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'Shared efforts, brighter smiles': a protocol for a randomised controlled study on the effectiveness of a parent-child orofacial myofunctional therapy programme post-adenoidectomy

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ABSTRACT

Introduction Adenoid hypertrophy has a high prevalence in children, often causing early orofacial muscle dysfunction that worsens facial deformities over time. While adenoidectomy (AT) alleviates airway obstruction, it only partially addresses the condition, leaving persistent neuromuscular habits. Orofacial myofunctional therapy is necessary for post-AT recovery but faces challenges such as poor adherence and ineffective parent-child communication. Dyadic interventions, which actively involve both parents and children, have shown advantages in improving treatment adherence and enhancing orofacial muscle function. Evidence suggests that dyadic intervention addresses both the child's recovery needs and the caregiving capacity of parents, offering a more comprehensive solution for long-term intervention. Therefore, our team developed a parent-child dyadic orofacial myofunctional therapy (PCD-OMT) programme, offering insights into its potential application in paediatric healthcare to support comprehensive family-centred care.

Method and analysis This two-arm, parallel-design, randomised controlled trial will recruit 80 dyads whose children performed AT from two hospitals in Qingdao, China. Dyads will be randomly allocated to two arms. Dyads randomly assigned to the intervention group will receive the PCD-OMT programme. Dyads randomly assigned to the control group will receive regular care. The primary outcomes are orofacial myofunction in children and parental care abilities. The secondary outcomes are children's engagement and parental functioning. A feasibility and acceptability process will be employed to evaluate the viability in clinical practice. Outcomes will be collected at three checkpoints: baseline (T0), postintervention (T1) and after a 12-week follow-up phase (T2).

Ethics and dissemination This study was approved by the Ethics Committee of Medical College of Qingdao University (QDU-HEC-2023216). The results will be published in peer-reviewed publications and presented in international conferences.

Trial registration number ChiCTR2400091466.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Programs incorporated hospital-home link training and social media engagement to mimic natural caregiving environments.
⇒ Internet-dependent design excludes digitally disconnected families.
⇒ The 24-week follow-up period limits the assessment of long-term craniofacial outcomes.

INTRODUCTION

According to recent data on paediatric otolaryngology, the prevalence of adenoid hypertrophy (AH) in children, based on convenience sampling, is estimated to range from 42% to 70%.[1] AH is notably prevalent among children and can lead to obstructive sleep apnoea,[2 3] which may subsequently cause characteristic facial changes, while direct craniofacial deformities remain a common complication. In mainland China, as many as 46.42% of children are initially diagnosed with AH primarily due to facial abnormalities.[4] Such a high prevalence, coupled with the progressive nature of these facial alterations, not only affects the orofacial muscles but can also lead to the eventual solidification of maladaptive neuromuscular patterns.[5–7] This, in turn, raises concerns about future facial aesthetic anxiety and increases the likelihood of requiring plastic surgery or orthodontic interventions later in life.[8 9]

Currently, the standard treatment for AH is adenoidectomy (AT), a procedure that effectively alleviates upper airway obstruction and partially addresses breathing pattern difficulties.[10–12] However, the long-standing neuromuscular habits formed due to AH often persist even after surgery,[13 14] necessitating targeted muscle

functional correction therapies.[15] In this regard, orofacial myofunctional therapy (OMT) has garnered significant support from evidence-based research, consistently demonstrating its positive impact on orofacial muscles, particularly in preschool-aged children.[12 16–19] Nevertheless, despite its potential, real-world clinical practice often encounters substantial challenges—chief among them being issues of treatment adherence and the complexity of effective parent-child communication.[20 21] Dyadic interventions provide a platform for parents to demonstrate their healthcare abilities,[22 23] increasing their awareness and attention to their children's orofacial recovery post-AT. Nap-van der Vlist *et al* found that a parent-child dyadic intervention helps both children requiring long-term treatments and their parents by establishing shared appraisal and collaborative management, leading to optimal health outcomes.[24] A recent systematic review involving 1144 participants shows that parent-child interaction can enhance related skills and reduce stress for both.[25] Studies in OMT clinical practice indicate higher efficiency when parents participate, as family involvement boosts children's morale. Sustained parental participation is essential.[26] These factors suggest that dyadic intervention, targeting the health and well-being of both children and parents, can facilitate more comprehensive family-oriented care in primary healthcare.

Moreover, recent studies underscore the effectiveness of interventions based on the parent-child dyad in managing paediatric conditions.[27 28] However, most of the research is only focused on the application outcomes of OMT in children. It is worth noting that parental care and feelings from their guardians are dismissed, which is essential for the family support system and important for clinical researchers to investigate the family raising burden in OMT application.[20] What is more, no prior research has specifically explored the impact of dyadic interventions within the context of OMT. To address this gap, we have developed a comprehensive intervention programme for children post-AT, grounded in the parent-child dyad dual communication model. This parent-child dyadic orofacial myofunctional therapy (PCD-OMT) programme was structured into both intervention and follow-up phases and critical components, including parent-child dyad involvement, motivational engagement, dyadic behavioural skills training and a designed follow-up regimen.

The programme encompassed multiple stages—assessment, intervention, follow-up and re-evaluation—each designed to ensure a holistic approach to the programme. This study aims to evaluate the programme's effects on children's orofacial myofunction, adherence to treatment and their parents' caregiving capacity and parental functioning. Additionally, the study will assess the feasibility, acceptability and preliminary outcomes of the intervention, thereby providing valuable insights into its potential broader application.

Study objective

1. To demonstrate the feasibility and acceptability of the PCD-OMT programme through recruitment, retention, drop-out, adherence and satisfaction ratings.
2. To investigate the effects of the PCD-OMT programme on a range of outcome measures.
3. To amend the PCD-OMT programme details based on the results of this randomised controlled trial (RCT).
4. To use data from this study for sample size calculation for future large multiple-centred RCTs.

METHODS AND ANALYSIS

Design

This will be a two-arm, parallel-design, assessor blind, RCT. The first families we planned to enrol ought to be around Oct 2024, and we expect to complete the programme around 2025 fall. Children and their legal guardians who meet the eligibility criteria and provide written consent will be assigned randomly in a 1:1 ratio to one of two groups: a PCD-OMT programme group or a control group. The two groups will be compared at baseline (T0), postintervention (T1) and at 12-week follow-up (T2). After the baseline assessment, participants will receive a PCD-OMT programme for approximately 12 weeks, with another 12 weeks of follow-up. The study design and process flow are presented in figures 1 and 2.

Eligibility

Dyads who meet the inclusion criteria will be approached to participate in this study. The inclusion criteria are as follows: (1) children with potential facial changes undergoing AT for the first time; (2) cranial CT-confirmed AH, with an adenoid-to-nasopharyngeal cavity thickness ratio (A/N>0.61) and classified as Grade II or higher diagnosed by an otolaryngologist; (3) with Angle Class II malocclusion, as documented by an orthodontic specialist during preoperative assessment[29]; (4) children and main caregivers with good communication abilities in Chinese/English; (5) children aged 3–7 years and main parents aged over 18 years and (6) voluntary participation and informed consent.

Any dyads who meet one of the following criteria will be excluded from the study: (1) one or both have a history of psychiatric conditions related to hallucinations or delusions, or severe cognitive impairment, as its symptoms could affect their ability to participate in the programme; (2) children with congenital craniofacial deformity: cleft lip and/or cleft palate, craniosynostosis syndromes, Treacher Collins syndrome, midface and skull defects and other rare craniofacial syndromes; (3) parents' inability to access the internet daily; (4) family with long-term outing plans and (5) participation in other studies.

Recruitment

Participants will be recruited from one tertiary hospital (Department of Otorhinolaryngology) and one specialised otorhinolaryngology hospital in Qingdao, Shandong Province, China. These hospitals, among the

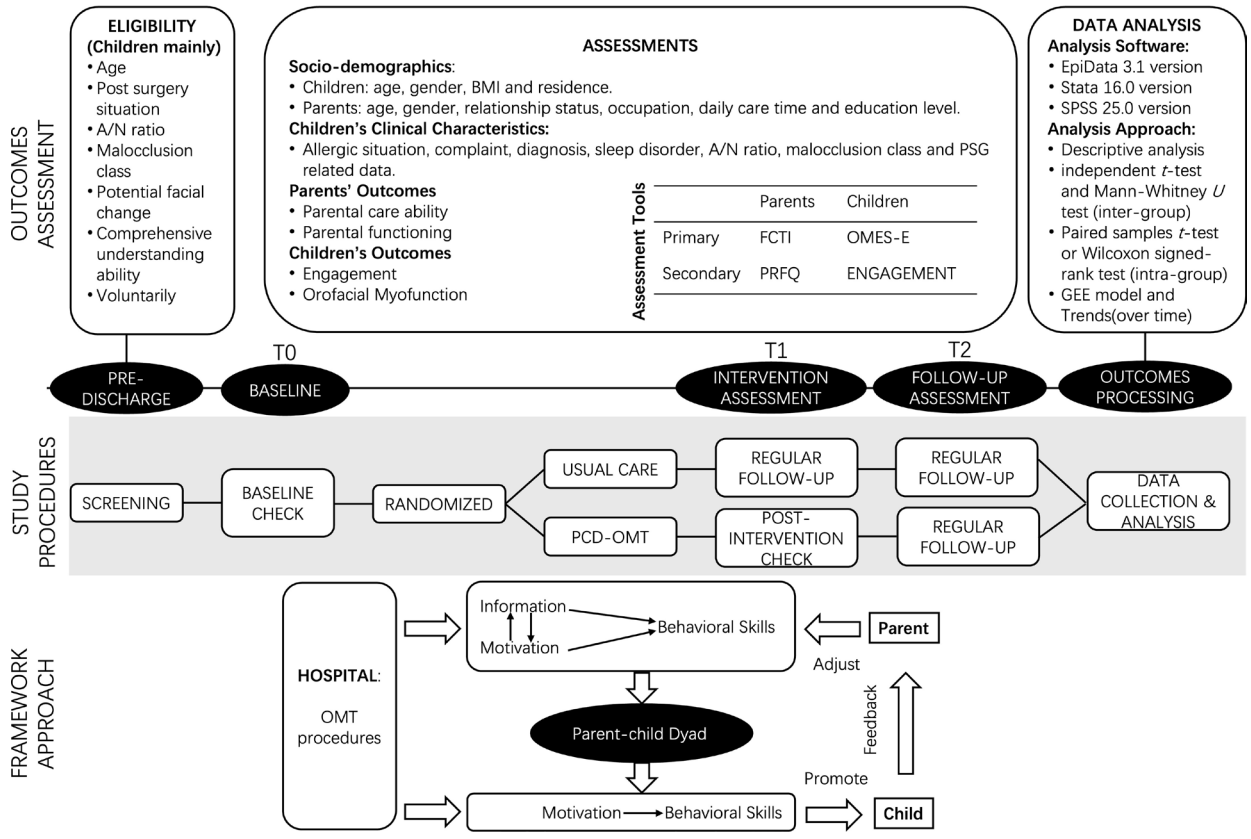

Figure 1 Study design and overview. This figure summarises the protocol design with timeline. Key components include the following: (1) eligibility: children meeting criteria (age, postoperative status, A/N ratio, malocclusion class, comprehension ability, voluntary participation); (2) assessments: socio-demographics (child/parent characteristics), clinical metrics (allergies, sleep disorders, PSG data), outcomes (parental care capacity; child engagement/orofacial myofunction) and related analysis methods; (3) timeline: baseline (T0), postintervention (T1) and follow-up (T2); (4) workflow: screening → randomisation → usual care or PCD-OMT → follow-ups → analysis; (5) intervention: combines hospital-home link orofacial myofunctional therapy with family strategies. A/N ratio, a ratio between adenoid thickness (A) and nasopharyngeal cavity width (N); BMI, body mass index; FCTI, Family Caregiver Task Inventory; GEE, generalised estimating equations; OMES-E, Expanded Protocol of Orofacial Myofunctional Evaluation with Scores; OMT, orofacial myofunctional therapy; PRFQ, Parental Reflective Functioning Questionnaire; PSG, polysomnography.

top-level medical providers in Shandong, offered high-quality medical services and venues for research. They were comparable in terms of service levels, clinical staff strength, resources, medical technology and quality of care. All surgeons held doctoral degrees, were nationally board-certified specialists with ≥10 years of clinical experience, involved met equivalent qualification standards and performed a comparable monthly caseload of AT (19±6 cases/month). To ensure procedural consistency, all surgeries will follow identical techniques and perioperative care. The principal researcher will review the medical records of children before AT and communicate with potential dyads for further assessment according to the study's inclusion and exclusion criteria under a registered nurse. And an informed consent form will be signed after acknowledging (online supplemental file 1).

Randomisation

Eligible dyads will be randomly assigned to a PCD-OMT group or control group using a computer-generated block randomisation method with a fixed block size of four. An independent statistician will generate the randomisation sequence and conceal it via the SealedEnvelope platform, ensuring allocation concealment until baseline assessments are finalised. Access to group assignments will be restricted to the research coordinator until post-baseline data collection to prevent selection bias. Owing to the nature of the intervention, it will be impossible to avoid contamination among dyads. Moreover, the outcome assessors and data analysts will be blinded to the group allocation.

Intervention

Parent-child dyadic orofacial myofunctional therapy group

The intervention group will undergo the PCD-OMT programme, a comprehensive intervention meticulously crafted by a multidisciplinary research team consisting of an otorhinolaryngologist, a dentist, clinical nurses and master's level researchers. Initially, semistructured interviews were conducted with 13 families, whose children either had adenoid facies or experienced anxiety stemming from the condition. These interviews sought

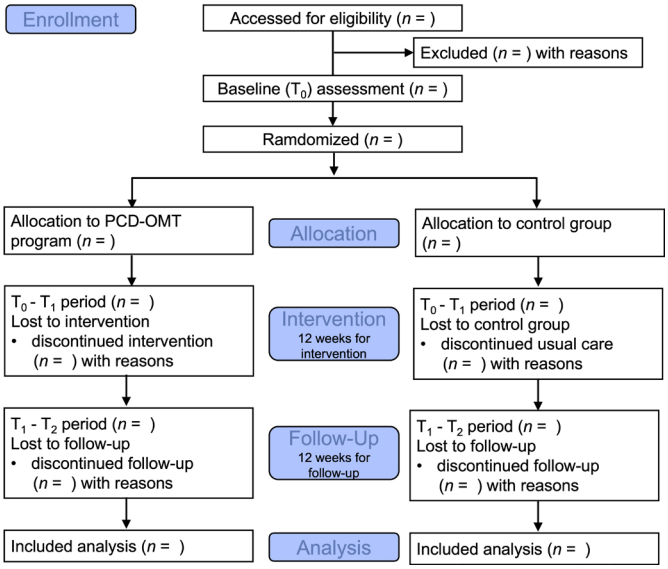

Figure 2 Study process flow. This figure illustrates the participant flow through the study phases: (1) enrollment: initial eligibility screening with exclusions noted; (2) baseline (T0): eligible participants undergo baseline assessments and randomisation to the intervention or control group; (3) intervention phase (T0–T1): 12-week intervention period, with attrition recorded; (4) follow-up phase (T1–T2): 12-week follow-up period, tracking losses to follow-up; (5) final analysis: number of participants included in outcome analysis. Attrition details (discontinued intervention/follow-up) and group allocation are specified at each stage.

to uncover their perspectives on OMT and assess their willingness to engage in treatment. Following this, a thorough review of pertinent literature provided foundational insights that shaped the preliminary design of the programme. Building on this, structured interviews were conducted with 12 relevant families and 16 healthcare professionals, allowing the research team to further refine the programme. The refinement process focused on determining the frequency of interventions, the thematic focus, the goals and the detailed content of each session. Finally, 16 medical professionals, clinical nurses, university professors from relevant fields and psychology experts were invited to participate in two rounds of Delphi consultations. Through this collaborative effort, the programme was finalised based on the collective expertise and consensus of the participating specialists.

The PCD-OMT programme was adapted from the latest guideline of OMT. This guideline is technical standards for the facial muscular treatment of paediatric total facial management.[30] Thus, based on the basic technical operation of the guideline, supplemented by the parent-child dyadic paradigm,[31] we conducted the PCD-OMT programme. The programme will begin 7–10 days post-AT, timed with standard wound checks. Studies confirm surgical sites typically reach WHO Grade I healing by this stage,[32] ensuring safety and stability. The programme will involve establishing a 'hospital-home' network, designed to facilitate a seamless connection between hospital care and home-based support. This network will include personalised dyadic profiles that embed critical modules such as the child's health record, follow-up plans, content arrangements and expected outcomes, with access limited to the research team and participants. Additionally, an intervention diary will be integrated to help track and retrospectively assess progress towards established goals. Key elements of the programme will include multimedia presentations and live demonstrations of OMT. For the soft palate, tongue, face, oral and mandibular swallowing, the specific actions are presented in table 1. These actions will be demonstrated one-on-one before discharge and at follow-up visits, supplemented by easy-to-follow activities like balloon blowing and English pronunciation practice, which will be integrated into home training with their parents through playful, engaging formats such as animated videos, learning games and joint parent-child exercises. To ensure continued engagement, parents will be guided on effective use of feedback techniques and encouraged to incorporate game-based methods to spark the child's interest in OMT. Diaries will be provided to help parents monitor their child's weekly progress and record their observations throughout the process. Biweekly family discussion meetings, which will be conducted both offline and online, serve as platforms for parents to raise challenges faced during the interventions. These interfamily's meetings will offer collective problem-solving and are supplemented by educational sessions such as mini-lectures and reward-based quizzes, designed to motivate both children and parents. Additionally, flipped classroom methods, monthly 'Today I'm the Little Doctor' events, will allow children and parents to demonstrate their OMT skills while reflecting on their experiences. This also will provide a space for sharing insights with peers and receiving feedback.

Follow-up reminders will be scheduled postdischarge, with encouragement for families to return for in-person visits whenever necessary. Weekly online updates, along with group chat notifications, will further ensure that parents remain informed and engaged. Reminders to review previous session summaries and guidance materials will be regularly sent, reinforcing ongoing participation and adherence to the intervention plan.

A total of 21 cartoon videos related to OMT were designed online for free to access, and each video is between 40 and 90 s long. We will be sending the video link via the social media they preferred. The children will receive a free dental examination when finished the intervention and follow-up to ensure and keep good adherence. Moreover, the dyads will have the right to request a roll-out at any time.

Control group

The control group will receive routine in-person healthcare provided by the research team, including perioperative care, post-AT emergency guidance and routine follow-up. These follow-ups will include a postoperative wound assessment 7–10 days after surgery and two

Table 1 Orofacial myofunctional therapy recommended actions and frequency

Actions	Frequency
Soft palate	
Intermittently pronouncing the vowel 'A' to elevate and strengthen the soft palate	3 min/session, 5 sessions/day
Continuously pronouncing vowels 'A, E, I, O, U'	3 min/session, 5 sessions/day
Performing movements that elevate the soft palate without clenching teeth or opening the mouth	Not specified
Pressing the tongue against the soft palate while producing 'G, K' sounds	Several repetitions/sessions, 3–5 sessions/day
Moving the soft palate upwards while pronouncing the small tongue 'X, Q' sounds	Several repetitions/sessions, 3–5 sessions/day
Tongue	
Pressing the tongue against the roof of the mouth, particularly the anterior and lateral palatal surfaces	5 repetitions/session, 3 sessions/day
Extending the tongue tip to the upper palate and sliding it forward and backward	3 min/session, 5 sessions/day
Forcefully sucking the tongue against the upper palate	3 min/session, 5 sessions/day
Elevating the tongue's middle and contracting it towards the floor of the mouth	3 min/session, 5 sessions/day
Extending the tongue outward, pressing it against the upper and lower lips	30 s/session, 3–5 sessions/day
Moving the tongue from side to side in a sweeping motion from the front to the back	30 s/session, 3–5 sessions/day
Curving the tongue upward towards the soft palate while extending forward	Not specified
Pushing the tongue against the upper and lower molars bilaterally	Not specified
Suctioning the tongue against the upper palate and releasing with an audible sound	Not specified
Maintaining suction on the tongue while pressing it against the soft palate	Not specified
Rotating the tongue while using external resistance applied by the hand under the chin	10 repetitions/session, 5 sessions/day
Extending the tongue forward and backward, then downwards	Not specified
Face	
Applying pressure to the chin muscles while pushing upward	30 repetitions/day
Performing facial movements like puffing the cheeks or applying gentle facial massages	Not specified
Massaging under the chin using fingertips, pressing deeply	10 repetitions/session, 5 sessions/day
Valsalva manoeuvre (holding breath while puffing cheeks)	5 s/session, 5 sessions/day
Circular massaging movements from the front of the chin towards the neck	1 min/day
Gently pressing the chin muscles upward	10 repetitions/day
Oral and mandibular chewing	
Practicing diaphragmatic breathing and proper chewing techniques	Not specified
Inflating a balloon by blowing into it and maintaining pressure without deflating the cheeks	5 repetitions/session, 1 session/day
Chewing exercises to strengthen the muscles involved in oral functions	20 repetitions/day
Proper oral closure while chewing and breathing correctly to align upper and lower teeth	Each meal

additional free oral health examinations at later measurement points.

Outcome measures

Baseline characteristics

Baseline data will be systematically collected through standardised instruments and clinical assessments for both children and their parents.

For children, key variables include the following: demographic and anthropometric measures: age, gender and body mass index measured by calibrated devices and residence; clinical characteristics: type and number of allergies, primary complaints, physician-confirmed diagnosis, parent-reported sleep disturbances, A/N ratio, malocclusion class and polysomnography-related data.

Table 2 Details of feasibility and acceptability measurements

Outcomes	Assessment tools	Descriptions
Feasibility	Recruitment rate	Proportion of participants who participate in this study in relation to the number of participants who meet the inclusion and exclusion criteria.
	Retention rate	Proportion of participants who complete the overall study in relation to the number of participants who participate in this study.
	Drop-out rate	Percentage of participants who drop out during intervention and follow-up.
	Adherence rate	Percentage of the number of sessions completed by participants in the total number of sessions.
Acceptability	Participants' satisfaction	Participants will rate on a visual scale with five scores (from very dissatisfaction to very satisfaction) weekly on website anonymously.
	Intervention diaries	Participants will fill intervention diaries weekly on children's performance and care feelings.
	Reasons for dropping out	Participants who withdraw from the study will be inquired their reasons for dropping out.

For parents, sociodemographic data will include age, gender, relationship status, occupation, daily care time for the child and education level.

Feasibility and acceptability

The feasibility of recruitment and follow-up processes as well as the feasibility and acceptability of the PCD-OMT programme will be employed to verify the viability in clinical practice. The details of the primary outcome measures are presented in table 2.

The primary outcomes are orofacial myofunction in children and parental care abilities. The secondary outcomes are children's engagement and parental functioning. These factors are used to evaluate the utility in clinical practice.

Orofacial myofunction

Orofacial myofunction will be measured by the Expanded Protocol of Orofacial Myofunctional Evaluation with Scores (OMES-E).[33] This tool, which evaluates appearance, mobility and functions, requires an experienced dentist and takes 10–15 min to administer. This assessment will be conducted through visual inspection, supplemented by video analysis when necessary to enhance accuracy. A chocolate-stuffed cookie (BONO, Nestlé, Brazil) will be used to assess mandibular function. The time taken to chew the food will be monitored with a chronometer. Higher ranks indicate better performance in appearance, mobility and function during the programme. Compared with specific laboratory equipment, OMES-E provides a quick and acceptable assessment during children's physical examinations with high sensitivity (positive correlation: 0.91).

The evaluation will be performed by two independent therapists who have undergone prestudy training by the same qualified speech therapist to ensure consistency and reliability. Prior to the formal assessment phase, the evaluators conducted simulated assessments on 20 children who had undergone AT to calibrate their scoring. The inter-rater reliability assessment demonstrated high consistency, confirming their ability to apply the protocol accurately. All assessments will be conducted with participants seated in a height-adjustable chair and the same camera (Nikon D3400) to maintain proper postural alignment to minimise bias. In cases where additional clarification is required, video recordings will be analysed to improve scoring reliability.

Parental care abilities

Parental care ability and information mastery will be measured by the Chinese version of the Family Caregiver Task Inventory.[34] This scale comprises 25 items divided into the following dimensions: learning to cope with new role (attending to and accepting responsibility for one's own ability to cope with new tasks in caregiving), providing care according to care-receiver's needs (establishing patterns and routines to meet the care-receiver's daily activities), managing own emotional needs (dealing with personal feelings towards the care-receiver and caregiving), appraising supportive resources (reflecting satisfaction) with the support received and with the number and composition of one's interpersonal ties and balancing caregiving needs and one's own needs (attaining self-actualisation and fulfilment). Each dimension contains five items. Parents rate items from 0 to 3 (from not difficult to extremely difficult), with a minimum total score of 0 and a maximum total score of 75. Higher scores indicate more perceived difficulty in caregiving tasks. In a previous study in a child-parent dyadic programme, Cronbach's alpha was 0.89.[35]

Children's engagement

Engagement will be measured using the Early Childhood Parent Report Engagement–Persistence 6a by *PROMIS*. This 6-item scale uses a response format ranging from 1 to 5 (from never to always). Higher scores indicate positive engagement in children's motivation.

Parental functioning

Parental functioning will be measured using the Chinese version of the Parental Reflective Functioning Questionnaire.[36] Each item is scored from 1 to 5 (from strongly disagree to strongly agree). This scale comprises 16 items divided into three dimensions: prementalising (five items), certainty (six items) and interest (five items). A mean score is calculated for each dimension. Higher scores indicate better parental reflective functioning. Cronbach's alpha for the dimensions was 0.49, 0.79 and 0.66, respectively.[37]

Sample size calculation

A priori estimation of sample size was based on the effect sizes calculated from mean differences in all involved variables from similar trials, choosing the possible maximum sample size.[38] Using G*Power (V.3.1), a sample size of 68 (34 per group) was required to detect a significant difference in primary outcomes between the intervention and control groups, with a statistical power of 80% and a two-sided significance level of 0.05. Considering an average attrition rate of 15% from previous trials, 80 dyads were required (40 per group).

Study hypotheses

Hypothesis 1: Feasibility and acceptability: The programme will show an acceptable and adequate performance on feasibility and acceptability. There will be no reports of dissatisfaction during the programme.

Hypothesis 2: Parental impact: Parents participating in the programme will show significantly higher levels of better parental functioning and enhanced abilities related to their children's OMT care and monitoring.

Hypothesis 3: Children's impact: Children participating in the programme will demonstrate significantly higher levels of engagement and improved outcomes in orofacial myofunction.

Data collection and management

Data will be collected at baseline, postintervention and at 12-week follow-up by trained independent assessors in our team. Outcomes for children will be collected by fixed trained assessors, while outcomes for parents will be collected by the other assessor. All assessors have undergone standardised training to ensure compliance with assessment protocols and to minimise bias. During questionnaire administration and procedural guidance, they will refrain from providing any suggestive language to reduce misinterpretation and evaluator bias. At baseline, except for the following outcome variables, general information concerning the participants will also be collected. Any privacy information about participants and individual cases will be stored in password-protected files on a designated device. All data will be destroyed after the research results are published. The schedule of enrolment, interventions and assessments is presented in table 3 and figure 2.

Statistical analyses

Data analyses will be employed using IBM SPSS (V.25.0). Data visualisation is realised through Stata (V.16.0). All data will be entered by two independent assessors using EpiData (V.3.1). Descriptive statistics will be used for the feasibility outcomes and acceptability outcomes. For the efficacy outcomes, an intention-to-treat analysis will be performed. Continuous data will be expressed as mean

Table 3 The schedule of enrolment, interventions and assessments

Study period	Enrolment	Baseline (T0)	Postintervention (T1)	12-week follow-up (T2)
Enrollment				
Eligibility screen	X			
Informed consent	X			
Allocation	X			
Interventions				
PCD-OMT group		←	→	
Control group		←	→	
Assessments				
Sociodemographic		X		
Feasibility		X	X	X
Acceptability			X	X
OMES-E		X	X	X
FCTI		X	X	X
Engagement		X	X	X
PRFQ		X	X	X

FCTI, Family Caregiver Task Inventory; OMES-E, Expanded Protocol of Orofacial Myofunctional Evaluation with Scores; PCD-OMT, parent-child dyadic orofacial myofunctional therapy; PRFQ, Parental Reflective Functioning Questionnaire.

and SD or median (IQR), depending on the Shapiro-Wilk normality tests. Categorical variables will be described by frequency. For intergroup comparisons, continuous data will be analysed using the independent t-tests or Mann-Whitney *U* tests. Categorical data will be analysed using the χ^2 test for between-group comparisons. For intragroup comparisons, paired sample t-tests or Wilcoxon signed-rank tests will be applied as appropriate. Generalised estimating equation model will evaluate the effects of primary and secondary outcomes over time, and variables' trends will be presented as a visual figure via Stata. A p value<0.05 will be considered statistically significant.

Patient and public involvement

Before constructing the programme, we have approached the family members whose children are diagnosed with AH to join in qualitative interviews to understand their experiences and feelings about their children's current facial appearance. During the development of the programme, we also conducted structured interviews involving 12 families and 16 healthcare professionals for optimisation.

In the process of programme construction, dyads, otorhinolaryngologists, dentists, relevant physicians, nurses and psychologists have been invited and offered valuable suggestions for the programme.

Ethics and dissemination

The study protocol was approved by the Ethics Committee of Medical College of Qingdao University (QDU-HEC-2023216) and conducted in compliance with the Declaration of Helsinki and registered in the Chinese clinical trial registry (ChiCTR2400091466). All participants will be required to sign a written informed consent form after being informed of the study. Participants will have the right to drop out at any time. Participants' information collected in this study will be securely stored in a password-protected file accessible only to specified members of the research team. The findings of this RCT will be published in a peer-reviewed clinical journal for widespread publication.

DISCUSSION

The PCD-OMT programme focuses on positive regulation and feedback for parents and active engagement for children with dyadic communication and reflection. Throughout the programme, researchers will provide multiple and repeated information outputs, conduct group meetings with various themes, address parents' urgent concerns and facilitate interfamily communication to promote information mastery, motivation and parental skill updates. This approach will also promote the growth of children's motivation and development of OMT skills. This study may provide a new approach for families whose children may be facing facial unconfidence post-AT and enhancing therapy adherence.

This study has several strengths. First, AT provides the availability of an optimal intervention window, which encompasses preoperative case evaluation, perioperative management and routine postoperative follow-up, facilitating consistent and effective monitoring throughout the study. In addition, this programme is specifically designed for dyads who are willing to spare effort on it, which makes the whole programme easy to conduct and trace. Importantly, the Delphi method has been employed to refine the programme, which consists of otorhinolaryngologists, dentists, relevant physicians, nurses and psychologists' valuable suggestions and considered the actual demand in children's families. Lastly, evidence will be provided for future conducting high-quality full-scale clinical trials via the findings of this preliminary RCT. It will provide more specific information in parental care and functioning in family support systems and children's performance when families encounter new challenges.

This study has some limitations. First, this study calculated a small sample size, and the results may not show decisive findings about the effects in some variables. Moreover, enrolments may face difficulties due to the fact that AT is a seasonal surgery. Especially in vacations, there will be a high flow. In addition, the study only performs 24 weeks, which may not be able to evaluate the long-term ongoing effect on craniofacial changes. Finally, this study focuses on parent-child dyads with preschoolers, which may not be applicable to school-aged children due to the weakened parent-child link.

In conclusion, this RCT will evaluate the feasibility, acceptability and preliminary effects of the PCD-OMT programme. The primary findings of this study will enhance our understanding of this programme and can be used to inform the sample size calculation and intervention programme optimisation of future large-sample RCTs and clinical practice.

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