

TITLE: Feasibility and Acceptability of the Promoting Resilience in Stress Management-Parent (PRISM-P) Intervention for Caregivers of Children with Craniofacial Conditions

RUNNING TITLE: Caregiver Resilience Intervention

AUTHORS: Kaitlyn M. Fladeboe, PhD^{1,2*}; Nicola Marie Stock, DPhil^{3*}; Carrie L. Heike, MD, MS^{1,2}; Kelly N. Evans, MD^{1,2}; Courtney Junkins, PsyD²; Laura Stueckle, MPH²; Alison O'Daffer, BA²; Abby R. Rosenberg, MD, MA, MS^{4,5,6}; Joyce P. Yi-Frazier, PhD²

**co-first authors*

AFFILIATIONS

¹University of Washington School of Medicine, Department of Pediatrics; Seattle, WA

²Seattle Children's Research Institute, Center for Clinical & Translational Research; Seattle, WA

³Centre for Appearance Research, University of the West of England; Bristol, UK

⁴Dana-Farber Cancer Institute, Department of Psychosocial Oncology and Palliative Care; Boston, MA

⁵Department of Palliative Care, Boston Children's Hospital; Boston, MA

⁶Department of Pediatrics, Harvard Medical School

CORRESPONDING AUTHOR

Joyce Yi-Frazier, PhD

Seattle Children's Research Institute

1900 Ninth Avenue, MS CURE-4

Seattle WA 98101

206-884-1456

Joyce.yi-frazier@seattlechildrens.org

FUNDING: This project was supported by the discretionary funds of Dr. Carrie Heike at Seattle Children's Research Institute. The opinions here reflect those of the authors and not necessarily those of the funder.

CONFLICTS OF INTEREST: The authors have no conflicts of interest to declare.

TABLES: 4

FIGURES: 0

SUPPLEMENTARY FILES: 2

Abstract

Objectives: Few evidence-based psychosocial programs exist within craniofacial care. This study (a) assessed feasibility and acceptability of the Promoting Resilience in Stress Management-Parent (PRISM-P) intervention among caregivers of children with craniofacial conditions and (b) described barriers and facilitators of caregiver resilience to inform program adaptation.

Design: In this single-arm cohort study, participants completed a baseline demographic questionnaire, the PRISM-P program, and an exit interview.

Participants: Eligible individuals were English-speaking legal guardians of a child <12-years-old with a craniofacial condition.

Intervention: PRISM-P included 4 modules (stress-management, goal-setting, cognitive-restructuring, meaning-making) delivered in 2 one-on-one phone or videoconference sessions 1-2 weeks apart.

Main Outcome Measures: Feasibility was defined as >70% program completion among enrolled participants; acceptability was defined as >70% willingness to recommend PRISM-P. Intervention feedback and caregiver-perceived barriers and facilitators of resilience were summarized qualitatively.

Results: Twenty caregivers were approached and 12 (60%) enrolled. The majority were mothers (67%) of a child <1-year-old diagnosed with a cleft lip and/or palate (83%) or craniofacial microsomia (17%). Of these, 8 (67%) completed PRISM-P and 7 (58%) completed interviews; 4 (33%) were lost-to-follow-up before PRISM-P and 1 (8%) before the interview. Feedback was highly positive, with 100% willing to recommend PRISM-P. Perceived barriers to resilience included uncertainty about their child's health; facilitators included social support, parental identity, knowledge, and control.

Conclusions: PRISM-P was acceptable among caregivers of children with craniofacial conditions but not feasible based on program completion rates. Barriers and facilitators of resilience support the appropriateness of PRISM-P for this population and inform adaptation.

Key words: Psychosocial Adjustment, Parental Perception, Social Support, Quality of Life

Introduction

Caregivers of children with congenital craniofacial conditions are at risk for psychological distress.¹⁻³ Following their child's diagnosis, caregivers must take on a wealth of new information regarding their child's diagnosis, treatment, and long-term medical needs, as well as cope with their own complex emotions which may include grief, guilt, and anxiety about their child's future.¹ Thereafter, their child will follow a multidisciplinary treatment pathway throughout childhood and into adulthood. This represents an ongoing and chronic stressor for caregivers, as they must cope with novel challenges related to treatment, medical outcomes, and psychosocial adjustment at each phase of their child's life.^{1,4} These stressors may impact caregiver mental health, family functioning, and marital relationships and have negative downstream effects on children's own wellbeing.^{2,5-7} Despite these challenges, few evidence-based psychosocial interventions exist for caregivers of children with craniofacial conditions.⁸

One intervention that offers potential for this population is the Promoting Resilience in Stress Management (PRISM) intervention.^{9,10} PRISM is a brief, skills-based program designed to enhance perceived resilience and mitigate psychological distress in adolescents and young adults (AYAs) with serious illness and their families.^{9,10} Within this program, resilience is operationalized as a process of identifying and harnessing new and existing resources to maintain wellbeing during and after any stressor.¹¹ The manualized PRISM program aims to bolster resilience by targeting four 'resilience resources': Stress Management, Goal-Setting, Cognitive Restructuring, and Meaning-Making (**Table 1**). PRISM has been shown to be feasible and acceptable among AYAs with new and advanced cancer, Type I diabetes, and Cystic Fibrosis,^{9,12,13} and efficacious among AYAs with cancer.¹⁴⁻¹⁶ A parent-version ("PRISM for Parents," or "PRISM-P") has been shown to be feasible and acceptable among parents of children with cancer and Type I diabetes^{10,17} and efficacious among parents of children with cancer.¹⁸

Given its success in other populations, PRISM-P shows promise for caregivers of children with craniofacial conditions. First, specialist clinicians have highlighted the need to prevent as well as treat psychological distress in this population.¹⁹ PRISM has been shown to have both a preventative and interventional effect on psychological wellbeing and thus has potential to meet this need.^{14,15,18} Second, extant studies have demonstrated that skills similar to those taught within PRISM (e.g., active coping strategies, optimism) are associated with improved psychosocial health among caregivers of children with craniofacial conditions.^{6,20,21} Finally, PRISM can be successfully delivered by bachelor's- or master's-level staff⁹ and thus has potential to be disseminated in a cost effective manner.²² Though PRISM is designed to be applicable across different populations of individuals dealing with serious illness, it may be tailored based on the unique needs of the population to maximize success. Identifying factors that help or hinder caregivers' ability to feel resilient (i.e., facilitators or barriers of resilience) in the context of craniofacial conditions may critically inform future tailoring of PRISM and/or similar psychosocial interventions for this population.

The goals of the current study were to: (1) conduct a single-arm cohort study to assess whether the standard PRISM-P intervention is feasible and acceptable among caregivers of children diagnosed with craniofacial conditions; and (2) qualitatively describe caregiver-perceived barriers and facilitators of resilience in the context of their child's craniofacial condition to inform future adaptation of psychosocial interventions for this population.

Method

Participants

Ethical approval for this study was granted by the Institutional Review Board at (*Institution*). Caregivers were eligible to participate in the intervention if they were the legal guardian of a child aged 12 years or under who had been diagnosed with a craniofacial condition and was receiving medical care at (*Hospital*); able to speak and read in English; and were

cognitively able to participate in interactive sessions. Though PRISM-P is designed for caregivers of children at any age, caregivers of children >12 years-old were not eligible to avoid potential contamination with a concurrently recruiting psychosocial intervention study for adolescents with craniofacial conditions. Multiple caregivers from the same family (i.e., spouses) were each eligible to enroll though were treated as separate/individual study participants.

Procedure

Recruitment was conducted from June 2019 through April 2020. Following a convenience sampling approach, the research team screened caregivers for eligibility via electronic health records. Eligible caregivers were introduced to the study via an emailed flyer or during their scheduled clinic visit by a known craniofacial provider. Consent conferences took place via phone or in-person during a subsequent clinic visit. Study staff reviewed the consent forms with potential participants including study activities, potential risks and benefits, and procedures to protect confidentiality and privacy, and provided opportunity for questions. All participants provided informed consent prior to starting the intervention. Enrolled participants were invited to complete a brief demographic survey for which they received a \$10 gift card. Surveys were completed via paper-and-pencil or online via Research Electronic Data Capture (REDCap), a secure HIPAA-compliant web application for data collection, based on participant preference. Participants who completed the demographic survey then completed the PRISM-P program.

Following the PRISM-P program, participants completed a follow-up interview for which they received \$10. Follow-up interviews were conducted one-on-one via telephone by one of five trained research assistants who had not had prior contact with the participant. First, a series of structured questions were used to solicit intervention feedback, including willingness to recommend PRISM to other caregivers; general feedback regarding intervention content, timing, and delivery; and suggestions for improvement. Second, a series of semi-structured questions assessed caregivers' definitions of resilience and their perceived barriers and facilitators of resilience in the

context of their child's craniofacial condition and care. See **Supplementary Table 1** for full interview guide. Interviews lasted approximately 10-15 minutes and were audio-recorded. Recordings were transcribed verbatim by trained research assistants.

Intervention Content & Delivery

PRISM-P is comprised of four skills-based components delivered 1:1.^{9,10} For this study, PRISM-P was offered as two 45-60-minute sessions, each of which included two components (**Table 1**). Sessions were delivered 1-2 weeks apart via phone or videoconference. This format has been shown to be feasible and acceptable among caregivers of children with other chronic conditions primarily treated in an outpatient setting.¹⁰ The first session ('Managing Stress') occurred within 2-weeks following completion of the baseline demographic survey and the second session ('Building Resilience') occurred 1-2 weeks later. To practice skills between sessions, participants received paper-pencil worksheets reviewing each PRISM skill and were invited to download the PRISM mobile app to practice the skills on their smartphone (**Supplemental Figure 2**). Sessions were delivered by trained bachelor- or masters-level professionals ('coaches') with oversight from licensed clinical psychologists, as indicated by previous models.^{9,10,15} Four coaches were trained based on established protocols involving eight hours of group-based in-person training, practice sessions, and role plays. All sessions were audio-recorded and monitored for fidelity by the lead coach (a licensed clinical psychologist) using a standardized tool. Specifically, the lead coach monitored fidelity of the first 2 sessions delivered by each coach and thereafter randomly selected 1 in every 3 sessions. This resulted in approximately 10 total hours of fidelity monitoring. Coaches received 30-minute biweekly 1:1 supervision sessions which included directed feedback and re-training if necessary.

Data Analysis

Demographic and clinical variables were summarized descriptively. Feasibility of PRISM-P was assessed based on the percentage of enrolled participants who completed the two-session

program, defined *a priori* as >70%. This was defined based on rates observed in prior studies examining feasibility of the PRISM program.^{9,10,12} Acceptability was assessed based on qualitative interview feedback, defined *a priori* as >70% of interviewed caregivers responding positively to the question, “Are you willing to recommend PRISM to other caregivers?”. All remaining follow-up interview data, including both program feedback and caregiver resilience experiences, were analyzed using directed content analysis²³ and following the Standards for Reporting Qualitative Research (SRQR)²⁴ guidelines. Coding was conducted by co-first authors (a developmental and research psychologist, respectively) using a combination of inductive and deductive approaches. For the first section of the follow-up interviews (intervention feedback), the coding team constructed an *a priori* codebook comprised of structural codes based on interview questions. Second, each coder independently coded the corresponding section of each transcript and met to resolve any discrepancies. For the second section of the follow-up interviews (resilience experiences), each coder first open-coded the corresponding section of each transcript to identify emergent codes. Coders then met to compare results and create a final codebook. Each coder independently re-coded each transcript with the final code book and met to resolve any coding discrepancies. Finally, codes were organized into broader categories.

Results

Sample Characteristics

Twenty eligible caregivers were approached over a 10-month recruitment period. Of these, 12 (60%) agreed to participate and provided informed consent, 8 (67%) of whom were co-enrolled with their spouse or partner (spouse/partners were treated as separate, independent study participants). Enrolled caregivers included 8 mothers (67%) and 4 fathers (33%) of children ($M_{\text{age}} = 10$ mos., $SD = 3$ mos., range = 1-17 mos.) diagnosed with cleft lip and/or palate (CL/P; 83%) or craniofacial microsomia (CFM; 17%). There were no consistent differences between caregivers

who enrolled vs. did not enroll based on child age or diagnosis; the most common reason for not enrolling in the study was a lack of perceived time.

Four caregivers were lost-to-follow-up before completing any study components. Thus, the final sample included 8 caregivers (**Table 2**): 6 mothers (75%) and 2 fathers (25%) among whom 4 (50%) were co-enrolled with their spouse or partner (i.e., 2 mother/father couples). Sample characteristics are shown in **Table 2**. Caregivers were 32 years-old on average (SD = 7 years). The majority self-identified their race as White (75%), followed by Asian (13%), or more than one race (13%). All self-identified their ethnicity as non-Hispanic (100%).

Feasibility of PRISM-P

Feasibility was determined based on the proportion of enrolled caregivers who completed the PRISM-P intervention. Of the 12 caregivers who enrolled in the study, 8 (67%) began and completed the two-session program. The median number of days between sessions was 11 and all sessions were delivered with 100% fidelity.

Acceptability of the PRISM-P

Seven participants completed feedback interviews (58% of enrolled caregivers, 88% of caregivers who completed the program). One caregiver was lost-to-follow-up after completing PRISM-P but prior to their interview. The median number of days between intervention completion and follow-up interviews was 23. Among those who completed interviews, all 7 (100%) provided positive responses to the question, “Are you willing to recommend PRISM to other caregivers?” Five structural codes described caregivers’ additional feedback regarding the PRISM-P program (**Table 3**). Overall, feedback was highly positive. Regarding *content*, caregivers found skills helpful and relevant and appreciated the PRISM app and information handouts. Regarding *timing*, caregivers described both session duration and timing between sessions as appropriate and convenient. Regarding *format*, caregivers felt the phone- and/or video-based delivery was highly convenient. Caregivers also provided *suggestions for adaptation* regarding when PRISM should be

offered to caregivers and how it could fit within routine care. Many suggested that the ideal time to receive PRISM-P would be shortly after the child's diagnosis. This was seen to be the most challenging period, particularly if the child had spent time in the neonatal intensive care unit (NICU). All caregivers believed PRISM-P could be a useful tool in routine care and would fit well alongside other psychological services. Finally, one caregiver noted that additional follow-up for the goal setting module would be helpful to assess progress and re-evaluate roadblocks.

Caregiver Perceptions of Resilience

Caregivers' perceptions of resilience were organized into three categories: definitions, facilitators, and barriers of resilience (**Table 4**).

Definitions of Resilience. Two codes encompassed caregivers' definitions of resilience in the context of their child's craniofacial condition. They described resilience as the process of *persisting*, meaning the act of moving forward, taking things one day at a time, and striving to improve. As one mother of a 12-month-old with CL/P said,

"There's so much that goes into it, and just focusing on one day at a time. One little chunk of progress at a time."

They also described resilience as *feeling capable*, meaning believing in one's ability to deal with challenges and handle adversity. One mother of a 2-month-old with CFM described a challenging experience in her child's treatment as a source of her perceived capability, saying:

"Having been through the NICU, like that's built resiliency because you went through something pretty challenging, and you're through it, and it builds that strength muscle of knowing that you're capable of challenges."

Facilitators of Resilience. Four codes encompassed facilitators of resilience. *Feeling supported* helped caregivers feel resilient. Many described their spouse as their primary source of support, though others also mentioned parents, religious community, and their child's medical team. Describing her support system, one mother of a 10-month-old with CL/P said,

“[My husband] is my closest support system... we’re really close with my parents so that’s been helpful too.”

Some caregivers described ***being a parent*** as a source of resilience. They discussed drawing on their parental identity as a source of strength and reason for persisting in the face of challenges. As one mother of a 2-month-old with CFM said,

“Being a mom, you know, being giving to your kids. There’s not really a choice. I mean you just wake up and you gotta take care of them. But it builds resiliency.”

Caregivers also described ***learning and knowledge*** as a contributor to their resilience. They described this in terms of learning about their child’s craniofacial condition as well as their own mental health needs. One mother of an 8-month-old with CL/P described feeling supported by her child’s medical team via their provision of knowledge about her child’s condition, saying,

“I think being informed about everything. Knowing the facts on things instead of being in the dark or not really interested in it. The doctors and the people that help you to understand when you really have no clue about it, I think that helps me to be resilient—learning and understanding.”

Finally, caregivers described a process of ***seeking and relinquishing control*** as part of their resilience. Some noted the importance of feeling in control by taking action to remediate challenges or trying to focus on controllable stressors. As one mother of a 7-month-old with CL/P said,

“The patient’s perception of control is a large part of resilience. Because if it feels like you don’t have control of the situation, then that tends towards more anxiety and more inaction. If you feel like you have control, then you can take action, which is what resilience is all about.”

Many caregivers also acknowledged the utility of learning to relinquish control, particularly concerning their child’s treatment. One mother of a 10-month-old with CL/P described this process, saying,

“I feel like I’m at the point where I just kind of roll with it pretty well now. I guess just accepting that it’s all part of a bigger plan that [hospital] has for [child] and that I really don’t have much say in it anyways. I just

have to show up and be the mom and let the surgeons be the surgeons and let the doctors be the doctors and the nurses be the nurses.”

Barriers to Resilience. One code encompassed barriers to resilience. Caregivers described *feeling uncertain* as a major source of anxiety and distress. Many struggled with the unpredictability of their child’s treatment, with rescheduled or postponed surgeries experienced as especially difficult. As one mother of a 7-month-old with CL/P said,

“Give me confirmation if [child’s surgery] is going to happen like it’s scheduled or if it’s going to get cancelled like the last time... we don’t know if it’s going to get cancelled again or if it’s going to happen... they haven’t let us know so now we’re like, ‘uh?’ That would be helpful.”

Caregivers also described uncertainty about how their child’s craniofacial condition may affect their future, both in terms of their physical health and psychosocial adjustment. One mother of a 2-month-old with CFM described this experience, saying,

“What worries me? How he’s going to fit in with his peers. Is he going to be made fun of? Is he going to have friends because he looks differently? Also, I mean, the surgery’s coming up, like his breathing, heart, there’s the medical side of it, it’s scary... but then there’s like the social part. How people are going to... mostly, how he’s going to feel himself?”

Discussion

Having a child with a craniofacial condition can be highly stressful for caregivers¹ yet evidence-based psychosocial interventions for this population are lacking.⁸ In the current study, we aimed to examine feasibility and acceptability of the Promoting Resilience in Stress Management – Parent (PRISM-P) intervention for caregivers of children born with craniofacial conditions and describe caregiver-perceived barriers and facilitators of resilience to inform future program tailoring. Results indicated that (a) PRISM-P was not feasible based on program completion rates due to early passive attrition, though retention was high among those who began the program; (b) PRISM-P was acceptable and program feedback was highly positive; and (c) caregivers’ perceived

contributors and inhibitors of resilience were generally well-aligned with skills taught in PRISM-P, though also suggested novel intervention targets for this population.

Enrollment rates were similar to other PRISM studies,^{9,10,12} suggesting there is general interest in and a need for psychosocial supportive care programs among caregivers of children with craniofacial conditions. Passive attrition between enrollment and the first intervention session was higher than expected, though it is unlikely that session-related burden or content concerns were driving factors as these caregivers were lost to follow up before completing any study components. Rather, some caregivers may have enrolled initially due to social desirability factors or lacked time to continue following enrollment. Indeed, other PRISM studies have identified perceived lack of time and scheduling challenges as key barriers to participation.^{10,18,25} This suggests that successful delivery of psychosocial programs in this population may require novel strategies to promote retention, such as truncating timelines between enrollment and intervention delivery, combining interventions with in-person clinical care, or strengthening follow-up efforts to promote engagement. Notably, period effects may also have influenced retention in this instance. Most attrition occurred during the early weeks of the COVID-19 pandemic, a time in which caregivers of children with craniofacial conditions experienced elevated stress related to managing their child's medical needs in a rapidly shifting hospital environment²⁶ and participation in additional research may have been too burdensome.

Despite attrition, PRISM-P was well-received by those who completed the program. All caregivers who completed baseline surveys subsequently completed both PRISM-P sessions, aligning with prior PRISM studies demonstrating high levels of engagement among those who begin the program.^{12,15,18} PRISM-P was also highly acceptable, with acceptability rates mirroring those observed in other caregiver and patient populations,^{9,10,12} and program feedback was positive overall. Caregivers found program content helpful; perceived the length and timing between session as appropriate; and appreciated flexible modes of delivery. This suggests that skill-based interventions are appealing to this population and that offering remote options (e.g., phone or

videoconference) enables participation for busy caregivers. Regarding timing of delivery, caregivers suggested that PRISM would be most useful if delivered during the postnatal period and/or to caregivers whose child had required a stay in the neonatal intensive care unit (NICU). Though this suggestion may be specific to the needs of caregivers of young children with craniofacial conditions, it aligns with extant research describing the stressful nature of the postnatal period¹ and the unique needs of NICU caregivers.^{27,28} Thus, psychosocial programs such as PRISM-P may be maximally beneficial for parents of young children in these contexts.

Caregivers' perceptions of resilience were generally well-aligned with extant resilience literature and reflected content and skills taught within the PRISM program. This suggests that program content was appropriate for this population and that caregivers identified with and/or adopted concepts learned through the program. Caregivers' definitions of resilience focused on personal strength and resilience as an evolving process. This is well-aligned with definitions described by other caregiver populations and taught within the PRISM program (i.e., resilience defined as a process of harnessing resources to maintain wellbeing).^{11,29,30} Caregivers also described resilience barriers (i.e., worry, uncertainty) and facilitators (i.e., learning to seek vs. relinquish control) that are targeted by existing PRISM skills. For example, PRISM's "Catching Negative Self-Talk" skill teaches participants to manage worry by distinguishing what is uncontrollable (i.e., situational factors) from what is controllable (i.e., one's response to the situation) and to use cognitive reframing to address the latter.^{9,10} Caregivers also described unique facilitators of resilience that inform novel intervention targets and avenues for program tailoring. Specifically, caregivers described learning, becoming knowledgeable, and drawing on their identity as a parent as facilitators of resilience. Thus, programs like PRISM-P may benefit from extending behavioral skills such as goal setting to focus on caregivers' knowledge-related goals; adding components focused on medical and/or psychosocial education in the context of craniofacial care; and integrating self-affirmation skills that encourage caregivers to reflect on their parental roles and identities as a source of strength. Future studies should also examine the extent to which these

factors may be unique to caregivers of infants with craniofacial conditions or extend to caregivers of older children.

Limitations

Findings should be considered in light of methodological limitations. First, we did not collect feedback from those who were lost to follow-up after enrolling, which limited our ability to understand and address reasons for attrition. Second, sample homogeneity limits generalizability of findings. Eligibility criteria were not limited to caregivers of infants or children with specific craniofacial conditions. However, our recruitment approach involved introducing the study during a scheduled craniofacial clinic visit. Thus, most families we approached were those with children <1 year-old with CL/P who tended to have more frequent clinic visits. Thus, it is unclear whether these findings would generalize to caregivers of older children or caregivers of children with other craniofacial conditions. Additionally, most participating caregivers were White, non-Hispanic, married, and highly educated mothers; and, as half of participating caregivers were co-enrolled with their spouse, our sample represented a limited number of families. Thus, an important future direction will be examining the feasibility and acceptability of this program in a larger, more diverse caregiver sample including caregivers from racially minoritized groups; LGBTQ+ caregivers; fathers; and single-parent caregivers. Finally, this study overlapped with the onset of the COVID-19 pandemic, which truncated our enrollment window and potentially influenced attrition, data completion, and caregivers' perspectives on resilience. Future studies should replicate these findings in other temporal contexts.

Conclusion

This small-scale feasibility study demonstrates the potential of the PRISM-P intervention for caregivers of children with craniofacial conditions. Our findings suggest that psychosocial interventions are acceptable and well-received within this population, though participant retention may be a feasibility challenge. Our qualitative findings contribute to an ongoing discussion

regarding what constitutes resilience in the context of long-term health conditions. Given the current lack of evidence for psychosocial interventions in this population, this study addresses an important gap by providing preliminary evidence for the potential of psychosocial supportive care and novel insights informing the design and delivery of future trials.

References

1. Nelson P, Glennly AM, Kirk S, Caress AL. Parents' experiences of caring for a child with a cleft lip and/or palate: a review of the literature. *Child: care, health and development*. 2012;38(1):6-20.
2. Feragen KB, Stock NM, Myhre A, Due-Tønnessen BJ. Medical stress reactions and personal growth in parents of children with a rare craniofacial condition. *Cleft Lip Palate Craniofac J*. 2020;57(2):228-237.
3. Feragen KB, Stock NM. Psychological adjustment to craniofacial conditions (excluding oral clefts): a review of the literature. *Psychology & health*. 2017;32(3):253-288.
4. Murthy J. Burden of care: management of cleft lip and palate. *Indian J Plast Surg*. 2019;52(03):343-348.
5. Crerand CE, Rosenberg J, Magee L, Stein MB, Wilson-Genderson M, Broder HL. Parent-reported family functioning among children with cleft lip/palate. *Cleft Lip Palate Craniofac J*. 2015;52(6):651-659.
6. Stock NM, Costa B, White P, Rumsey N. Risk and protective factors for psychological distress in families following a diagnosis of cleft lip and/or palate. *Cleft Lip Palate Craniofac J*. 2020;57(1):88-98.
7. Zeytinoğlu S, Davey MP, Crerand C, Fisher K, Akyil Y. Experiences of couples caring for a child born with cleft lip and/or palate: Impact of the timing of diagnosis. *J Marital Fam Ther*. 2017;43(1):82-99.
8. Norman A, Persson M, Stock N, et al. The effectiveness of psychosocial intervention for individuals with cleft lip and/or palate. *Cleft Lip Palate Craniofac J*. 2015;52(3):301-310.
9. Rosenberg AR, Yi-Frazier JP, Eaton L, et al. Promoting resilience in stress management: a pilot study of a novel resilience-promoting intervention for adolescents and young adults with serious illness. *J Pediatr Psychol*. 2015;40(9):992-999.
10. Yi-Frazier JP, Fladeboe K, Klein V, et al. Promoting Resilience in Stress Management for Parents (PRISM-P): An intervention for caregivers of youth with serious illness. *Fam Syst Health*. 2017;35(3):341.
11. Rosenberg AR, Yi-Frazier JP. Commentary: Resilience defined: An alternative perspective. *J Pediatr Psychol*. 2016;41(5):506-509.
12. Fladeboe KM, O'Donnell MB, Barton KS, et al. A novel combined resilience and advance care planning intervention for adolescents and young adults with advanced cancer: A feasibility and acceptability cohort study. *Cancer*. 2021;127(23):4504-4511.
13. Toprak D, Nay L, McNamara S, Rosenberg AR, Rosenfeld M, Yi-Frazier JP. Resilience in adolescents and young adults with cystic fibrosis: a pilot feasibility study of the promoting resilience in stress management intervention. *Pediatr Pulmonol*. 2020;55(3):638-645.
14. Lau N, Bradford MC, Steineck A, et al. Exploratory analysis of treatment response trajectories in the PRISM trial: Models of psychosocial care. *Psychooncology*. 2019;
15. Rosenberg AR, Bradford MC, McCauley E, et al. Promoting resilience in adolescents and young adults with cancer: results from the PRISM randomized controlled trial. *Cancer*. 2018;124(19):3909-3917.
16. Steineck A, Bradford MC, Lau N, Scott S, Yi-Frazier JP, Rosenberg AR. A Psychosocial Intervention's Impact on Quality of Life in AYAs with Cancer: A Post Hoc Analysis from the Promoting Resilience in Stress Management (PRISM) Randomized Controlled Trial. *Children*. 2019;6(11):124.
17. Rosenberg AR, Zhou C, Bradford MC, et al. Parent Perspectives after the PRISM-P Randomized Trial: A Mixed-Methods Analysis. *J Palliat Med*. 2021;24(10):1505-1515.
18. Rosenberg AR, Bradford MC, Junkins CC, et al. Effect of the Promoting Resilience in Stress Management Intervention for Parents of Children With Cancer (PRISM-P): A Randomized Clinical Trial. *JAMA Netw Open*. 2019;2(9):e1911578-e1911578.

19. Stock NM, Zucchelli F, Hudson N, Kiff JD, Hammond V. Promoting psychosocial adjustment in individuals born with cleft lip and/or palate and their families: current clinical practice in the United Kingdom. *Cleft Lip Palate Craniofac J*. 2020;57(2):186-197.
20. Baker SR, Owens J, Stern M, Willmot D. Coping strategies and social support in the family impact of cleft lip and palate and parents' adjustment and psychological distress. *Cleft Lip Palate Craniofac J*. 2009;46(3):229-236.
21. Sischo L, Clouston SA, Phillips C, Broder HL. Caregiver responses to early cleft palate care: A mixed method approach. *Health Psychol*. 2016;35(5):474.
22. Rosenberg AR, Steiner J, Lau N, et al. From theory to patient care: a model for the development, adaptation, and testing of psychosocial interventions for patients with serious illness. *J Pain Symptom Manage*. 2021;62(3):637-646.
23. Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. 2005;15(9):1277-1288.
24. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med*. 2014;89(9):1245-1251.
25. Rosenberg AR, Junkins CC, Sherr N, et al. Conducting Psychosocial Intervention Research among Adolescents and Young Adults with Cancer: Lessons from the PRISM Randomized Clinical Trial. *Children*. 2019;6(11):117.
26. Costa B, McWilliams D, Blighe S, et al. Isolation, Uncertainty and Treatment Delays: Parents' Experiences of Having a Baby with Cleft Lip/Palate During the Covid-19 Pandemic. *Cleft Lip Palate Craniofac J*. 2021:10556656211055006.
27. Lefkowitz DS, Baxt C, Evans JR. Prevalence and correlates of posttraumatic stress and postpartum depression in parents of infants in the Neonatal Intensive Care Unit (NICU). *J Clin Psychol Med Settings*. 2010;17(3):230-237.
28. Purdy I, Craig J, Zeanah P. NICU discharge planning and beyond: recommendations for parent psychosocial support. *J Perinatol*. 2015;35(1):S24-S28.
29. Rosenberg AR, Baker KS, Syrjala KL, Back AL, Wolfe J. Promoting resilience among parents and caregivers of children with cancer. *J Palliat Med*. 2013;16(6):645-652.
30. Rosenberg AR, Wolfe J, Bradford MC, et al. Resilience and psychosocial outcomes in parents of children with cancer. *Pediatr Blood Cancer*. 2014;61(3):552-557.

Table 1*PRISM-P Intervention Sessions*

PRISM-P Session	Skills Taught	Details
Session 1: Managing Stress	Stress management	Deep breathing techniques; visualization exercise; “Leaves on a stream” mindfulness exercise
	Goal setting	Setting specific, realistic, actionable, measurable, timebound (SMART) goals; planning for roadblocks; strategies for dealing with roadblocks; identifying how caregiver can meet goal
Session 2: Building Resilience	Cognitive restructuring	Recognizing relation between thoughts and emotions; identifying unrealistic/negative thoughts, replacing these thoughts with positive/manageable ones
	Meaning making	Recognizing meaning in current experience; practicing gratitude, self-reflection, journaling
Follow-Up		Reflection of intervention strategies and overall satisfaction, identification and recognition of successes, and referrals for further resources needed

Note. PRISM-P = Promoting Resilience in Stress Management Intervention for Parents

Table 2*Demographic Information for Study Participants (N=8)*

Caregiver Characteristic		N (%)	Child Characteristic		N (%)
Gender	Male	2 (25)	Gender	Male	8 (100)
	Female	6 (75)			
Race	White	6 (75)	Diagnosis ¹	Cleft lip and/or palate	6 (75)
	Asian	1 (13)		Craniofacial microsomia	2 (25)
	More than 1 race	1 (13)			
Ethnicity	Non-Hispanic	8 (100)	Age at diagnosis	At or before birth	6 (75)
				< 2 months after birth	2 (25)
Marital status	Married	8 (100)	Treatment ²	Surgery < 6 mos.	6 (75)
				Scheduled craniofacial clinic visits < 6 mos.	3 (38)
Employment status	Employed	4 (50)	Health coverage	Private insurance	6 (75)
	Keeping house	3 (38)		Military health care	2 (25)
	Student	1 (13)			
Education	High school	1 (13)			
	Bachelor's degree	3 (38)			
	≥ Master's degree	4 (50)			

Note. Percentages may not total to 100 due to rounding. Caregivers reported demographic information within baseline survey. ¹Child diagnosis was collected from electronic health record during screening. ²Categories are not mutually exclusive.

Table 3*Acceptability Analysis Codes and Exemplar Quotes*

Code	Exemplar Quotations
Recommend PRISM	“I absolutely would [recommend PRISM]... I think anyone could benefit from this.” Mother, 8 mo with CL/P
	“Absolutely... It served as an opportunity for me to have this time out from my day... I felt really calm afterward. Those skills...they could certainly be applicable to not only having a kid who’s having surgery or has a ton of appointments...but just everyday life, really.” Mother, 10 mo with CL/P
Content & Materials	“The content was very well thought out...deep-breathing, mindfulness, visualization...they were wonderful...especially for parents who don’t know these tools exist.” Father, 7 mo with CL/P
	“[The app] was everything I needed but in a more accessible way on my phone... I like the examples it gives you, it’s very user-friendly...it goes through everything and gives you the steps to practice.” Mother, 11 mo with CL/P
	“Now that I have these tools, I can go back to them whenever I want.” Mother, 8 mo with CL/P
Format	“I loved [doing PRISM by phone]... I have young children and I live outside the city, so for me, that made it possible to participate... I felt [coach] was able to convey everything over the phone.” Mother, 2 mo with CL/P
Timing	“I think a week or two would be the most. I think if you went longer, it would probably be too far to keep it fresh, keep it connected. Mine was good, I think I did it a week apart.” Mother, 2 mo with CFM
	“I thought it was perfect... In the end it was about 3 hours total or less, and I felt that was completely doable. I got all the info I needed in that time.” Mother, 11 mo with CL/P
Suggestions for Adaptation	“At the time of the intervention I felt like I was doing fine, and I think it would have been more helpful shortly after birth.” Mother, 7 mo with CL/P
	“I did [the intervention] during my stay at the NICU...being home, it’s a little different now, but the NICU was extremely stressful, so any extra support while you’re there I think is helpful.” Mother, 2 mo with CFM
	“I was thinking...if everybody [affected by craniofacial conditions] could have access to this. Maybe to be told about this and to have the app from the beginning, when they first learn about what is going on with their child... It could be very helpful and would be very much appreciated.” Mother, 8 mo with CL/P
	“My husband and I...did our own counselling... [PRISM] definitely works with other outside counseling.” Mother, 2 mo with CFM

Note. PRISM = Promoting Resilience in Stress Management Intervention; MO = months-old; CL/P = Cleft Lip and/or Palate; CFM = Craniofacial Microsomia

Table 4*Caregiver Perceptions of Resilience Codes and Exemplar Quotes*

Category	Code	Exemplar Quotation
Definitions of Resilience	Persisting	“I guess just putting on a brave face for it and just keep on showing up for these triggers and stressors.” Mother of 10 mo with CL/P
	Feeling Capable	“I know I’m good enough. I know I can do this, and I’m going to do this, and nobody is going to get in my way.” Mother of 7 mo with CL/P
Facilitators of Resilience	Feeling support	“I think having support also builds your resiliency. Family that loves you or having a partner who also wants to do their best.” Mother of 2 mo with CFM
	Being a Parent	“My kids [make me resilient]...I guess it’s easy not to be resilient, but you’re going to be resilient eventually.” Mother of 8 mo with CL/P
	Learning & Knowledge	“By doing counselling, by seeing what I can do personally to change, that’s how I feel stronger and more confident. The ability to see myself...and maybe how I created some of my own challenges, it just gives me more power... I can create things, so my attitude, my belief system affect how I see the world, and those can be changed and learned.” Mother of 2 mo with CFM
	Seeking and Relinquishing Control	“I tend to... focus on the things that I can change and not worry about the things I can’t change. If my son is in surgery, I can’t really change what they do... me stressing about it is not helping anybody.” Father of 7 mo with CL/P
Barriers to Resilience	Feeling Uncertain	“Always the possibility of something going wrong...I kinda go down the rabbit hole of everything negative when nothing’s really even happened yet. Worst case scenario is everything goes wrong, so that’s obviously one of my fears.” Mother of 10 mo with CL/P

Note. MO = months-old; CL/P = Cleft Lip and/or Palate; CFM = Craniofacial Microsomia

Supplement 1

Feedback & Resilience Interview Guide

Interview Section	Structured Interview Questions
Intervention	What did you think of the intervention?
Feedback	What helped? What should be different? What did you think of the timing? What did you think of the content? What did you think of the materials? Would you recommend PRISM-P to other parents? (Why/why not?) How can PRISM-P be used for other families as part of routine care? Did you or your family receive any other psychological services? (If yes) Could you share how PRISM-P fits in with the work you did with other providers? How would you suggest we approach other parents about a program like this?
Perceptions of Resilience	What makes you resilient? How have you learned to be resilient during your child's treatment? How have you handled adversity in the past? Who supports you? What worries you? What could we do to help support you better?

Note. PRISM-P = Promoting Resilience in Stress Management Intervention for Parents

Supplement 2

Sample of Promoting Resilience in Stress Management for Parents (PRISM-P) Mobile Application Content

