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The effect of the family-centered care model on the health literacy of family caregivers of pediatric patients after low-risk congenital heart defect surgeries

Mahmood Hosseinzadeh Maleki[1#], Vahideh Karimi[2], Mozhdeh Taheri Afshar[3#], Amirhossein Nadi[4], Maliheh Eshaghzadeh[5*], Mohsen Yaghubi[6]**

1. Department of Cardiac Surgery, Imam Reza Hospital, Mashhad University of Medical Sciences, Mashhad, Iran.
2. Department of Pre-Hospital Emergency Care, Abhar School of Nursing, Zanjan University of Medical Sciences, Zanjan, Iran.
3. Student Research Committee, Ramsar Fatemeh Zahra School of Nursing and Midwifery, Health Research Institue, Babol University of Medical Sciences, Babol, Iran.
4. Student Research Committee, Department of Nursing, Torbat Heydariyeh University of Medical Sciences, Torbat Heydariyeh, Iran.
5. Department of Nursing, School of Nursing and Midwifery, Torbat Heydariyeh University of Medical Sciences, Torbat Heydariyeh, Iran.
6. Department of Extra-Corporeal Circulation, Razavi Hospital, Imam Reza International University, Mashhad, Iran.

**** Corresponding Authors:***

1- Maliheh Eshaghzadeh, Department of Nursing, School of Nursing and Midwifery, Torbat Heydariyeh University of Medical Sciences, Torbat Heydariyeh, Iran. m.eshaghzadeh93@gmail.com
2- Mohsen Yaghubi, Department of Extra-Corporeal Circulation, Razavi Hospital, Imam Reza International University, Mashhad, Iran. n.m.yaghubi@gmail.com

 # These authors contributed equally and share first authorship on this work.

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Abstract

Background: Family caregivers of infants with congenital heart defects (CHD) require high health literacy to manage complex postoperative care. However, effective interventions to improve their health literacy are underexplored.

Objectives: This study aimed to evaluate the effect of a family-centered care model intervention on the health literacy of family caregivers of pediatric patients following low-risk congenital heart defect surgery.

Methods: This quasi-experimental study with a before-and-after design was conducted from January 2020 to December 2025 at Imam-Reza Hospital, Mashhad, Iran. A total of 100 family caregivers of pediatric patients (under 2 years) who underwent RACHS (Risk Adjustment for Congenital Heart Surgery) I-II surgeries were allocated into experimental (n=50) and control (n=50) groups using block randomization. The experimental group participated in five weekly multimedia family-centered education sessions, while the control group received routine hospital education. Health literacy was measured using the Health Literacy for Iranian Adults (HELIA) scale at three time points: baseline, immediately post-intervention, and three months' post-intervention. Data were analyzed using independent t-tests, paired t-tests, and repeated-measures ANOVA in SPSS version 26.0.

Results: A total of 98 caregivers (intervention: n=48, control: n=50) completed the study. The mean age was 39.37±9.15 years in the intervention group and 37.14±10.11 years in the control group. The majority were mothers (72% in intervention, 68% in control). No significant difference was found between groups in baseline health literacy scores (p=0.06). Immediately after the intervention, the mean health literacy score in the experimental group was significantly higher than the control group (58.09±7.24 vs. 31.42±6.56; p<0.001). This significant difference was maintained at the three-month follow-up (57.72±6.12 vs. 34.72±4.98; p<0.001). Repeated measures ANOVA revealed a significant time-by-group interaction (p<0.001), indicating the intervention's effectiveness over time.

Conclusion: The family-centered care intervention significantly improved health literacy among caregivers of children after low-risk CHD surgery, and this effect was sustained at three months. However, given the limited follow-up duration, future studies with longer-term follow-up (≥12 months) are recommended to confirm the durability of the effect.

Keywords: Health Literacy, Congenital Heart Defects, Cardiac Surgery, Perioperative Care, Caregiver.

1. Introduction

Congenital anomalies are a leading cause of morbidity and mortality in pediatric populations worldwide (1). Among these, congenital heart disease (CHD) is the most prevalent major malformation, affecting approximately 0.9% of live births (2). While advancements in surgical techniques and catheter interventions have significantly improved survival rates, CHD remains a

complex condition requiring lifelong management and continuous patient education (3, 4).

Effective post-surgical management extends beyond hospital walls and relies heavily on family caregivers' capabilities. These caregivers must navigate a technically complex medical journey, making critical decisions regarding medication, nutrition, and symptom recognition (5, 6). This capacity is fundamentally underpinned by health literacy—defined not merely as reading care key notes, but as the ability to obtain, process, and understand basic health information to make appropriate health decisions (7).

Despite its importance, many family caregivers suffer from inadequate health literacy. A lack of disease-specific knowledge and insufficient information provision regarding diagnosis and post-discharge care significantly hinder a caregiver's ability to manage patient needs effectively (8, 9). Research indicates that low health literacy among caregivers is a major barrier to optimal patient outcomes and is associated with increased stress and higher hospital readmission rates (10, 11).

One promising strategy to address this gap is implementing a family-centered care (FCC) model. Unlike traditional care, which focuses solely on the patient, FCC fosters a collaborative partnership between healthcare providers and the family, positioning the patient and family as a single unit of care (12). This model is designed to identify specific family needs, provide tailored education, and offer emotional and practical support. FCC interventions are considered cost-effective, safe, and capable of empowering caregivers by enhancing their knowledge, skills, and confidence (13).

While the benefits of FCC on general outcomes such as stress reduction are well documented, there is a paucity of research specifically quantifying its impact on caregivers' measurable health literacy in pediatric cardiac surgery. Most existing studies have focused on adult chronic diseases, or have not included a follow-up period to assess sustainability (14). Furthermore, few studies have measured all five dimensions of health literacy using a validated tool in this population. Therefore, this study aimed to determine the effect of a structured family-centered care model intervention on the health literacy of family caregivers of pediatric patients following low-risk congenital heart defect surgeries.

2. Methods:

2.1. Study Design, Population, and Setting

This study used a quasi-experimental, before-and-after design with block randomization. Although random allocation was performed, blinding of participants and the intervention provider was not feasible due to the educational nature of the intervention; therefore, the design is reported as quasi-experimental. Only the outcome assessor and statistician were blinded. It was conducted on consecutive pediatric patients under 2 years of age who underwent congenital heart defect surgeries classified as risk adjustment for congenital heart surgery (RACHS) I-II from January 2020 to December 2025 at the Department of Cardiac Surgery, Imam-Reza Hospital, Mashhad, Iran. Participants were selected via convenience sampling.

2.2. Sample Size Calculation

The sample size was determined using G*Power software based on a two-sample independent t-test. Assuming a moderate effect size (Cohen's d = 0.6) for the primary outcome (health literacy score), with 80% power ($\beta = 0.20$) and a significance level of 5% ($\alpha = 0.05$), the required sample size was 45 participants per group. To account for a potential attrition rate of 10%, 50 participants were enrolled in each group.

2.3. Sampling Method

Allocation to the experimental and control groups was performed using a block-randomized design with a block size of 6. Figure 1 shows the flow of patients' allocation between the experimental and control groups.

2.4. Inclusion and Exclusion Criteria

The inclusion criteria included age 18–65 years, a first-degree family relationship with the patient, a history of at least 6 months of patient care, undergoing congenital cardiac surgery within the 6 months prior to study enrolment, and reading and writing literacy. Basic reading and writing literacy were assessed by self-report and was required solely to enable independent completion of the HELIA questionnaire; it was not used as a proxy for health literacy. Health literacy itself was subsequently measured by the validated HELIA scale, so individuals with low health literacy but basic reading skills were not excluded. Also, Provision of written informed consent, and absence of diagnosed cognitive or psychiatric disorders that would impair questionnaire completion were considered as inclusion criteria.

The exclusion criteria included unwillingness to continue participating in the study, undergoing other surgery within the six months, missing more than 2 educational intervention sessions, or death of the pediatric patient during the study period (in which case the caregiver would be excluded from further participation, as the outcome would no longer pertain to active caregiving). In the present study, no patient death occurred in either group.

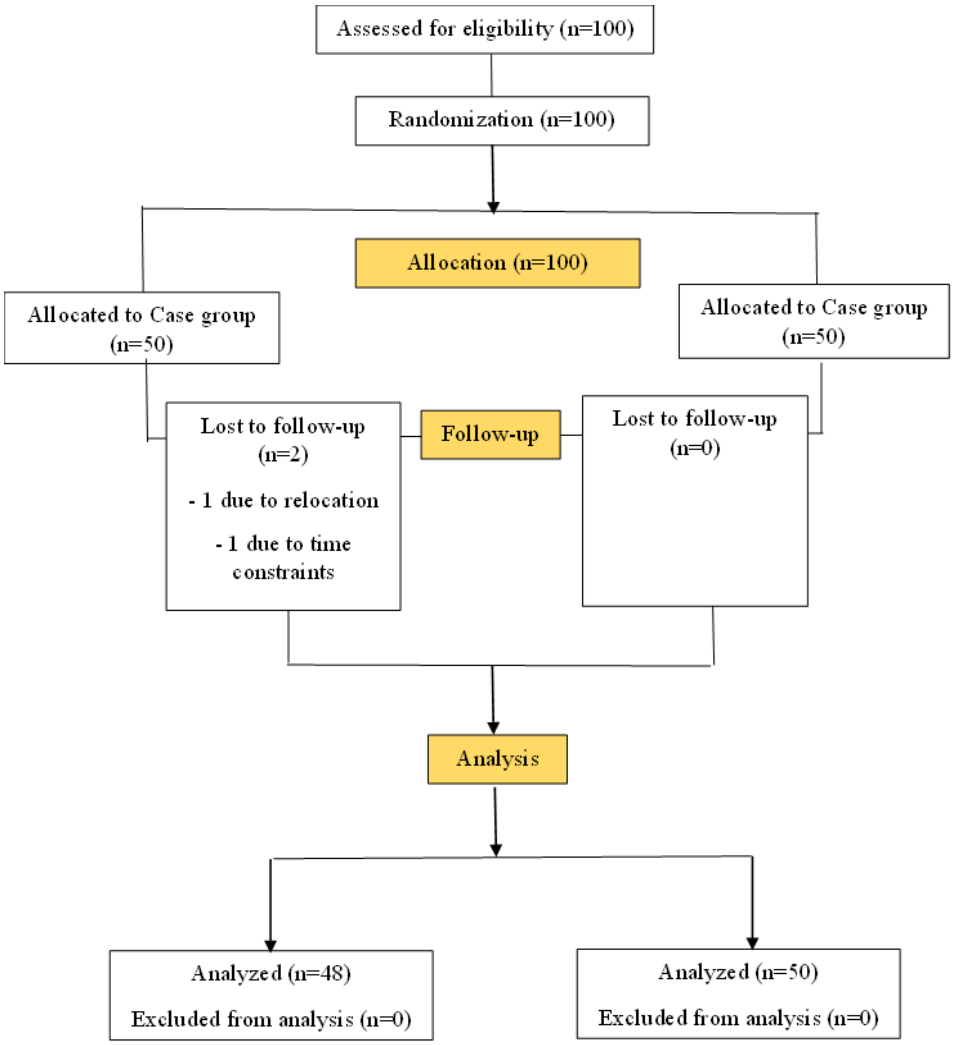

Figure 1. Consort diagram showing the flow of participants allocated to the experimental and control groups.

2.5. Data Collection Instruments, Intervention, and Outcome Measurement

In addition to standard care, the experimental group participated in a structured, family-centered care program comprising five weekly sessions, each lasting 60 to 90 minutes. Family caregivers were divided into subgroups of 10 to facilitate interaction. The content was delivered using lectures, group discussions, question-and-answer sessions, educational booklets, and multimedia CDs. All sessions were conducted by the principal investigator, who is a trained cardiac nurse with 5 years of experience in pediatric cardiac care.

Table 1: The content of the different experimental sessions.

Session	Title	Content	Teaching Methods	Time duration
1	Orientation and Baseline Assessment	Rapport building, programme overview, introduction to CHD, baseline HELIA administration	Lecture, group discussion	60 minutes
2	Disease Knowledge and Medication	Causes, symptoms, prognosis, common cardiac medications, side effects, adherence	Lecture, Q&A, booklet	75 minutes
3	Symptom Management and Safety	Emergency signs, referral criteria, nutrition, home modifications	Lecture, video, discussion	75 minutes
4	Coping and Problem-Solving	Stress management, communication, time management, daily care problem-solving	Group discussion, role-play	90 minutes
5	Self-Care and Resources	Caregiver self-care (sleep, rest, exercise), support resources, post-intervention HELIA	Lecture, Q&A, pamphlet	60 minutes

Health literacy was measured at three time points: (T0) before the intervention (baseline), (T1) immediately after the last session (week 5), and (T2) three months after the intervention.

To ensure consistency across the extended recruitment period (2020–2025), all educational sessions were delivered by the same principal investigator using a standardized written curriculum and identical multimedia materials. Hospital discharge protocols for cardiac surgery patients remained unchanged during this period, as confirmed by hospital administrative records.

The control group received only routine hospital education and care before discharge.

The demographic questionnaire contained 7 items covering age, gender, education level, marital status, relationship to the patient, occupation, and duration of caregiving.

Due to the educational nature of the intervention, blinding of participants and the principal investigator was not feasible. However, the outcome assessor who scored the HELIA questionnaires and the statistician who performed the data analysis were blinded to group allocation to minimize detection bias.

The data collection tools employed in this study were a demographic characteristics form and the HELIA scale.

The HELIA scale includes 33 items across five areas: access (6 items), reading skills (4 items), comprehension (7 items), evaluation (4 items), and decision-making and application of health information (12 items). The questionnaire's total mean score was divided into four categories: insufficient (>50%), not very sufficient (50.1%–66%), sufficient (66.1%–84%), and excellent (84.1%–100%). The questionnaire's construct validity was confirmed through an

exploratory factor analysis of 33 items across five dimensions. Furthermore, the Montazeri et al. Confirmed the reliability of this questionnaire using Cronbach's alpha method with an alpha of 0.72–0.89 (14).

2.6. Statistical Analysis

Statistical analysis was conducted using SPSS software version 26.0 (Chicago, IL, USA). Quantitative results were presented as mean ± standard deviation (SD) and median. For normally distributed variables, the independent Student's t-test was used; for non-normally distributed quantitative variables, the Mann-Whitney test was used. Fisher's exact test and the chi-square test for independence were used to assess the homogeneity of categorical variables between groups. Quantitative variables were compared using the paired-samples t-test. To examine the effect of measurement time (as a repeated-measures variable) and the interaction between measurement time and categorical group variables, a repeated-measures ANOVA was used. The statistical significance level was set at $P < 0.05$.

3. Results

A total of 98 participants completed the study (intervention: n=48; control: n=50). Two participants in the intervention group were lost to follow-up at three months (one due to relocation, one due to lack of time) and were excluded from the final analysis. The experimental and control groups were homogeneous with respect to baseline demographic characteristics. There were no statistically significant differences in gender, marital status, or education level ($p > 0.05$).

The majority of caregivers were mothers (70% overall), married (72%), and had at least a high school education (58%). The overall mean age of caregivers was 38.3±9.7 years (Experimental and control groups was 39.37 ± 9.15 and 37.14 ± 10.11 years, respectively). The distribution of caregivers is shown in Table 2.

Table 2: Distribution of caregivers of congenital cardiac defect surgery pediatrics based on some demographic characteristics.

Variable		Study groups N (%)		P-value
		Experimental	Control	
Gender	Male	23 (48%)	21 (42%)	0.08
	Female	25 (42%)	29 (48%)	
Education status	Pre-diploma	8 (17%)	10 (20%)	0.07
	Diploma	10 (21%)	9 (18%)	
	Bachelor's degree	12 (25%)	15 (30%)	
	Postgraduate and higher degree	18 (37%)	16 (32%)	
Marital status	Single	18	27	0.09
	Married	28	20	
	Divorced	2	3	

The main findings of this study showed that the mean health literacy score before the intervention was not statistically different between the two groups ($p > 0.05$). However, immediately after the intervention, the scores in the intervention group were significantly higher than those in the control group (58.09 ± 7.24 vs. 31.42 ± 6.56; $t(98) = 18.92$, $p < 0.001$), representing a very large effect size (Cohen's $d = 3.9$). This significant difference was sustained at the three-month follow-up (57.72 ± 6.12 vs. 34.72 ± 4.98; $t(98) = 20.41$, $p < 0.001$).

Repeated-measures ANOVA revealed a statistically significant main effect of time ($F(2, 196) = 280.45$, $p < 0.001$) and a significant time × group interaction ($F(2, 196) = 320.56$, $p < 0.001$). This interaction confirms that the change in health literacy scores over time differed significantly between the two groups; the experimental group showed a substantial increase that remained stable at follow-up, while the control group remained relatively constant (Table 3).

Table 3: The mean health literacy score of caregivers of pediatric patients after congenital heart defect surgery before, immediately after, and three months after the intervention in the experimental and control groups.

Time period	Group		P-value (Intergroup Comparison)
	Experimental Mean ± SD	Control Mean ± SD	
Before the intervention (T0)	28.67 ± 6.76	30.78 ± 7.89	0.06
Immediately after the last session (T1)	58.09 ± 7.24	31.42 ± 6.56	< 0.001*
Three months after the intervention (T2)	57.72 ± 6.12	34.72 ± 4.98	< 0.001*

***:** Significant difference.

The mean scores for the health literacy dimensions (reading, access, understanding, decision-making, and appraisal) in the pre-intervention and post-intervention phases showed a statistically significant difference ($p < 0.001$). Among the components of health literacy, the decision-making component and the reading and appraisal component had the highest and lowest scores, respectively (Table 4).

Table 4: Comparison of health literacy domain scores between groups across three time points.

	Variable	The investigation time	Group		P-Value of intergroup comparison
			Control Mean ± S.D	Experimental Mean ± S.D	
Dimensions of health literacy	Read	Before the intervention	13.10 (2.85)	13.08 (3.12)	0.19
		Immediately after the last session	13.28 (1.89)	15.64 (2.02)	< 0.001*
		Three months after the intervention	13.25 (2.09)	15.58 (3.12)	< 0.001*
	Access	Before the intervention	15.12 (2.96)	15.68 (3.51)	0.15
		Immediately after the last session	15.08 (1.98)	21.63 (3.01)	< 0.001*
		Three months after the intervention	15.89 (1.12)	21.51 (2.63)	< 0.001*
	Understanding and comprehensions	Before the intervention	11.12 (0.96)	12.28 (1.15)	0.16
		Immediately after the last session	12.02 (2.19)	28.17 (4.12)	< 0.001*
		Three months after the intervention	12.24 (1.91)	28.88 (4.22)	< 0.001*
	Decision making	Before the intervention	25.60 (3.87)	25.96 (2.69)	0.4
		Immediately after the last session	25.32 (4.31)	39.12 (4.98)	< 0.001*
		Three months after the intervention	25.63 (4.85)	38.78 (4.33)	< 0.001*
	Appraisal	Before the intervention	11.54 (2.42)	13.02 (3.64)	0.06
		Immediately after the last session	13.48 (3.63)	16.14 (2.18)	< 0.001*
		Three months after the intervention	13.12 (2.87)	15.80 (1.97)	< 0.001*

***:** Significant difference.

4. Discussion

This research sought to evaluate the efficacy of a family-centered care program in enhancing caregivers' health literacy for pediatric recipients undergoing low-risk congenital cardiac surgery. The findings demonstrate that the intervention significantly improved caregivers' health literacy immediately post-treatment and, crucially, this improvement was sustained over 3 months. It supports the hypothesis that structured, family-oriented education is a powerful tool for empowering caregivers.

The main finding revealed a substantial enhancement in caregivers' health literacy following the intervention, as mean scores shifted from the insufficient to the sufficient range. It indicates that training support can significantly improve caregivers' health literacy. The results of Hayati et al. investigation (15) align with those of the current study, demonstrating that family-centered care programs foster an environment supportive of both physical and mental recuperation in patients.

Furthermore, empowering caregivers increases their knowledge, understanding, and skills, supports effective care, and enhances their role performance (16). Research has further established that caregiver training initiatives enhance understanding of care requirements in multiple areas of patient management (17). Wu et al. demonstrated that a decrease in the level of health knowledge among patients and their family members affected patients' knowledge and self-care, and that family members' low health literacy also affected the caregiver's and the patient's knowledge (18).

Paralleled with our findings, additional research suggests that family empowerment contributes to enhanced knowledge and attitudes, improved performance, increased capacity for self-care, better quality of care, accelerated patient recovery, and reduced complications (19).

The present study found that caregivers of CHD patients had moderate health literacy across all five dimensions after the intervention. Among the health literacy components, the decision-making component and the reading and appraisal component had the highest and lowest scores, respectively. Ghulam Farid and colleagues (20)showed that most participants had moderate literacy, and the highest mean score was also associated with decision-making and behavior. In contrast. the lowest mean score was for reading skills. Nevertheless, the strength of our research lies in its measurement of health literacy dimensions, which aligns with Gholami et al.'s study (21).

The findings of other research are contrary to the present study, which revealed that participants had an insufficient understanding (22-23). The discrepancy between our findings and those of Sheikh Sharafi & Seyed Amini (2017) and Türker & Bedük (2025) may be attributed to differences in study populations (adult heart failure patients versus paediatric caregivers), shorter intervention durations, and the use of different health literacy measurement tools.

The efficacy of patient and caregiver education is contingent upon the successful comprehension of the imparted knowledge. Accordingly, a principal objective within health education is to prioritize pedagogical approaches that employ clear, simple, and universally accessible language, thereby optimizing knowledge transfer and promoting positive health outcomes. In this matter, the Bozorgzad et al. (24) reported higher appraisal scores than we observed. This difference likely reflects the longer disease experience of their population (chronic heart failure), whereas our caregivers were in the early postoperative

phase, which may limit their ability to appraise health information effectively.

This study has several strengths, including its controlled design, use of a validated health literacy instrument, blinded outcome assessment, and three-month follow-up. Despite its strengths, this study has several limitations. First, the use of convenience sampling from a single center limits the generalizability of the findings to other populations or healthcare settings. Second, while we blinded the data analyst, blinding participants was impossible, which may introduce performance bias. Third, the follow-up period, while adequate to show sustainability, was only three months; a longer follow-up is needed to assess the very long-term retention of health literacy gains. Finally, this study measured health literacy as a proxy outcome; future research should investigate whether this improvement translates directly to improved clinical outcomes for the child, such as reduced readmission rates or fewer postoperative complications. Additionally, although we standardised the intervention, the extended enrolment period may have introduced unmeasured temporal effects; future studies with shorter recruitment windows are recommended.

To enable caregivers and patients to evaluate health information effectively, they must have access to complete and reliable information sources. Consequently, greater emphasis should be placed on developing structured training programs to transmit treatment-related information to patients and their caregivers, alongside efforts to enhance healthcare professionals' response capacity. On the other hand, to improve caregivers' knowledge base and skill sets, and ultimately empower them, it is crucial to cultivate competencies across several key areas. These include monitoring and interpreting clinical information, making accurate decisions, adhering to treatment protocols, utilizing support resources, collaborating with multidisciplinary healthcare teams, and adapting to the complexities of the healthcare system. It is recommended that future research investigate the applicability of such interventions among caregivers of pediatric patients with other congenital abnormalities after cardiac surgeries with complicated care plans. Furthermore, subsequent studies examine the impact of these interventions on additional psychosocial variables, including caregiver satisfaction.

5. Conclusion

This study provides robust evidence for short- and medium-term (up to three months) improvement in caregivers' health literacy following a family-centered intervention. However, conclusions regarding long-term sustainability beyond this period should be made cautiously. Future research with at least 12 months of follow-up is warranted to confirm the durability of the effect and to evaluate its impact on child clinical outcomes.

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Conflicts of interest: The authors have no conflicts of interest to declare.

Consent for publication: Not applicable.

Ethics approval and consent to participate: This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. This study received ethical approval from the Research Ethics Committee of Mashhad University of Medical

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