseline, post-intervention, and at 3-month follow-up. **Implications.** Detailed description of an intervention protocol may help further replication and may contribute to clarify if a boost on parents' participation promotes better outcomes for children with DCD. **Trial registration.** Clinical Trials, NCT02893852. (https://clinicaltrials.gov/ct2/show/NCT02893852)

Abrégé

Description. Le trouble développemental de la coordination entraîne une réduction du rendement occupationnel et des restrictions dans la participation. L'approche CO-OP est efficace et, étant donné que le soutien parental joue un rôle fondamental, il semble pertinent d'étudier cette approche. **But.** Décrire un protocole de recherche qui comparera les effets de cette approche d'intervention, avec et sans coaching du rendement occupationnel, sur les activités et la participation d'enfants atteints d'un trouble développemental de la coordination. **Méthodologie.** Essai randomisé contrôlé, auprès de participants de 7 à 12 ans affectés à un groupe expérimental (intervention CO-OP + coaching du rendement occupationnel) ou témoin (intervention CO-OP). Les deux groupes bénéficieront d'une intervention CO-OP traditionnelle, mais dans le groupe expérimental, les parents bénéficieront de quatre séances supplémentaires en groupe. **Questions clés.** Amélioration du rendement occupationnel réel et perçu, atteinte des objectifs sélectionnés par les enfants et participation des enfants, amélioration de la performance motrice et des fonctions exécutives. Trois collectes de données seront réalisées, soit avant et après l'intervention, de même que trois mois après la fin de l'intervention. **Conséquences.** La description détaillée d'un protocole d'intervention permettra de reproduire l'étude et de déterminer si une participation accrue des parents mène à de meilleurs résultats auprès des enfants atteints d'un trouble développemental de la coordination.

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Introduction

Children with developmental coordination disorder (DCD) have difficulties to perform activities that require motor skills, which negatively impact their everyday life and participation (Blank et al., 2019; Izadi-Najafabadi et al., 2019; Magalhaes et al., 2011; Sylvestre et al., 2013). The Diagnostic and Statistical Manual of Mental Disorders—fifth edition (DSM-5) describes four criteria to diagnose DCD: (a) the acquisition and execution of coordinated motor skills are substantially below that expected regarding the child's age and opportunity to learn and use a skill and the difficulties are manifested as clumsiness, slowness, and inaccuracy of performance of motor skills; (b) those motor deficits significantly and persistently interfere with activities of daily living appropriate to chronological age and impacts academic/school productivity, prevocational and vocational activities, leisure, and play; (c) symptoms occur in the early developmental period; and (d) the motor skills deficits are not better explained by intellectual disability or visual impairment, and they are not due to a neurological condition affecting movement (American Psychiatric Association, 2013).

The most reported prevalence of DCD in children is 5%−6% regardless of their culture, race, and socioeconomic conditions, affecting boys more than girls (Blank et al., 2019) with higher prevalence amongst children who were born prematurely (Zwicker et al., 2013a, 2013b). Children with DCD may have deficits in essential cognitive functions (executive functions—EF) (Wilson et al., 2013), such as the ability to control attention, behavior, and emotions (inhibitory control), to keep information and to work mentally with it (working memory), and to change or to adjust perspectives to changed demands (cognitive flexibility) (Diamond, 2013). Those deficits can interfere on movement planning preventing the acquisition of more complex motor skills, and ultimately impacting school performance (Diamond, 2013; Sartori et al., 2020).

Children with DCD are susceptible to lower academic performance and peer problems that can be increased by the association with attention deficit disorder, learning disabilities, low self-esteem, and low self-efficacy (Missiuna & Campbell, 2014). They experience participation restrictions (Izadi-Najafabadi et al., 2019), and they frequently refuse to engage in active play, and leisure activities, which may increase socialization problems (Cairney et al., 2012). According to the International Classification of Functioning, Disability, and Health (ICF, World Health Organization, 2007) participation mean "involvement of a life situation," while participation restrictions are described as "problems that the person may experience when involving in a life situation." Studies report that feelings of self-efficacy and self-perception might influence the motivation of children with DCD to participate and to engage in peer relationships (Engel-Yeger & Hanna-Kasis, 2010; Poulsen et al., 2007; Tal-Saban et al., 2012).

Blank et al. (2019) indicate that activity- and participation-oriented approaches are the best interventions to improve functional performance in individuals with DCD, but rigorous randomized controlled trials (RCTs) with follow-up are needed to evaluate long-term outcomes related to psychological problems, engagement, and sustained participation (Miyahara et al., 2017; Smits-Engelsman et al., 2018). A few studies investigated whether participation patterns of children with DCD change with intervention (Blank et al., 2019). The Cognitive Orientation to daily Occupational Performance Approach (CO-OP) is an occupation-based, goal-based, activity- and participation-oriented intervention (Polatajko, 2017). Through cognitive strategy use, the therapist helps the child to learn and acquire skills to improve occupational performance, generalization, and transfer (Polatajko, 2017; Polatajko & Mandich, 2004). Generalization is the ability to perform the same skill in different contexts with variation of places, people, or time (McEwen & Houldin, 2017). Transfer is the ability to use similar skills to learn and perform a different task within a different context (McEwen & Houldin, 2017).

During CO-OP, the therapist teaches the global strategy of goal-plan-do-check to the child, which acts as a framework for the problem-solving process. Through guided discovery, the therapist engages the child on a problem-solving process to identify performance breakdowns and to discover specific cognitive strategies to overcome these breakdowns and to accomplish goals related to daily occupations (Polatajko & Mandich, 2004). CO-OP is effective with children with DCD and it was adapted to other clinical populations and into different intervention formats (length, number of sessions, and groups) (Martini et al., 2014; Scammell et al., 2016; Zwicker et al., 2015).

Children with DCD with problems in executive functions tend to have difficulty to do everyday tasks, and they may require more support from parents and teachers (Bernardi et al., 2018). The performance of new tasks can also represent a challenge as the ability to change actions already turned automatic (cognitive flexibility and inhibitory control) to do different activities in other contexts (generalization and transfer) is compromised. CO-OP is highly embedded in learning theories, and the use of strategies to solve performance problems is one of its main objectives, but studies that investigate whether the intervention might improve executive functions are still to be done.

Although the involvement of parents and significant others was defined as *key feature* of CO-OP, parents' role during intervention must be better explored (Capistran & Martini, 2016; Chan, 2007; Missiuna et al., 2010; Scammell et al., 2016). The strategies suggested by Cameron et al. (2017) are important to apply during CO-OP, and those are expected to be used in family-centered practices. Cameron et al. (2017) described that parents had specific difficulties to use the strategies with their child at home, to ask the right questions, to have enough time to implement CO-OP and to do the homework. Capistran and Martini (2016) found similar barriers related to the parents' involvement and reported other issues like lack of space at home and avoiding conflicts with the child.

Previous research shed light on the matter, and barriers to the effective CO-OP implementation by parents converged as

an issue to be addressed. Parent's involvement and the quality of their participation in CO-OP rarely are the primary objectives. Those studies somehow analyzed parental involvement, but they had small sample sizes and diverse designs that did not specifically address the topic (Araújo et al., 2019; Capistran & Martini, 2016; Chan, 2007; Missiuna et al., 2010). Evidence is beginning to emerge (Cameron et al., 2017), but according to Scammel et al. (2016), research is still limited.

Power et al. (2002) identified multiple challenges that may hinder success in helping families. The characteristics of the family and the child, and cultural issues can influence adherence to treatment strategies, the completion of homework, therefore, increasing the family's stress level. Environmental and personal factors of children and parents may determine how they engage in therapy (Power et al., 2002). Socioeconomic status, history of parents' behavior, and practices should also be considered in investigations with the CO-OP approach. Some parents may need systematic assistance to set their own goals to enable their children to use cognitive strategies at home, to improve their own performance helping their children during CO-OP homework, and to find enough time to compromise, considering that these factors can potentially interfere with occupational performance change.

Graham et al. (2009) and Graham and Rodger (2010) proposed the Occupational Performance Coaching (OPC) to guide parents to solve problems related to their performance, including the improvement of their role as parents (Graham & Rodger, 2010; Graham et al., 2009). OPC focus on the enablement of children's and parents' participation in occupations at home and in the community facilitating parent-identified solutions to performance barriers (Graham et al., 2009). OPC is based on enablement principles, family-centered, and occupation-based practices (Graham et al., 2009) which align with CO-OP (Polatajko & Mandich, 2004). OPC considers generalization and transfer of skills and can be added to existing intervention programs (Graham & Rodger, 2010). The authors recommend its use when goal achievement is dependent on the context or when parents want to develop their own skills to support their children's learning and performance (Graham et al., 2009). These are key features to successful parental involvement, especially for children, and parents can affect their performance and choices, influencing on the achievement of occupational performance goals (Graham et al., 2009).

It seems reasonable to investigate OPC as a possible strategy to boost parents' engagement on their child's occupational therapy with CO-OP. OPC is a systematic approach that can improve the collaboration with parents, and if applied in group format may contribute to a sharing experience environment for parents. To date, there is no OPC intervention in groups of parents. In this study, we will explore the use of OPC in parental groups in addition to CO-OP to improve their involvement, and to investigate whether this will imply on better outcomes for children with DCD.

The primary objectives are: (a) to investigate the efficacy of CO-OP approach with (CO-OP+OPC) and without OPC (CO-OP) on perceived and actual occupational performance and satisfaction of children with DCD and their parents on trained and transfer goals, and on participation; and (b) to compare the efficacy of CO-OP+OPC versus CO-OP on the same outcomes. The secondary objectives are: (c) to investigate and to compare the efficacy of CO-OP+OPC and CO-OP on motor performance; and (d) executive functions (i.e., cognitive flexibility, inhibition, and mental planning) of children with DCD. The trial's hypotheses are that CO-OP+OPC and CO-OP will be effective on improving outcome measures of children and parents; children submitted to CO-OP + OPC will have superior results on primary and secondary outcomes post intervention and at a 3-month follow-up.

Method

Design and Setting

This study is a parallel randomized clinical trial with an add-on component. The CO-OP approach will be delivered to all participants. One group (experimental group) will receive an addition of four sessions of coaching in groups for parents which will be compared to the control group, receiving only CO-OP. The study was approved by the Ethics on Research Committee of the Universidade Federal de Minas Gerais/Brazil (Protocol number 1.520.296, April 20, 2016, and registered at Clinical Trials.gov (NCT2893852) by the United States Institutes of Health.

The study will take place at School of Physical Education, Physical and Occupational Therapy of the Federal University of Minas Gerais (EEFFTO/UFMG), at the city of Belo Horizonte, state of Minas Gerais, southeastern Brazil. The first author (CRSA) will be responsible for all intervention procedures. She is an experienced clinician, used to deal with groups of parents and teachers, who was trained on CO-OP Approach™ (Polatajko & Mandich, 2004).

Participants and Procedures

Children (aged 7−12 years) who meet the DSM-5 diagnostic criteria for DCD will be eligible. Recruitment will occur by active search at the waiting list of the Investigation and Intervention on the Development of Children and Adolescence (IDEIA laboratory) which offers OT services at the university of the study; primary schools and rehabilitation clinics; advertisements in social medias. To assess for eligibility criteria, parents will be interviewed, and they will respond to a health questionnaire.

Participation in the study will be offered if they fulfill all the following inclusion criteria, in accordance with the DSM-5 diagnostic criteria for DCD but using the cut-off points as suggested by Smits-Engelsman et al. (2015): (A) acquisition and execution of motor skills substantially below that expected given chronological age and opportunity for skill learning and use—assessed with the Movement Assessment Battery for Children Second Edition (MABC-2) (Henderson et al., 2007), a total percentile of <16 is needed

for inclusion; (B) those deficits significantly interfere with activities of daily living and impacts academic productivity, leisure, and play as appropriate to chronological age, assessed with the Brazilian version of the Developmental Coordination Disorder Questionnaire (DCDQ-Brazil) (Prado et al., 2009); (C) symptoms occur in the early developmental period, according to parents' reports on their children's health and educational conditions to establish the onset of the motor coordination problems and its repercussions on daily life; (D) motor skills deficits are not explained by intellectual disability or other neurodevelopmental conditions—cognitive performance will be assessed with the Brazilian version of the Wechsler Intelligence Scale for Children Fourth Edition (WISC-IV) (Wechsler, 2013), a total IQ $\geq$ 70 will be needed for inclusion and the developmental and medical history reported by parents on the health questionnaire or a medical source if needed.

Children with co-occurring conditions, such as ADHD or learning disorders, or children with a history of preterm birth will be eligible to participate. Children will be characterized by the presence or not of attention problems, anxiety/depression issues, self-perception, while parents will be described by parenting style, number of school years, and socioeconomic status. Exclusion criteria: child meets criteria for any diagnostic condition that could interfere with motor performance (visual impairment, cerebral palsy, autism spectrum disorder, and neuromuscular conditions affecting movement); child presents oppositional defiant disorder (ODD) influencing negatively on behavior (Figure 1).

Parents will be advised about the nature of the study and the possibility or not to be invited to participate. If the child does not meet inclusion criteria, he/she will be properly referred. Parents and children included will be required to signed informed consent and assent forms, respectively, to confirm participation. Two trained evaluators external to the study will assess the children with the MABC-2 and a psychologist will evaluate children with WISC-IV.

Participant timeline. The timeline of participants is set by starting from initial eligibility screening through allocation, pre-post intervention assessments, intervention period, and follow-up, until the study close-out (Figure 2).

Sample size. An a priori sample size test of power was performed using the software G*Power. Data from the pilot study of Miller et al. (2001) were used to detect clinically relevant differences between intervention and control group in one of the primary outcome measures (performance ratings on COPM), with an α value of 5% and a power of 80%. The analysis accounted for at least 10% dropout rate. Eleven participants per group are needed to detect clinically relevant effects.

Allocation. Children who meet inclusion criteria will have a number and this information will be concealed. After baseline assessment, they will be sequentially allocated (allocation ratio 1:1), by the research coordinator, to either experimental or control group, according to the random allocation computer generated by *randomization.com*.

Blinding. The main investigator is the occupational therapist who will provide care for both groups. Consequently, due to the nature of the therapeutic intervention, participants (children and parents) are unable to be blinded to group allocation. To reduce participants' (parents) bias, they will not be informed of the study hypotheses. Assessors will be blinded to group allocation and assessment order. Data will be entered by a research assistant who is not directly involved with the intervention. Data analysts will be blind to group allocation.

Interventions

CO-OP will be delivered for 10 weeks with one or two 60-min sessions per week. Parents of children in the experimental group will receive four extra 60-min sessions, in groups with a minimum of four participants, every other week to be arranged and scheduled according to parents' needs. Parents of both groups shall be present in at least eight out of ten intervention sessions. There will be a 3-month follow-up period.

To keep adherence and compliance to treatment, the decision of one or two sessions per week will be given to parents and children. Participants will not be asked to leave other types of intervention, like psychology or school tutorials, but they will be asked not to engage in other occupational or physical therapy.

The original CO-OP protocol will be used (Polatajko & Mandich, 2004). The parents of the experimental group will have four extra sessions in a group format following the OPC protocol developed by Graham et al. (2009) and Graham and Rodger (2010). Both CO-OP and OPC protocols are available through manuals (Graham & Rodger, 2010; Polatajko & Mandich, 2004). The occupational therapist conducting the interventions has more than 10 years of clinical experience.

All parents will receive a booklet designed for this study and based on previous experience, with information regarding CO-OP and additional suggestions on how to implement cognitive strategies use and guided discovery to support occupational performance and participation at home

CO-OP approach protocol. The original CO-OP protocol will be applied in both experimental and control groups. One of the main assumptions on the development of CO-OP is that the use of a global strategy (goal-plan-do-check) encourages metacognitive processes and helps the child to think and reflect about the goal, to formulate a plan to achieve it, and correct the plan if needed (Polatajko & Mandich, 2004). The main objective is to guide the child, through strategy use, to do task analysis and understand what the potential problems are interfering with performance. The therapist guides the child to select the best skill or strategy, to refine the plans, and to

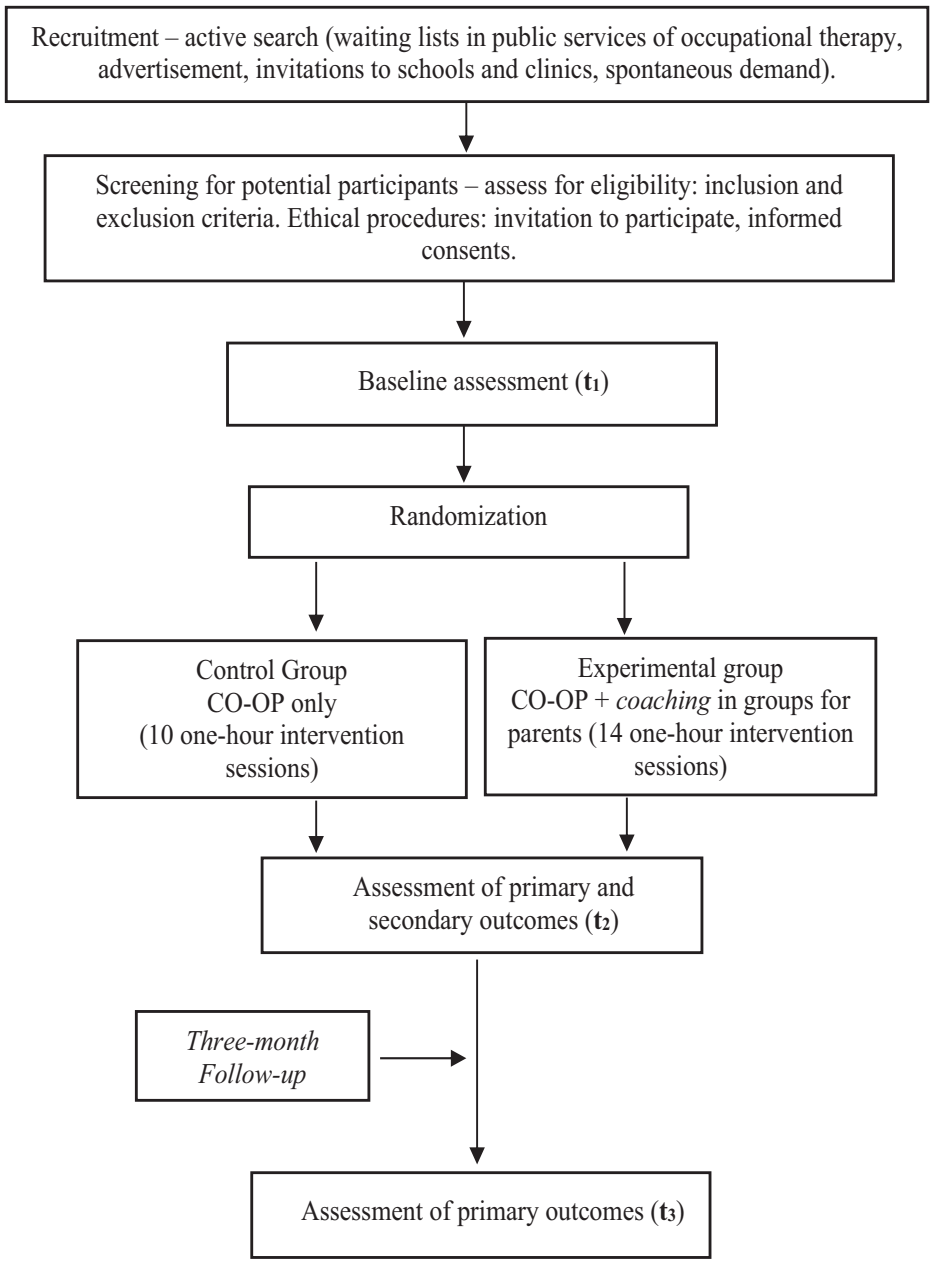

Figure 1. Flowchart of the study.

achieve the goal (Polatajko & Mandich, 2004). During the interactions, the therapist uses guided discovery techniques (i.e., asks questions and do one thing at a time). Guided discovery is an active learning process in which the therapist or teacher supports the child to find out actions, relationships or rules that he or she was not previously aware, and which can help to improve performance (Skidmore et al., 2017). As part of the original CO-OP protocol the following steps will be taken after the selection of goals (Table 1).

The intervention sessions will be divided as follows: (a) 5−10 min to discuss the homework; (b) 45−50 min on task: revision and refinement of plans, practising skills and tasks, checking what works best; (c) 5−10 min for sum-up and decide about next homework. Child, family, and therapist will share decisions about what task will be addressed in each session. The child's opinion will prevail to keep motivation and adherence.

The sessions will be videotaped to check for fidelity, by a clinician with experience on delivering CO-OP sessions, according to the fidelity checklist proposed by McEwen et al. (2012) and translated to Brazilian Portuguese by our research team.

Parental coaching in groups. The experimental group will receive the addition of four 60-min sessions of parental coaching, delivered in groups with a minimum of four parents. This protocol was constructed based on the OPC (Graham &

	STUDY PERIOD				
	Enrolment	**Allocation**	**Post-allocation**		**Follow-up and Close-out**
TIMEPOINT	$-t_1$	t_0	t_1	t_2	t_3
ENROLMENT:					
Eligibility screen	X				
Informed consents	X				
Allocation		X			
INTERVENTIONS:					
[CO-OP + Parental coaching in groups]			⟷		
[CO-OP+OPC]			⟷		
ASSESSMENTS:					
Motor performance; cognitive function; levels of anxiety/depression; signs of ADHD; self-perception and self-efficacy.	X	X			
Parental style; parents' demographics	X	X			
Primary outcomes: occupational performance, satisfaction – children, parents, external assessors			X	X	X
Primary outcome: participation			X	X	
Secondary outcomes: motor performance, cognitive flexibility, mental planning			X	X	

Figure 2. Schedule of enrolment, interventions, and assessments.

Rodger, 2010). OPC combines performance analysis frameworks of live performance (observation of tasks in natural context) with coaching techniques to engage parents, in collaborative and goal-specific conversations, to identify enablers and barriers to improve the child, parent, and family performance within the home and community.

The OPC incorporates three domains: (a) emotional support; (b) information exchange; (c) structured process. Each parent will set their own goals in every session and the goals will be related to: (1) provision of support for occupational performance and participation of children at home and in the community, (2) identification of barriers to implement strategy use in other contexts, (3) enabling solutions to implement strategy use and guide discovery with their children. During each session, parents and therapist will be expected to engage in collaborative analysis of the goals to support occupational performance and participation of their children (Table 2).

The group sessions will happen in the same facility of the children's sessions, in a room designed for group meetings. The four sessions will be delivered every other week, beginning

Table 1
Proposed Actions According to the Original CO-OP Protocol for Both Groups

Study Time frame	Steps	Actions
t_1	(1)	Child and family will set scores on occupational performance and satisfaction
t_1	(2)	Child will perform the chosen tasks that will be videotaped to be scored by the external evaluators
t_2	(3)	Therapist view the tapes to analyse performance breakdowns in order to select the best strategies to solve performance problems and guide the child in discovering possible solutions
t_2	(4)	Therapist presents the global strategy goal-plan-do-check using a puppet or other mnemonic resource
t_2	(5)	Child, therapist, and family will engage on the intervention session for 60 min
t_2	(6)	During the intervention phase, the child will receive homework designed to stimulate strategy use at home and other contexts, to foster generalization and transfer
t_2	(7)	The child will be videotaped performing the same tasks filmed previously and child and parents will set scores on occupational performance and satisfaction
t_3	(8)	After 3 months the child will be videotaped performing same the tasks again and child and family will set scores on occupational performance and satisfaction

right after the second intervention session on CO-OP approach (which is the first session of strategy use using guided discovery). Families and therapist will share decisions concerning time, the sessions will be scheduled to encourage engagement and adherence.

This is the first time that OPC protocol is being used in the Brazilian context. Researchers will follow the manual proposed by Graham and Rodger (2010) and the sessions will be videotaped to check for accuracy of the developed protocol.

Goal Setting. Children and parents will be asked to talk about their daily activities and to choose three goals to achieve during the intervention and one extra goal (transfer goal) as the outcome measure for transfer (Capistran & Martini, 2016). Children will choose their goals with the perceived efficacy and goal setting system (PEGS) (Missiuna et al., 2004; Ruggio et al., 2018), which helps children to evaluate self-efficacy and choose therapy goals. PEGS is a structured interview with 24 paired cards with drawings of children doing poor or good performance on typical childhood activities. It can be used with six-year-old children and older and comprises parents' and teachers' questionnaires to combine perspectives. The occupational therapist will ask the children and parents to score each goal with the Canadian Occupational Performance Measure (COPM) 10-point scale scoring system. Children will be videotaped performing all the chosen goals to be analyzed regarding actual performance on the external assessment.

Data Collection

Instruments

Characteristics of participants. The Swanson, Nolan, and Phelham (SNAP-IV) (Mattos et al., 2006) will be used to screen for signs of attention deficit and hyperactivity disorder (ADHD). SNAP-IV statements comprehend nine symptoms of inattention, six of hyperactivity, and three of impulsivity and will be answered by parents. It is a 4-point scale that screens if one statement is "not at all" (zero point) to "a lot like" (three points) to the behavior of the children.

Socioeconomic status will be estimated by the Economic Classification Criteria Brazil (Associação Brasileira de Empresa de Pesquisa [ABEP], 2014), which estimates the purchasing power of urban people and families, providing the classification of the population in economic classes.

Parents will answer the Child Behaviour Checklist (CBCL) (Achenbach, 1991; Bordin et al., 1995) to screen for emotional, behavioral, and social problems possibly co-occurring with DCD. The CBCL evaluates eight different categories of symptoms: anxious/depressed, withdrawn/depressed, somatic complaints, social problems, thought problems, attention problems, rule-breaking behavior, and aggressive behavior. The CBCL also analyzes competence on activities, social relations, and at school. The child's symptoms can be classified into three groups: clinical, borderline, or non-clinical. The authors report test-retest reliabilities of 0.73−0.94, internal consistency reliabilities of 0.63−0.97, and inter-rater reliabilities of 0.57−0.88.

Self-perception profile for children (SPPC) (Harter, 1988; Valentini et al., 2010): this evaluates the perceived competence of children aged 8−12 years; with six subscales in five specific domains of competence—school competence, social acceptance, athletic competence, physical appearance, and behavioral conduct, in addition to the global self-concept subscale. The SPPC has 36 questions, scored on a Likert scale of 1−4 points, in which the child identifies how much each item is perceived as "really true" or "partially true" for her/him (Valentini et al., 2010). SPPC has strong test-retest reliability ($r = 0{,}83$) and Tucker and Lewiśs index of fit (TLI $\leq$ 0,962) of confirmatory factor analysis.

The parental style inventory (IEP) (Gomide, 2006) is a questionnaire to identify parental practices that are used and their potential influence on the child's behavioral development. It is composed of 42 statements that the mother or father needs to indicate how they act or would act according to the situation described. The results of IEP account for these educational

Table 2
Coaching Protocol for the Experimental Group Based on OPC Principles for Each of the Four 60-min Extra Sessions

OPC enabling principle	Key facilitating actions
Emotional support	Listening to parents' information and interpretation of the child's performance
	Motivators for change
	Learning needs in implementing change and previous success in enabling performance
	Expressing empathy
	Assisting parents in reframing their perceptions of the child's performance
	Enabling performance and guiding parents' reflections and choices of action
	Encouraging persistence and future independent problem-solving
Information exchange	Discussion between the group of parents and the therapist regarding
	a. Collaborative performance analysis
	b. Understanding typical development
	c. DCD children, common co-occurrences and their challenges
	d. Teaching and learning strategies
	e. Finding and accessing community resources
	f. Implementation of guided discovery in different settings
Structure the process	Goal setting
	Explore available options to support their children's occupational performance and participation
	Action planning
	Figuring out how to carry out the plan
	Checking performance and generalization

practices: (A) positive monitoring, (B) moral behavior, (C) negligence, (D) inconsistent punishment, (E) relaxed discipline, (F) negative monitoring, and (G) physical abuse. The interpretation follows the percentile obtained: from 75 to 99—optimal parental style, with a marked presence of positive parenting practices and absence of negative practices; 55 to 70—good parenting style, above average; 30 to 50—good parenting style, but below average; below 25—refers to a risky parenting style. Data interpretation will be performed by the collaborating psychologist.

Outcome measures. Outcomes will be assessed by professionals previously trained and checked for reliability. Assessors will be blind to group allocation, except the therapist, the main investigator, that will provide the intervention.

Primary outcome measures—related to the first and second study objectives. Occupational performance and satisfaction for children and parents. The Canadian Occupational Performance Measure (COPM) (Law et al., 2009) 10-point score system will be used to score occupational performance and satisfaction by the children and their parents at baseline, post intervention, and after a 3-month follow-up. COPM is a semi-structured interview that helps clients on goal setting. It comprises three scoring systems—importance, performance, and satisfaction with performance on a specific goal—on a 10-point scale ranging from 1 = not satisfied to 10 = totally satisfied. Test-retest reliability was determined for different populations and it varied from 0.84 to 0.92 (Law et al., 2009). It is useful with children and adaptations might help (Law et al., 2009). Two-point change is considered clinically relevant (Law et al., 2009).

Actual occupational performance (external evaluation). The Performance Quality Rating Scale—Generic (PQRS-G) (Martini et al., 2015; Polatajko & Mandich, 2004) will be used by external, blinded evaluators at baseline, post intervention and after a 3-month follow-up. They will analyze videoclips of children performing their goals on a random sequence to mask for timeline. They will be trained to establish a good reliability index. The PQRS-G is an observational measure on a 10-point scale originally developed by Polatajko and Mandich (2004) to be used with the CO-OP approach. PQRS-G has moderate inter-rater correlations with ICCs varying from .71 to .77. A change in a score of 3 is considered clinically relevant (Martini et al., 2015).

Participation. The Participation and Environment Measure for Children and Youth (PEM-CY) (Coster et al., 2010) is a questionnaire developed to help parents, therapists, and researchers to better understand participation of children and youth, five to 17 years old, with and without disabilities. Parents will be interviewed by research assistants at baseline and post intervention. PEM-CY measures frequency, type of activities, and level of involvement regarding participation and the potential influence of environmental factors in 25 activities in different contexts: home, school, and community. PEM-CY has moderate-to-good indexes of internal consistency ($\alpha = .59$ and .91) and test-retest reliability (ICC = .58 and .95) (Coster et al., 2011).

Transfer of skills. The transfer goal that will not be trained during intervention. Occupational performance and satisfaction of children and parents on the transfer goal will be assessed with COPM's scoring system and PQRS-G will be used by the external evaluators at baseline, post intervention, and after a 3-month follow-up. The use of an extra goal to assess transfer was reported by Capistran and Martini (2016) with children, and by Dawson et al. (2009) with adults.

Secondary outcome measures—related to the third and fourth study objectives. Motor performance. The Movement

Assessment Battery for Children Second Edition (MABC-2) (Henderson et al., 2007). The child is observed performing eight tasks in the domains of manual dexterity, aiming, and catching (ball skills) and balance. High scores represent better performance. The inter-rater (ICC values from .86 to .99) and the intra-rater reliability (ICC values from .68 to .85), the test–retest reliability is strong and positive ($r = .74$, Valentini et al., 2014). MABC-2 will be used to screen for eligibility it will be repeated post intervention. Two blinded trained examiners will assess the children.

Executive functioning will be examined via measures of cognitive flexibility and inhibitory control, and a measure of mental planning. Cognitive flexibility and inhibitory control will be evaluated by the five digits test (FDT) (Sedó et al., 2015) which was designed to evaluate the processing speed of executive functions and attentional functioning in individuals with different clinical conditions. It requires a minimal linguistic knowledge to read the numbers one to five, count quantities of one to five, be capable of ignoring (or to inhibit) an automated processing routine (reading) in favor of a controlled one (counting) and be capable of alternating dynamically between the reading and counting. FDT has four sections—reading, counting, selecting, and switching—that inform about processing speed, verbal fluency, and sustained attention. It provides scores on percentile indexes of inhibition and cognitive flexibility. It has good construct and criterion validity for patients of different ages, educational, and cultural backgrounds, and it also has significant correlations with other attention and executive function tests (correlations with the Stroop test were between .65 and .71) (Sedó & Decristoforo, 2001; Sedó et al., 2015).

Mental planning. The tower of London test (TOL) (Shallice, 1982; Krikorian et al., 1994) will be used for measuring planning and aspects of problem solving. The child is asked to move three colored balls and organize them according to 12 different patterns using a minimum number of moves while following three rules: only one ball can be moved at a time, a ball in the lower row cannot be moved when another ball is above, three balls must be placed on the tallest peg, two balls on the middle peg, and one ball on the shortest peg. The participant scores three points for each problem solved at the first attempt, two points at the second, one point in the third, and zero if it is not solved (Malloy-Diniz et al., 2008; Shallice, 1982). Raw scores and solution time will be computed before and after intervention. TOL has been validated for use with children by Anderson et al. (1996). A psychologist will be responsible for all the neuropsychological assessments.

Data management. Data will be entered by a research assistant into Microsoft Office Excel®. All the participants' information will be stored at the laboratory computer protected by a password. All data, including videos, paper-based assessment, intervention notes will be stored at the laboratory for five years according to the approval from the research Ethics Committee.

Adverse events. Adverse events, including pain, discomfort, and disagreements will be recorded throughout intervention and at each outcome measure timepoint. If adverse events are related to the therapy, activities or sessions can be modified or discontinued. If significant or unintended adverse events occur, parents will be encouraged to have the child examined by a physician or allied health care professional.

Data Analysis. First and second objectives will be analyzed with: (a) mean and median changes on in the scores of perceived occupational performance and satisfaction from the COPM provided by both children and their parents from baseline (t_1) to post intervention (t_2) and a 3-month follow-up (t_3); (b) mean and median changes on actual performance scored according to the PQRS-G based on video-analysis by external assessors from t_1 to t_2 and t_3; (c) mean and median changes in the scores on the frequency of participation, number of activities in which the child participates, and the level of involvement of the child at home, in the community and at school provided by PEM-CY from t_1 to t_2; (d) mean and median changes on perceived and actual performance in the scores on COPM and PQRS-G on transfer goals to analyze transfer of skills from t_1 to t_2 and t_3,

Third and fourth objectives will be analyzed with: (e) mean and median changes in the total score on motor performance on the MABC-2 from t_1 to t_2; (2) mean and median changes in the percentile scores on cognitive flexibility and inhibitory control on the FDT from t_1 to t_2; (3) mean and median changes in the time of completion and scores on mental planning on the TOL test from t_1 to t_2.

Statistical methods

Qualitative and quantitative variables will be described by absolute and relative frequencies and measures of central tendency, dispersion, and position.

Fisher's exact test will be used to check for homogeneity between characterization variables (SNAP-IV, CBCL, socioeconomic status, parental styles, parent's level of education, gender—possible confounding variables). Mann-Whitney *U*-test will check homogeneity for age, self-perception, and cognitive performance, and homogeneity of variables of interest at baseline (performance, satisfaction, participation, motor performance, and executive functioning).

Wilcoxon signed-rank test will be used to investigate the efficacy of CO-OP approach with and without OPC on perceived and actual occupational performance, and satisfaction on trained and transfer goals, participation, motor performance, executive functioning for all participants at t2.

Generalized equations estimating (GEE), a method to account for the correlation between repeated measures (Liang & Zeger, 1986), will be used to compare the efficacy of CO-OP+OPC versus CO-OP on the primary and secondary outcomes. Analysis will account for potential confounders, i.e., possible differences between groups at t1. Marginal models will analyze possible factors influencing the variables of interest. Time and group interactions will be included in the multivariate models.

Statistical significance set at $p < .05$. Effect sizes will be calculated by means of *Cohen's d*. The software R (version 3.5.0) will be used in the analyses.

Implications

Over the last two decades, CO-OP accumulated evidence of its effectiveness to reduce functional problems of children with DCD (Blank et al., 2019). The availability of a well described protocol, possibly helped on the replication of studies with CO-OP (Scammel et al., 2016). Despite those advantages, parents', and significant others' engagement, one of the key features of the intervention, still lacks investigation. OPC was developed based on recent evidence regarding the use of coaching, it has some evidence of effectiveness (Graham et al., 2013), but it was not used with parents or children with DCD. It is also important to study whether, how, and to what extent parents might contribute to occupational performance and participation of their children using CO-OP approach alone, or whether there is any difference if added support is given to parents using a protocol based on OPC. Additionally, we will investigate the potential factors influencing change on children's occupational performance after occupational therapy using both approaches.

Over the last years, there was an increase in the publication of clinical trials in rehabilitation sciences, particularly in occupational therapy. Randomized clinical trials can produce empirical data to support clinical practice and advance research in our field. It is important, however, to provide and report clinical research pathways with transparency. Protocols play a valuable role in planning, implementing, conducting, and interpreting results. We hope that the publication of the plan for the study will benefit clinicians, researchers and others interested in this area.

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Availability of data and materials

The datasets and informed consent materials used and/or analyzed during the study will be available from the corresponding author upon request.

Author Contributions

Clarice R.S. Araújo: conceived and planned investigation, conceived, wrote and revised the text; Ana A. Cardoso e Lívia C. Magalhães: conceived and supervised the research project, revised the text.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Dissemination policy

The findings will be published in peer-reviewed journals. Communications will be submitted to conferences and a brief video clip will be developed and available on internet to foster knowledge translation.

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