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RESEARCH ARTICLE

Addressing the Unmet Needs of Parent Mental Health: Protocol for a Pilot Feasibility Trial of Focused Acceptance and Commitment Therapy for Parents of Infants Born with Cleft Lip and Palate

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ABSTRACT

Background: Congenital anomalies are a leading cause of infant morbidity and mortality. Cleft lip and/or palate (CL/P) is the most common craniofacial anomaly, affecting approximately 6,000–8,000 infants annually in the United States. Parents of children with CL/P report elevated levels of stress, anxiety, and depression, particularly during the first year of life when feeding challenges, medical procedures, and social stressors are most intense. Despite well-documented impacts on both parent and child outcomes, psychological support is not routinely integrated into cleft care. Focused Acceptance and Commitment Therapy (FACT) is a brief, scalable intervention designed to enhance psychological flexibility and reduce distress. However, FACT has not been evaluated in parents of infants with CL/P.

Methods: This single-site pilot study will evaluate the feasibility and proof of concept of FACT among 30 parents or caregivers of infants (0–12 months) receiving outpatient CL/P care. Participants will attend two 90-minute virtual FACT group sessions delivered in cohorts of 3–5 families. Primary outcomes include parental stress (Perceived Stress Scale-10) and anxiety (Generalized Anxiety Disorder-7), assessed at baseline and two weeks post-intervention. Secondary outcomes include depressive symptoms (Patient Health Questionnaire-9), traumatic stress (Impact of Events Scale-Revised), and psychological flexibility (Acceptance and Action Questionnaire-II). Feasibility metrics will include recruitment, retention, assessment completion, and intervention completion rates, supplemented by qualitative feedback. Proof-of-concept analyses will use the Reliable Change Index to assess clinically meaningful individual-level changes. We hypothesize that FACT will be feasible to deliver and associated with meaningful reductions in parental stress and anxiety. Mixed-methods findings will inform future refinement and implementation strategies.

Discussion: This pilot study represents the first evaluation of FACT specifically for parents of infants with CL/P and the first to examine its effects on stress-related outcomes within cleft care during the first year of life. By embedding a brief, scalable psychological intervention within multidisciplinary cleft services, this study addresses a persistent gap between documented psychosocial need and routine care delivery. If feasible and effective, FACT could offer an accessible, early intervention model to strengthen parental psychological flexibility and mental health during a critical developmental window, with potential downstream benefits for feeding, parent–infant interaction, and child developmental outcomes.

Keywords: Cleft lip and palate, Congenital anomalies, Parent stress, Psychological flexibility, Acceptance and Commitment Therapy, Integrated behavioral health, Pilot feasibility study.

Introduction

Congenital anomalies are the leading cause of infant morbidity and mortality. Cleft lip and/or palate (CL/P) is the most common craniofacial congenital anomaly. Between 6,000 and 8,000 children are born yearly in the United States with a cleft lip and/or palate. In the United States, about 1 in 1,050 babies is born with cleft lip with or without cleft palate, and about 1 in 1,600 babies is born with cleft palate alone[1]. Although CL/P may co-occur with other birth differences, it most often presents in isolation.

Cleft lip and/or palate (CL/P) can be associated with feeding difficulties and failure to thrive, airway concerns, and other complications that may prompt procedural or surgical interventions, breastfeeding challenges, or urgent transfer to a tertiary center for cleft-specialist evaluation[2]. Caregivers of children with CL/P frequently require education and support from trained healthcare professionals to help manage or avoid many of these issues without hospitalization, tube feeding, assistive airway devices, or life-threatening complications.

The period immediately following diagnosis through the first year after birth is consistently identified as the most challenging for parents of a child with CL/P[2]. The diagnosis is often experienced as devastating, leaving parents and caregivers shocked and adjusting to unexpected differences in their child's appearance and anticipated medical needs[3]. The visible nature of CL/P can complicate early bonding and invite unwanted or insensitive social reactions, further intensifying parental distress[4,5]. Concurrent feeding difficulties and medical uncertainties are strongly associated with increased parental anxiety and frustration[6]. Reflecting this cumulative burden, family quality of life is lowest during the first year – particularly at two months and one year – and tends to improve only after surgical correction[7].

Parents of children with CL/P are at risk for psychosocial challenges that can affect both their own well-being and their child's outcomes[8]. Mothers and primary caregivers are particularly vulnerable, with depression occurring in 23.6% over the first year of the child's life, peaking at 33.3% between four and six months postpartum[9]. Parenting stress is strongly associated with increased depressive symptoms, underscoring the central role of stress in early mental health risk[9]. Importantly, early parental mental health is a significant predictor of infant bonding, feeding interactions, and long-term emotional and behavioral trajectories[10,11]. These data highlight the first year of life – when families report the greatest quality of life burden – as a critical window for intervention; however, psychological support for parents is not routinely integrated into cleft care during this high-risk period[12]. Structural barriers, including stigma, inadequate screening, and limited access to specialized care contribute to substantial treatment gaps[13], leaving many parents unidentified and untreated.

To address this gap, interventions must be brief, scalable, and feasible for integration within multidisciplinary cleft care. How caregivers interpret and respond to their child's medical condition plays a central role in family adjustment. In CL/P, more negative parental appraisals are associated with poorer quality of life both initially and years later[6]. These findings align with broader evidence that caregiver interpretations of illness shape both parent well-being and child outcomes. Importantly, these appraisals are modifiable[6].

Psychological flexibility – the ability to notice and accept difficult thoughts and feelings without becoming overwhelmed by them, while continuing to act in accordance with personal values – has been identified as a key mechanism of addressing stress[14]. Acceptance and Commitment Therapy is an evidence-based, transdiagnostic intervention designed to strengthen psychological flexibility through mindful awareness, acceptance, and values-driven action[15]. Rather than attempting to eliminate distressing thoughts or emotions, ACT helps individuals change their relationship to them, making it well-suited for medical contexts in which stressors cannot be removed.

Focused Acceptance and Commitment Therapy (FACT) is a brief adaptation of ACT that has demonstrated meaningful reductions in parent stress, anxiety, and depression in as few as one to two sessions in families of children with neurodevelopmental disorders[16]. However, FACT has not yet been tested in parents of infants with CL/P, nor specifically evaluated for stress-related outcomes in this population during the first year of life, a critical developmental window for both parent and child. If effective in this population, FACT could offer a scalable, integrated model of early psychological support within cleft treatment settings internationally[17]. To optimize FACT for parents of infants with CL/P, our team adapted the intervention using formative research methods to address condition-specific stressors. The next critical step is feasibility and proof-of-concept testing within multidisciplinary cleft care.

This manuscript describes the protocol for a prospective pilot feasibility and proof-of-concept study that will evaluate Focused Acceptance and Commitment Therapy (FACT) for improving the mental health of parents of infants with CL/P. The study will assess the feasibility of delivering a brief, group-based FACT intervention within a cleft care setting and examine preliminary signals of improvement in parental stress and anxiety during the first year of life. Findings from this pilot will inform refinement of the intervention and the design of a future fully powered clinical trial aimed at integrating early psychological care during a critical developmental window for both parents and infants within multidisciplinary cleft treatment settings. Publication of this protocol is intended to enhance transparency, support methodological rigor, and facilitate replication of psychological intervention research within pediatric specialty care settings[18,19]

Methods

STUDY DESIGN

This is a proof-of-concept study in which we will conduct a prospective, non-randomized clinical trial of Focused Acceptance and Commitment Therapy (FACT), a brief two-session group intervention modified for the goal of improving mental health of parents of children with CL/P. Parents, including non-biological caregivers, will receive the group-based intervention in cohorts of approximately 3-5 families. We expect to hold 8-10 groups to reach our intended sample size of 30 families, and will administer outcome measures at pre- and two-weeks post-intervention. The study design is illustrated in Figure 1.

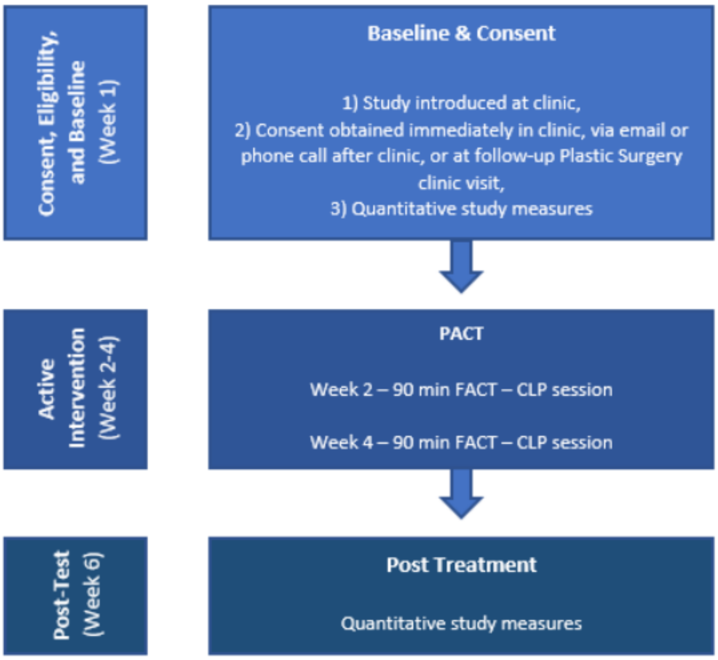

Figure 1: Study Design.

SPECIFIC AIMS AND HYPOTHESES

The first aim of this study is to evaluate the effectiveness of FACT in reducing mental health (MH) problems among parents of children with CL/P. We hypothesize that parents receiving FACT will demonstrate clinically meaningful change in stress and anxiety using the Reliable Change Index (RCI; success defined as $RCI > 1.96$). The second aim is to identify factors that impact the feasibility of intervention delivery. We anticipate that these procedures will be feasible, with feasibility success defined as recruitment rate above 60%, and retention, assessment completion, and intervention completion rate above 80%. Mixed methods data collection will identify factors that impact 1) recruitment rate (qualitative surveys, percentage meeting inclusion criteria, number of contact attempts), 2) retention rates (qualitative surveys, baseline characteristics, treatment group), 3) assessment completion rate (qualitative surveys, measure type), and 4) treatment completion rate (qualitative surveys, scheduling, treatment location).

PARTICIPANTS

We aim to enroll 30 sets of parents. To be eligible, parents must be aged ≥18 years and the primary caregiver of a 0–12-month-old child with CL/P. Their child must be receiving outpatient CL/P treatment at the large Midwestern pediatric hospital in which this study is conducted. Parents will be excluded from participation if they have significant cognitive impairments, do not speak English, have a child with suspected syndrome or Pierre Robin sequence, or they are unable to join virtual meetings. Of note, we are excluding non-English speaking participants because the behavioral intervention is currently only available in English. In the future, we hope to translate this intervention for non-English speaking patients but are unable to do this for the present study.

Parents will be approached at their initial multidisciplinary Cleft Clinic team visit and given an introductory overview of the study. Due to the length and potential stress involved in Cleft Clinic visits, families will be given the option to complete consent procedures at that time, via email or phone call after the Cleft Clinic visit, or at a subsequent Plastic Surgery visit. Both parents may be enrolled in the study if logistically feasible and if they both meet study criteria. If one parent isn't available at the Cleft Clinic visit, an information letter containing study team contact information will be sent home with the enrolled parent inviting the second parent to opt in to the study. If they choose to participate in the study, consent with the second parent will be completed virtually at a time convenient to the parent. However, if the parent at clinic indicates that the other parent is not a caregiver for the child, the information letter will not be sent.

PROCEDURE

Study Intervention

Enrolled parents will complete two 90-minute FACT group sessions with a study interventionist, two weeks apart. Interventionists will be individuals with at least master's-level training (or equivalent) in mental health or a related field. The intervention sessions will be conducted virtually through Microsoft Teams to reduce barriers to participation (e.g., travel, childcare).

The FACT intervention is based on the Focused Acceptance and Commitment Therapy treatment literature[20] and the two-session FACT approach utilized by Brown[21,22] and Whittingham[23,24] with parents of children with neurodevelopmental conditions. Intervention content includes 1) education about parent MH problems among parents of children with CL/P, 2) interactive learning of FACT skills, including cognitive defusion, present-moment awareness, and value-based decision making, and 3) education about the importance of positive parent-child interactions and how to apply FACT skills to their interactions with their child with CL/P (See Table 1). Groups will be offered to enrolled families on a quarterly basis.

Table 1: FACT Session Outline

Session 1	Welcome and Introductions
	Introduce Acceptance and Commitment Therapy
	Stress and Parenting Discussion
	The Struggle Metaphor and Acceptance
	Passengers on the Bus Metaphor
	Introducing Values
	Conclusion and Wrap-up
Session 2	Welcome Back and Review
	Present-Moment Awareness
	Cognitive Defusion
	Putting Values into Action
	Connect Back to Relevant Parenting Tasks
	Summary and Wrap-up

MEASURES

Parents will complete the standard study outcome measure battery at baseline and 2 weeks post-intervention.

Demographics

Parents will provide information on their own and child's age, sex/gender, race/ethnicity, education, and socioeconomic status at baseline. Parents will also report on their own mental health history and child medical history. Any additional relevant child medical details will be accessed via chart review.

Primary Outcomes Measures

Anxiety. Parent anxiety will be measured with the GAD-7, a 7-item self-report measure of anxious symptoms across the prior two weeks[25]. Items are rated on a scale from 0 "Not at all" to 3 "Nearly every day," with scores of 10 or more indicating probable anxiety. The GAD-7 has evidenced excellent internal consistency ($\alpha = .95$).

Perceived Stress. Parent perceived stress will be measured with the Perceived Stress Scale (PSS-10), a 10-item self-report measure of perceived stress across the prior month[26]. Items are rated on a scale of 0 "Never" to 4 "Very often," with scores of 14 or greater indicating at least moderate stress. The PSS has evidenced acceptable internal consistency ($\alpha = .78$).

Secondary Outcome Measures

Depressive Symptoms. Parent depressive symptoms will be measured with the Patient Health Questionnaire depression module (PHQ-9), a 9-item self-report measure of depressive symptoms across the prior two weeks[27]. Items are rated on a scale from 0 "Not at all" to 3 "Nearly every day," with scores of 10 or more indicating probable depression[28]. The PHQ-9 has evidenced good internal consistency ($\alpha = .81 - .89$).

Traumatic Stress. Parent symptoms of traumatic stress will be measured using the Impact of Event Scale – Revised (IES-R), a 22-items self-report scale measuring posttraumatic stress symptom severity, based on DSM-IV criteria, over the prior week[29]. Items are rated on a scale of 0 "Not at all" to 4 "Extremely," with higher scores indicating greater distress and scores of 22 or more indicating probable PTSD[30]. The IES-R has demonstrated excellent internal consistency ($\alpha = .96$).

Psychological Flexibility. Parent psychological flexibility will be measured with the Acceptance and Action Questionnaire-II (AAQ-II), a 7-item self-report measure of experiential avoidance and psychological inflexibility[31]. Items are rated on a scale from 1 "Never true" to 7 "Always true," with higher scores reflecting less psychological flexibility and scores of 24-28 or greater being associated with symptoms of depression and/or anxiety. The AAQ-II has demonstrated good internal consistency ($\alpha = .84$).

Feasibility and Acceptability

Quantitative Measures. Feasibility success will be defined as recruitment rate above 60% and retention, assessment completion, and intervention completion rate above 80%.

Qualitative Measures. A qualitative survey assessing factors impacting feasibility will be completed by parents at the 2-week follow-up. Specifically, the survey will ask for qualitative feedback related to helpfulness of the intervention, perceived benefits, challenges and barriers to participation, and recommendations for intervention improvement.

STATISTICAL ANALYSIS PLAN

Data will be analyzed using the most current version of SPSS. We will conduct descriptive statistics to evaluate demographic and baseline variables, as well as primary and secondary outcome variables. We will conduct correlations between demographic factors and outcome variables.

Quantitative Feasibility Analyses

Descriptive statistics (e.g., frequency counts, %s) will determine recruitment, retention, assessment, and intervention delivery success and will be compared to identified benchmarks of success (recruitment rate above 60% and retention, assessment completion, and intervention completion rate above 80%). Factors that may impact success (e.g., baseline characteristics, contact methods, scheduling procedures, treatment group, measure type) will be evaluated in relation to these outcomes using t- and chi-squared tests.

Qualitative Feasibility Analyses

Parent free text responses to feasibility questions will be imported into NVivo 12 software for coding. A coding tree will be developed a priori and periodically revised to include relevant inductive codes as emergent themes arise. Qualitative responses will then be double coded by the study psychologist and a graduate research assistant. Interrater reliability will be coded, with the goal of achieving 80% interrater reliability. The primary investigator will provide direct supervision of data collection and analysis.

Proof of Concept Analyses

We will use the Reliable Change Index (RCI; success defined as RCI > 1.96) to determine if there is a reliable signal of change for participants from baseline to post-treatment and follow-up. The RCI is a psychometric criterion used to evaluate whether change is significant at the level of the individual. An RCI will be calculated for each participant using the following formula: RCI = observed difference score between measurements divided by the standard error of measurement of the difference. We will assess proof of concept for change in parent stress and parent anxiety as our primary outcome measures.

Given the feasibility and proof-of-concept nature of this study, we are interested in whether study procedures are feasible and lead to meaningful improvements (e.g., several points of improvement on rating scales) rather than statistical significance. The sample size was therefore selected to ensure that a large enough group of participants can be evaluated to be reflective of a heterogeneous group of parents.

Results

Results will be disseminated in scholarly journals following the completion of the project.

Discussion

This will be the first study of an intervention specifically targeted at addressing stress and anxiety among parents of children newly diagnosed with CL/P. Congenital differences such as CL/P are incredibly stressful for parents and lead to a great deal of uncertainty about their child's future[32]. There are also many complex implications of CL/P, specifically on parenting during the neonatal period, including possible surgeries, hospitalizations, medical appointments, therapies, and feeding challenges[33]. It is known that increased parent stress and anxiety have downstream effects on child wellbeing and parent-infant bonding[34]. Despite this knowledge, it is not yet standard of care to provide mental health support to parents of these infants in pediatric settings as the parents are not viewed as patients in the pediatric healthcare setting. However, many pediatric subspecialties have begun to realize the vital importance of addressing parent mental health within critical pediatric settings such as neonatal intensive care and pediatric oncology[35-37]. This study is a fundamental step toward understanding how we might be able to best address parent mental health within the paradigm of pediatric CL/P care. If successful, this intervention could improve parent mental health during this critical window of heightened risk, and as a result contribute to improved bonding, developmental, and feeding outcomes for children with CL/P [38].

We anticipate that parents will find this intervention feasible to engage in given our efforts to reduce barriers associated with cost, travel, and childcare by delivering the intervention via an online platform (Microsoft Teams). We also know that brief interventions have the potential to improve feasibility as parents of children with medical conditions report time to be very limited[39]. It is important to note that brief interventions are likely not sufficient for all parents, and some may need to be connected to more traditional long-term therapy options to support optimal outcomes. However, having a history of positive therapy experiences is associated with increased likelihood to re-engage with therapy, and therefore a brief treatment that is easy to access may serve as a positive bridge to willingness to participate in additional therapy for many families[40]. Additionally, even incremental improvements for parents experiencing significant stress or anxiety could have substantial long-term effects on the trajectory of their child's health and wellbeing given the critical window of opportunity for child development during the first year of life[41].

We anticipate that this intervention will demonstrate proof-of-concept and be feasible for family participation. If feasible and effective, this intervention could provide an accessible model for integrating early parent psychological support within multidisciplinary cleft care. Publishing this protocol promotes transparency, enables early evaluation of the methodological approach, and may support replication and adaptation of integrated psychological interventions in other pediatric specialty settings. If successful, we will also make modifications to the treatment and research protocol based on feedback from families during this pilot study to ensure the approach is refined prior to pursuing a larger clinical trial of this intervention.

Conclusions

In conclusion, to optimize developmental and treatment outcomes for babies with CL/P, holistic care must also include attention to parental mental health. Adaptation and implementation of the FACT intervention for parents navigating this diagnosis provides a brief treatment which minimizes barriers to participation while maximizing positive impact on parental mental health as the foundation for overall health of the family unit. Future directions include completion of proof-of-concept and feasibility in this parental population; adjustments and modifications based upon pilot results and feedback; and future randomized clinical trials resulting in expansion of team-based care to include more robust parental mental health resources. Finally, development and implementation of this intervention illuminate the importance of cross-specialty expertise and collaboration; by expanding care outside the traditional pediatric framework to prioritize parental mental health, true multidisciplinary care is redefined.

Conflict of Interest Statement:

We do not have any conflicts to disclose.

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