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Parent-administered pediatric tuina for the treatment of attention deficit hyperactivity disorder symptoms: Process evaluation of a pilot randomized controlled trial

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ABSTRACT

Background: A pilot randomized controlled trial (RCT) was conducted in mainland China to examine the feasibility, acceptability, and preliminary effects of parent-administered pediatric *tuina* on attention deficit hyperactivity disorder (ADHD) symptoms in preschool children. An embedded process evaluation was performed to explore barriers and facilitators in the implementation, identify additional questions, and refine the study design for a future fully powered study.

Methods: The process evaluation comprises the following parts: (a) self-reported questionnaires on parents ($n = 43$), traditional Chinese medicine (TCM) practitioners ($n = 2$), outcome assessor ($n = 1$), and research assistant ($n = 1$); (b) parent logbook on parent-administered pediatric *tuina* ($n = 32$); and (c) focus group interview sessions ($n = 15$). Accomplishment of the self-report questionnaires was voluntary for all participants and compulsory for research personnel and TCM practitioners. The parent logbook on the intervention was filled out by all participants in the intervention group. Participants of focus group interviews were selected via purposive sampling, and data were analyzed with template analysis. Qualitative findings were summarized in tables, while the mean was calculated to reflect the quantitative findings.

Results: Perceived benefits, acceptability of parents and children, and professional support from the research team facilitated the implementation of the intervention. Meanwhile, the TCM pattern identification using online mode may limit the accuracy and lead to parents doubting the precision of the TCM pattern. This limitation was regarded as a major barrier. Parents perceived improvements in terms of children's appetite, sleep quality, and parent-child relationship. Participants were generally satisfied with the settings of parent-administered pediatric *tuina* and showed satisfactory adherence to the implementation.

Conclusions: Implementation of parent-administered pediatric *tuina* intervention is feasible and acceptable. The intervention can be refined by improving the TCM pattern identification procedure and adjusting outcome settings in a fully powered study in the future.

1. Background

Attention deficit hyperactivity disorder (ADHD) is a prevalent neurodevelopmental condition of childhood.[1] Core symptoms of ADHD are inattention, hyperactivity, and impulsivity, while comorbidities include extensive physical problems (e.g., obesity, seizures, and migraine) and psychiatric disorders (e.g., conduct disorders, sleep disorders, and learning disabilities).[2] Both ADHD core symptoms and comorbidities may cause negative influences on many aspects, such as academic problems, strained family relationship, and social skill difficulties.[3] Two conventional interventions for ADHD in children are medication and cognitive behavioral therapy (CBT). Both interventions present their

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own important advantages and inevitable disadvantages. For example, medicine demonstrates rapid onset for ADHD core symptoms but is also accompanied by relevant side effects and limited for children below 6 years. Meanwhile, CBT is the first-line intervention for young individuals with minimal adverse events despite requiring a high level of family involvement.[4] ADHD is a chronic condition related to heavy parental stress due to social stigma, limited social support, and economic issues.[5–7] Symptoms that may persist into adulthood for 30–60% of children with ADHD further impair their sociability and executive functioning and may even lead to criminal behavior.[3] Therefore, timely interventions are necessary for children with ADHD at a young age.

Pediatric *tuina*, also called pediatric *anmo* or traditional Chinese medicine (TCM) pediatric massage, is a modality of TCM interventions. Pediatric *tuina* is a special branch of TCM massage system because of its specified acupoints, locations, and corresponding specific manipulations on children's body surface that serve as an external intervention. The majority of pediatric *tuina* acupoints are located at the upper limbs, face, and head and are typically surfaces, lines, and circles rather than points. Corresponding manipulations, such as pressing, kneading, circling, nipping, pushing, and others, vary for different acupoints. Pediatric *tuina* is a complementary and alternative therapy with goals of health care or prevention and treatment of pathological conditions in children. This method satisfies parents' needs for natural health care and serves as a convenient, simple, effective, and economic external intervention.[8] Previous studies on the effects of pediatric *tuina* for treating ADHD in children demonstrated that pediatric *tuina* may present beneficial effects on children with ADHD.[9] However, evidence from a properly designed randomized controlled trial (RCT) is lacking and studies on testing parent-delivered pediatric *tuina* are limited. Therefore, we performed a pilot RCT of parent-delivered pediatric *tuina* in this program to examine the effects of parent-delivered *tuina* for ADHD symptoms in preschool children.[10] Parent-administered pediatric *tuina* is a complex combination of parent-administered interventions and the conventional pediatric *tuina*. The interaction between participants and research personnel, parent–child interaction, physical touch, and manipulation delivery may contribute to changes. Outcome assessment may provide limited information on the feasibility or acceptability of the intervention at the pilot stage due to the small sample size. Process evaluation is performed by researchers and practitioners to obtain an in-depth understanding of this complex intervention. Although many clinical trials on pediatric *tuina* have been conducted in the past several years, process evaluation to assess the implementation process are few. Therefore, we designed and carried out this process evaluation to summarize the barriers and facilitators in the implementation of parent-administered pediatric *tuina*, identify additional issues that may arise during the process evaluation, and adjust the intervention implementation for subsequent stages of the study.

2. Methods

2.1. Study design

The process evaluation of this study was embedded in a pilot two-arm parallel RCT of a two-month parent-administered pediatric *tuina* intervention for preschool children aged 3–7 years with ADHD symptoms (hyperactivity, impulsivity, and anxiety). Recruitment was conducted both in the outpatient clinic of Shandong University of Traditional Chinese Medicine Affiliated Hospital and online. Sixty-four preschool children with parental participation and consent were recruited. The study protocol was approved by the Research Ethics Committees of both Hong Kong Polytechnic University (HSEARS20190824002) and Shandong University of Traditional Chinese Medicine Affiliated Hospital ([2019] 伦审第[044]号 – KY). Complete details of the study design was provided and published in another article.[10,11] Intervention was implemented during the academic year 2020–2021 in mainland China.

2.2. Description of the intervention

The intervention of pediatric massage was delivered by parents. Implementation of the intervention was performed online. Parents systematically learned the knowledge and manipulations of pediatric *tuina* on ADHD symptoms in children through a training program (total of 5 h) under the supervision of TCM practitioners. Parents then conducted the intervention on their children in the two-month intervention period on the basis of prescriptions provided by TCM practitioners (Appendix 1: Content and a sample of pediatric tuina prescription). These prescriptions were formulated according to the results of TCM pattern identifications, which were conducted on each child by TCM practitioners each month. Videos of manipulations and electronic notes were sent to all the parents to assist their mastery and application of pediatric *tuina*. A pragmatic textbook was delivered to each parent via express mail. Timely professional guidance was provided to participants through WeChat groups. An individual WeChat group, including a parent, a TCM practitioner, a research assistant, and the project principal investigator (PI), was created for each participant. The PI monitored the whole process of the intervention implementation in each WeChat group. TCM practitioners with working experience of more than 3 years in the pediatric *tuina* department of Shandong University of Traditional Chinese Medicine Affiliated Hospital oversaw the intervention implementation. The research assistant was responsible for conveying information between participants and TCM practitioners and arranging study plans. The independent researcher took charge of screening participants, performing focus group interviews, and collecting and analyzing data. Both outcome and process evaluations were conducted. Fig. 1 shows the contents of the intervention implementation.

2.3. Process evaluation components

The process evaluation plan, including qualitative and quantitative components, was grounded in the protocol of the project, and created to assess the implementation process, dose, reach, adaption, and fidelity of the intervention.[12] Demographic characteristics, including information on both parents and children, were collected at the outset of the project. Confidentiality and anonymity of all data obtained were maintained to protect the privacy of participants.

2.3.1. Self-reported questionnaire

A self-report questionnaire was used to gather information about the experience and suggestions on the intervention application from participants, instructors, and other research personnel using qualitative and quantitative methods. Questionnaires were sent to all the parent participants at the end of week 8, and the parents were informed that accomplishing the questionnaire was completely voluntary. TCM practitioners, the research assistant, and the outcome assessor filled out questionnaires at the intervention period end point of each wave of participants. The self-report questionnaire investigated their overall experience, satisfaction with the intervention, and satisfaction with auxiliary supports using an 11-point Likert scale. Open-ended questions and suggestions were used to explore possible barriers they may have encountered. Questionnaire distribution and collection were conducted through the *Wenjuanxing* platform. We calculated the mean value (standard deviation) of all participants for quantitative questions. Meanwhile, we formulated a table to summarize the key points of the results for other open-ended questions.

2.3.2. Focus group interview

In-depth focus group interviews were used to identify internal and external barriers as well as facilitators in the implementation of the intervention period while optimizing the intervention design. Focus group interview sessions were conducted and reported according to the 32-item checklist for the CAM model manuscript (Appendix 2: COREQ: a

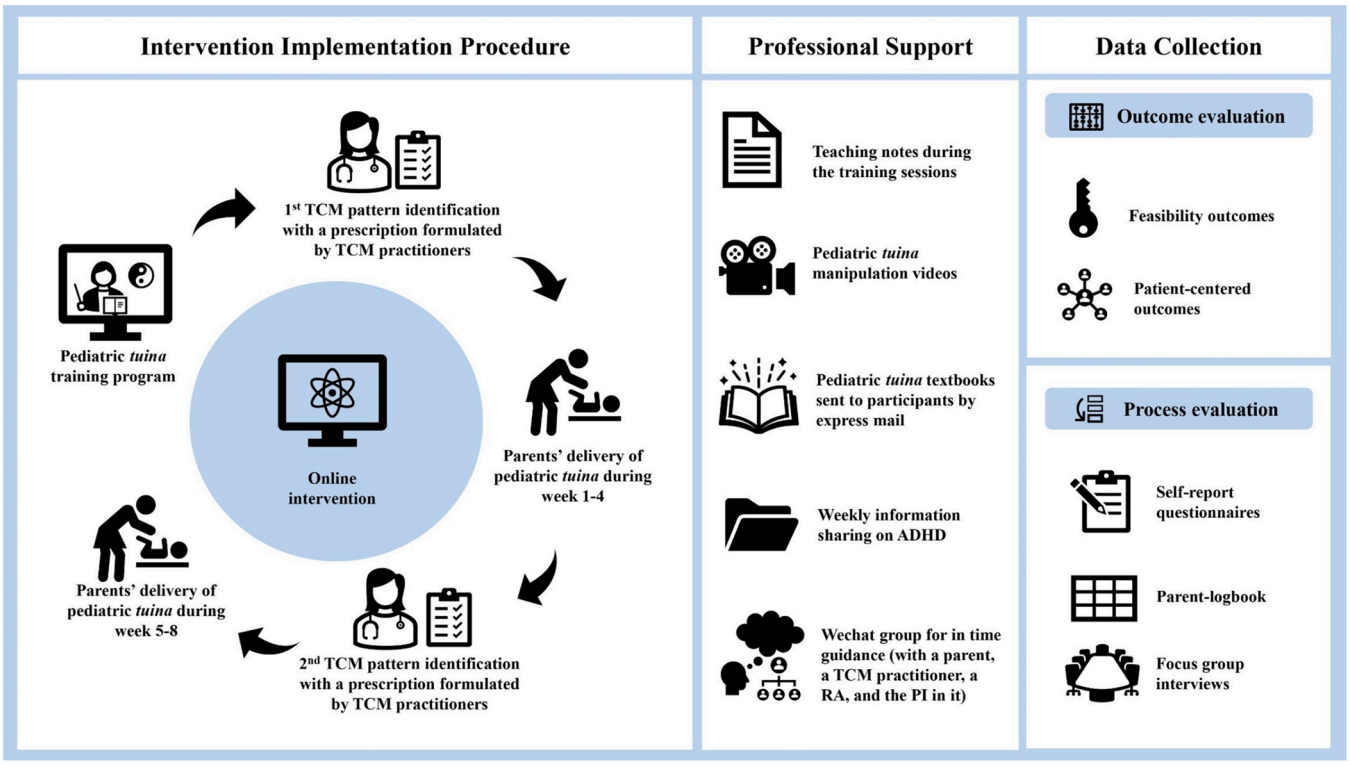

Fig. 1. Contents of parent-administered pediatric *tuina* intervention implementation in this project.

32-item checklist for the CAM model manuscript). Participants were selected using purposive sampling. The interview transpired via the Tencent Meeting platform. All interviews were audio-taped and transcribed verbatim. Questions were focused on the facilitators and barriers of the intervention (Appendix 3: Questions for the semi-structured interview). Identifiers were absent in all recordings and transcriptions to avoid revealing the identities of participants. The recordings were transcribed verbatim by a trained research assistant present in all the interviews. Data from the interviews were reviewed by the PI (WFY) to ensure accuracy and then analyzed using long tables, scissors, and colored marking pens. Question clusters and subthemes were revalidated by the researcher by reviewing the original transcript to ensure the accuracy of data.

2.3.3. Parent logbook

The parent logbook is the quantitative method used to record the practice of intervention delivery. All parent participants were required to complete the logbook prospectively by recording the intervention implementation adherence each time and submitting the logbook to the research assistant by weeks 4 and 8. Logbooks contain the participant code, date, all acupoints in prescriptions, and duration of practice for each acupoint. A participant who conducted the intervention at least 24 times during the two-month intervention period with the duration of each manipulation longer than 20 min was considered a completer. We also counted the total manipulation sessions of each participant, daily manipulation duration of each participant, number of completers for different lengths of manipulation duration, and mean of the total manipulation sessions of all participants for different lengths of manipulation duration. Charts were utilized to illustrate the adherence of participants.

2.3.4. Protocol revision in process evaluation

The process evaluation was revised to include the use of a combination of quantitative and qualitative methods rather than applying only qualitative methods similar to our previous published protocol. First, Likert scales were used in the self-report questionnaires for parents, TCM practitioners, research assistant, and outcome assessors to quantify their responses on the effects of pediatric *tuina* and parents' satisfaction on this intervention. Participants completed the questionnaire at the end of week 8. TCM practitioners and other researchers completed the questionnaires at the treatment end point of each wave of participants. Second, the content of the parent logbook was updated by counting the minimum duration each day and the minimum number of manipulation days each week. Finally, we explore and model the association between the outcome evaluation and participants' adherence in the secondary analysis.

3. Results

3.1. Sample characteristics

Sample characteristics, such as gender, educational background, and treatments for ADHD, were similar across all samples in the self-report questionnaire ($n = 43$), focus group interviews ($n = 15$), and parent logbook ($n = 32$). Details of the sample characteristics are listed in Table 1.

3.2. Adjusted logic model of the intervention

We adjusted the logic model of the intervention during the data collection process to fit our project properly and satisfy the requirements of participants. The updated logic model is presented in Fig. 2.

3.3. Quantitative findings

Quantitative data were collected from the quantitative part of the self-report questionnaire and parent logbook records. Parents demonstrated a high level of satisfaction in their overall experience of the project process at a mean score of 9.44 ($SD = 0.91$). Parents were generally satisfied with the parent-administered pediatric *tuina*

Table 1
Demographic characteristics of participants.

Characteristics	Self-report questionnaire *(n = 43)*	Focus group interviews *(n = 15)*	Parent Logbook *(n = 32)*
Parents			
Age, mean (SD)	38.42 (10.12)	38.20 (5.02)	38.69 (10.04)
Gender, no. (%)			
Male	3 (6.98)	1 (6.67)	5 (15.62)
Female	40 (93.02)	14 (93.33)	27 (84.38)
Educational Background, no. (%)			
Primary education	1 (2.33)	0 (0.00)	2 (6.25)
Secondary education	2 (4.65)	2 (13.33)	3 (9.37)
Tertiary education	40 (93.02)	13 (86.67)	27 (84.38)
Children			
Age, mean (SD)	5.70 (1.41)	6.33 (0.98)	6.13 (1.43)
Gender, no. (%)			
Male	28 (65.11)	14 (93.33)	9 (28.12)
Female	15 (34.89)	1 (6.67)	23 (71.88)
BMI, kg/m^2, mean (SD)	17.79 (2.46)	15.78 (2.86)	18.64 (2.99)
Children with current treatments on ADHD, no. (%)	26 (60.47)	13 (86.67)	20 (62.50)
Current treatments on ADHD, no. (%)			
CBT	12 (27.91)	7 (46.67)	7 (21.88)
Conventional medicine	6 (13.95)	2 (13.33)	8 (25.00)
TCM herb	3 (6.98)	3 (20.00)	2 (6.25)
SIT	7 (16.28)	2 (13.33)	4 (12.5)
Dietary	7 (16.28)	4 (26.67)	1 (3.12)
Supplements	5 (11.63)	2 (13.33)	4 (12.5)
Children with previous treatments on ADHD, no. (%)	21 (48.83)	11 (73.33)	16 (50.00)
Previous treatment on ADHD, no. (%)			
CBT	7 (16.28)	3 (20.00)	5 (15.62)
Conventional medicine	6 (13.95)	2 (13.33)	5 (15.62)
TCM herb	5 (11.63)	3 (20.00)	2 (6.25)
SIT	15 (34.89)	7 (46.67)	9 (28.13)
Dietary	6 (13.95)	1 (6.67)	2 (6.25)
Supplements	4 (9.30)	4 (26.67)	3 (9.38)

Abbreviation: SD: standard deviation; BMI: body mass index; CBT: cognitive behavioral therapy; SIT: sensory integration therapy; TCM: traditional Chinese medicine.
※Data are presented as mean(SD) or number (%).

intervention and auxiliary support, such as weekly information sharing, with mean scores of 8.53 (*SD = 1.68*) and 8.70 (*SD = 1.73*), respectively. According to the returned logbook, the total manipulation sessions of each participant during the two-month intervention period ranged from 13 to 56, and the average manipulation duration during the intervention period of each participant ranged from 14 min to 49 min, excluding the two subjects that were not subjected to the intervention from the beginning. Among the 32 participants, 31 from the intervention group completed all the training lessons and 20 were completers according to the protocol of finishing at least 24 delivery sessions during the intervention period. Fig. 3 shows the relationship between the number of completers and the minimum manipulation times for each session based on the collected logbook. The quantitative data showed the significant adherence of participants.

3.4. Qualitative findings

Qualitative data include the quality part of the self-report questionnaire and focus group interview. According to the self-report questionnaires, parent-experienced manipulation difficulties mainly related to the long manipulation duration (*n = 18*), acupoint location (*n = 17*), and manipulation skills (*n = 19*). Other barriers include time management, poor execution of ADHD parents, poor cooperation of ADHD children, lack of effective monitor, and cold weather for conducting certain manipulations on the back in winter. Parents' suggestions focused on providing them with long-term professional support and combining pediatric *tuina* with other interventions or games, such as parent–child yoga. Parents expressed their strong expectations of receiving ADHD-related professional information. Thirty-eight parents were willing to attend our following focus group interviews on the implementation of the parent-administered pediatric *tuina*. Self-reported questionnaires on TCM practitioners and research assistants mainly focused on adjusting the content of intervention training courses, changing the TCM pattern identification mode and platform, and enhancing the communication efficiency between the parents and the research team (Appendix 4: Summary of the content of the parent self-report questionnaire). Two themes (facilitators to the intervention implementation and barriers to the intervention implementation) were identified from the focus group interviews. Four subthemes were included under the theme of facilitators in the intervention implementation: (a) perceived benefits on children and parents, (b) acceptability of parents and children, (c) professional support, and (d) parents' expectations on the long-term use of the intervention. Three specific subthemes were described under the theme of barriers in the intervention implementation: (a) limited benefits of pediatric *tuina* on children's inattention symptoms, (b) manipulation management issues, and (c) limitations of online TCM pattern identification (Appendix 5: Coding structure and quotation examples).

4. Discussion

The process evaluation in this study specifically identified barriers and facilitators in the implementation of parent-administered pediatric *tuina* for ADHD symptoms in preschool children. We combined outcome and mix-method process evaluations, including quantitative measures of effects of interventions and in-depth qualitative data, to comprehend the intervention implementation. Implementers actively collected and summarized the barriers and facilitators in the intervention implementation at the pilot stage, explored issues arising from the data collection period in a small scale, and adjusted the intervention to facilitate the project in a future study stage in a large scale with high diversity.[12] The effect size of this pilot RCT may provide a feasible sample size estimation for the masked main RCT in the future. This pilot RCT can be used to help design the fully powered trial in the reference to the intervention implementation, acceptability, feasibility, and participants' expectations and suggestions.

Facilitators of the intervention implementation include the appropriate setting of the treatment schedule and manipulation duration, perceived benefits of pediatric *tuina*, acceptability of parents and children, and timely professional support from the research team. The dose of intervention implementation is closely related to the adherence of participants.[13] Furthermore, a regular reminder of intervention delivery[14–16] and use of auxiliary support (e.g., weekly information sharing and manipulation textbook distribution) can enhance parents' compliance to our study design.[17] Further studies may use these settings or incentives to improve the adherence of participants.

Online TCM pattern identification was very important to parents. Similar to online consultation, the online diagnosis mode provided pattern information and prescriptions to participants in time, energy, and budget while simplifying and enhancing the efficiency of the health care system.[18] The online TCM pattern identification mode was improved as follows.[1] A standard checklist was designed by TCM practitioners to collect TCM-related symptoms and manifestation of children.[19] The questionnaire should be submitted before TCM pattern

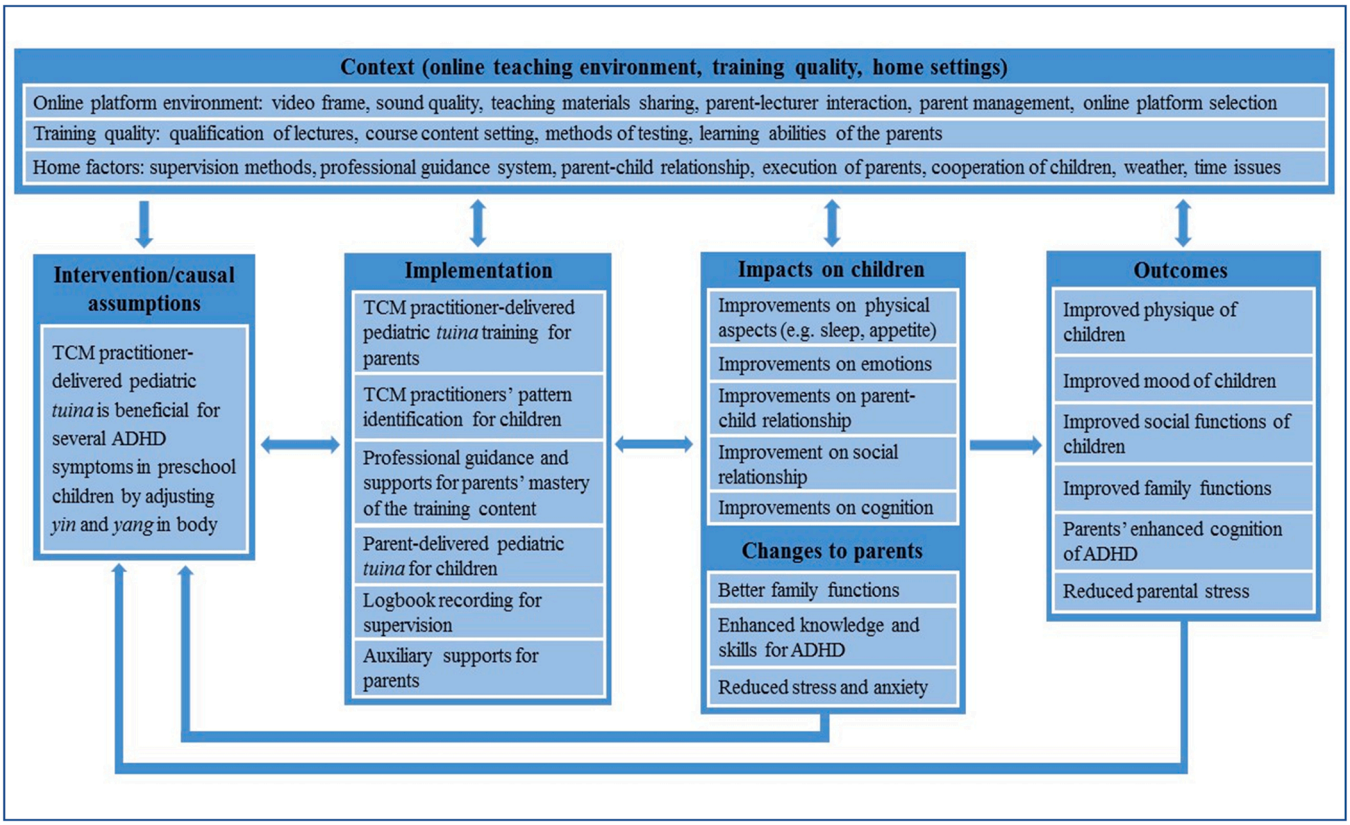

Fig. 2. Adjusted logic model of parent-administered pediatric *tuina* intervention.

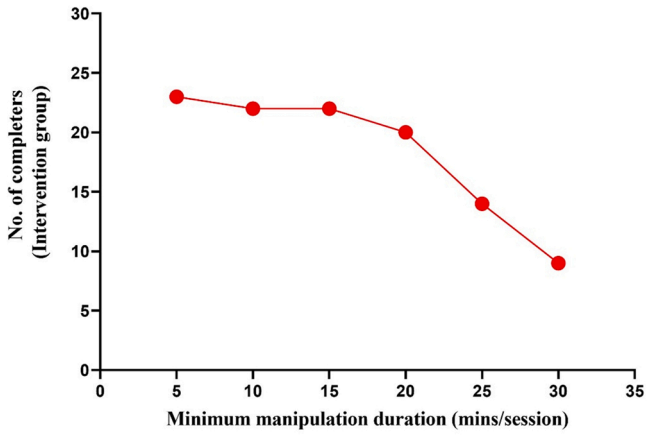

Fig. 3. The relationship between the number of completers and the minimum manipulation time for each session (Intervention group).

identification to allow the TCM practitioner to formulate an initial understanding of the child.[2] A clear picture of the children's tongue should be taken and then sent to TCM practitioners together with the accomplished questionnaire (Fig. 4: Samples of pictures of children's tongue). Tongue diagnosis is an essential part of TCM because it demonstrates the overall health of a person.[20] This diagnosis mode can be applied to additional clinical trials on TCM interventions, especially during the Covid-19 outbreak.

The process evaluation findings also created new points that could be tested with quantitative methods in the outcome evaluation. Studies can be conducted to examine the effects of parent-administered pediatric *tuina* for children's appetite and parent–child relationship. Parent pediatric *tuina* training can be combined with games or parental behavioral training to detect the specific effects of pediatric *tuina* and increase the participants' adherence given that children with ADHD may be deeply involved in the things they like and may experience difficulty in focusing on the things uninteresting to them.[21] We also realized that parents need professional information on choosing interventions. Performing qualitative research on parents' information-seeking experiences can provide new insights into the cultivation of children with ADHD and further exploration of their needs. Previous studies on self-administered acupressure asked participants to fill in a logbook to monitor compliance.[22–25] Methods for supervising the compliance of participants can be improved by applying additional online software programs while considering the ways of dealing with possible participant contamination.[26] Online software tools can provide an alternative to face-to-face written assessments, which are used to evaluate participants separately, while increasingly intelligent software programs can enable the online supervision of intervention delivery. Appropriate online instant tools should be used in future investigations to monitor the intervention delivery of parents at any time rather than use a logbook that must be collected each month.[27] Notably, a long intervention period can be set in future studies if chronic symptoms (e.g., inattention) are measured.

The major strength of this process evaluation lies in the combination of quantitative and qualitative approaches from all implementers of this intervention. In addition, the findings supplemented the outcome evaluation and were applied to examine the preliminary effectiveness of the intervention and explore additional issues that need to be tested by the outcome evaluation in a fully powered study in the future. This study presents the following limitations. Problems related to intervention delivery and parents' needs from the process evaluation can be used to help improve the study design in this area. However, some information on the negative aspects of the intervention implementation may be missed given that participation of parents in accomplishing the self-report questionnaire is only voluntary. Meanwhile, opinions of

Fig. 4. Samples of the pictures of children's tongue collects in this project for the adjusted online TCM pattern identification.

participants who abandoned the study halfway through the data collection process were not contacted. Therefore, their opinions were excluded from this process evaluation. Finally, researchers may miss some of the reasons behind the uncooperativeness or unwillingness of children to receive *tuina* because children's viewpoints were collected indirectly from their parents.

5. Conclusion

Implementation of parent-administered pediatric *tuina* intervention is feasible and acceptable. The intervention implementation can be refined by improving the TCM pattern identification procedure. Outcomes, such as children's appetite, sleep quality, and parent-child relationship, can be examined quantitatively in a future fully powered investigation. Professional support was needed when parents administered pediatric *tuina*. Parents generally demonstrated high expectations on the long-term effects of pediatric *tuina* on children.

Trial registration

NCT04237259 (ClinicalTrials.gov).

CRediT authorship contribution statement

Chen Shu-Cheng: Conceptualization, Methodology, Data collection, Writing – original draft. **Yeung Wing-Fai**: Conceptualization, Methodology, Reviewing the Manuscript. **Han Le-Fei**: Data collection, Data analysis. **Wu Guo-Tao**: Data analysis and interpretation. **Zhang Ru-Yi**: Recruitment promotion, Data collection. **Cheng Hui-Lin**: Reviewing the manuscript. **Suen Lorna Kwai-Ping**: Reviewing the manuscript. **Chen Xi**: Data collection.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ctim.2022.102854.

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