Study Protocol and Statistical Analysis Plan

Title: Occupational Performance Coaching With Parents of Young Children With Developmental Disability

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1 Introduction

High rates of restricted community participation have been reported in young children with developmental disabilities. Occupational performance coaching (OPC), grounded in self-determination theory, aims to facilitate children's participation in life situations through coaching parents. However, there have been limited randomized controlled trials demonstrating the efficacy of OPC, especially with a specific focus on children's community participation. The proposed study is the first step in evaluating the feasibility and acceptability of conducting a pilot randomized controlled trial of OPC in Hong Kong and testing its initial efficacy (in comparison to parent consultation) in promoting children's community participation.

In this document, we report a study protocol that will be used in the Phase 1 Randomized Control Trial (RCT) which aims to evaluate the feasibility of conducting an RCT of OPC in Hong Kong, the acceptability of the coaching intervention, and the initial efficacy of OPC on promoting children's community participation.

2 Materials and Methods

2.1 Trial Design

We propose a two-arm parallel, double-blind design for this Phase 1 RCT of OPC. Parents of young children with DD will be randomly assigned to the intervention group (receiving OPC), and the control group (receiving parent consultation) and will be blinded to the group type that they are assigned to. Parent consultation is chosen as the component-equivalent control treatment, because it is a common approach used by rehabilitation therapists to improve children's adaptive behavior and parenting skills. Meanwhile, both groups will continue to receive usual care during the study period. The trial design is illustrated in Figure 1. The present protocol was prepared according to the recommendation for good practice in RCT feasibility and pilot design.

2.2 Study Setting and Participants

The RCT will be conducted in Hong Kong across three major geographical regions (Hong Kong Island, Kowloon, and New Territories). The target population will comprise families with young children awaiting or receiving early intervention services. To be eligible for the study, participants will have to (a) be one/both parent(s) of a child aged 2–6 years old who have been clinically diagnosed with a DD (including but not limited to intellectual disability, developmental delay, or autism spectrum disorder) given by pediatricians/psychiatrists; (b) be the child's main caregiver who has a long-term parenting

role with at least 50% of caregiving responsibilities; (c) be able to converse in Chinese; and (d) have the desire to improve their child's participation in four community activities that are selected from the Young Children's Participation and Environment Measure (YC-PEM, detailed later).

Participants will be excluded if their child has DD combined with physical impairment (e.g., amputation, cerebral palsy, spina bifida) or sensory impairment (e.g., blindness, deafness). This is because the support and resources needed to improve community participation for these children may differ from those for children with DD without physical/sensory constraints.

2.3 Sample Size

The sample size was calculated using Morgan and Case's formula with the following set-up: type I error of 0.05, power of 0.90, 1-to-1 random allocation, and variance ratio of 0.44, using a conservative assumption for the compound symmetry correlation structure. A large effect size (Cohen's *d*) of 0.80 was determined based on the pooled effect sizes derived from our previous study and a recent RCT. Therefore, a minimum sample size of 30 participants will be required in this pilot RCT to test for 2 × 3 mixed design analysis of covariance (i.e., the number of two groups with three repeated measurements, adjusted for individual differences in baseline assessments). Allowing for an attrition rate of 40% that was observed in the previous study, a total of 50 parent-child dyads (25 in each group) will be recruited.

2.4 Recruitment Method

Participants will be recruited from early intervention services within three non-governmental organizations in Hong Kong. Occupational therapists who work in each service will assist in the initial screening of potentially eligible families of children receiving services. They will then provide the parents of interest with the study information sheet and consent form. Once the signed consent forms are returned, a research assistant who oversees the trial will contact parents by phone to further screen for study participation eligibility. Posters and social media will be used to recruit families of children who are awaiting early intervention services. Parents of interest will be asked to contact the same research assistant for screening and, if eligible, to complete the consent forms.

2.5 Randomization and Blinding

Block randomization stratified by engagement in early intervention services (awaiting vs. receiving) based on the 1-to-1 allocation ratio will be used to assign participants to the intervention or control group. The randomization sequence will be computer-generated, and allocation will be completed by another research assistant not associated with the study.

Participants and independent outcome assessors will be blinded.

2.6 Intervention and Control Treatment

2.6.1 Intervention Treatment: Parent Coaching (OPC)

The OPC intervention comprises three components defined as the enabling domains: (1) connect – building parents' trust in the coach by using verbal and nonverbal strategies such as listening, empathizing, and partnering; (2) structure – building parents' competence by adopting a problem-solving framework of setting goals, exploring options, planning action, carrying out plans, checking performance, and generalizing; and (3) share – building parents' autonomy by reciprocally exchanging information between the coach and parents with an emphasis on eliciting parents existing knowledge. In particular, collaborative performance analysis is used to explore the options for a particular goal. In this collaborative performance analysis, the coach follows four steps: (a) identify parents' perception of what currently happens, (b) identify what they would like to happen, (c) explore barriers and bridges to the desired performance, and (d) identify their needs to take actions to achieve goals. Throughout these steps, parents are guided to find strategies to facilitate their children's performance in order to support goal achievement.

In this pilot RCT, we propose that the OPC intervention will consist of four to eight weekly (or fortnightly) sessions in correspondence with the number of goals identified by parents and the progress of the goal achievement. Each session will last 30 minutes to one hour. Depending on parents' needs, coaching sessions will be delivered in person with one or both parent(s) in therapeutic/office rooms located at participating early education and training centers, special child care centers, university campuses, or via telephone or other communication applications (e.g., Zoom or WhatsApp). Parents will be allocated to the same coach throughout the intervention period, and the coach will not be the treating therapist of their child. Because OPC focuses on coaching parents, children's attendance at the coaching sessions will be at the parents' discretion.

Coaches who deliver OPC will be occupational therapists working in participating non-governmental organizations who have at least two years of experience working with children/parents. A total of 29 therapists attended a 16-hours online training workshop delivered by the OPC developer (i.e., the last author) in March 2020. The workshop involved the translation of coaching techniques to participants using case examples, video, live demonstrations, role play, discussion, and active planning for implementation in specific practice settings. Further, 14 of the therapists attended a four-hours follow-up training by the OPC developer in May 2020, and eight of them were mentored for various hours relating to intervention fidelity by the first author, who is a qualified OPC trainer. In total, the training for each coach was at least 24 hours cumulatively, and they will be dropped if they do not

demonstrate >80% fidelity in the practice of one real case prior to study commencement. This is the minimum requirement recommended in the OPC manual for conducting related research projects. Once the intervention begins, the researchers will provide the coaches with continuous supervision and mentoring through individual meetings and/or Google forums when their self-rated fidelity of OPC in any sessions does not achieve 80%. All coaching sessions will be audio-recorded to monitor intervention fidelity.

2.6.2 Control Treatment: Parent Consultation

Parents who are randomized to the control treatment will receive consultation regarding community resources from occupational therapists or occupational therapy students who are not involved in OPC training or meetings in the study. A toolbox of community resources has been developed by the research team by identifying public playgrounds, play groups, and sports programs sponsored by non-governmental organizations or government from the website of the Leisure and Cultural Services Department (www.lcsd.gov.hk/en/). It also included generic supportive strategies for parents of children with disabilities, as drawn from the existing literature. Occupational therapists or master of occupational therapy students who have studied rehabilitation psychology and fundamental occupational therapy subjects will use the toolbox to provide parents with available environmental resources and strategies to enhance the community participation of their child with DD, followed by an understanding of the current situation and the identification of problems encountered by parents. The direct informing approach will be used to instruct parents about the availability of environmental resources close to their living areas and what they can plan to do by using possible supportive strategies. In addition, information about child disability and/or developmental milestones may be provided if needed. However, the OPC key elements, such as parents' involvement in the action-reflection process and collaborative performance analysis will be avoided in the consultation.

The consultations will be conducted for four to eight weekly/fortnightly sessions depending on the parents' needs, and each session may last 30 minutes to one hour. The consultations will be delivered in person or in tele-format at the parents' discretion. Prior to the study, occupational therapists and occupational therapy students will be trained by the first author in the use of the toolbox. A two-hour training session will be held including the introduction of strategies and resources included in the toolbox and the procedure to provide consultation, followed by role-play practice. They will be supervised regularly in monthly meetings throughout the study period. Parents will be allocated to the same trained therapists or students for consultation during the study period.

2.6.3 Usual Care

Children who are randomized to either the intervention or control group will continue to receive usual care. Depending on individual needs or status, usual care may include (a)

waiting to access early intervention services; (b) services provided by the training/care centers, such as occupational therapy, physiotherapy, and speech therapy on a weekly/monthly basis; and (c) private therapy. Of the early intervention services, occupational therapy in Hong Kong focuses on improving children's fundamental skills (e.g., fine motor, sensory integration, visual perception, and pre-writing) and self-care abilities—mostly through direct training on children. Thus, it will have a minimal effect on children's community participation. To understand the variability in usual care received by children between the intervention and control groups, parents will be asked to complete a therapy-activity log during the study period, which will record the type(s) and duration of service(s) children receive on a weekly basis.

2.7 Outcome Measures

2.7.1 Assessment timing

This pilot RCT will use four assessment points similar to the design of Graham et al.'s study. The four time points are: 5–6 weeks before intervention (time 0 for baseline assessment), 1–2 weeks before intervention (time 1 for pre-intervention assessment), 1–2 weeks after intervention (time 2 for post-intervention assessment), and 8–9 weeks after the intervention (time 3 for follow-up assessment).

2.7.2 Study assessments

2.7.2.1 Feasibility of the Trial

The feasibility of the trial will be evaluated using five indicators (recruitment, retention, adherence, blinding success, and fidelity) with predetermined criteria, as shown in Table 1. In particular, the OPC Fidelity Measure Version 3.0 will be used by the first author to rate the audio recordings of the eight selected coaching sessions to verify the intervention fidelity of each coach. The eight sessions that will be selected will include the first participants' first two sessions and then four randomly selected sessions from the remaining sessions of the first two and other participants who are coached by the coach.

2.7.2.2 Acceptability of OPC

The acceptability of the OPC intervention will be assessed through semi-structured interviews with parents at time 2 (i.e., 1–2 weeks after the intervention) and with coaches at the end of the study. Parents will be asked about their satisfaction with the coaching sessions (e.g., relationship with the coach, schedule, and duration), experience in being coached (e.g., what they have learned, what they like most/least, and the challenges experienced), and the perceived impact of OPC on children's participation in community activities. Coaches will be interviewed to evaluate their experience of delivering OPC intervention (e.g., perceived

effectiveness, challenges, optimal coaching schedule/duration, and opinions on cultural suitability).

2.7.2.3 Initial Efficacy of OPC

2.7.2.3.1 Primary Outcome Measures

Canadian Occupational Performance Measure (COPM). The COPM will be used to measure parents' perceptions of children's participation in specific community activities. This measure is selected for use because it can identify individualized problems in participation in occupations and then help to formulate goals related to child participation through semi-structured interviews. In the interview, parents are further prompted to rate their child's performance and their satisfaction with the current status on a 10-point Likert scale (1 = *not good/satisfied at all* and 10 = *optimal performance/satisfaction*). High scores indicate greater children's participation performance and parents' satisfaction. In this pilot RCT, we propose that parents' identified goals will not be limited to the community participation but will also be extended to other life areas. An adequate internal consistency (Cronbach's α = 0.73–0.88) of the COPM has been reported. The prioritized problems using the COPM in parents of children with disabilities were also found to be corresponding with specific items in the Pediatric Evaluation of Disability Inventory, demonstrating construct validity of the COPM.

Young Children's Participation and Environment Measure (YC-PEM). The YC-PEM will be used to capture children's overall community participation patterns. This measure is selected because it is a parent report questionnaire that can be used for young children with various disabilities. The YC-PEM also has a community section that includes 11 participation items across four broad categories of neighbourhood and community outings, classes and groups, community-sponsored activities, and recreational activities and trips. In each item, parents are asked to rate: (a) how often their child has participated in the past four months using an 8-point Likert scale (0 = *never* and 7 = *once or more each day*); (b) how involved the child is during participation using a 5-point Likert scale (1 = *not very involved* and 5 = *very involved*); and (c) parental desire for change in the child's participation (yes/no and, if yes, six nominal options for the type of desired change can be selected). Total scores are generated by averaging all items in the participation frequency and involvement dimensions. High scores indicate greater children's participation frequency and involvement. The YC-PEM participation scale has acceptable internal consistency (α = 0.64–0.78) and test-retest reliability (intraclass correlation coefficients [ICC] = 0.82–0.89). Moreover, it demonstrates known-group validity between children with and without disabilities and convergent validity by correlating with functional performance of children with disabilities.

2.7.2.3.2 Secondary Outcome Measures

Parenting Sense of Competence Scale (PSOC). The PSOC is a parent report

questionnaire to obtain parents' perceptions of their parenting role, and this scale is selected because it will help to examine whether parents who receive OPC will have improved parenting competence. The PSOC has two dimensions: efficacy (eight items) and satisfaction (nine items). Parents are asked to rate each item on a 6-point Likert scale (6 = *strongly disagree* and 1 = *strongly agree*). Total scores are generated by summing all items in each dimension (after reversing the scores of some items). High scores indicate greater competence and satisfaction with parenting, respectively. The PSOC has demonstrated good internal consistency (α = 0.77–0.80) and test-retest reliability (ICC = 0.82–85).

Depression, Anxiety, and Stress Scale-21 (DASS-21). The DASS-21 is a self-report questionnaire that includes 21 items assessing people's negative emotional states of depression, anxiety, and stress (seven items in each subscale). In the proposed RCT, the use of the DASS-21 is determined because it can be completed by parents to provide insight into the beneficial impact of OPC on promoting parents' emotional states. In the DASS-21, each item is rated on a 4-point Likert scale (0 = *did not apply to me at all* and 3 = *applied to me very much or most of the time*). Total scores are generated by summing all items in each subscale, with high scores indicating greater emotional problems. Good internal consistency (α = 0.77–0.87) of the DASS-21 has been reported.

KINDL questionnaire. This questionnaire measures health-related quality of life in children and has three age versions with both child and parent reports, including Kiddy-KINDL for parents of children aged 3–6 years. Because self-report is difficult for young children with DD, the parent-report version of Kiddy-KINDL is determined for use in the proposed RCT to explore whether children have improved psychosocial health after the OPC intervention. The Kiddy-KINDL comprises 24 items that assess parents' perceptions of their child's health-related quality of life across physical well-being (four items), emotional well-being (four items), self-esteem (four items), family (four items), social contacts (four items), and school functioning (four items). The recall period covers the last month in this study, and each item is rated using a 5-point Likert scale (0 = *never* and 4 = *all the time*). A psychosocial health score is generated by summing item scores from the emotional, self-esteem, family, and social contacts domains. High scores indicate greater psychosocial health. The Kiddy-KINDL has demonstrated acceptable internal consistency (α = 0.70–0.89).

2.7.2.3.3 Other Exploratory Measures

Demographic questionnaire. In the proposed RCT, we will design a parent-report questionnaire to collect demographic information such as child age and gender, family structure, family income, employment of a domestic helper, as well as parents' age, occupation, and education. Parents will also be asked to report the type(s) of clinical diagnosis or disability which their child has and rate the severity of their child's DD as a whole using a 4-point Likert scale (1 = *very mild* and 4 = *severe*). The demographic and

clinical information will be used to characterize children and their parents in the intervention and control groups for comparison.

Additionally, we consider that the availability and intensity of early intervention services may have an effect on children's functional performance and participation based on literature. Therefore, this questionnaire will also ask parents to report the type(s) and duration of early intervention service(s) their child has received in the past month. The information in the total number of the early intervention service hours will be categorized and used as a control variable adjusted for baseline differences in the analysis of the efficacy of OPC.

Pediatric Evaluation of Disability Inventory Computer-Adaptive Tests (PEDI-CAT). The PEDI-CAT is a parent-report, computer-based assessment of children's functional performance across four domains: daily activity, social/cognitive function, mobility, and responsibility. In the proposed RCT, we will select the use of the first two domains, operated by the speedy feature, for the purpose of exploring the improvement in children's daily activities and social/cognitive function. The speedy feature allows reducing administration time by selecting suitable 10–15 items to assess based on the relative difficulty of preceding items and parents' responses to those items (instead of completing a full set of items). In each PEDI-CAT item, parents rate their child's typical performance using a 4-point Likert scale (1 = *unable* and 4 = *easy*). Scaled scores of each domain are derived based on the estimates of the placement of individual children along the hierarchical scales that have been calibrated using item-response theory in the standardization samples. The PEDI-CAT scaled scores are on a 20–80 metric and have been recommended for use to evaluate changes over time. The PEDI-CAT has demonstrated excellent agreement with the full-length version (Pearson's r = 0.94–0.99) and satisfactory test-retest reliability (ICC = 0.86–0.92).

Environmental support scale of the YC-PEM. In the community section of the YC-PEM mentioned earlier, parents will also be asked to evaluate the impact of the types of environmental features (10 items) and resources (seven items) regarding their child's participation in community settings. This scale is selected for use because we would like to explore whether parents who receive OPC have higher perceived environmental support for their children's community participation. In the environmental support scale, a 3-point Likert scale is used to assess the level of parents' perceived impact of environmental features (1 = *usually makes it harder* and 3 = *no impact/usually helps*) and resources (1 = *usually no* and 3 = *not needed/usually yes*) on participation, respectively. Total scores are generated by averaging all items on this scale, with high scores indicating greater environmental support. This environmental support scale has acceptable internal consistency (α = 0.83) and test-retest reliability (ICC = 0.78).

Session Rating Scale (SRS). The SRS is a four-item visual analog scale that assesses therapeutic alliance at the end of each session, and this scale is used because it provides insight into the potential mechanism of parents' intrinsic motivation to enact actions during

OPC. Each of the four items captures a key dimension of effective therapeutic relationships, including respect and understanding, relevance of the goals and topics, approach used in therapy, and overall alliance. Parents are asked to place a mark on a 10-cm line nearest the pole that best describes their experience with their OPC coach. Total scores are generated by summing up the marks made by parents measured to the nearest centimeter on each of the four lines. Higher scores indicate greater therapeutic alliance. The SRS has been reported to be internally consistent (α = 0.88–0.96) and reliable over time (r = 0.63).

Health Care Climate Questionnaire (HCCQ). The HCCQ assesses people's perceptions of health care practitioners' autonomy support in a given program grounded by self-determination theory. It consists of 15 items rated on a 7-point Likert scale (1 = *strongly disagree* and 7 = *strongly agree*). One example item is "I feel that my health-care practitioner has provided me with choices and options about regular exercise." Total scores are calculated by averaging all item scores, with higher scores indicating greater autonomy support. The HCCQ has been adapted by Chan et al. for use in the physiotherapy context by replacing "health-care practitioner" with "physiotherapist" and eliminating the statement of the specific program (e.g., regular exercise). In the proposed RCT, we will adopt Chan et al.'s version with a slight amendment of the wording to "my coach." The modified version of the HCCQ will allow us to understand parents' perceptions of the degree to which their coach is autonomy supportive (vs. controlling) in coaching them regarding their child's participation. The HCCQ has demonstrated acceptable internal consistency (α = 0.94–0.95) in various studies.

Patient Global Impression of Change (PGIC). This measure is proposed for use, because it can provide an indicator of parents' global impression of whether their child's participation in community activities has been better, about the same, or worse since the start of the given intervention. The PGIC includes only one item that is scored on a 7-point Likert scale (1 = *very much improved* and 7 = *very much worse*). This measure has been reported to demonstrate good clinimetric properties.

2.8 Data Analysis

Descriptive statistics will be used to characterize the participants and evaluate the trial feasibility according to our a priori success criteria (see Table 1). The t-test (or Mann-Whitney U test) and chi-square statistics will be used to test for between-group baseline differences. Prior to the efficacy analyses of OPC, the normality of the data for the studied variables will be examined and, if the data are not normally distributed, transformation methods will be applied.

To evaluate the acceptability of OPC intervention, interviews with parents and coaches will be transcribed and then analyzed separately using qualitative methods. Specifically, thematic analysis using a data-driven inductive approach will be used to scrutinize the parents'

interview transcripts and interpret their coaching experience as well as perceived impact. Thematic analysis is chosen, because it provides a flexible method for identifying, analyzing, and reporting patterns (themes) within data without a prior coding scheme. Alternatively, coaches' interview transcripts will undergo conventional content analysis to describe their experience in delivering OPC intervention. We choose content analysis because only eight coaches will be involved in the proposed RCT and data saturation may not be achieved if thematic analysis is used. Two research team members will be involved in the thematic and content analyses by following the recommended procedure. To establish the trustworthiness of the thematic and content analyses, code-recode, peer checking, and team discussions will be used.

To evaluate the initial efficacy of OPC on the primary and secondary outcomes, we will use the repeated-measures analysis of covariance (ANCOVA) by controlling for baseline variability at time 0 as well as the variations in treatment dosage and delivery format (e.g., in person or tele-format). That is, the repeated-measures ANCOVAs will be used to compare the change in the scores of outcome measures across the three time points (at times 1, 2, and 3) by controlling for baseline differences and treatment variations. For participation goals identified by parents in the COPM, only community-related participation goals will be targeted for analysis. Principles of intent-to-treat analysis will be applied and, if participants withdraw after the coaching/consultation sessions, their data for subsequent time points will be imputed by carrying the last assessment forward. Post-hoc analyses using the Schffé method will be performed when the main comparison results are significant. Statistical significance will be set at $p < 0.05$. Estimates of effect sizes with 95% confidence intervals will be calculated for each outcome measure.

TABLE 1: A priori success criteria to assess the feasibility of the trial

	Definition	**Success criteria**
Recruitment	Percentage of eligible families agreeing to participate in the study	≥20% recruitment response rate achieved
Retention	Percentage of participants who complete the trial	≥60% retention rate achieved (i.e., completion of all assessments)
Adherence	Percentage of coaching sessions attended by parents in the intervention group	≥75% adherence rate achieved, based on our previous research of similar duration (42)
Blinding success	Percentage of parents who guess treatment allocation correctly after the study	50% based on the guess of treatment by chance (50/50)
Fidelity	Degree to which the OPC is implemented by coaches as intended	≥80% fidelity on the OPC Fidelity Measure Version 3.0 in four selected session per coach

Note: The OPC Fidelity Measure Version 3.0 consists of 18 items across five domains: relationship, goal, reflection, analysis and action, client response, and distinguishing. Each item is rated on a 3-point Likert scale (1 = *low* and 3 = *high*). The percentage score will be calculated by dividing the total score by the possible maximum score. Higher percentage scores indicate higher fidelity, and the cut-off of sufficient fidelity of OPC per session is set at 80%.