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Exploring the role of fathers' preoperative preparation in reducing anxiety and enhancing self-efficacy before pediatric open-heart surgery

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Abstract

Introduction Parents of children undergoing cardiac surgery face significant anxiety. This study evaluated a preoperative preparation program for fathers of children (aged 3–7 years) having open-heart surgery.

Methods In this semi-experimental study, 60 fathers were randomly assigned to an intervention group ($n = 30$) receiving structured preparation (hospital tours, group counseling, education) or a control group ($n = 30$) receiving standard care. Anxiety and self-efficacy were measured using the VAS-A and PSAM at three timepoints.

Results Preoperative preparation significantly reduced fathers' anxiety (mean difference: -2.1 points; 95% CI -3.4 to -0.8 , $p = 0.002$) and increased self-efficacy ($+8.7$ points, 95% CI 5.2 to 12.1; $p < 0.001$) compared to controls. These improvements persisted through discharge ($p < 0.05$). Structured interventions, including education and hospital tours, effectively alleviated paternal distress while enhancing confidence during their child's cardiac surgery.

Conclusion Preoperative preparation for fathers, including education about their child's condition and treatment, significantly reduces anxiety and enhances self-efficacy. These interventions alleviate psychological distress and improve coping strategies, demonstrating the value of targeted support for fathers of children undergoing cardiac surgery.

Keywords Paternal anxiety, Congenital heart disease, Preoperative education, Parental self-efficacy, Pediatric cardiac surgery

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Introduction

Congenital heart disease (CHD) is the most common fetal disease and the second leading cause of death among infants and children [1]. Globally, congenital heart disease (CHD) affects approximately 8 to 10 per 1,000 live births (0.8–1.0%), with variations across regions and studies [2, 3]. In Iran, the prevalence of congenital heart disease (CHD) ranges from 9.7 to 17.5 per 1,000 live births, as reported in recent epidemiological studies [4, 5]. Despite significant advancements in diagnostic and therapeutic technology, the exact etiology of this disease is still unknown, and only 10 to 20% of cases are attributed to genetic and environmental factors [5].

The majority of CHD cases become symptomatic during infancy, and more than half of them undergo surgery in this period [6]. This disease impacts families psychologically, physically, and economically [7].

The hospitalization and surgical treatment of a child with CHD represent a profound crisis for families, disrupting normal family functioning and imposing unique stressors on parents. Fathers, in particular, face distinct challenges that differ from those experienced by mothers. Research indicates that fathers of children with CHD frequently report feeling marginalized in healthcare settings, while simultaneously bearing primary responsibility for financial stability and family decision-making [7, 8]. These compounded stressors – emotional distress, financial pressures, and perceived exclusion from caregiving roles – create a complex psychological burden that current support systems often fail to address. Furthermore, the traditional focus on maternal experiences has resulted in healthcare systems that are poorly equipped to identify and support paternal mental health needs during their child's medical treatment [9].

Parental self-efficacy, defined as an individual's belief in their capacity to execute caregiving tasks and manage health-related challenges, emerges as a crucial protective factor in this context. For fathers of children undergoing open-heart surgery, self-efficacy may be particularly significant as it influences their ability to process complex medical information, participate effectively in treatment decisions, and provide emotional support to both their child and partner [10]. Recent studies suggest that fathers with higher self-efficacy demonstrate greater engagement in their child's care and report lower levels of psychological distress [11]. However, the specific factors that enhance or undermine paternal self-efficacy during the perioperative period remain poorly understood, representing a critical knowledge gap in pediatric cardiac care [12].

The potential of preoperative preparation programs to reduce parental anxiety and enhance self-efficacy has been well-documented for mothers [13]. These interventions typically include components such as hospital

tours, procedural education, and peer support opportunities. However, remarkably, almost all existing programs have been designed with mothers as the primary target audience despite fundamental differences in how mothers and fathers typically process stress and seek support [14, 15]. This oversight is particularly concerning given emerging evidence that fathers may benefit more from concrete, action-oriented information and peer interactions with other fathers, rather than the emotion-focused approaches often favored by mothers. This gap underscores the necessity for tailored, father-centric interventions designed to reduce anxiety by providing concrete, actionable information and peer support, rather than the emotion-focused approaches traditionally offered to mothers.

The current study addresses these critical gaps by investigating the impact of a tailored preoperative preparation program on anxiety levels and self-efficacy among fathers of children (aged 3–7 years) undergoing open-heart surgery for CHD. Our intervention was specifically designed to meet fathers' unique psychological needs, incorporating practical, detailed information about surgical procedures and hospital protocols, guided tours of clinical areas led by male healthcare providers, and structured peer support sessions with other fathers who have experienced similar challenges [16]. We hypothesize that this targeted approach will significantly reduce paternal anxiety and enhance self-efficacy compared to standard care, with benefits sustained through the postoperative period.

This research carries important implications for clinical practice and healthcare policy. By demonstrating the effectiveness of father-specific interventions, we aim to challenge the prevailing maternal-centric model of family support in pediatric cardiology, provide evidence for the integration of paternal mental health screening into routine care protocols, and establish best practices for engaging fathers in their child's medical care [17]. Ultimately, addressing the psychological needs of fathers represents not only a matter of equity but also a strategic opportunity to improve outcomes for the entire family system facing the challenges of CHD [18].

The significance of this study extends beyond immediate clinical applications. As survival rates for CHD continue to improve, with more children living into adulthood, the long-term psychological adjustment of families becomes increasingly important [19]. Fathers who successfully navigate the initial surgical experience with adequate support and coping resources may be better positioned to manage subsequent challenges in their child's developmental trajectory [20]. Furthermore, by establishing effective models for father engagement in pediatric cardiac care, this research may inform interventions for other serious childhood conditions requiring

intensive medical treatment. The present study is focused on the level of anxiety and self-efficacy of fathers of children aged 3 to 7 undergoing open-heart surgery due to CHD.

Methods

Study design

The present study is a semi-experimental intervention with a control group conducted in 2024 on fathers of children aged 3 to 7 with CHD who had been referred to the Children's Medical Center Hospital in Tehran, Iran.

The sample size of 60 (30 per group) was determined based on feasibility and comparable studies in pediatric preoperative anxiety research. While formal power analysis was not conducted, post hoc calculations confirmed adequate power ($\beta \geq 0.80$) to detect moderate effects ($d \geq 0.5$) at $\alpha = 0.05$ [15, 21].

The sample size of 60 participants (30 per group) was determined based on feasibility and comparable studies in pediatric preoperative anxiety research [15, 21]. Although a formal a priori power analysis was not conducted, a post hoc power analysis was performed using G Power 3.1 based on the observed effect sizes for anxiety (Cohen's $d = 1.02$) and self-efficacy (Cohen's $d = 1.15$). The analysis revealed a statistical power exceeding 99% for both outcomes ($1 - \beta > 0.99$) at $\alpha = 0.05$, indicating that the sample size was adequate to detect the intervention's effects on the primary outcomes of this study.

Then, participants were randomly divided into the intervention and control groups based on file number. Even and odd file numbers were put in the control and the intervention groups, respectively. Finally, 30 participants entered the study. Admission criteria included having children with CHD between the ages of 3 and 7 as candidates for open-heart surgery, the ability to speak Farsi, not having visual issues, auditory issues, or speech problems, gaining a low score in the anxiety and self-efficacy scale, and living with a spouse and child in a house. Exclusion criteria included discharge or death of the child and withdrawal of the father from the study. After that, the following information was gathered through the intervention using research tools.

The inclusion criteria for low scores on the anxiety and self-efficacy scales: Eligibility required fathers to score below clinically significant thresholds on both scales (VAS-A < 30 and PSAM < 60), as validated in prior pediatric studies [22, 23].

The intervention protocol

After receiving ethical approvals and confirmation from the research office at the hospital, the fathers of children aged 3 to 7 in need of open-heart surgery were selected based on the inclusion criteria. The main objective of the research was to study the influence of preparing fathers

on their extent of anxiety and self-efficacy. The training content and intervention protocol were developed in collaboration with a multidisciplinary team, including pediatric cardiologists, clinical psychologists, and experienced nurses specializing in pediatric cardiac care. Their expertise ensured the intervention's relevance and appropriateness for addressing fathers' anxiety and self-efficacy. The intervention included visits to the operating room and the intensive care unit, as well as group consultation with fathers having the same experience. Initially, the intervention group attended the educational sessions. The control group received their respective training at different times.

The training of the intervention group included the following components:

Educational Sessions: Verbal and written explanations about congenital heart disease (CHD), surgical procedures, and postoperative care.

Hospital Tours: Visits to the operating room and intensive care unit to familiarize fathers with the clinical environment.

Group Consultations: Peer-support sessions with other fathers who had undergone similar experiences.

Stress-Management Techniques: Guidance on coping strategies, such as mindfulness and relaxation exercises.

Resource Materials: Pamphlets, educational packages, and digital resources were presented to fathers aiming to enhance their awareness and lower their stress levels. The control group received routine hospital education (e.g., preoperative leaflets and verbal instructions from nurses) during their child's admission, but did not participate in structured tours or counseling or receive supplemental materials. This occurred in the same hospital setting, with timing matched to the intervention group's schedule to control for temporal confounders.

The contact information of fathers was collected, and the anxiety as well as self-efficacy scales were explained to them. The measurement tools in this study were administered at three specific time points to assess the fathers' anxiety and self-efficacy:

1. Before the Intervention (Preoperative): Baseline measurements of anxiety (VAS-A) and self-efficacy (PSAM) were taken prior to any preparation or training.
2. Immediately After the Intervention (Post-Preparation): Both scales were re-administered right after the fathers completed the educational sessions

(which included hospital tours, group consultations, and informational packages).

3. Upon Discharge (Postoperative): Final measurements were taken after the child's surgery, during the discharge phase, to evaluate the sustained effects of the intervention.

Data collection

Demographic and clinical questionnaire

This questionnaire included two sections. The first section was related to the children, and the second section collected information about the fathers (the first section: questions about age, gender, birth order, history of previous hospitalizations, date of hospitalization, and type of cardiac disease. The second section included age, job, marital status, monthly income, residence, and the education of the father. This questionnaire was developed by the research team.

Visual analogue scale of anxiety

This scale was first used in 1960 for pain measurement. Gradually, its capability of measuring other psychological aspects was detected [14]. Due to its simplicity and user-friendly nature, this scale has turned into the primary tool for assessing anxiety and includes emotional and psychological aspects. The validity of this scale has been proven through comparison with such standard tools as STAI and studying score correlation. This scale has been used as an effective tool in anxiety measurement under different conditions, including clinical and social conditions, in internal and international studies. Also, the reliability of this scale in measuring anxiety has been confirmed by a reliability coefficient of 0.88, and this has made it a reliable tool for psychological studies [24]. In the Iranian context, Motahari Niya & Hojjati (2019) confirmed the VAS-A's reliability ($\alpha = 0.85$) for measuring parental anxiety in pediatric settings [24].

Parenting self-agency measure (PSAM)

This measure was developed in 2016 by Cuzzocrea et al. and includes 22 items that are evaluated using a 5-point Likert scale [25]. This measure has a score range from 22 to 110, and the highest score illustrates the highest self-efficacy among fathers. The psychometric characteristics of this tool were studied in 2014 by Abarashi et al., showing acceptable validity and reliability. Construct validity and its reliability have been measured through factor analysis and internal consistency, respectively, in Iran [26]. However, not many studies using this tool have been found in Iran or abroad. The scale is designed such that lower total scores indicate higher levels of parenting self-efficacy. Consequently, a decrease in the PSAM score from baseline reflects an improvement in the fathers' perceived self-efficacy.

Scale validity and reliability

Quantitative and qualitative methods were used to determine the validity of the visual analogue scale of anxiety and parenting self-efficacy measure. For content validity, the opinions of 10 faculty members of the university were collected, and the scale was modified based on the expert opinions. To confirm face validity, the opinions of 10 fathers about the simplicity and clarity of the scale were evaluated. The reliability of the visual analogue scale of anxiety and the parenting self-efficacy measure was reported with an agreement coefficient of 0.80 and Cronbach's alpha of 0.92, both indicating the suitability of this scale.

Data analysis

Finally, the results were reported as mean \pm standard deviation for quantitative data and as quantity (percent) for qualitative data. The distribution normality of quantitative variables was studied using the Kolmogorov-Smirnov non-parametric test. [To account for potential confounding, analysis of covariance (ANCOVA) was used to compare the post-intervention and discharge outcomes (anxiety and self-efficacy scores) between the groups, while controlling for baseline scores and identified confounding variables (fathers' age, socioeconomic status, and child's history of prior surgeries).] The significance in all tests was 0.05, and all computations were performed in SPSS, version 24.

Results

Demographic analysis revealed no significant differences between intervention and control groups regarding children's birth order ($p=0.553$), age (4.63966200 ± 1.32 vs. 4.33 ± 1.18 years, $p=0.924$), gender (56.7% vs. 40% female, $p=0.196$), or surgical history (26.7% vs. 30% with prior surgery, $p=0.774$). Most children were second-born (48.3% overall) with no prior surgeries (73.3% vs. 70%). Parental demographics also showed comparability in education, economic status, and employment (all $p>0.05$), except for fathers' age (40.1 ± 7.27 vs. 42.8 ± 4.79 , $p=0.009$). These results confirm baseline homogeneity, supporting the validity of between-group comparisons (Table 1).

Parental demographics showed comparable education levels (45% of fathers and 51.7% of mothers held bachelor's degrees) and economic status (75% middle-income). Most fathers were self-employed (56.7%). However, the intervention group fathers were younger (40.1 ± 7.27 years) than controls (42.8 ± 4.79 , $p=0.009$). A majority (60%) reported a family disease history, while most variables were balanced ($p>0.05$) (Table 2).

Analysis of anxiety levels revealed no baseline difference between groups (intervention: 20.76 ± 2.26 vs. control: 21.20 ± 3.04 , $p=0.564$). Post-intervention, the

Table 1 Descriptive findings of children under study

Variable	Intervention group (N=30)	Control group (N=30)	Cumulative percentage	p-value
Birth order				
1st	14	12	3.43	0.553
2nd	14	15	3.48	
3rd	2	3	3.8	
Age average (year)	4.63 ± 1.32	4.33 ± 1.18		0.924
Gender				
Female	17 (56.7%)	12 (40%)		0.196
Male	13 (43.3%)	18 (60%)		
History of previous surgeries				
Yes	8 (26.7%)	9 (30%)		0.774
No	22 (73.3%)	21 (70%)		

Table 2 Descriptive findings of parents under study

Variable	Intervention group (N=30)	Control group (N=30)	Cumulative percentage	p-value
Education of the father				
3rd grade of middle school	4	0	6.7	0.837
Secondary education diploma	10	13	38.3	
Bachelor's degree	10	17	45	
Master's degree	6	0	10	
Education of mother				
3rd grade of middle school	4	2	10	0.814
Secondary education diploma	10	9	31.7	
Bachelor's degree	15	16	51.7	
Master's degree	1	3	6.7	
Economic status				
Weak	6	6	20	0.273
Average	22	23	75	
Good	2	1	5	
Age of father				
Mean	40.10 ± 7.27	42.8 ± 4.79		0.009
Father's job				
Unemployed	1	1	3.3	0.965
Self-employed	17	18	56.7	
Employee	12	11	40	
History of familial disease				
Yes	12	11	40	0.816
No	18	19	60	

intervention group showed significantly reduced anxiety (18.93 ± 1.16) compared to controls (19.87 ± 2.06 , $p = 0.031$), with sustained effects at discharge (18.63 ± 1.27 vs. 19.81 ± 1.03 , $p = 0.011$). The mean anxiety reduction was greater in the intervention group (-2.1 points; 95% CI -3.4 to -0.8) versus minimal change in controls. Repeated measures ANOVA confirmed significant group-by-time interaction effects (F-statistic $p < 0.05$), demonstrating the intervention's effectiveness in reducing paternal anxiety throughout the surgical process. [This effect remained significant after controlling for fathers' age, socioeconomic status, and the child's history of prior surgeries ($p < 0.05$).] These findings support the hypothesis that structured preoperative preparation significantly lowers anxiety levels in fathers of children

undergoing cardiac surgery compared to standard care (Table 3).

Baseline self-efficacy scores showed no significant difference between groups (intervention: 69.5 ± 8.46 vs. control: 71.4 ± 6.4 , $p = 0.891$). Following the intervention, the preparation group demonstrated a significant improvement in self-efficacy, as reflected by a decrease in PSAM scores (60.16 ± 3.66) compared to controls (52.93 ± 4.14 , $p = 0.026$), with the benefit maintained at discharge (61.86 ± 7.32 vs. 53.43 ± 5.06 , $p = 0.014$). The intervention group showed a mean improvement in self-efficacy of $+8.7$ points (as indicated by the reduction in PSAM scores) (95% CI 5.2 to 12.1) versus minimal change in controls.

Table 3 Anxiety of fathers at different stages of the study

Variable	Intervention group	Control group	p-value
Anxiety of fathers	(Before)	(Before)	0.564
	20.76 ± 2.26	21.20 ± 3.04	
	(Immediately after)	(Immediately after)	0.031
	18.93 ± 1.16	19.87 ± 2.06	
	(Upon discharge)	(Upon discharge)	0.011
	18.63 ± 1.27	19.81 ± 1.03	
Mean Change from Baseline (95% CI)	2.13 (3.4 to 0.8)	1.39 (2.1 to 0.6)	

Table 4 Self-efficacy of fathers at different stages of the study

Variable	Intervention group	Control group (N = 30)	p-value
Self-efficacy of fathers	(Before)	(Before)	0.891
	69.5 ± 8.46	71.4 ± 6.4	
	(Immediately after)	(Immediately after)	0.026
	60.16 ± 3.66	52.93 ± 4.14	
	(Upon discharge)	(Upon discharge)	0.014
	61.86 ± 7.32	53.43 ± 5.06	
Mean Change from Baseline (95% CI)	8.34 (5.2 to 12.1)	17.97 (16.5 to 19.4)	

Repeated measures analysis confirmed significant group-by-time interaction effects ($p < 0.05$), indicating the structured preparation program effectively enhanced fathers' caregiving confidence throughout the surgical process. These results demonstrate that targeted preoperative education significantly boosts paternal self-efficacy compared to standard care approaches (Table 4).

Discussion

This study demonstrates that a structured preoperative preparation program significantly reduced anxiety and enhanced self-efficacy among fathers of children undergoing cardiac surgery, with sustained benefits observed until discharge. The lack of significant baseline differences between the intervention and control groups strengthens the conclusion that these improvements are attributable to the intervention. Our findings align with existing literature on parental preparation, which consistently highlights its role in mitigating psychological distress [16, 27]. Furthermore, the results extend this evidence base by confirming that tailored interventions are equally effective in addressing the unique needs of fathers, a population often overlooked in pediatric support services [28].

The effectiveness of the intervention can be attributed to its multi-component design, which directly addressed key sources of paternal distress. By providing concrete, action-oriented information through hospital tours and procedural education, the intervention likely reduced fear of the unknown and increased fathers' sense of predictability and control. Concurrently, the group consultation sessions offered peer modeling and normalized their emotional experiences, thereby enhancing their self-efficacy in coping with the caregiving role. This synergistic

approach effectively targeted the core sources of paternal distress, leading to the significant improvements in both primary outcomes—*anxiety* and *self-efficacy*—that were sustained through discharge [17, 29]. While factors like socioeconomic status may influence outcomes [28], our tailored protocol effectively created a buffer against the universal stressors of the surgical experience. Future interventions could be enhanced by addressing fathers' specific stressors, such as financial pressures and decision-making burdens. Incorporating targeted support like financial counseling and coping strategies for medical decisions would provide more holistic, father-centered care, potentially further reducing anxiety and boosting self-efficacy.

Recent studies have clearly shown the importance of preparation on the mental health of parents of hospitalized children, especially fathers [10, 19, 30]. According to the results of the present study, the anxiety score of fathers in the control group increased after the preparation at two specific times, that is, after the transfer of the child and upon their discharge [31]. This is due to the effect of the hospital environment and concerns of parents about their child's status [32]. Moreover, lack of information on the part of fathers about the surgical process may increase their sense of anxiety and lack of control [21]. If preparation is not effective, fathers will face stress arising from the discharge of the child as well as future challenges [11, 20]. For this, Osilva et al. demonstrated that using simple preparation methods such as provision of pamphlets, holding hospital tours, play therapy, short films, and education will be effective in lowering the anxiety of parents [33]. Yin x et al. showed in the study performed in 2024 that an appropriate educational intervention may enable parents to confront parenting duties and decrease their anxiety by modifying feedback

and perceptions [34]. Therefore, the decrease in self-efficacy scores of fathers is another finding of this study that is related to mental pressure arising from the critical status of the child and lack of sufficient information [35]. Therefore, educational methods must be developed and improved for fathers so that their mental health and quality of care for their children can be enhanced.

In addition, the results show significant differences between the two groups at different times. In other words, the intervention has a positive impact on the scores of anxieties and self-efficacy of fathers [15]. Preparation lowered anxiety and increased self-efficacy through education, giving care skills, and psychological support. Upon referral to the cardiology clinic, the anxiety scores were higher in the control group, and the self-efficacy scores were lower. However, the score of anxiety decreased significantly in the intervention group. As results show, the intervention group had better scores compared to the control group at the time of the child's discharge, and this proves the long-term effectiveness of the educational intervention. Furthermore, Amin Tojar et al. (2020) studied the effect of hospital tours on the preoperative anxiety of mothers of children with CHD. The results show that verbal explanations were more effective in lowering the anxiety of mothers. Also, groups receiving an operating room tour and hospital rounds had a greater decrease in anxiety compared to the control group [36].

Therefore, a person's control over their emotions may increase their self-efficacy and decrease anxiety through positive perceptions of their abilities [37]. Educational intervention will result in a decrease in anxiety and an increase in self-efficacy in parents of sick children [38]. Increasing parents' knowledge and skills in the treatment process reduces their anxiety [39]. Thus, similar educational programs seem necessary for the improvement of self-efficacy and the lowering of anxiety of parents in hospitals. Using simple educational methods and stress management techniques may help mothers confront stressful situations more effectively and improve the quality of care for their children. Additionally, the ability of parents to manage anxiety will increase by enhancing awareness and educating fathers about illness, the process of treatment, and lowering anxiety.

Looking ahead, a critical direction for future research involves expanding this work to multi-center settings with larger, more heterogeneous samples. Such studies should aim to recruit participants from varied geographic, socioeconomic, and cultural backgrounds. This would not only enhance the generalizability of the findings but also allow for subgroup analyses to determine if the intervention's effectiveness varies based on factors such as the specific type of CHD, family structure, or paternal socioeconomic status. Establishing the efficacy

of this preparatory model across diverse contexts is an essential step toward its widespread implementation as a standard of care in pediatric cardiac surgery. Furthermore, cultural norms significantly influence paternal roles in healthcare settings. In some contexts, fathers may be primary decision-makers, while in others they might assume more supportive roles. Future cross-cultural studies could explore how these variations affect paternal anxiety and self-efficacy, enabling the development of culturally tailored interventions.

Conclusion

This study demonstrates that structured preoperative education significantly reduces paternal anxiety and enhances self-efficacy during a child's open-heart surgery. Targeted interventions, such as hospital tours, peer support, and procedural education, equip fathers with practical tools to navigate the surgical process, yielding sustained psychological benefits. These findings underscore the need for gender-sensitive approaches in pediatric care, as fathers' needs differ from those of mothers. Nurses play a pivotal role in delivering this education and fostering collaboration between families and healthcare teams. To optimize outcomes, hospitals should integrate paternal mental health support into standard care protocols, ensuring fathers receive tailored resources. Future research should expand to diverse settings and include long-term follow-up to assess broader applicability. By addressing paternal psychological needs, healthcare systems can improve family-centered care and overall treatment experiences for children with congenital heart disease.

Limitations

This study has limitations, including its single-hospital setting, intermittent father participation, and prolonged sampling, which may have limited the sample diversity and may reduce generalizability. To enhance future research, multi-center studies across diverse geographic locations are recommended to improve data variety. Better methods for accessing and following up with fathers throughout treatment would yield more comprehensive results. Additionally, examining factors like socioeconomic status and specific disease types could provide deeper insights into parental needs and challenges. These improvements would strengthen the validity and applicability of findings while addressing current gaps in understanding paternal experiences during pediatric cardiac care.

Furthermore, the lack of long-term follow-up beyond discharge limited our understanding of the intervention's sustained impact. Future studies should include extended evaluations to determine the durability of benefits for

paternal mental health and their effect on broader family functioning.

Abbreviations

CHD	Congenital heart disease
VAS-A	Visual Analog Scale for Anxiety
PSAM	Parenting Self-Agency Measure

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s40359-025-03922-3>.

Supplementary Material 1.

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Trial registration number

ISRCTN11662988 (<https://www.isrctn.com/ISRCTN11662988>).

Registration date

18/11/2025

Informed consent statement

Informed consent was obtained from all subjects involved in the study.

Authors' contributions

R.Z.: Conceptualization, Data collection, Methodology. H.K.: Writing—final draft preparation. A.S.F. & M.N.: Conceptualization, Supervision, Reviewing and Editing. M.N.: Data analysis, Methodology, Preparation original draft. K.N.: Supervision, Reviewing and Editing. S.V.: Conceptualization, Reviewing and Editing.

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Data availability

The original contributions presented in the study are included in the article material; further inquiries can be directed to the corresponding authors.

Declarations

Ethics approval and consent to participate

All ethical considerations were observed in this study based on the Declaration of Helsinki. The code of ethics was also obtained from Shahid Beheshti University of Medical Sciences. IR.SBMU.PHARMACY.REC.1401.193. According to the Declaration of Helsinki, the following were also observed in this study:

1. The well-being and health of the individual took precedence over the scientific interests of the researcher and the demands of society.
2. Inform consent was obtained.
3. The results were made available to the participants after the research was completed.

Competing interests

The authors declare no competing interests.

Conflict of interest

The authors have no conflict of interest in publishing this study.

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