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

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1	Title: Protocol for a mixed-methods randomised controlled trial evaluating the		
2	effectiveness of a dyadic expressive arts-based intervention in improving the		
3	psychosocial well-being of children with intellectual disability and their mothers		
4			
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2 3 4	29	Protocol for a mixed-methods randomised controlled trial evaluating the
5 6	30	effectiveness of a dyadic expressive arts-based intervention for improving the
7 8	31	psychosocial well-being of children with intellectual disability and their mothers
9 10 11	32	
12 13	33	Abstract
14 15	34	
16 17 18	35	Introduction: Mothers of children with intellectual disability (ID) are often distressed
19 20	36	because of intensive workloads and difficulties in communicating with their children.
21 22	37	Given the interdependence between the psychosocial well-being of such dyads,
23 24 25	38	interventions that promote parent-child relationships and mutual communication would
25 26 27	39	be beneficial. Arts provide alternative avenues for expression and offer an imaginative
28 29	40	and playful environment for discovering new communication strategies. Given the lack of
30 31	41	studies on arts-based dyadic interventions, this study aims to examine the effectiveness of
32 33 34	42	dyadic expressive arts-based intervention (EXAT) in improving the psychosocial
35 36	43	outcomes of children with ID and their mothers and the mother-child relationships.
37 38	44	Methods and analysis: This study will adopt a mixed-methods randomised controlled
39 40 41	45	trial design, wherein 154 dyads of children with ID and their mothers will be randomised
42 43	46	into either the dyadic EXAT group or treatment-as-usual waitlist control group.
44 45	47	Quantitative data will be collected at 4 time points: baseline $(T_0)$ , post-intervention $(T_1)$ ,
46 47 48	48	3-month post-intervention $(T_2)$ , and 6-month post-intervention $(T_3)$ . Qualitative data will
49 50	49	be collected from a subset of 30 mothers in the intervention group at $T_1$ and $T_3$ to
51 52	50	document their experiences and perceived changes after the intervention. Mixed-effects
53 54 55 56 57 58	51	models and path analysis will be adopted to analyse the quantitative data, whereas

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52	thematic analysis will be applied to the qualitative data. Both sets of data will be
53	triangulated for an integrated view of the effectiveness and mechanism of the
54	intervention.
55	Ethics and dissemination: Ethical approval has been obtained from the Human
56	Research Ethics Committee of the University of Hong Kong (Ref. no.: EA200329).
57	Written consent forms will be obtained from all recruited participants (mothers, children
58	with ID, and teachers/social workers) before data collection. The study findings will be
59	disseminated in international conferences and peer-reviewed academic journals.
60	
61	Trial registration number NCT05214859, prospectively registered
62	
63	Keywords: Mother-child relationship, Psychosocial well-being, Expressive arts therapy,
64	Intellectual disability, Randomised controlled trial
65	
66	Strengths and Limitations of the Study
67	- This will be the first study to explore the effectiveness of dyadic EXAT in improving
68	the psychosocial well-being of children with ID and their mothers and the mother-
69	child relationships.
70	- Empirical evidence from this study will inform the application of art(s)-related
71	interventions for similar populations, such as children with developmental disabilities
72	or special education needs.
73	- Given the high comorbidity of diagnosis with ID and autism spectrum disorder, the
74	study will not exclude children with diagnosis of autism spectrum disorder to ensure a

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2 3	75	sufficient number of eligible participants.
4	75	sufficient number of engible participants.
5 6	76 -	Owing to the nature of this trial, only the data analyst will be blinded from the
7 8	77	participants' allocation results.
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78	Introduction
79	Intellectual disability (ID) refers to a developmental disability that significantly
80	limits intellectual functioning and adaptive behaviours, which impedes daily
81	functioning. <sup>1</sup> ID onset typically occurs before adulthood <sup>1</sup> and affects 0.05–1.55% of the
82	global population. <sup>2</sup> The ID prevalence in Hong Kong is 1.0–1.4%, <sup>3</sup> affecting
83	approximately 0.89% of the school-age population. <sup>4</sup> As caring for children with ID
84	requires intensive care, effort and resources, the parents of children with ID are prone t
85	emotional distress and poor quality of life.
86	Existing findings have shown that the parents of children with disabilities
87	experience higher parental stress than those of children without disabilities. <sup>56</sup> Caring for
88	children with ID can be taxing due to the high risk of behavioural and emotional
89	problems. <sup>78</sup> For example, children with ID exhibit deficits in emotional regulation and
90	expression, <sup>9</sup> and may display more anger and aggressive behaviours than children
91	without ID. <sup>10</sup> Limitations in attention, responsiveness, salient cues, and use of language
92	in communication also restrict their social engagements with others. <sup>11-14</sup> In particular, t
93	poor expression of feelings and emotions has been commonly observed when children
94	with ID communicate with their family members;15 these unhealthy communication
95	patterns have been correlated with poor psychological conditions in parents. <sup>15</sup>
96	Moreover, children with ID are known to have high comorbidity with other
97	developmental disorders such as autism spectrum disorder and related behavioural and
98	emotional issues, which can further complicate caregiving. <sup>17 18</sup>
99	Compared with other caregivers in the family, such as fathers and siblings,
100	mothers are more likely to experience caregiving burdens. <sup>19</sup> This may be due to

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101	entrenched patriarchal beliefs in Hong Kong society, which expects mothers to be
102	caregivers and homemakers and fathers to be breadwinners. <sup>20</sup> Mothers are known to
103	devote enormous amounts of time and energy to caring for children with ID, which
104	subjects them to intensive stress, marital issues, psychological disturbance, disrupted
105	social lives, poor physical health, and uncertainty about the future. <sup>16 21-23</sup> Furthermore, the
106	mothers of younger or school-aged children with ID have reported experiencing more
107	stress than the mothers of older children with ID as younger children require higher levels
108	of care. Mothers also often face dilemmas in decision-making, such as when choosing
109	schools and rehabilitation programmes. <sup>18 23</sup>
110	Extensive interventions or services have been provided for support children with
111	ID and their families, such as in the form of parenting skills training, psychoeducational
112	support for parents, and behavioural management programmes for children. <sup>24 25</sup>
113	Nonetheless, few interventions focus on enhancing communication, relationships, and
114	overall well-being for mother-child dyads. The provision of dyadic support for this
115	population is crucial as the psychosocial well-being of mothers and children with ID are
116	interconnected. <sup>26</sup> Caregiving burdens have been shown to impair the mothers' mental
117	health, which is detrimental to the quality of mother-child relationships <sup>16</sup> and
118	communication with the children. <sup>27</sup> Therefore, it is essential to promote positive
119	interactions, mutual understanding and communication between mothers and their
120	children. <sup>24</sup>
121	Need for Arts
122	Arts can serve as alternative pathways for expressing emotions and be particularly
123	helpful for individuals who find verbal self-expression difficult, <sup>28</sup> such as children with

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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;<sup>29</sup> 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.<sup>30</sup> It adheres to an intermodal approach, which posits that the experience of expressing oneself can be deepened and expanded by interchanging art modalities.<sup>31</sup> 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.<sup>32</sup> 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 6month 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

1 2		
2 3 4	147	mechanism by which the intervention acts on mother-child dyads; the study will
5 6	148	investigate the relationships between psychosocial variables and intervention
7 8 9	149	effectiveness, such as mediation or moderation effects. Qualitative interviews wi
9 10 11	150	used to document the subjective experiences of and changes in mothers after par
12 13	151	in the intervention.
14 15 16	152	
16 17 18	153	Methods and Analysis
19 20	154	This study will employ a two-arm, mixed-methods, randomised controlle
21 22	155	design. The intervention phase will last for eight weeks. The outcome measures
23 24 25	156	assessed at 4 time points: baseline $(T_0)$ , 2-month after baseline (post-intervention
26 27	157	month after baseline (3-month post-intervention follow-up, $T_2$ ), and 8-month after
28 29	158	baseline (6-month post-intervention follow-up, $T_3$ ). This will help capture the im
30 31 32	159	and sustained effects of the dyadic EXAT on mother-child relationships and psyc
33 34	160	well-being. In addition to quantitative outcome measures, qualitative interviews
35 36	161	subset of mothers (i.e., 30 mothers) from the intervention group will be conducted
37 38 30	162	and T <sub>3</sub> . The interviews will help document information regarding the experience
39 40 41	163	participating in the dyadic EXAT and whether these experiences shape the careg
42 43	164	experience, particularly the relationship between mothers and their children and
44 45	165	mothers' coping strategies during caregiving. Adopting the mixed-methods desig
46 47 48	166	help triangulate the findings and enhance our understanding of the effects of the
49 50	167	EXAT on mother-child dyads. Figure 1 depicts the schedule of enrolment, allocation
51 52	168	assessments. Figure 2 shows the study flow based on the CONSORT flow diagra
53 54 55	169	
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148	investigate the relationships between psychosocial variables and intervention
149	effectiveness, such as mediation or moderation effects. Qualitative interviews will be
150	used to document the subjective experiences of and changes in mothers after participating
151	in the intervention.
152	
153	Methods and Analysis
154	This study will employ a two-arm, mixed-methods, randomised controlled trial
155	design. The intervention phase will last for eight weeks. The outcome measures will be
156	assessed at 4 time points: baseline $(T_0)$ , 2-month after baseline (post-intervention, $T_1$ ), 5-
157	month after baseline (3-month post-intervention follow-up, T <sub>2</sub> ), and 8-month after
158	baseline (6-month post-intervention follow-up, T <sub>3</sub> ). This will help capture the immediate
159	and sustained effects of the dyadic EXAT on mother-child relationships and psychosocial
160	well-being. In addition to quantitative outcome measures, qualitative interviews with a
161	subset of mothers (i.e., 30 mothers) from the intervention group will be conducted at $T_1$
162	and T <sub>3</sub> . The interviews will help document information regarding the experiences of
163	participating in the dyadic EXAT and whether these experiences shape the caregiver
164	experience, particularly the relationship between mothers and their children and the
165	mothers' coping strategies during caregiving. Adopting the mixed-methods design will
166	help triangulate the findings and enhance our understanding of the effects of the dyadic
167	EXAT on mother-child dyads. Figure 1 depicts the schedule of enrolment, allocation and
168	assessments. Figure 2 shows the study flow based on the CONSORT flow diagram.
169	

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## 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.

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	Process	Purposes
	Greetings - Greetings and check-in - Introducir theme	<ul> <li>Transit from the real world to a therapeutic space</li> <li>Build rapport</li> <li>Give participants a brief idea of the theme</li> <li>Give the therapist a brief idea of</li> </ul>
	Warm-up - Participati warm-up activities/	process
	Art(s)-Participationcreation andart(s)-makeresponseactivities	ing in - Cultivate insights from the art(s)- making process based on - Promote mutual support among ated theme groupmates f art(s)- cperiences
	Closure - Closing ri	
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105		
195	The dyads in the treatm	ent-as-usual control group will continue their normal
195	-	ent-as-usual control group will continue their normal invited to join the intervention group upon completion
	-	
196	routines and care. They will be	
196 197	routines and care. They will be all assessments. Randomisation and Blinding	
196 197 198	routines and care. They will be all assessments. <b>Randomisation and Blinding</b> Eligible dyads will be a	invited to join the intervention group upon completion
196 197 198 199	routines and care. They will be all assessments. <b>Randomisation and Blinding</b> Eligible dyads will be a as-usual waitlist control group	invited to join the intervention group upon completion llocated to either the dyadic EXAT group or the treatme on a 1:1 basis based on a list of non-repeating computer
196 197 198 199 200	routines and care. They will be all assessments. <b>Randomisation and Blinding</b> Eligible dyads will be a as-usual waitlist control group generated random numbers. Th	invited to join the intervention group upon completion
196 197 198 199 200 201	routines and care. They will be all assessments. <b>Randomisation and Blinding</b> Eligible dyads will be a as-usual waitlist control group generated random numbers. Th in the trial. The designated staf	invited to join the intervention group upon completion llocated to either the dyadic EXAT group or the treatme on a 1:1 basis based on a list of non-repeating computer e list will be generated by a staff who will not be involve
196 197 198 199 200 201 201	routines and care. They will be all assessments. <b>Randomisation and Blinding</b> Eligible dyads will be a as-usual waitlist control group generated random numbers. Th in the trial. The designated staf	invited to join the intervention group upon completion llocated to either the dyadic EXAT group or the treatme on a 1:1 basis based on a list of non-repeating computer e list will be generated by a staff who will not be involv f of each school will be notified of the allocation results
196 197 198 199 200 201 202 202 203	routines and care. They will be all assessments. <b>Randomisation and Blinding</b> Eligible dyads will be a as-usual waitlist control group generated random numbers. The in the trial. The designated staff research assistant will be respo procedures.	invited to join the intervention group upon completion llocated to either the dyadic EXAT group or the treatme on a 1:1 basis based on a list of non-repeating computer e list will be generated by a staff who will not be involv f of each school will be notified of the allocation results

procedures are predetermined for revealing the participants' allocation during the trial.

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208	However, the data analyst will be blinded. A research assistant will recode the group
209	information in the dataset before passing it on to the data analyst for data analysis.
210	Sample Size
211	The sample size was estimated using the analysis software $G^*power 3.1.^{33}$ A
212	moderate effect size (Cohen's $d = 0.5$ ) was expected based on a previously unpublished
213	local study conducted in 2017 (Li IMY. The effectiveness of an attachment-based
214	expressive arts therapy parenting programme for parents with special needs children
215	(Unpublished Thesis). Hong Kong: The University of Hong Kong; 2017). Assuming an
216	attrition rate of 20%, a total sample of 154 dyads will be needed (i.e., 77 dyads per arm)
217	to reach 80% statistical power and attain a moderate effect size (Cohen's $d = 0.5$ ) in the
218	proposed 2-arm randomised controlled trial with four measurement time points at a 5%
219	level of statistical significance.
220	Participants
221	The recruitment of participants will be carried out at special schools in Hong
222	Kong. This study will collaborate with the Hong Chi Association, a major non-
223	
	governmental organisation (NGO) in Hong Kong that provides special education services
224	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
224 225	
	for students with different grades of ID. This study will also aim to collaborate with
225	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
225 226	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
225 226 227	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

1 2						
2 3 4	230	eligibility of mother-child dyads will be determined using the following inclusion and				
5 6	231	exclusion criteria.				
7 8 9	232	Inclusion criteria				
10 11	233	- The child is 6–12 years old;				
12 13	234	- The child is diagnosed with mild to moderate ID;				
14 15 16	235	- By the judgement of the health/school professional staff, the child is both physically				
17 18	236	and psychologically stable for participation;				
19 20	237	- The dyad is willing and able to give consent for participation.				
21 22 23	238	Exclusion criteria				
23 24 25	239	- The child is diagnosed with attention-deficit/hyperactivity disorder;				
26 27	240	- The dyad is currently participating in other behavioural or pharmacological trial(s);				
28 29	241	- Either the mother or child has other contraindications or severe comorbidities that				
30 31 32	242	may impede participation (e.g., severe physical disabilities).				
33 34	243	Outcome Measures				
35 36	244	The outcome measures of this trial will comprise (a) psychosocial condition of				
37 38 39	245	mothers; (b) psychosocial condition of children; (c) mothers' perceptions of parent-child				
40 41	246	relationships; and (d) demographics and clinical profiles of the dyads. The mothers will				
42 43	247	complete a self-administered questionnaire regarding their psychosocial conditions,				
44 45 46	248	perceived parent-child relationships and the dyads' demographic and clinical information.				
40 47 48	249	Research assistants will assist children in responding to the mood scale. An EXAT				
49 50	250	therapist, a trained research assistant or an EXAT trainee under supervision will				
51 52	251	administer the Face Stimulus Assessment (FSA). Teachers or social workers of each				
53 54 55 56 57 58	252	child will also be invited to fill the behavioural checklist. To enhance retention of the				

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25	participants, data will be collected from places convenient for the participants, such as the
25	4 dyads' homes or special schools. Research assistants will send reminders to the
25	5 participants to attend appointments for data collection.
25	6 Mothers' Psychosocial Outcomes and Perceived Parent-Child Relationships
25	7 <b>Parenting Stress.</b> The 36-item Parenting Stress Index (4th Ed., short form) will
25	8 be adopted to assess parenting stress. <sup>34</sup> The scale consists of three subscales, parental
25	9 distress, parent-child dysfunctional interaction and difficult child, and each item is
26	0 measured on a 5-point Likert scale. The official Chinese translated version from
26	1 Psychological Assessment Resources (PAR, Inc.) will be administered.
26	2 <b>Burnout.</b> The level of burnout of mothers will be captured by the Chinese version
26	3 of the 6-item client burnout subscale of the Copenhagen Burnout Inventory (CBI), <sup>35</sup> with
26	4 each item rated on a 5-point Likert scale.
26	5 <b>Parent-Child Relationship.</b> Parent-child relationship will be captured by two
26	6 subscales with a total of 19 items from the Parent-Child Relationship Inventory (PCRI):
26	7 parent-child communication and satisfaction with parenting. <sup>36</sup> The PCRI assesses
26	8 attitudes towards parent-child relationship on a 4-point Likert scale. The research team
26	9 has obtained permission from the publisher to translate the items into traditional Chinese
27	0 and validate the translation.
27	<b>Positive and Negative Affect.</b> The mothers' positive and negative affectivity will
27	2 be assessed by the Chinese version of the 10-item International Positive and Negative
27	3 Affectivity Schedule – Short Form (I-PANAS-SF). <sup>37</sup> The scale has two subscales, one
27	each for positive and negative affect, and each item is rated on a 5-point Likert scale.
27	5 <b>Quality of Life.</b> The mothers' quality of life will be captured by the 28-item Hong

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2 3 4	276	Kong Chinese brief version of the World Health Organization Quality of Life Measure		
5 6 7	277	(WHOQOL-BREF, HK). <sup>38</sup> It assesses the subjective quality of life in four domains:		
7 8 9	278	physical, psychological, social relationship, and environmental.		
10 11	279	Psychological Well-Being. The mothers' psychological well-being will be		
12 13	280	documented by the Hong Kong Cantonese version of the 5-item World Health		
14 15	281	Organisation Five Well-Being Index (WHO-5). <sup>39</sup> It measures subjective psychological		
16 17 18	282	well-being on a 6-point Likert scale.		
19 20	283	Children's Psychosocial Outcomes		
21 22	284	Mood States. The Ottawa Mood Scale will be adopted to measure the children's		
23 24 25	285	mood states. <sup>40</sup> It is a visual analogue scale composed of five items that assess mood,		
25 26 27	286	anger, worry, stress and self-regulation. Relevant faces, icons or images will be shown to		
28 29	287	help children choose the most suitable answer that reflects their mood states. This scale		
30 31	288	has been validated in a Malaysian young adult sample. <sup>41</sup> The research team has obtained		
32 33 34	289	permission to translate the scale into traditional Chinese and validate the translated		
35 36	290	version.		
37 38	291	Emotional Expression. The emotional expression of children with ID will be		
39 40	292	captured by the Face Stimulus Assessment (FSA). <sup>42</sup> It is a projective drawing test that		
41 42 43	293	requires children to use the provided colour markers on three A4-size drawing templates:		
44 45	294	first on a pre-drawn face, second on an outline of a face, and third on a blank sheet of		
46 47	295	paper. The sketches will be analysed based on the guidelines mentioned in the FSA E-		
48 49	296	Packet and Rating Manual (2nd Ed.), provided by the author of the assessment. The		
50 51 52	297	sketches will be digitally scanned to extract the patterns of colour usage. <sup>43</sup> The research		
53 54 55	298	team has obtained permission to translate the guidelines into traditional Chinese and		
56				

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.<sup>44</sup> 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.<sup>45</sup> 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

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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<sup>46</sup> and to ensure sufficient data after potential dropouts at  $T_3$ .

327 Data Analysis

328 Quantitative Analysis

The intent-to-treat principle will be used to address the effects of crossovers and 329 330 dropouts. Missing data will be handled by full information maximum likelihood. 331 Descriptive statistics will be used to summarise the socio-demographic characteristics of 332 the participants at all time points. Treatment outcomes will be examined by computing 333 mixed-effects regression models. This analytical method will analyse the repeated 334 measures between the groups to obtain the time effect, group effect, and time x group 335 interaction effect. Demographic and clinical variables will be controlled for in the 336 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 337 338 and caregiver burnout. Mediation effects will be determined based on the significance of 339 the indirect effects of the intervention on psychological distress and caregiver burnout via 340 the mediators. As the data distribution is expected to be skewed, bootstrapping will be 341 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 342 statistical significance set at 5%. 343

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> **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<sup>47</sup> 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

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3 4	368	electronic files will be encrypted and stored in a password-protected desktop computer at
5 6	369	the PI's research centre. All the hard and soft copies will keep for a maximum of three
7 8	370	years after the publication of the first paper. Only the relevant research staff members,
9 10 11	371	i.e., the PI, the Co-Is, research assistants, and data analysts, will be granted access to the
12 13	372	raw data files and trial data set.
14 15 16	373	Patient and Public Involvement
17 18	374	Patients and the public were not involved in designing the protocol. The findings
19 20	375	and protocols of the study will be disseminated to the participants upon request.
21 22	376	Ethics and Dissemination
23 24 25	377	Ethical approval has been obtained from the Human Research Ethics Committee
26 27	378	of the University of Hong Kong (EA200329). The protocol of this study has been
28 29	379	registered with the Clinical Trial Registry (NCT05214859). Any amendments to the
30 31 32	380	protocol will be reported to the ethics committee and clinical trial registry. Trained
33 34	381	research assistants will explain the rights of the participants and objectives of the study to
35 36	382	participants and obtain their written consent before data collection. The data collection
37 38 39	383	and dyadic EXAT are not expected to cause any physical or psychological harm. If the
40 41	384	participants are disturbed by the data collection or intervention process, they can choose
42 43	385	to skip or terminate any procedures. Professional referrals can be made upon request. All
44 45 46	386	such incidents will be reported to the PI. Regarding disseminating the findings, the team
40 47 48	387	will present at internal or local conferences and will publish in peer-reviewed academic
49 50	388	journals.
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391	Discussion
392	The mothers of children with ID are under high caregiving strain, and the children
393	themselves experience difficulties in channelling their emotions. This study hopes to raise
394	awareness of the psychosocial well-being of both children with ID and their mothers.
395	Interventions are needed to mitigate their psychological distress and boost their
396	psychosocial well-being. As dyadic interventions, particularly art(s)-based dyadic
397	interventions, have been limited, the proposed study will aim to fill this gap by providing
398	evidence of the effectiveness of dyadic EXAT in improving the psychosocial well-being
399	of children with ID and their mothers. The dyads are expected to benefit from the
400	intervention in terms of nurturing mutual understanding, providing opportunities for
401	expression and fostering psychosocial well-being. The findings will inform on the
402	mechanism underlying dyadic EXAT and shed light on how arts can benefit mother-child
403	dyads. In the future, art(s)-based interventions can be considered as one of the
404	intervention strategies to provide psychosocial support for this population. Furthermore,
405	the findings of this study can will contribute to the development and further application
406	of art(s)-based interventions for children with ID and their families or for families with
407	children with other disabilities or special needs.
408	
409	Figure legends
410	Figure 1: The schedule of enrolment, allocation and assessments.
411	Figure 2: The study flow based on the CONSORT flow diagram.
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2 3 4	414	Footnotes			
5 6	415	Contributors: HRTH and WAHY conceived the study. HRTH, WAHY, WPKS, and			
7 8 9	416	LHHM contributed to the study design, and they are the research grant holders (named			
9 10 11	417	investigators)., FTCT, CCKP, WPKS, and LHHM provided methodological expertise and			
12 13	418	resources. LTLT, WAHY, and HRTH prepared the draft of this study protocol. All the			
14 15	419	authors reviewed and approved the final manuscript.			
16 17	420	Funding: This work was supported by the General Research Fund, Research Grants			
18 19 20	421	Council of Hong Kong (GRF/HKU/1760121). The study funder has no role in the study			
21 22	422	design; collection, collection, management, analysis, and interpretation of data; writing of			
23 24	423	the report; and the decision to submit the report for publication.			
25 26 27	424	Competing interests: None declared.			
27 28 29	425	Patient and public involvement: Patients and/or the public were not involved in the			
30 31	426	design, or conduct, or reporting, or dissemination plans of this research.			
32 33	427	Patient consent for publication: No participants' data were presented in this article.			
34 35 26	428	<b>Ethics approval</b> : Ethical approval has been obtained from the Human Research Ethics			
36 37 38	429	Committee of the University of Hong Kong (EA200329).			
39 40	430				
41		<b>Data availability statement</b> : Data sharing is not applicable to this article as no new data			
42 43	431	were created or analysed in this article.			
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		E nrolment	Allocation	Interv (8 w e		Post intervention (5 m onths from to)	Post intervention (8 months from tv)
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Informed consent		х					
Allocation			х				
INTERVENTIONS:							
EX4T <sup>a</sup>				+			
Control							
ASSESSMENTS:							
Mother & Child	Socio- demographic			Х			
Mother & Child	Clinical information			Х			
Mother	Psycho-social outcomes			Х	х	х	х
Mother	Perceiv ed parent-child relationship			х	х	х	х
M other <sup>b</sup>	Perceiv ed changes and experiences of EXAT				x		х
Child	Psycho-social outcomes			х	х	х	Х

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 semistructured 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.

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Allocation Assigned to Treatment-as-Usual Waitlist Baseline assessment (T<sub>0</sub>) Intervention Normal routine and care Follow-up Post-intervention assessment (T1) 2 months from baseline 3-month post-intervention follow-up 5 months from baseline 6-month post-intervention follow-up 8 months from baseline Analysis

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Control group

(n = 77)

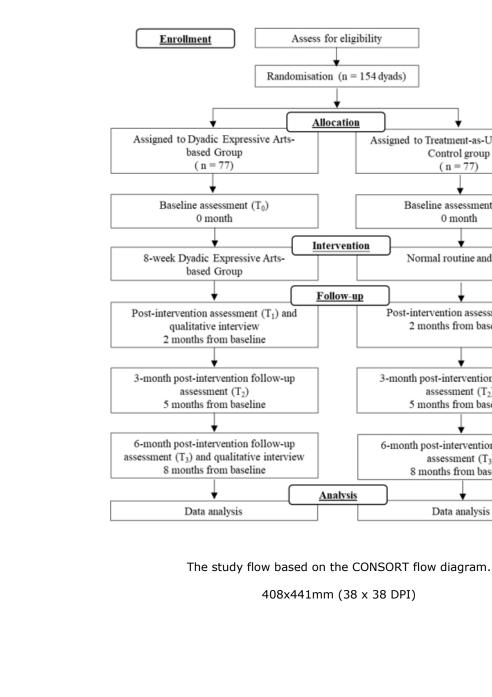
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assessment (T2)

assessment (T3)

Data analysis

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Supplementary 1: Interview guides for Qualitative interview

## Interview guide at post-intervention (T1)

## 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.

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3 4	<b>Interview guide at 6-month post-intervention (T3)</b>
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6	1. Current situation of the mother-child dyad
7 9	
8 9	• How have you and your child been in these six months?
10	
11	2. Perceived changes six months after participating in the dyadic expressive arts-based
12	group
13 14	<ul> <li>How do you perceive/are there any changes in the following aspects?</li> </ul>
15	<ul> <li>Your child's behaviour</li> </ul>
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17	<ul> <li>Your psychological condition</li> </ul>
18 19	<ul> <li>Caregiving experience</li> </ul>
20	<ul> <li>Relationship with your child</li> </ul>
21	
22 23	3. Possible reasons for the perceived changes
23	
25	• (If the mother experienced changes) Are there any possible reasons for the previously
26	mentioned changes?
27 28	• (If the mother experienced no change) Why do you think there are no changes?
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30	4. Closing
31 32	
33	• Do you have anything else that you would like to share?
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36 37	*The interview will not be limited to the above questions. The interviewer may slightly adjust
38	the interview guide based on the sharing of each interviewee.
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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	ItemNo	Description	
Administrative in	formation		
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	5a	Names, affiliations, and roles of protocol contributors	p.1;p.21
responsibilities	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

1				
1 2	Objectives	7	Specific objectives or hypotheses	p.8-9
3 4 5 6 7 8	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
9 10 11	Methods: Participa	nts, inte	rventions, and outcomes	
12 13 14 15 16	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
17 18 19 20 21 22	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
23 24 25 26	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
27 28 29 30 31 32		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
33 34 35 36		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	p.10
37 38 39 40		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
41 42 43 44 45 46 47 48 49	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
50 51 52 53 54 55 56 57 58 59 60	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

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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: Assignm	ent of int	erventions (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 coll	lection, m	anagement, 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

1	Data managamant	19	Plans for data entry, coding, security, and storage,	p.18-19
2 3 4 5 6 7	Data management	19	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.10-19
8 9 10 11 12 13	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
14 15 16		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
17 18 19 20 21 22		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
23 24	Methods: Monitorin	ng		
25 26 27 28 29 30 31 32 33	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
34 35 36 37 38 39		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
40 41 42 43 44 45	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
46 47 48 49 50	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
50 51 52	Ethics and dissemi	ination		
52 53 54 55 56 57 58 58	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p.19

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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
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

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# **BMJ Open**

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

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1	Title: Protocol for a mixed-methods randomised controlled trial evaluating the
2	effectiveness of a dyadic expressive arts-based intervention in improving the
3	psychosocial well-being of children with intellectual disability in special schools and
4	their mothers
5	
6	Authors: Temmy L. T. Lo <sup>a 1</sup> , Adrian, H. Y. Wan <sup>a b1</sup> , Ted, C.T. Fong <sup>a</sup> , Phyllis K. S.
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3 4	30	Protocol for a mixed-methods randomised controlled trial evaluating the
5 6	31	effectiveness of a dyadic expressive arts-based intervention in improving the
7 8	32	psychosocial well-being of children with intellectual disability in special schools and
9 10 11	33	their mothers
12 13	34	Abstract
14 15	35	
16 17	36	Introduction: Mothers of children with intellectual disability (ID) are often distressed
18 19 20	37	because of intensive workloads and difficulties in communicating with their children.
21 22	38	Given the interdependence between the psychosocial well-being of such dyads,
23 24 25	39	interventions that promote parent-child relationships and mutual communication would
25 26 27	40	be beneficial. Arts provide alternative avenues for expression and offer an imaginative
28 29	41	and playful environment for discovering new communication strategies. Given the lack of
30 31	42	studies on arts-based dyadic interventions, this study aims to examine the effectiveness of
32 33 34	43	dyadic expressive arts-based intervention (EXAT) in improving the psychosocial
35 36	44	outcomes of children with ID and their mothers and the mother-child relationships.
37 38	45	Methods and analysis: This study will adopt a mixed-methods randomised controlled
39 40 41	46	trial design, wherein 154 dyads of children with ID and their mothers will be randomised
42 43	47	into either the dyadic EXAT group or the treatment-as-usual waitlist control group.
44 45	48	Quantitative data will be collected at 4 time points: baseline $(T_0)$ , post-intervention $(T_1)$ ,
46 47 48	49	3-month post-intervention ( $T_2$ ), and 6-month post-intervention ( $T_3$ ). Qualitative data will
49 50	50	be collected from a subset of 30 mothers in the intervention group at $T_1$ and $T_3$ to
51 52	51	document their experiences and perceived changes after the intervention. Mixed-effects
53 54 55 56 57 58	52	models and path analysis will be adopted to analyse the quantitative data, whereas

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53	thematic analysis will be applied to the qualitative data. Both sets of data will be
54	triangulated for an integrated view of the effectiveness and mechanism of the
55	intervention.
56	Ethics and dissemination: Ethical approval has been obtained from the Human
57	Research Ethics Committee of the University of Hong Kong (Ref. no.: EA200329).
58	Written consent forms will be obtained from all recruited participants (mothers, children
59	with ID, and teachers/social workers) before data collection. The study findings will be
60	disseminated in international conferences and peer-reviewed academic journals.
61	
62	Trial registration number NCT05214859, prospectively registered
63	
64	Keywords: Mother-child relationship, Psychosocial well-being, Expressive arts therapy,
65	Intellectual disability, Randomised controlled trial
66	
67	Strengths and Limitations of the Study
68	- This randomised controlled trial will be the first to explore the effectiveness of dyadic
69	EXAT in improving the psychosocial well-being of children with ID and their
70	mothers and the mother-child relationships.
71	- The qualitative component of the study will explore the experiences of participating
72	in the dyadic EXAT and its mechanism in affecting the dyad's psychosocial well-
73	being and relationship.
74	- The study will include children with a diagnosis of autism spectrum disorder (ASD)
75	to ensure a sufficient number of eligible participants.

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2 3 4	76	- The study will include all the children in the primary section of special schools with a
5 6	77	relatively wide range of ages.
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79	Introduction
80	Intellectual disability (ID) refers to a developmental disability that significantly
81	limits intellectual functioning and adaptive behaviours, which impedes daily functioning
82	[1]. ID onset typically occurs before adulthood [1] and affects 0.05–1.55% of the global
83	population [2]. The DSM-5 classifies ID with four different severity levels, "mild,"
84	"moderate," "severe," and "profound," to differentiate one's capacity in adaptive
85	functioning and life skills [3]. With appropriate care and developmental training,
86	individuals with mild or moderate level ID are capable of acquiring some life skills and
87	living independently in familiar settings [4]. The ID prevalence in Hong Kong is 1.0-
88	1.4% [5], affecting approximately 0.84% of the primary school-age population [6], and
89	around 88% of primary school students with ID are diagnosed with mild or moderate ID
90	[6]. As caring for children with ID relatively requires more care, effort and resources, the
91	parents of children with ID are prone to emotional distress and poor quality of life.
92	Parents of children with intellectual disabilities are more likely to report higher
93	parental stress than average [7,8]. Interactions between parents and children with
94	different levels of ID are also less effective due to children's lack of initiation,
95	responsiveness and salient cues during communication and their behavioural problems
96	[9-11]. School-age children with ID also exhibit less secure and more disorganised
97	attachment behaviour that may affect their relationship with adults [12]. Parents may also
98	be more likely to adopt negative parenting styles to manage their children, such as being
99	unsupportive and controlling [13,14]. Moreover, children with ID, particularly with a
100	moderate level of ID, may also be comorbid with other developmental disorders, such as
101	autism spectrum disorder (ASD), which may further induce stress and impair the quality

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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.

107 A recent local survey has demonstrated that more than 90% of caregivers of 108 children with special educational needs, including intellectual disabilities, are mothers 109 [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]. 110 111 Compared with other family caregivers, such as fathers and siblings, mothers may be at a 112 higher risk of psychosocial difficulties because of the lack of social support, low income, 113 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 114 115 intensive stress, marital issues, psychological disturbance, disrupted social lives, poor 116 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 117 118 mothers of older children with ID, as younger children require higher levels of care. 119 Mothers also often face dilemmas in decision-making, such as when choosing schools 120 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

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125 overall well-being for mother-child dyads. The provision of parent-child support for this 126 population is crucial as the quality of the relationship and interactions between parents 127 and the child with ID determines the development and mental health of the children 128 [29,30]. Positive parenting behaviour and parent-child relationship also help infuse 129 resilience that may lower parental stress and may also help reduce the frequency of 130 externalizing behaviour problems in children with mild or borderline ID [31,32]. 131 Therefore, it is essential to promote positive interactions, mutual understanding and communication between mothers and their children [27]. Support is also needed to 132 133 improve the mother's mental health and equip them with strategies to cope with the children's behaviours [33]. 134 135 **Need for Arts** Arts can serve as an avenue for self-expression and communication, particularly 136

for individuals who find verbal self-expression difficult [34], like children with ID. 137 Previous studies on arts-based dyadic interventions for parents and their children with or 138 139 without disabilities have also demonstrated an array of benefits, including promoting mothers' mental health, decreasing child's behavioural problems, nurturing secure 140 141 attachment, expanding playfulness, and facilitating interconnection, communication, understanding, and synchrony within dyads [35-40]. All these effects benefit children 142 143 with ID and their mothers in terms of developing a positive relationship and promoting 144 mutual understanding and communication. In addition to applying a single art modality approach, this study will employ an expressive arts-based intervention (EXAT) that 145 146 utilises different art modalities, such as music, drama, movement, and visual arts, to 147 attain therapeutic goals [41]. It adheres to an intermodal approach, which posits that the

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148	experience of expressing oneself can be deepened and expanded by interchanging art
149	modalities [42]. The flexibility of the use of arts can also allow dyads to explore and
150	experiment with different arts materials. A group dyadic setting will also be adopted as it
151	provides room for cultivating mutual support and connections within and across dyads,
152	which possibly create impacts on the parent-child relationships and empower the mothers
153	[39]. While there are existing studies on parent-child dyadic arts intervention in different
154	populations, studies focusing on children with ID and their mothers and with more
155	rigorous designs, such as those with larger samples or comparable control groups, are still
156	limited. Including a treatment-as-usual control group in the study design helps reveal the
157	treatment effects of EXAT on top of the generic routine and care of the dyads.
158	Research Objectives
159	The primary objective of the study is to examine the effectiveness of the dyadic
160	EXAT in improving psychosocial outcomes of children with ID and their mothers and the
161	mother-child relationships compared to a treatment-as-usual waitlist control group across
162	different time points. The sustainability of the effects will be examined at 3-month and 6-
163	month post-intervention follow-up time points. It is hypothesised that dyads in the EXAT
164	group will experience improved psychosocial conditions and mother-child relationships,
165	relative to the dyads in the control group. The second objective is to explore the
166	mechanism by which the intervention acts on mother-child dyads; the study will
167	investigate the relationships between psychosocial variables and intervention
168	effectiveness, such as mediation or moderation effects. Qualitative interviews will be
100	and the demonstration of the section

169 used to document the subjective experiences of and changes in mothers after participating

in the intervention.

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3 4	171	Methods and Analysis
5 6	172	This study will employ a two-arm, mixed-methods, randomised controlled trial
7 8 9	173	design. The intervention phase will last for eight weeks. The outcome measures will be
) 10 11	174	assessed at 4 time points: baseline ( $T_0$ ), 2-month after baseline (post-intervention, $T_1$ ), 5-
12 13	175	month after baseline (3-month post-intervention follow-up, $T_2$ ), and 8-month after
14 15	176	baseline (6-month post-intervention follow-up, T <sub>3</sub> ). This will help capture the immediate
16 17 18	177	and sustained effects of the dyadic EXAT on mother-child relationships and psychosocial
19 20	178	well-being. In addition to quantitative outcome measures, qualitative interviews with a
21 22	179	subset of mothers (i.e., 30 mothers) from the intervention group will be conducted at $T_1$
23 24 25	180	and T <sub>3</sub> . The interviews will help document information regarding the experiences of
26 27	181	participating in the dyadic EXAT and whether these experiences shape the caregiver
28 29	182	experience, particularly the relationship between mothers and their children and the
30 31	183	mothers' coping strategies during caregiving. Adopting the mixed-methods design will
32 33 34	184	help triangulate the findings and enhance our understanding of the effects of the dyadic
35 36	185	EXAT on mother-child dyads. Figure 1 depicts the schedule of enrolment, allocation and
37 38	186	assessments. Figure 2 shows the study flow based on the CONSORT flow diagram.
39 40 41	187	Intervention
42 43	188	Dyads in the intervention group will receive eight 90-min weekly sessions. The
44 45	189	sessions will be conducted at the children's schools by either a registered EXAT therapist,
46 47 48	190	an EXAT trainee or a mental professional trained in EXAT. Each session will be
49 50	191	conducted in a small group of 3-4 dyads. The group facilitators will receive training in
51 52	192	the standardised protocol and safety precautions. The principal investigator (PI;
53 54 55	193	corresponding author) will provide on-site and/or off-site supervision to ensure treatment
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194 fidelity. Themes related to mother-child relationships will be covered. The content of the 195 intervention was informed by the previous works on applying arts-based activities or 196 interventions for individuals with ID or mother-child dyads in Hong Kong [36,43,44]. 197 Each session will comprise four stages, which will involve both within dyads or across 198 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) 199 200 activities. Table 1 depicts the themes and objectives of each session. Some selected 201 examples of arts activities are also listed. Table 2 describes the stages of each session.

Themes	Objectives	Selected examples of art(s) activities
Session 1		
Communication: Interaction with or without words	<ul> <li>To experience non-verbal communication through art(s)</li> </ul>	- 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 charad
Session 5		
Interaction: Creative interaction	- To find one's own space and time	- Draw on the same pape 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 cel	ebrate and farewell	
	Table 2: Structur	re of each session		
	Stages	Process	Purposes	Format
	Greetings and check-in	<ul> <li>Greetings</li> <li>Introducing the theme</li> </ul>	<ul> <li>Transit from the real world to a therapeutic space</li> <li>Build rapport</li> <li>Give participants a brief idea of the theme</li> <li>Give the therapist a brief idea of the participants' conditions</li> </ul>	- Across dyads
	Warm-up	- Participating in warm-up activities/games	- Prepare for the art(s)- making process	<ul> <li>Mainly within dyads, may also encourage across dyads</li> </ul>
	Art(s) creation and response	<ul> <li>Participating in art(s)-making activities based on the designated theme</li> <li>Sharing of art(s)- making experiences and insights</li> </ul>	<ul> <li>Cultivate insights from the art(s)-making process</li> <li>Promote mutual support among groupmates</li> </ul>	<ul> <li>Arts-making within dyads first and/or then across dyads</li> <li>Sharing acros dyads</li> </ul>
	Closure	- Closing rituals	<ul> <li>Conclude the session</li> <li>Transit back to the real world</li> </ul>	- Across dyads
	The dva	is in the treatment-as-r	usual control group will continu	e their normal
	-		to join the intervention group u	
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 rando	m numbers. The list w	ill be generated by a staff who w	vill not be involve
		1	h school will be notified of the	

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3 4	212	research assistant will be responsible for the randomisation and case allocation
5 5 7	213	procedures.
/ 3 9	214	Given the nature of the trial, it will not be feasible to blind the participants (dyads
10 11	215	and teachers/social workers) and therapists to the group allocation results. No unblinding
12 13	216	procedures are predetermined for revealing the participants' allocation during the trial.
14 15	217	However, the data analyst will be blinded. A research assistant will recode the group
16 17 18	218	information in the dataset before passing it on to the data analyst for data analysis.
19 20	219	Sample Size
21 22	220	The sample size was estimated using the analysis software $G^*$ power 3.1 [45]. A
23 24 25	221	moderate effect size (Cohen's $d = 0.5$ ) was expected based on a previously unpublished
26 27	222	local study conducted in 2017 (Li IMY. The effectiveness of an attachment-based
28 29	223	expressive arts therapy parenting programme for parents with special needs children
30 31	224	(Unpublished Thesis). Hong Kong: The University of Hong Kong; 2017). Assuming an
32 33 34	225	attrition rate of 20%, a total sample of 154 dyads will be needed (i.e., 77 dyads per arm)
34 35 36	226	to reach 80% statistical power and attain a moderate effect size (Cohen's $d = 0.5$ ) in the
37 38	227	proposed 2-arm randomised controlled trial with four measurement time points at a 5%
39 40 41	228	level of statistical significance.
42 43	229	Participants
44 45	230	The recruitment of participants will be carried out at special schools for children
46 47	231	with intellectual disability in Hong Kong. The study has been started on July 9, 2022, and
48 49 50	232	is estimated to be ended on December 31, 2025. This study will collaborate with the
51 52	233	Hong Chi Association, a major non-governmental organisation (NGO) in Hong Kong that
53 54	234	provides special education services for students with different grades of ID. This study
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235	will also aim to collaborate with special schools run by other NGOs. Social workers and
236	teachers at the interested schools will assist with the screening procedures and refer
237	potential participants to the research team. The eligibility of mother-child dyads will be
238	determined using the following inclusion and exclusion criteria.
239	Inclusion criteria
240	- The child is 6–12 years old (primary school student);
241	- The child is diagnosed with mild to moderate ID, IQ score ranges from 35 to 69
242	(based on the assessment conducted by certified clinicians);
243	- By the judgement of the health/school professional staff, the child is capable of
244	responding to assessments and participating in group activities.;
245	- The dyad is willing and able to give consent for participation.
246	Exclusion criteria
247	- The child is diagnosed with attention-deficit/hyperactivity disorder;
248	- The dyad is currently participating in other behavioural or pharmacological trial(s);
249	- Either the mother or child has other contraindications or severe comorbidities that
250	may impede participation (e.g., severe physical disabilities).
251	Outcome Measures
252	The outcome measures of this trial will comprise (a) psychosocial condition of
253	mothers; (b) psychosocial condition of children; (c) mothers' perceptions of parent-child
254	relationships; and (d) demographics and clinical profiles of the dyads. The mothers will
255	complete a self-administered questionnaire regarding their psychosocial conditions,
256	perceived parent-child relationships and the dyads' demographic and clinical information.
257	Research assistants will assist children in responding to the mood scale. An EXAT

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3 4	258	therapist, a trained research assistant or an EXAT trainee under supervision will
5 6	259	administer the Face Stimulus Assessment (FSA). Teachers or social workers of each
7 8 9	260	child will also be invited to fill the behavioural checklist. To enhance retention of the
) 10 11	261	participants, data will be collected from places convenient for the participants, such as the
12 13	262	dyads' homes or special schools. Research assistants will send reminders to the
14 15	263	participants to attend appointments for data collection.
16 17 18	264	Mothers' Psychosocial Outcomes and Perceived Parent-Child Relationships
19 20	265	Parenting Stress. The 36-item Parenting Stress Index (4th Ed., short form) will
21 22	266	be adopted to assess parenting stress [46]. The scale consists of three subscales, parental
23 24 25	267	distress, parent-child dysfunctional interaction and difficult child, and each item is
25 26 27	268	measured on a 5-point Likert scale. The official Chinese translated version from
28 29	269	Psychological Assessment Resources (PAR, Inc.) will be administered.
30 31	270	Burnout. The level of burnout of mothers will be captured by the Chinese version
32 33 34	271	of the 6-item client burnout subscale of the Copenhagen Burnout Inventory (CBI) [47],
35 36	272	with each item rated on a 5-point Likert scale.
37 38	273	Parent-Child Relationship. Parent-child relationship will be captured by two
39 40 41	274	subscales with a total of 19 items from the Parent-Child Relationship Inventory (PCRI):
41 42 43	275	parent-child communication and satisfaction with parenting [48]. The PCRI assesses
44 45	276	attitudes towards parent-child relationship on a 4-point Likert scale. The research team
46 47	277	has obtained permission from the publisher to translate the items into traditional Chinese
48 49 50	278	and validate the translation.
51 52	279	Positive and Negative Affect. The mothers' positive and negative affectivity will
53 54 55 56 57	280	be assessed by the Chinese version of the 10-item International Positive and Negative
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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

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3 4	304	paper. The sketches will be analysed based on the guidelines mentioned in the FSA E-
5 6	305	Packet and Rating Manual (2nd Ed.), provided by the author of the assessment. The
7 8	306	sketches will be digitally scanned to extract the patterns of colour usage [43]. The
9 10 11	307	research team has obtained permission to translate the guidelines into traditional Chinese
12 13	308	and validate the translated version.
14 15	309	Child Behaviour. The behaviours of children with ID will be assessed by the
16 17 18	310	teachers or social workers via the Chinese version of the Child Behaviour Checklist
19 20	311	Teachers' Report Form (CBCL-TRF/6-18) for school age children [56]. The checklist
21 22	312	yields aggregate scores on externalising, internalising, and total behavioural problems,
23 24 25	313	and on eight syndrome scales: anxious/depressed, withdrawn/depressed, somatic
26 27	314	complaints, social problems, thought problems, attention problems, rule-breaking
28 29	315	behaviour, and aggressive behaviour [57].
30 31 32	316	Socio-demographic and Clinical Information
33 34	317	Demographics. Socio-demographic information of the mothers, namely age,
35 36	318	gender, education level, family composition, and financial status, and the children,
37 38 39	319	namely age, gender, grade, and level of ID, will be collected from the mothers through
40 41	320	self-report questionnaires.
42 43	321	Clinical Information. Clinical profiles of the mother-child dyads, such as time
44 45	322	since diagnosis of the children with ID, time of onset and history of psychiatric disorders,
46 47 48	323	presence of any comorbidities (e.g., physical disabilities, hypertension, diabetes mellitus,
49 50	324	other cognitive disturbances), and history of community and rehabilitation service
51 52	325	utilisation will be documented.
53 54 55 56 57 58	326	Individual Semi-Structured In-Depth Interviews

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A subset of mothers (i.e., 30 mothers) from the intervention group will be randomly invited to attend individual, semi-structured interviews at T<sub>1</sub> and T<sub>3</sub>. 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  $T_3$ .

336 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

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3 4	350	used to estimate the confidence intervals of the indirect effects. Statistical tests will be
5 6	351	performed using Mplus 8.3 (Muthén & Muthén, 1998–2017) and will be two-tailed with
7 8 9	352	statistical significance set at 5%.
9 10 11	353	Qualitative Analysis
12 13	354	Audio recordings of the in-depth interviews will be transcribed verbatim by the
14 15	355	research staff. All of the transcripts will be imported to NVivo 12.0 (QSR International
16 17 18	356	Pty Ltd., 2018) or above for data analysis. The thematic analysis approach [59] will be
19 20	357	used to identify codes and themes related to the experiences of the dyadic EXAT and the
21 22	358	possible mechanism of the intervention. Two research staff members will be involved in
23 24 25	359	data analysis to ensure the credibility of the findings.
23 26 27	360	Study Monitoring and Data Management
28 29	361	The progress and safety of the study will be monitored by the General Research
30 31	362	Fund of the Research Grants Council (RGC). A mid-term progress report and interim
32 33 34	363	analyses will be submitted after having implemented the study for 18 months. In case of
35 36	364	RGC identifies any serious problem or unsatisfactory progress, the trial may be
37 38	365	terminated. A final report will be submitted upon completion of the study.
39 40 41	366	Regarding data entry, quantitative data collected from the participants will be
42 43	367	entered into the dataset by research assistants. After inputting all of the data, the data
44 45	368	analyst will perform data screening to check its validity. Invalid inputs will be cross-
46 47 48	369	checked and re-submitted by another research assistant. Regarding qualitative data, the
48 49 50	370	audio recordings will be transcribed into text files, and the sketches created by the
51 52	371	children will be digitally scanned by research assistants. The data analyst will check the
53 54	372	transcripts by concurrently listening to the audio and reading the transcripts.
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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

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2 3	396	journals.
4 5 6	397	Discussion
7 8	398	The mothers of children with ID are under high caregiving strain, and the children
9 10	399	themselves experience difficulties in channelling their emotions. This study hopes to raise
11 12	400	awareness of the psychosocial well-being of both children with ID and their mothers.
13 14	401	Interventions are needed to mitigate their psychological distress and boost their
15 16		
17 18	402	psychosocial well-being. As dyadic interventions, particularly art(s)-based dyadic
19 20	403	interventions, have been limited, the proposed study will aim to fill this gap by providing
21 22	404	evidence of the effectiveness of dyadic EXAT in improving the psychosocial well-being
23 24 25	405	of children with ID and their mothers. The dyads are expected to benefit from the
25 26 27	406	intervention in terms of nurturing mutual understanding, providing opportunities for
28 29	407	expression and fostering psychosocial well-being. The findings will inform on the
30 31	408	mechanism underlying dyadic EXAT and shed light on how arts can benefit mother-child
32 33 34	409	dyads. In the future, art(s)-based interventions can be considered as one of the
35 36	410	intervention strategies to provide psychosocial support for this population. Furthermore,
37 38	411	the findings of this study can will contribute to the development and further application
39 40 41	412	of art(s)-based interventions for children with ID and their families or for families with
42 43	413	children with other disabilities or special needs.
44 45	414	Despite the strengths of the study, there are several limitations. Given the high
46 47 48	415	comorbidity of diagnosis with ID and ASD, it is difficult to recruit sufficient participants
49 50	416	with children with ID only. To ensure there are sufficient participants for the project,
51 52	417	children diagnosed with ID and ASD will also be included. However, it will be
53 54	418	complicated to differentiate whether the child's behaviours are related to ID or ASD and
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419	if the maternal stress is caused by ID or ASD-related issues. This study will also include
420	all primary school students aged from 6 to 12. While lower and higher primary school
421	children may have different needs, the themes of the intervention shall be applicable to
422	all primary school students. The therapist will fine-tune the process to meet the
423	immediate needs and preferences of participants without changing the session's overall
424	objectives, themes and structure. The proposed randomisation procedures may cause
425	contamination across groups as participants may know each other in the same school.
426	However, participants in the control group will also be invited to join the intervention
427	later, and the dyads will be reminded to keep their experiences of the intervention
428	confidential to minimise contamination. Although the process of designing the
429	intervention did not involve the public, the content of the intervention took references
430	from previous local studies on applying arts as a medium in promoting the well-being of
431	individuals with ID and facilitating the communication between mother-child dyads
432	[36,43,44].
433	
434	Figure legends
435	Figure 1: The schedule of enrolment, allocation and assessments.
436	Figure 2: The study flow based on the CONSORT flow diagram.
437 438	
438 439	Footnotes
440	Contributors: HRTH and WAHY conceived the study. HRTH, WAHY, WPKS, and
441	LHHM contributed to the study design, and they are the research grant holders (named
442	investigators)., FTCT, CCKP, WPKS, and LHHM provided methodological expertise and

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2 3 4	443	resources. LTLT, WAHY, and HRTH prepared the draft of this study protocol. All the
5 6	444	authors reviewed and approved the final manuscript.
7 8 9	445	Funding: This work was supported by the General Research Fund, Research Grants
10 11	446	Council of Hong Kong (GRF/HKU/1760121). The study funder has no role in the study
12 13	447	design; collection, collection, management, analysis, and interpretation of data; writing of
14 15 16	448	the report; and the decision to submit the report for publication.
16 17 18	449	Competing interests: None declared.
19 20	450	Patient consent for publication: No participants' data were presented in this article.
21 22	451	Ethics approval: Ethical approval has been obtained from the Human Research Ethics
23 24 25	452	Committee of the University of Hong Kong (EA200329).
26 27	453	Data availability statement: Data sharing is not applicable to this article as no new data
28 29 30	454	were created or analysed in this article.
31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58	455	i i i i i i i i i i i i i i i i i i i

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		STUDY PERIOD				
		Enrolment & Allocation		ention eeks)	Post intervention (5 months from t <sub>0</sub> )	Post intervention (8 months from t <sub>0</sub> )
	TIMEPOINT	-to	to	t1	t2	<i>t</i> 3
I	ENROLMENT:					
Eligibility screen		х				
Informed consent		х				
Allocation		х				
INTERVENTIONS:						
EXAT <sup>a</sup>			+			
Control						
AS	SSESSMENTS:					
Mother & Child	Socio- demographic		х			
Mother & Child	Clinical information		х			
Mother	Psycho-social outcomes		x	х	х	Х
Mother	Perceived parent-child relationship		х	х	х	х
Mother <sup>b</sup>	Perceived changes and experiences of EXAT			x		х
Child	Psycho-social outcomes		х	x	x	х

a. EXAT: Dyadic Expressive arts-based group

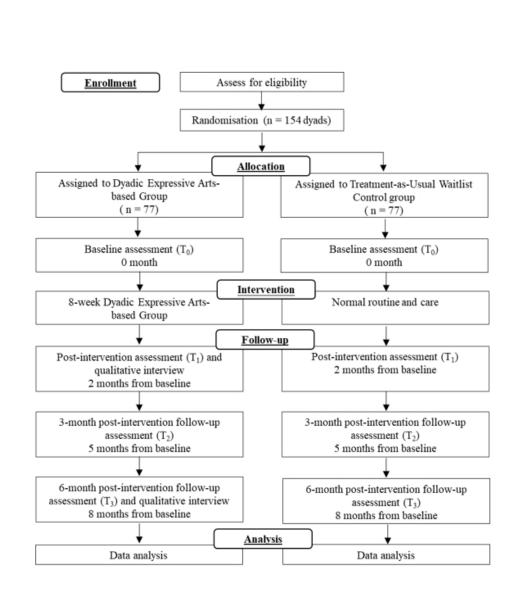
b. Only a subset of mothers in the intervention group (i.e., 30 mothers) will participate in a semi-structured indepth interview for understanding their perceived changes and experiences after participating in the dyadic Expressive arts-based group.

The schedule of enrolment, allocation and assessments.

201x223mm (96 x 96 DPI)

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The study flow based on the CONSORT flow diagram.

408x441mm (38 x 38 DPI)

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Supplementary 1: Interview guides for Qualitative interview

# Interview guide at post-intervention (T1)

# 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.

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4	<b>Interview guide at 6-month post-intervention (T3)</b>
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6 7	1. Current situation of the mother-child dyad
8	• How have you and your child been in these six months?
9	
10 11	2. Perceived changes six months after participating in the dyadic expressive arts-based
12	group
13	
14 15	• How do you perceive/are there any changes in the following aspects?
16	<ul> <li>Your child's behaviour</li> </ul>
17	<ul> <li>Your psychological condition</li> </ul>
18 19	<ul> <li>Caregiving experience</li> </ul>
20	<ul> <li>Relationship with your child</li> </ul>
21	
22 23	3. Possible reasons for the perceived changes
24	
25	• (If the mother experienced changes) Are there any possible reasons for the previously
26 27	mentioned changes?
28	• (If the mother experienced no change) Why do you think there are no changes?
29	
30 31	4. Closing
32	• Do you have anything else that you would like to share?
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34 35	
36	*The interview will not be limited to the above questions. The interviewer may elightly adjust
37	*The interview will not be limited to the above questions. The interviewer may slightly adjust
38 39	the interview guide based on the sharing of each interviewee.
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# 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 info	ormation		
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

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2 3		6b	Explanation for choice of comparators	p.8-9
4	Objectives	7	Specific objectives or hypotheses	р. 9
5 6 7 8 9 10	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
11 12 13	Methods: Participa	nts, inte	rventions, and outcomes	
14 15 16 17 18	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
19 20 21 22 23 24	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
25 26 27 28	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
29 30 31 32 33 34		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
35 36 37 38 39		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	p.10-11
40 41 42		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
43 44 45 46 47 48 49 50 51	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
52 53 54 55 56 57 58 59 60	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

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Allocation: Sequence generation	14 15 ment of in 16a	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations Strategies for achieving adequate participant enrolment to reach target sample size <b>terventions (for controlled trials)</b> 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 these who enrol participants or	p.13 p.13-14 p.12-13
Methods: Assignr Allocation: Sequence generation	ment of in	to reach target sample size terventions (for controlled trials) 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	
Allocation: Sequence generation		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	p.12-13
Sequence generation	16a	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	p.12-13
generation	16a	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	p.12-13
		that is unavailable to those who enrol participants or assign interventions	
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 co	llection, n	nanagement, 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

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1 2 3 4 5 6 7	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				
8 9 10 11 12 13	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				
14 15 16		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A				
17 18 19 20 21 22		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				
23 24	Methods: Monitoring							
25 26 27 28 29 30 31 32 33	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				
34 35 36 37 38 39		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				
40 41 42 43 44 45	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				
46 47 48 49 50	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				
51 52	Ethics and dissemi	ination						
52 53 54 55 56 57 58 58	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	p.20				

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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
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

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