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Protocol for a mixed-methods randomised controlled trial evaluating the effectiveness of a dyadic expressive arts-based intervention for improving the psychosocial well-being of children with intellectual disability and their mothers

Abstract

Introduction: Mothers of children with intellectual disability (ID) are often distressed because of intensive workloads and difficulties in communicating with their children. Given the interdependence between the psychosocial well-being of such dyads, interventions that promote parent-child relationships and mutual communication would be beneficial. Arts provide alternative avenues for expression and offer an imaginative and playful environment for discovering new communication strategies. Given the lack of studies on arts-based dyadic interventions, this study aims to examine the effectiveness of dyadic expressive arts-based intervention (EXAT) in improving the psychosocial outcomes of children with ID and their mothers and the mother–child relationships.

Methods and analysis: This study will adopt a mixed-methods randomised controlled trial design, wherein 154 dyads of children with ID and their mothers will be randomised into either the dyadic EXAT group or treatment-as-usual waitlist control group. Quantitative data will be collected at 4 time points: baseline (T_0), post-intervention (T_1), 3-month post-intervention (T_2), and 6-month post-intervention (T_3). Qualitative data will be collected from a subset of 30 mothers in the intervention group at T_1 and T_3 to document their experiences and perceived changes after the intervention. Mixed-effects models and path analysis will be adopted to analyse the quantitative data, whereas

thematic analysis will be applied to the qualitative data. Both sets of data will be triangulated for an integrated view of the effectiveness and mechanism of the intervention.

Ethics and dissemination: Ethical approval has been obtained from the Human Research Ethics Committee of the University of Hong Kong (Ref. no.: EA200329). Written consent forms will be obtained from all recruited participants (mothers, children with ID, and teachers/social workers) before data collection. The study findings will be disseminated in international conferences and peer-reviewed academic journals.

Trial registration number NCT05214859, prospectively registered

Keywords: Mother-child relationship, Psychosocial well-being, Expressive arts therapy, Intellectual disability, Randomised controlled trial

Strengths and Limitations of the Study

- This will be the first study to explore the effectiveness of dyadic EXAT in improving the psychosocial well-being of children with ID and their mothers and the mother-child relationships.
- Empirical evidence from this study will inform the application of art(s)-related interventions for similar populations, such as children with developmental disabilities or special education needs.
- Given the high comorbidity of diagnosis with ID and autism spectrum disorder, the study will not exclude children with diagnosis of autism spectrum disorder to ensure a

sufficient number of eligible participants.

- Owing to the nature of this trial, only the data analyst will be blinded from the participants' allocation results.

Introduction

Intellectual disability (ID) refers to a developmental disability that significantly limits intellectual functioning and adaptive behaviours, which impedes daily functioning.[1] ID onset typically occurs before adulthood[1] and affects 0.05–1.55% of the global population.[2] The ID prevalence in Hong Kong is 1.0–1.4%,[3] affecting approximately 0.89% of the school-age population.[4] As caring for children with ID requires intensive care, effort and resources, the parents of children with ID are prone to emotional distress and poor quality of life.

Existing findings have shown that the parents of children with disabilities experience higher parental stress than those of children without disabilities.[5 6] Caring for children with ID can be taxing due to the high risk of behavioural and emotional problems.[7 8] For example, children with ID exhibit deficits in emotional regulation and expression,[9] and may display more anger and aggressive behaviours than children without ID.[10] Limitations in attention, responsiveness, salient cues, and use of language in communication also restrict their social engagements with others.[11-14] In particular, the poor expression of feelings and emotions has been commonly observed when children with ID communicate with their family members;[15] these unhealthy communication patterns have been correlated with poor psychological conditions in parents.[15 16] Moreover, children with ID are known to have high comorbidity with other developmental disorders such as autism spectrum disorder and related behavioural and emotional issues, which can further complicate caregiving.[17 18]

Compared with other caregivers in the family, such as fathers and siblings, mothers are more likely to experience caregiving burdens.[19] This may be due to

entrenched patriarchal beliefs in Hong Kong society, which expects mothers to be caregivers and homemakers and fathers to be breadwinners.[20] Mothers are known to devote enormous amounts of time and energy to caring for children with ID, which subjects them to intensive stress, marital issues, psychological disturbance, disrupted social lives, poor physical health, and uncertainty about the future.[16 21-23] Furthermore, the mothers of younger or school-aged children with ID have reported experiencing more stress than the mothers of older children with ID as younger children require higher levels of care. Mothers also often face dilemmas in decision-making, such as when choosing schools and rehabilitation programmes.[18 23]

Extensive interventions or services have been provided for support children with ID and their families, such as in the form of parenting skills training, psychoeducational support for parents, and behavioural management programmes for children.[24 25] Nonetheless, few interventions focus on enhancing communication, relationships, and overall well-being for mother-child dyads. The provision of dyadic support for this population is crucial as the psychosocial well-being of mothers and children with ID are interconnected.[26] Caregiving burdens have been shown to impair the mothers' mental health, which is detrimental to the quality of mother-child relationships[16] and communication with the children.[27] Therefore, it is essential to promote positive interactions, mutual understanding and communication between mothers and their children.[24]

Need for Arts

Arts can serve as alternative pathways for expressing emotions and be particularly helpful for individuals who find verbal self-expression difficult,[28] such as children with

ID. The experience of co-creating artwork with others also creates opportunities for discovering communication patterns and experimenting with new communication strategies, which can promote effective communication within mother-child dyads in daily life;[29] this may be particularly beneficial for children with ID and their mothers. In addition to applying a single art modality approach, this study will employ an expressive arts-based intervention (EXAT) that utilises different art modalities, such as music, drama, movement, and visual arts, to attain therapeutic goals.[30] It adheres to an intermodal approach, which posits that the experience of expressing oneself can be deepened and expanded by interchanging art modalities.[31] This approach also creates a non-judgmental and safe environment for exploring new ideas. Although some studies in the field have applied art(s)-related interventions to individuals with ID or their parents, studies with more rigorous designs, such as those with larger samples or comparable control groups, have been limited.[32] Including a treatment-as-usual control group in the study design helps reveal the treatment effects of EXAT on top of the generic routine and care of the dyads.

Research Objectives

The primary objective of the study is to examine the effectiveness of the dyadic EXAT in improving psychosocial outcomes of children with ID and their mothers and the mother-child relationships compared to a treatment-as-usual waitlist control group across different time points. The sustainability of the effects will be examined at 3-month and 6-month post-intervention follow-up time points. It is hypothesised that dyads in the EXAT group will experience improved psychosocial conditions and mother-child relationships, relative to the dyads in the control group. The second objective is to explore the

mechanism by which the intervention acts on mother-child dyads; the study will investigate the relationships between psychosocial variables and intervention effectiveness, such as mediation or moderation effects. Qualitative interviews will be used to document the subjective experiences of and changes in mothers after participating in the intervention.

Methods and Analysis

This study will employ a two-arm, mixed-methods, randomised controlled trial design. The intervention phase will last for eight weeks. The outcome measures will be assessed at 4 time points: baseline (T_0), 2-month after baseline (post-intervention, T_1), 5-month after baseline (3-month post-intervention follow-up, T_2), and 8-month after baseline (6-month post-intervention follow-up, T_3). This will help capture the immediate and sustained effects of the dyadic EXAT on mother-child relationships and psychosocial well-being. In addition to quantitative outcome measures, qualitative interviews with a subset of mothers (i.e., 30 mothers) from the intervention group will be conducted at T_1 and T_3. The interviews will help document information regarding the experiences of participating in the dyadic EXAT and whether these experiences shape the caregiver experience, particularly the relationship between mothers and their children and the mothers' coping strategies during caregiving. Adopting the mixed-methods design will help triangulate the findings and enhance our understanding of the effects of the dyadic EXAT on mother-child dyads. Figure 1 depicts the schedule of enrolment, allocation and assessments. Figure 2 shows the study flow based on the CONSORT flow diagram.

Intervention

Dyads in the intervention group will receive eight 90-min weekly sessions. The sessions will be conducted at the children's schools by either a registered EXAT therapist, an EXAT trainee or a mental professional trained in EXAT. Each session will be conducted in a small group of 3–4 dyads. The group facilitators will receive training in the standardised protocol and safety precautions. The principal investigator (PI; corresponding author) will provide on-site and/or off-site supervision to ensure treatment fidelity. Themes related to mother-child relationships will be covered, such as fostering care, rebuilding connections, facilitating communication, and promoting mutual understanding. Each session will comprise four stages. First, the session will begin by greeting the participants and familiarising them with the therapeutic group setting. The group facilitator will introduce the theme and highlights for the session and observe the condition of each dyad. Second, warm-up activities or games, such as simple movement activities, will be introduced to prepare dyads for subsequent art(s)-making activities. Third, the group facilitator will guide the dyads to participate in art(s)-making activities based on the session's goals. Group sharing will be encouraged to help dyads consolidate their experiences, provide insights into their real-life situations and learn from other dyads' experiences. Fourth, the group facilitator will summarise the progress and recall the session's highlights. A closing ritual will be performed to end each session. Table 1 depicts the details of each stage.

Table 1: Structure of each session

	Process	Purposes
Greetings and check-in	- Greetings - Introducing the theme	- Transit from the real world to a therapeutic space - Build rapport - Give participants a brief idea of the theme - Give the therapist a brief idea of participants' conditions
Warm-up	- Participating in warm-up activities/games	- Prepare for the art(s)-making process
Art(s) creation and response	- Participating in art(s)-making activities based on the designated theme - Sharing of art(s)-making experiences and insights	- Cultivate insights from the art(s)-making process - Promote mutual support among groupmates
Closure	- Closing rituals	- Conclude the session - Transit back to the real world

The dyads in the treatment-as-usual control group will continue their normal routines and care. They will be invited to join the intervention group upon completion of all assessments.

Randomisation and Blinding

Eligible dyads will be allocated to either the dyadic EXAT group or the treatment-as-usual waitlist control group on a 1:1 basis based on a list of non-repeating computer-generated random numbers. The list will be generated by a staff who will not be involved in the trial. The designated staff of each school will be notified of the allocation results. A research assistant will be responsible for the randomisation and case allocation procedures.

Given the nature of the trial, it will not be feasible to blind the participants (dyads and teachers/social workers) and therapists to the group allocation results. No unblinding

procedures are predetermined for revealing the participants' allocation during the trial. However, the data analyst will be blinded. A research assistant will recode the group information in the dataset before passing it on to the data analyst for data analysis.

Sample Size

The sample size was estimated using the analysis software *G*power 3.1*.[33] A moderate effect size (Cohen's $d = 0.5$) was expected based on a previously unpublished local study conducted in 2017 (Li IMY. The effectiveness of an attachment-based expressive arts therapy parenting programme for parents with special needs children (Unpublished Thesis). Hong Kong: The University of Hong Kong; 2017). Assuming an attrition rate of 20%, a total sample of 154 dyads will be needed (i.e., 77 dyads per arm) to reach 80% statistical power and attain a moderate effect size (Cohen's $d = 0.5$) in the proposed 2-arm randomised controlled trial with four measurement time points at a 5% level of statistical significance.

Participants

The recruitment of participants will be carried out at special schools in Hong Kong. This study will collaborate with the Hong Chi Association, a major non-governmental organisation (NGO) in Hong Kong that provides special education services for students with different grades of ID. This study will also aim to collaborate with special schools run by other NGOs. A list of potential special schools will be made, and the research team will invite these schools to participate in the study. Schools that show interest in participation will be contacted by the research team to discuss the details of study implementation. Social workers and teachers at the interested schools will assist with the screening procedures and refer potential participants to the research team. The

eligibility of mother-child dyads will be determined using the following inclusion and exclusion criteria.

Inclusion criteria

- The child is 6–12 years old;
- The child is diagnosed with mild to moderate ID;
- By the judgement of the health/school professional staff, the child is both physically and psychologically stable for participation;
- The dyad is willing and able to give consent for participation.

Exclusion criteria

- The child is diagnosed with attention-deficit/hyperactivity disorder;
- The dyad is currently participating in other behavioural or pharmacological trial(s);
- Either the mother or child has other contraindications or severe comorbidities that may impede participation (e.g., severe physical disabilities).

Outcome Measures

The outcome measures of this trial will comprise (a) psychosocial condition of mothers; (b) psychosocial condition of children; (c) mothers' perceptions of parent-child relationships; and (d) demographics and clinical profiles of the dyads. The mothers will complete a self-administered questionnaire regarding their psychosocial conditions, perceived parent-child relationships and the dyads' demographic and clinical information. Research assistants will assist children in responding to the mood scale. An EXAT therapist, a trained research assistant or an EXAT trainee under supervision will administer the Face Stimulus Assessment (FSA). Teachers or social workers of each child will also be invited to fill the behavioural checklist. To enhance retention of the

participants, data will be collected from places convenient for the participants, such as the dyads' homes or special schools. Research assistants will send reminders to the participants to attend appointments for data collection.

Mothers' Psychosocial Outcomes and Perceived Parent-Child Relationships

Parenting Stress. The 36-item Parenting Stress Index (4th Ed., short form) will be adopted to assess parenting stress.[34] The scale consists of three subscales, parental distress, parent–child dysfunctional interaction and difficult child, and each item is measured on a 5-point Likert scale. The official Chinese translated version from Psychological Assessment Resources (PAR, Inc.) will be administered.

Burnout. The level of burnout of mothers will be captured by the Chinese version of the 6-item client burnout subscale of the Copenhagen Burnout Inventory (CBI),[35] with each item rated on a 5-point Likert scale.

Parent-Child Relationship. Parent-child relationship will be captured by two subscales with a total of 19 items from the Parent-Child Relationship Inventory (PCRI): parent-child communication and satisfaction with parenting.[36] The PCRI assesses attitudes towards parent-child relationship on a 4-point Likert scale. The research team has obtained permission from the publisher to translate the items into traditional Chinese and validate the translation.

Positive and Negative Affect. The mothers' positive and negative affectivity will be assessed by the Chinese version of the 10-item International Positive and Negative Affectivity Schedule – Short Form (I-PANAS-SF).[37] The scale has two subscales, one each for positive and negative affect, and each item is rated on a 5-point Likert scale.

Quality of Life. The mothers' quality of life will be captured by the 28-item Hong

Kong Chinese brief version of the World Health Organization Quality of Life Measure (WHOQOL-BREF, HK).[38] It assesses the subjective quality of life in four domains: physical, psychological, social relationship, and environmental.

Psychological Well-Being. The mothers' psychological well-being will be documented by the Hong Kong Cantonese version of the 5-item World Health Organisation Five Well-Being Index (WHO-5).[39] It measures subjective psychological well-being on a 6-point Likert scale.

Children's Psychosocial Outcomes

Mood States. The Ottawa Mood Scale will be adopted to measure the children's mood states.[40] It is a visual analogue scale composed of five items that assess mood, anger, worry, stress and self-regulation. Relevant faces, icons or images will be shown to help children choose the most suitable answer that reflects their mood states. This scale has been validated in a Malaysian young adult sample.[41] The research team has obtained permission to translate the scale into traditional Chinese and validate the translated version.

Emotional Expression. The emotional expression of children with ID will be captured by the Face Stimulus Assessment (FSA).[42] It is a projective drawing test that requires children to use the provided colour markers on three A4-size drawing templates: first on a pre-drawn face, second on an outline of a face, and third on a blank sheet of paper. The sketches will be analysed based on the guidelines mentioned in the FSA E-Packet and Rating Manual (2nd Ed.), provided by the author of the assessment. The sketches will be digitally scanned to extract the patterns of colour usage.[43] The research team has obtained permission to translate the guidelines into traditional Chinese and

validate the translated version.

Child Behaviour. The behaviours of children with ID will be assessed by the teachers or social workers via the Chinese version of the Child Behaviour Checklist Teacher Report Form (CBCL-TRF/6-18) for school age children.[44] The checklist yields aggregate scores on externalising, internalising, and total behavioural problems, and on eight syndrome scales: anxious/depressed, withdrawn/depressed, somatic complaints, social problems, thought problems, attention problems, rule-breaking behaviour, and aggressive behaviour.[45]

Socio-demographic and Clinical Information

Demographics. Socio-demographic information of the mothers, namely age, gender, education level, family composition, and financial status, and the children, namely age, gender, grade, and level of ID, will be collected from the mothers through self-report questionnaires.

Clinical Information. Clinical profiles of the mother-child dyads, such as time since diagnosis of the children with ID, time of onset and history of psychiatric disorders, presence of any comorbidities (e.g., physical disabilities, hypertension, diabetes mellitus, other cognitive disturbances), and history of community and rehabilitation service utilisation will be documented.

Individual Semi-Structured In-Depth Interviews

A subset of mothers (i.e., 30 mothers) from the intervention group will be randomly invited to attend individual, semi-structured interviews at T_1 and T_3. The first interview will explore their experiences of participating in the intervention and whether there are any immediate changes. The second interview will investigate possible changes

related to the intervention and whether these changes further induce changes in their daily lives and relationships with their children. The interviews will be conducted by the research team based on the interview guide (online supplementary file 1). The sample size will be set at 30 mothers as data saturation will be reached in under 25 interviews[46] and to ensure sufficient data after potential dropouts at T_3.

Data Analysis

Quantitative Analysis

The intent-to-treat principle will be used to address the effects of crossovers and dropouts. Missing data will be handled by full information maximum likelihood. Descriptive statistics will be used to summarise the socio-demographic characteristics of the participants at all time points. Treatment outcomes will be examined by computing mixed-effects regression models. This analytical method will analyse the repeated measures between the groups to obtain the time effect, group effect, and time x group interaction effect. Demographic and clinical variables will be controlled for in the analysis. Path analysis will be adopted to examine the mediating role of the parent-child relationship and parenting stress on the effect of dyadic EXAT on psychological distress and caregiver burnout. Mediation effects will be determined based on the significance of the indirect effects of the intervention on psychological distress and caregiver burnout via the mediators. As the data distribution is expected to be skewed, bootstrapping will be used to estimate the confidence intervals of the indirect effects. Statistical tests will be performed using *Mplus 8.3* (Muthén & Muthén, 1998–2017) and will be two-tailed with statistical significance set at 5%.

Qualitative Analysis

Audio recordings of the in-depth interviews will be transcribed verbatim by the research staff. All of the transcripts will be imported to *NVivo 12.0* (QSR International Pty Ltd., 2018) or above for data analysis. The thematic analysis approach[47] will be used to identify codes and themes related to the experiences of the dyadic EXAT and the possible mechanism of the intervention. Two research staff members will be involved in data analysis to ensure the credibility of the findings.

Study Monitoring and Data Management

The progress and safety of the study will be monitored by the General Research Fund of the Research Grants Council (RGC). A mid-term progress report and interim analyses will be submitted after having implemented the study for 18 months. In case of RGC identifies any serious problem or unsatisfactory progress, the trial may be terminated. A final report will be submitted upon completion of the study.

Regarding data entry, quantitative data collected from the participants will be entered into the dataset by research assistants. After inputting all of the data, the data analyst will perform data screening to check its validity. Invalid inputs will be cross-checked and re-submitted by another research assistant. Regarding qualitative data, the audio recordings will be transcribed into text files, and the sketches created by the children will be digitally scanned by research assistants. The data analyst will check the transcripts by concurrently listening to the audio and reading the transcripts. Amendments will be made if necessary.

Regarding data storage, all of the hard copies, after removing personal identifiers, will be stored in a locked cabinet at the PI's research centre. Soft copies and other related

electronic files will be encrypted and stored in a password-protected desktop computer at the PI's research centre. All the hard and soft copies will keep for a maximum of three years after the publication of the first paper. Only the relevant research staff members, i.e., the PI, the Co-Is, research assistants, and data analysts, will be granted access to the raw data files and trial data set.

Patient and Public Involvement

Patients and the public were not involved in designing the protocol. The findings and protocols of the study will be disseminated to the participants upon request.

Ethics and Dissemination

Ethical approval has been obtained from the Human Research Ethics Committee of the University of Hong Kong (EA200329). The protocol of this study has been registered with the Clinical Trial Registry (NCT05214859). Any amendments to the protocol will be reported to the ethics committee and clinical trial registry. Trained research assistants will explain the rights of the participants and objectives of the study to participants and obtain their written consent before data collection. The data collection and dyadic EXAT are not expected to cause any physical or psychological harm. If the participants are disturbed by the data collection or intervention process, they can choose to skip or terminate any procedures. Professional referrals can be made upon request. All such incidents will be reported to the PI. Regarding disseminating the findings, the team will present at internal or local conferences and will publish in peer-reviewed academic journals.

Discussion

The mothers of children with ID are under high caregiving strain, and the children themselves experience difficulties in channelling their emotions. This study hopes to raise awareness of the psychosocial well-being of both children with ID and their mothers. Interventions are needed to mitigate their psychological distress and boost their psychosocial well-being. As dyadic interventions, particularly art(s)-based dyadic interventions, have been limited, the proposed study will aim to fill this gap by providing evidence of the effectiveness of dyadic EXAT in improving the psychosocial well-being of children with ID and their mothers. The dyads are expected to benefit from the intervention in terms of nurturing mutual understanding, providing opportunities for expression and fostering psychosocial well-being. The findings will inform on the mechanism underlying dyadic EXAT and shed light on how arts can benefit mother–child dyads. In the future, art(s)-based interventions can be considered as one of the intervention strategies to provide psychosocial support for this population. Furthermore, the findings of this study can will contribute to the development and further application of art(s)-based interventions for children with ID and their families or for families with children with other disabilities or special needs.

Figure legends

Figure 1: The schedule of enrolment, allocation and assessments.

Figure 2: The study flow based on the CONSORT flow diagram.

Footnotes

Contributors: HRTH and WAHY conceived the study. HRTH, WAHY, WPKS, and LHHM contributed to the study design, and they are the research grant holders (named investigators)., FTCT, CCKP, WPKS, and LHHM provided methodological expertise and resources. LTLT, WAHY, and HRTH prepared the draft of this study protocol. All the authors reviewed and approved the final manuscript.

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Competing interests: None declared.

Patient and public involvement: Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication: No participants' data were presented in this article.

Ethics approval: Ethical approval has been obtained from the Human Research Ethics Committee of the University of Hong Kong (EA200329).

Data availability statement: Data sharing is not applicable to this article as no new data were created or analysed in this article.

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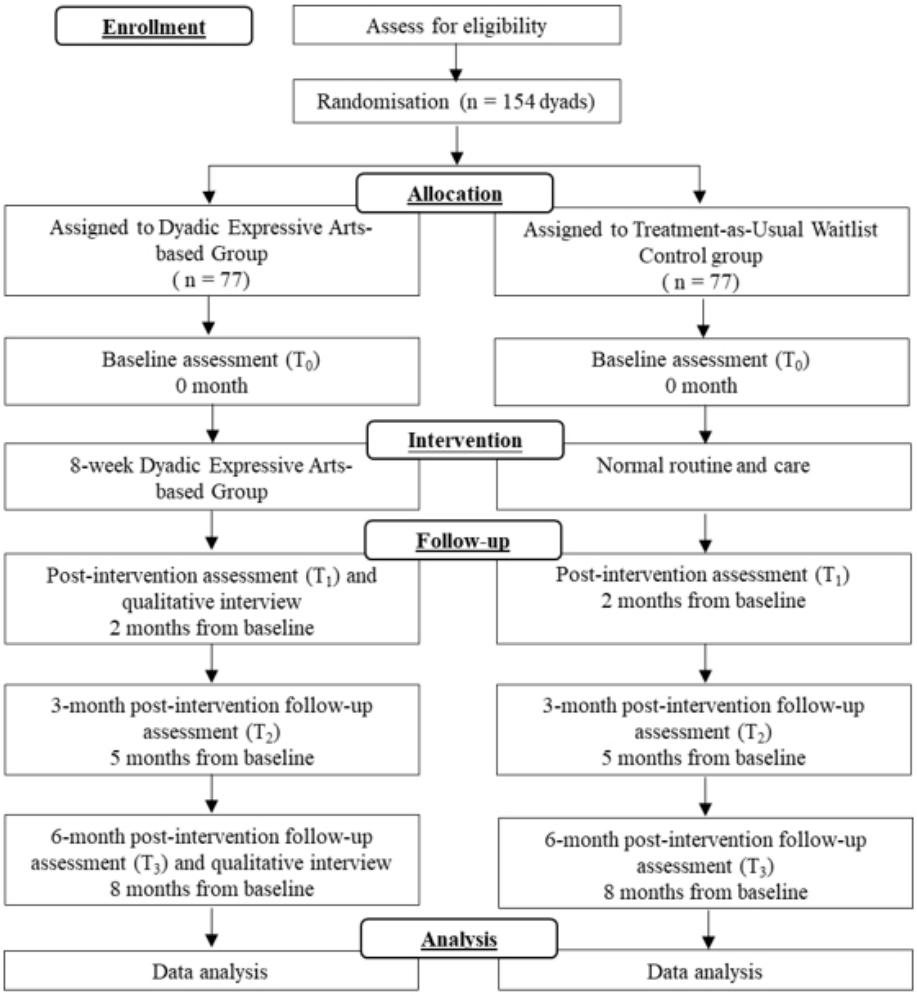
		STUDY PERIOD					
		Enrolment	Allocation	Intervention (8 weeks)		Post intervention (5 months from t_0)	Post intervention (8 months from t_0)
TIME POINT		$-t_1$	0	t_0	t_1	t_2	t_3
ENROLMENT:							
Eligibility screen		X					
Informed consent		X					
Allocation			X				
INTERVENTIONS:							
EXAT[a]				⟷			
Control							
ASSESSMENTS:							
Mother & Child	Socio-demographic			X			
Mother & Child	Clinical information			X			
Mother	Psycho-social outcomes			X	X	X	X
Mother	Perceived parent-child relationship			X	X	X	X
Mother[b]	Perceived changes and experiences of EXAT				X		X
Child	Psycho-social outcomes			X	X	X	X

a. EXAT: Dyadic expressive arts-based group

b. Only a subset of mothers in the intervention group (i.e., 30 mothers) will participate in a semi-structured in-depth interview for understanding their perceived changes and experiences after participating in the dyadic expressive arts-based group.

The schedule of enrolment, allocation and assessments.

445x525mm (38 x 38 DPI)



The study flow based on the CONSORT flow diagram.

408x441mm (38 x 38 DPI)

Supplementary 1: Interview guides for Qualitative interview

Interview guide at post-intervention (T_1)

1. **Perceived experiences of the dyadic expressive arts-based group**
   - Could you share your experiences in the 8-week dyadic expressive arts-based group intervention?

2. **Perceived changes after participating in the dyadic expressive arts-based group**
   - How do you perceive/are there any changes in the following aspects?
     - ❖ Your child's behaviour
     - ❖ Your psychological condition
     - ❖ Caregiving experience
     - ❖ Relationship with your child

3. **Possible reasons for the perceived changes**
   - (If the mother experienced changes) Are there any possible reasons for the previously mentioned changes?
   - (If the mother experienced no change) Why do you think there are no changes?

4. **Closing**
   - Do you have anything else that you would like to share?

*The interview will not be limited to the above questions. The interviewer may slightly adjust the interview guide based on the sharing of each interviewee.

Interview guide at 6-month post-intervention (T_3)

1. **Current situation of the mother-child dyad**
   - How have you and your child been in these six months?

2. **Perceived changes six months after participating in the dyadic expressive arts-based group**
   - How do you perceive/are there any changes in the following aspects?
     - ❖ Your child's behaviour
     - ❖ Your psychological condition
     - ❖ Caregiving experience
     - ❖ Relationship with your child

3. **Possible reasons for the perceived changes**
   - (If the mother experienced changes) Are there any possible reasons for the previously mentioned changes?
   - (If the mother experienced no change) Why do you think there are no changes?

4. **Closing**
   - Do you have anything else that you would like to share?

*The interview will not be limited to the above questions. The interviewer may slightly adjust the interview guide based on the sharing of each interviewee.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p.1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	p.4
	2b	All items from the World Health Organization Trial Registration Data Set	Listed on the ClinicalTrial. registry
Protocol version	3	Date and version identifier	p.2
Funding	4	Sources and types of financial, material, and other support	p.2;p.21
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p.1;p.21
	5b	Name and contact information for the trial sponsor	p.2
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	p.21
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	p.21
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	p.6-9
	6b	Explanation for choice of comparators	p.7-8

Objectives	7	Specific objectives or hypotheses	p.8-9
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	p.9
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	p.12
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	p.13
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	p.10-11; Table 1
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	p.10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	p.13-17
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1, 2

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	p.12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	p.12-13
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	p.11-12
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	p.11-12
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	p.11-12
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	p.11-12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	p.11-12
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	p.13-17
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	p.13-14

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	p.18-19
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	p.17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	p.17
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	p.18
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	p.18
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	p.19
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	p.18
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p.19

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	p.19
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	p.19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	p.18-19
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	p.21
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	p.18-19
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	p.19
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supp file 2
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the

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Protocol for a mixed-methods randomised controlled trial evaluating the effectiveness of a dyadic expressive arts-based intervention in improving the psychosocial well-being of children with intellectual disability in special schools and their mothers

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Title: Protocol for a mixed-methods randomised controlled trial evaluating the effectiveness of a dyadic expressive arts-based intervention in improving the psychosocial well-being of children with intellectual disability in special schools and their mothers

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Protocol for a mixed-methods randomised controlled trial evaluating the effectiveness of a dyadic expressive arts-based intervention in improving the psychosocial well-being of children with intellectual disability in special schools and their mothers

Abstract

Introduction: Mothers of children with intellectual disability (ID) are often distressed because of intensive workloads and difficulties in communicating with their children. Given the interdependence between the psychosocial well-being of such dyads, interventions that promote parent-child relationships and mutual communication would be beneficial. Arts provide alternative avenues for expression and offer an imaginative and playful environment for discovering new communication strategies. Given the lack of studies on arts-based dyadic interventions, this study aims to examine the effectiveness of dyadic expressive arts-based intervention (EXAT) in improving the psychosocial outcomes of children with ID and their mothers and the mother-child relationships.

Methods and analysis: This study will adopt a mixed-methods randomised controlled trial design, wherein 154 dyads of children with ID and their mothers will be randomised into either the dyadic EXAT group or the treatment-as-usual waitlist control group. Quantitative data will be collected at 4 time points: baseline (T_0), post-intervention (T_1), 3-month post-intervention (T_2), and 6-month post-intervention (T_3). Qualitative data will be collected from a subset of 30 mothers in the intervention group at T_1 and T_3 to document their experiences and perceived changes after the intervention. Mixed-effects models and path analysis will be adopted to analyse the quantitative data, whereas

thematic analysis will be applied to the qualitative data. Both sets of data will be triangulated for an integrated view of the effectiveness and mechanism of the intervention.

Ethics and dissemination: Ethical approval has been obtained from the Human Research Ethics Committee of the University of Hong Kong (Ref. no.: EA200329). Written consent forms will be obtained from all recruited participants (mothers, children with ID, and teachers/social workers) before data collection. The study findings will be disseminated in international conferences and peer-reviewed academic journals.

Trial registration number NCT05214859, prospectively registered

Keywords: Mother-child relationship, Psychosocial well-being, Expressive arts therapy, Intellectual disability, Randomised controlled trial

Strengths and Limitations of the Study

- This randomised controlled trial will be the first to explore the effectiveness of dyadic EXAT in improving the psychosocial well-being of children with ID and their mothers and the mother-child relationships.
- The qualitative component of the study will explore the experiences of participating in the dyadic EXAT and its mechanism in affecting the dyad's psychosocial well-being and relationship.
- The study will include children with a diagnosis of autism spectrum disorder (ASD) to ensure a sufficient number of eligible participants.

- The study will include all the children in the primary section of special schools with a relatively wide range of ages.

Introduction

Intellectual disability (ID) refers to a developmental disability that significantly limits intellectual functioning and adaptive behaviours, which impedes daily functioning [1]. ID onset typically occurs before adulthood [1] and affects 0.05–1.55% of the global population [2]. The DSM-5 classifies ID with four different severity levels, "mild," "moderate," "severe," and "profound," to differentiate one's capacity in adaptive functioning and life skills [3]. With appropriate care and developmental training, individuals with mild or moderate level ID are capable of acquiring some life skills and living independently in familiar settings [4]. The ID prevalence in Hong Kong is 1.0–1.4% [5], affecting approximately 0.84% of the primary school-age population [6], and around 88% of primary school students with ID are diagnosed with mild or moderate ID [6]. As caring for children with ID relatively requires more care, effort and resources, the parents of children with ID are prone to emotional distress and poor quality of life.

Parents of children with intellectual disabilities are more likely to report higher parental stress than average [7,8]. Interactions between parents and children with different levels of ID are also less effective due to children's lack of initiation, responsiveness and salient cues during communication and their behavioural problems [9-11]. School-age children with ID also exhibit less secure and more disorganised attachment behaviour that may affect their relationship with adults [12]. Parents may also be more likely to adopt negative parenting styles to manage their children, such as being unsupportive and controlling [13,14]. Moreover, children with ID, particularly with a moderate level of ID, may also be comorbid with other developmental disorders, such as autism spectrum disorder (ASD), which may further induce stress and impair the quality

of life of their parents [15]. Despite facing the immense challenge, some parents can still find positivity in parenting their children with ID [16]. Various supports, such as early screening with intervention and inclusive education [17], have been developed to promote the development of children with ID at different levels and to ameliorate the burden on the parents.

A recent local survey has demonstrated that more than 90% of caregivers of children with special educational needs, including intellectual disabilities, are mothers [18]. This may be due to entrenched patriarchal beliefs in Hong Kong society, which expects mothers to be caregivers and homemakers and fathers to be breadwinners [19]. Compared with other family caregivers, such as fathers and siblings, mothers may be at a higher risk of psychosocial difficulties because of the lack of social support, low income, and being forced to be unemployed [20,21]. Mothers are also known to devote enormous amounts of time and energy to caring for children with ID, which subjects them to intensive stress, marital issues, psychological disturbance, disrupted social lives, poor physical health, and uncertainty about the future [22-26]. Furthermore, the mothers of younger or school-age children with ID have reported experiencing more stress than the mothers of older children with ID, as younger children require higher levels of care. Mothers also often face dilemmas in decision-making, such as when choosing schools and rehabilitation programmes [25,26].

Extensive interventions or services have been provided to support children with ID and their families, such as in the form of parenting skills training, psychoeducational support for parents, and behavioural management programmes for children [27,28]. Nonetheless, few interventions focus on enhancing communication, relationships, and

overall well-being for mother-child dyads. The provision of parent-child support for this population is crucial as the quality of the relationship and interactions between parents and the child with ID determines the development and mental health of the children [29,30]. Positive parenting behaviour and parent-child relationship also help infuse resilience that may lower parental stress and may also help reduce the frequency of externalizing behaviour problems in children with mild or borderline ID [31,32]. Therefore, it is essential to promote positive interactions, mutual understanding and communication between mothers and their children [27]. Support is also needed to improve the mother's mental health and equip them with strategies to cope with the children's behaviours [33].

Need for Arts

Arts can serve as an avenue for self-expression and communication, particularly for individuals who find verbal self-expression difficult [34], like children with ID. Previous studies on arts-based dyadic interventions for parents and their children with or without disabilities have also demonstrated an array of benefits, including promoting mothers' mental health, decreasing child's behavioural problems, nurturing secure attachment, expanding playfulness, and facilitating interconnection, communication, understanding, and synchrony within dyads [35-40]. All these effects benefit children with ID and their mothers in terms of developing a positive relationship and promoting mutual understanding and communication. In addition to applying a single art modality approach, this study will employ an expressive arts-based intervention (EXAT) that utilises different art modalities, such as music, drama, movement, and visual arts, to attain therapeutic goals [41]. It adheres to an intermodal approach, which posits that the

experience of expressing oneself can be deepened and expanded by interchanging art modalities [42]. The flexibility of the use of arts can also allow dyads to explore and experiment with different arts materials. A group dyadic setting will also be adopted as it provides room for cultivating mutual support and connections within and across dyads, which possibly create impacts on the parent-child relationships and empower the mothers [39]. While there are existing studies on parent-child dyadic arts intervention in different populations, studies focusing on children with ID and their mothers and with more rigorous designs, such as those with larger samples or comparable control groups, are still limited. Including a treatment-as-usual control group in the study design helps reveal the treatment effects of EXAT on top of the generic routine and care of the dyads.

Research Objectives

The primary objective of the study is to examine the effectiveness of the dyadic EXAT in improving psychosocial outcomes of children with ID and their mothers and the mother-child relationships compared to a treatment-as-usual waitlist control group across different time points. The sustainability of the effects will be examined at 3-month and 6-month post-intervention follow-up time points. It is hypothesised that dyads in the EXAT group will experience improved psychosocial conditions and mother-child relationships, relative to the dyads in the control group. The second objective is to explore the mechanism by which the intervention acts on mother-child dyads; the study will investigate the relationships between psychosocial variables and intervention effectiveness, such as mediation or moderation effects. Qualitative interviews will be used to document the subjective experiences of and changes in mothers after participating in the intervention.

Methods and Analysis

This study will employ a two-arm, mixed-methods, randomised controlled trial design. The intervention phase will last for eight weeks. The outcome measures will be assessed at 4 time points: baseline (T_0), 2-month after baseline (post-intervention, T_1), 5-month after baseline (3-month post-intervention follow-up, T_2), and 8-month after baseline (6-month post-intervention follow-up, T_3). This will help capture the immediate and sustained effects of the dyadic EXAT on mother-child relationships and psychosocial well-being. In addition to quantitative outcome measures, qualitative interviews with a subset of mothers (i.e., 30 mothers) from the intervention group will be conducted at T_1 and T_3. The interviews will help document information regarding the experiences of participating in the dyadic EXAT and whether these experiences shape the caregiver experience, particularly the relationship between mothers and their children and the mothers' coping strategies during caregiving. Adopting the mixed-methods design will help triangulate the findings and enhance our understanding of the effects of the dyadic EXAT on mother-child dyads. Figure 1 depicts the schedule of enrolment, allocation and assessments. Figure 2 shows the study flow based on the CONSORT flow diagram.

Intervention

Dyads in the intervention group will receive eight 90-min weekly sessions. The sessions will be conducted at the children's schools by either a registered EXAT therapist, an EXAT trainee or a mental professional trained in EXAT. Each session will be conducted in a small group of 3–4 dyads. The group facilitators will receive training in the standardised protocol and safety precautions. The principal investigator (PI; corresponding author) will provide on-site and/or off-site supervision to ensure treatment

fidelity. Themes related to mother-child relationships will be covered. The content of the intervention was informed by the previous works on applying arts-based activities or interventions for individuals with ID or mother-child dyads in Hong Kong [36,43,44]. Each session will comprise four stages, which will involve both within dyads or across dyads arts activity. All the dyads will work together as a group during greetings and sharing, whereas dyads will mostly work individually during the warm-up and core art(s) activities. Table 1 depicts the themes and objectives of each session. Some selected examples of arts activities are also listed. Table 2 describes the stages of each session.

Table 1:Themes and objectives of each session

Themes	Objectives	Selected examples of art(s) activities
Session 1		
Communication: Interaction with or without words	- To experience non-verbal communication through art(s)	- Mirror each other's movement
Session 2		
Relationship: Happy moment and joyful relationship	- To create and recall joyful moments between dyads	- Create costumes using art materials for a party
Session 3		
Expression: Playfulness and de-stress expression	- To develop ways for de-stressing	- Relieve stress through drumming, moving and drawing
Session 4		
Empathy: Understanding and empathy through arts	- To enhance understanding between dyads	- Play movement charades
Session 5		
Interaction: Creative interaction	- To find one's own space and time	- Draw on the same paper or move together
Session 6		
Care: Love and concern	- To express love and care to each other	- Create a gift box for each other
Session 7		
Gratitude: Appreciation and gratitude	- To promote mutual appreciation	- Create a "Thank you" card
Session 8		
Connection: Collaboration and connection	- To strengthen the connections of the group members	- Create artwork and movement together, and share

	- To celebrate and farewell	

Table 2: Structure of each session

Stages	Process	Purposes	Format
Greetings and check-in	- Greetings - Introducing the theme	- Transit from the real world to a therapeutic space - Build rapport - Give participants a brief idea of the theme - Give the therapist a brief idea of the participants' conditions	- Across dyads
Warm-up	- Participating in warm-up activities/games	- Prepare for the art(s)-making process	- Mainly within dyads, may also encourage across dyads
Art(s) creation and response	- Participating in art(s)-making activities based on the designated theme - Sharing of art(s)-making experiences and insights	- Cultivate insights from the art(s)-making process - Promote mutual support among groupmates	- Arts-making within dyads first and/or then across dyads - Sharing across dyads
Closure	- Closing rituals	- Conclude the session - Transit back to the real world	- Across dyads

The dyads in the treatment-as-usual control group will continue their normal routines and care. They will be invited to join the intervention group upon completion of all assessments.

Randomisation and Blinding

Eligible dyads will be allocated to either the dyadic EXAT group or the treatment-as-usual waitlist control group on a 1:1 basis based on a list of non-repeating computer-generated random numbers. The list will be generated by a staff who will not be involved in the trial. The designated staff of each school will be notified of the allocation results. A

research assistant will be responsible for the randomisation and case allocation procedures.

Given the nature of the trial, it will not be feasible to blind the participants (dyads and teachers/social workers) and therapists to the group allocation results. No unblinding procedures are predetermined for revealing the participants' allocation during the trial. However, the data analyst will be blinded. A research assistant will recode the group information in the dataset before passing it on to the data analyst for data analysis.

Sample Size

The sample size was estimated using the analysis software *G*power 3.1* [45]. A moderate effect size (Cohen's $d = 0.5$) was expected based on a previously unpublished local study conducted in 2017 (Li IMY. The effectiveness of an attachment-based expressive arts therapy parenting programme for parents with special needs children (Unpublished Thesis). Hong Kong: The University of Hong Kong; 2017). Assuming an attrition rate of 20%, a total sample of 154 dyads will be needed (i.e., 77 dyads per arm) to reach 80% statistical power and attain a moderate effect size (Cohen's $d = 0.5$) in the proposed 2-arm randomised controlled trial with four measurement time points at a 5% level of statistical significance.

Participants

The recruitment of participants will be carried out at special schools for children with intellectual disability in Hong Kong. The study has been started on July 9, 2022, and is estimated to be ended on December 31, 2025. This study will collaborate with the Hong Chi Association, a major non-governmental organisation (NGO) in Hong Kong that provides special education services for students with different grades of ID. This study

will also aim to collaborate with special schools run by other NGOs. Social workers and teachers at the interested schools will assist with the screening procedures and refer potential participants to the research team. The eligibility of mother-child dyads will be determined using the following inclusion and exclusion criteria.

Inclusion criteria

- The child is 6–12 years old (primary school student);
- The child is diagnosed with mild to moderate ID, IQ score ranges from 35 to 69 (based on the assessment conducted by certified clinicians);
- By the judgement of the health/school professional staff, the child is capable of responding to assessments and participating in group activities. ;
- The dyad is willing and able to give consent for participation.

Exclusion criteria

- The child is diagnosed with attention-deficit/hyperactivity disorder;
- The dyad is currently participating in other behavioural or pharmacological trial(s);
- Either the mother or child has other contraindications or severe comorbidities that may impede participation (e.g., severe physical disabilities).

Outcome Measures

The outcome measures of this trial will comprise (a) psychosocial condition of mothers; (b) psychosocial condition of children; (c) mothers' perceptions of parent-child relationships; and (d) demographics and clinical profiles of the dyads. The mothers will complete a self-administered questionnaire regarding their psychosocial conditions, perceived parent-child relationships and the dyads' demographic and clinical information. Research assistants will assist children in responding to the mood scale. An EXAT

therapist, a trained research assistant or an EXAT trainee under supervision will administer the Face Stimulus Assessment (FSA). Teachers or social workers of each child will also be invited to fill the behavioural checklist. To enhance retention of the participants, data will be collected from places convenient for the participants, such as the dyads' homes or special schools. Research assistants will send reminders to the participants to attend appointments for data collection.

Mothers' Psychosocial Outcomes and Perceived Parent-Child Relationships

Parenting Stress. The 36-item Parenting Stress Index (4th Ed., short form) will be adopted to assess parenting stress [46]. The scale consists of three subscales, parental distress, parent–child dysfunctional interaction and difficult child, and each item is measured on a 5-point Likert scale. The official Chinese translated version from Psychological Assessment Resources (PAR, Inc.) will be administered.

Burnout. The level of burnout of mothers will be captured by the Chinese version of the 6-item client burnout subscale of the Copenhagen Burnout Inventory (CBI) [47], with each item rated on a 5-point Likert scale.

Parent-Child Relationship. Parent-child relationship will be captured by two subscales with a total of 19 items from the Parent-Child Relationship Inventory (PCRI): parent-child communication and satisfaction with parenting [48]. The PCRI assesses attitudes towards parent-child relationship on a 4-point Likert scale. The research team has obtained permission from the publisher to translate the items into traditional Chinese and validate the translation.

Positive and Negative Affect. The mothers' positive and negative affectivity will be assessed by the Chinese version of the 10-item International Positive and Negative

Affectivity Schedule – Short Form (I-PANAS-SF) [49]. The scale has two subscales, one each for positive and negative affect, and each item is rated on a 5-point Likert scale.

Quality of Life. The mothers' quality of life will be captured by the 28-item Hong Kong Chinese brief version of the World Health Organization Quality of Life Measure (WHOQOL-BREF, HK) [50]. It assesses the subjective quality of life in four domains: physical, psychological, social relationship, and environmental.

Psychological Well-Being. The mothers' psychological well-being will be documented by the Hong Kong Cantonese version of the 5-item World Health Organisation Five Well-Being Index (WHO-5) [51]. It measures subjective psychological well-being on a 6-point Likert scale.

Children's Psychosocial Outcomes

Mood States. The Ottawa Mood Scales will be adopted to measure the children's mood states [52]. It is a visual analogue scale composed of five items that assess mood, anger, worry, stress and self-regulation. Relevant faces, icons or images will be shown to help children choose the most suitable answer that reflects their mood states. Despite this scale only being validated in a young adult sample [53], the pictorial features in a scale can draw interest from children and may help obtain a more relevant response from them [54]. The research team has obtained permission to translate the scale into traditional Chinese and validate the translated version.

Emotional Expression. The emotional expression of children with ID will be captured by the Face Stimulus Assessment (FSA) [55]. It is a projective drawing test that requires children to use the provided colour markers on three A4-size drawing templates: first on a pre-drawn face, second on an outline of a face, and third on a blank sheet of

paper. The sketches will be analysed based on the guidelines mentioned in the FSA E-Packet and Rating Manual (2nd Ed.), provided by the author of the assessment. The sketches will be digitally scanned to extract the patterns of colour usage [43]. The research team has obtained permission to translate the guidelines into traditional Chinese and validate the translated version.

Child Behaviour. The behaviours of children with ID will be assessed by the teachers or social workers via the Chinese version of the Child Behaviour Checklist Teachers' Report Form (CBCL-TRF/6-18) for school age children [56]. The checklist yields aggregate scores on externalising, internalising, and total behavioural problems, and on eight syndrome scales: anxious/depressed, withdrawn/depressed, somatic complaints, social problems, thought problems, attention problems, rule-breaking behaviour, and aggressive behaviour [57].

Socio-demographic and Clinical Information

Demographics. Socio-demographic information of the mothers, namely age, gender, education level, family composition, and financial status, and the children, namely age, gender, grade, and level of ID, will be collected from the mothers through self-report questionnaires.

Clinical Information. Clinical profiles of the mother-child dyads, such as time since diagnosis of the children with ID, time of onset and history of psychiatric disorders, presence of any comorbidities (e.g., physical disabilities, hypertension, diabetes mellitus, other cognitive disturbances), and history of community and rehabilitation service utilisation will be documented.

Individual Semi-Structured In-Depth Interviews

A subset of mothers (i.e., 30 mothers) from the intervention group will be randomly invited to attend individual, semi-structured interviews at T_1 and T_3. The first interview will explore their experiences of participating in the intervention and whether there are any immediate changes. The second interview will investigate possible changes related to the intervention and whether these changes further induce changes in their daily lives and relationships with their children. The interviews will be conducted by the research team based on the interview guide (online supplementary file 1). The sample size will be set at 30 mothers as data saturation will be reached in under 25 interviews [58] and to ensure sufficient data after potential dropouts at T_3.

Data Analysis

Quantitative Analysis

The intent-to-treat principle will be used to address the effects of crossovers and dropouts. Missing data will be handled by full information maximum likelihood. Descriptive statistics will be used to summarise the socio-demographic characteristics of the participants at all time points. Treatment outcomes will be examined by computing mixed-effects regression models. This analytical method will analyse the repeated measures between the groups to obtain the time effect, group effect, and time x group interaction effect. Demographic and clinical variables will be controlled for in the analysis. Path analysis will be adopted to examine the mediating role of the parent-child relationship and parenting stress on the effect of dyadic EXAT on psychological distress and caregiver burnout. Mediation effects will be determined based on the significance of the indirect effects of the intervention on psychological distress and caregiver burnout via the mediators. As the data distribution is expected to be skewed, bootstrapping will be

used to estimate the confidence intervals of the indirect effects. Statistical tests will be performed using *Mplus 8.3* (Muthén & Muthén, 1998–2017) and will be two-tailed with statistical significance set at 5%.

Qualitative Analysis

Audio recordings of the in-depth interviews will be transcribed verbatim by the research staff. All of the transcripts will be imported to *NVivo 12.0* (QSR International Pty Ltd., 2018) or above for data analysis. The thematic analysis approach [59] will be used to identify codes and themes related to the experiences of the dyadic EXAT and the possible mechanism of the intervention. Two research staff members will be involved in data analysis to ensure the credibility of the findings.

Study Monitoring and Data Management

The progress and safety of the study will be monitored by the General Research Fund of the Research Grants Council (RGC). A mid-term progress report and interim analyses will be submitted after having implemented the study for 18 months. In case of RGC identifies any serious problem or unsatisfactory progress, the trial may be terminated. A final report will be submitted upon completion of the study.

Regarding data entry, quantitative data collected from the participants will be entered into the dataset by research assistants. After inputting all of the data, the data analyst will perform data screening to check its validity. Invalid inputs will be cross-checked and re-submitted by another research assistant. Regarding qualitative data, the audio recordings will be transcribed into text files, and the sketches created by the children will be digitally scanned by research assistants. The data analyst will check the transcripts by concurrently listening to the audio and reading the transcripts.

Amendments will be made if necessary.

Regarding data storage, all of the hard copies, after removing personal identifiers, will be stored in a locked cabinet at the PI's research centre. Soft copies and other related electronic files will be encrypted and stored in a password-protected desktop computer at the PI's research centre. All the hard and soft copies will keep for a maximum of three years after the publication of the first paper. Only the relevant research staff members, i.e., the PI, the Co-Is, research assistants, and data analysts, will be granted access to the raw data files and trial data set.

Patient and Public Involvement

Patients and the public were not involved in designing the protocol. The findings and protocols of the study will be disseminated to the participants upon request.

Ethics and Dissemination

Ethical approval has been obtained from the Human Research Ethics Committee of the University of Hong Kong (EA200329). The protocol of this study has been registered with the Clinical Trial Registry (NCT05214859). Any amendments to the protocol will be reported to the ethics committee and clinical trial registry. Trained research assistants will explain the rights of the participants and objectives of the study to participants and obtain their written consent before data collection. The data collection and dyadic EXAT are not expected to cause any physical or psychological harm. If the participants are disturbed by the data collection or intervention process, they can choose to skip or terminate any procedures. Professional referrals can be made upon request. All such incidents will be reported to the PI. Regarding disseminating the findings, the team will present at internal or local conferences and will publish in peer-reviewed academic

journals.

Discussion

The mothers of children with ID are under high caregiving strain, and the children themselves experience difficulties in channelling their emotions. This study hopes to raise awareness of the psychosocial well-being of both children with ID and their mothers. Interventions are needed to mitigate their psychological distress and boost their psychosocial well-being. As dyadic interventions, particularly art(s)-based dyadic interventions, have been limited, the proposed study will aim to fill this gap by providing evidence of the effectiveness of dyadic EXAT in improving the psychosocial well-being of children with ID and their mothers. The dyads are expected to benefit from the intervention in terms of nurturing mutual understanding, providing opportunities for expression and fostering psychosocial well-being. The findings will inform on the mechanism underlying dyadic EXAT and shed light on how arts can benefit mother–child dyads. In the future, art(s)-based interventions can be considered as one of the intervention strategies to provide psychosocial support for this population. Furthermore, the findings of this study can will contribute to the development and further application of art(s)-based interventions for children with ID and their families or for families with children with other disabilities or special needs.

Despite the strengths of the study, there are several limitations. Given the high comorbidity of diagnosis with ID and ASD, it is difficult to recruit sufficient participants with children with ID only. To ensure there are sufficient participants for the project, children diagnosed with ID and ASD will also be included. However, it will be complicated to differentiate whether the child's behaviours are related to ID or ASD and

if the maternal stress is caused by ID or ASD-related issues. This study will also include all primary school students aged from 6 to 12. While lower and higher primary school children may have different needs, the themes of the intervention shall be applicable to all primary school students. The therapist will fine-tune the process to meet the immediate needs and preferences of participants without changing the session's overall objectives, themes and structure. The proposed randomisation procedures may cause contamination across groups as participants may know each other in the same school. However, participants in the control group will also be invited to join the intervention later, and the dyads will be reminded to keep their experiences of the intervention confidential to minimise contamination. Although the process of designing the intervention did not involve the public, the content of the intervention took references from previous local studies on applying arts as a medium in promoting the well-being of individuals with ID and facilitating the communication between mother-child dyads [36,43,44].

Figure legends

Figure 1: The schedule of enrolment, allocation and assessments.

Figure 2: The study flow based on the CONSORT flow diagram.

Footnotes

Contributors: HRTH and WAHY conceived the study. HRTH, WAHY, WPKS, and LHHM contributed to the study design, and they are the research grant holders (named investigators)., FTCT, CCKP, WPKS, and LHHM provided methodological expertise and

resources. LTLT, WAHY, and HRTH prepared the draft of this study protocol. All the authors reviewed and approved the final manuscript.

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Competing interests: None declared.

Patient consent for publication: No participants' data were presented in this article.

Ethics approval: Ethical approval has been obtained from the Human Research Ethics Committee of the University of Hong Kong (EA200329).

Data availability statement: Data sharing is not applicable to this article as no new data were created or analysed in this article.

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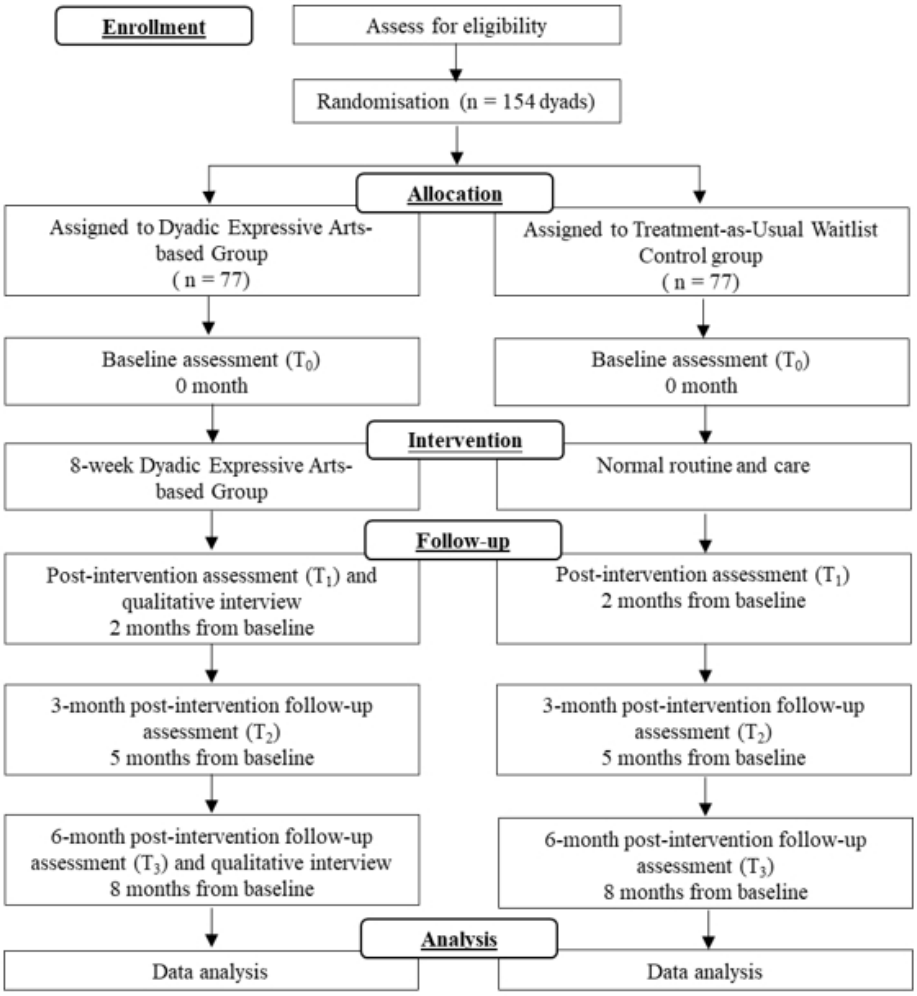
		STUDY PERIOD				
		Enrolment & Allocation	Intervention (8 weeks)		Post intervention (5 months from t_0)	Post intervention (8 months from t_0)
TIMEPOINT		$-t_0$	t_0	t_1	t_2	t_3
ENROLMENT:						
Eligibility screen		X				
Informed consent		X				
Allocation		X				
INTERVENTIONS:						
EXAT[a]			←	→		
Control						
ASSESSMENTS:						
Mother & Child	Socio-demographic		X			
Mother & Child	Clinical information		X			
Mother	Psycho-social outcomes		X	X	X	X
Mother	Perceived parent-child relationship		X	X	X	X
Mother[b]	Perceived changes and experiences of EXAT			X		X
Child	Psycho-social outcomes		X	X	X	X

a. EXAT: Dyadic Expressive arts-based group
b. Only a subset of mothers in the intervention group (i.e., 30 mothers) will participate in a semi-structured in-depth interview for understanding their perceived changes and experiences after participating in the dyadic Expressive arts-based group.

The schedule of enrolment, allocation and assessments.

201x223mm (96 x 96 DPI)



The study flow based on the CONSORT flow diagram.

408x441mm (38 x 38 DPI)

Supplementary 1: Interview guides for Qualitative interview

Interview guide at post-intervention (T_1)

1. **Perceived experiences of the dyadic expressive arts-based group**
   - Could you share your experiences in the 8-week dyadic expressive arts-based group intervention?

2. **Perceived changes after participating in the dyadic expressive arts-based group**
   - How do you perceive/are there any changes in the following aspects?
     - ❖ Your child's behaviour
     - ❖ Your psychological condition
     - ❖ Caregiving experience
     - ❖ Relationship with your child

3. **Possible reasons for the perceived changes**
   - (If the mother experienced changes) Are there any possible reasons for the previously mentioned changes?
   - (If the mother experienced no change) Why do you think there are no changes?

4. **Closing**
   - Do you have anything else that you would like to share?

*The interview will not be limited to the above questions. The interviewer may slightly adjust the interview guide based on the sharing of each interviewee.

Interview guide at 6-month post-intervention (T_3)

1. **Current situation of the mother-child dyad**
   - How have you and your child been in these six months?

2. **Perceived changes six months after participating in the dyadic expressive arts-based group**
   - How do you perceive/are there any changes in the following aspects?
     - ❖ Your child's behaviour
     - ❖ Your psychological condition
     - ❖ Caregiving experience
     - ❖ Relationship with your child

3. **Possible reasons for the perceived changes**
   - (If the mother experienced changes) Are there any possible reasons for the previously mentioned changes?
   - (If the mother experienced no change) Why do you think there are no changes?

4. **Closing**
   - Do you have anything else that you would like to share?

*The interview will not be limited to the above questions. The interviewer may slightly adjust the interview guide based on the sharing of each interviewee.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

**page no. refers to the clean version of the manuscript*

Section/item	ItemNo	Description	
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p.1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	p.4
	2b	All items from the World Health Organization Trial Registration Data Set	Listed on the ClinicalTrial. registry
Protocol version	3	Date and version identifier	p.2
Funding	4	Sources and types of financial, material, and other support	p.2;p.23
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	p.1;p.22
	5b	Name and contact information for the trial sponsor	p.2
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	p.23
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	p.23
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	p.6-9

	6b	Explanation for choice of comparators	p.8-9
Objectives	7	Specific objectives or hypotheses	p. 9
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	p.10
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	p.13-14
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	p.14
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	p.10-12; Table 1; Table 2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	p.10-11
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	p.14-18
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1, 2

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	p.13
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	p.13-14
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	p.12-13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	p.12-13
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	p.12-13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	p.12-13
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	p.12-13
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	p.14-18
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	p.14-15

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	p.19-20
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	p.18-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	p.18-19
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	p.19
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	p.19
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	p.20
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	p.19
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p.20

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	p.20
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	p.20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	p.19-20
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	p.23
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	p.19-20
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	p.20
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supp file 2
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the

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