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The effect of a family-centered care program on the psychological outcomes of births with congenital malformations: A study protocol

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Abstract:

BACKGROUND: The birth of a baby with a congenital abnormality causes emotional and psychological suffering for the parents. This study will aim to investigate the impact of a family-centered care program on psychological outcomes, including aggression and post-traumatic stress disorder (PTSD).

MATERIALS AND METHODS: This study will be a prospective, multicenter, single-blind randomized controlled trial. The participants will include 74 parents of children with malformations who will score above 24 on the PTSD assessment using the Revised Weiss and Marmar Impact of Event Questionnaire (IES-R). Sampling will be performed in a non-proportional random stratified manner. The CONSORT-SPI guideline and SPIRIT guideline will be adhered to in this study. The control group will receive the routine intervention of the department, while the intervention group will participate in a family-oriented educational-support program based on four steps: Information exchange, self-efficacy promotion, self-confidence (self-esteem), and evaluation. Anger assessment using the Spielberger trait-state anger inventory (STAXI-2) and PTSD assessment using the IES-R questionnaire will be conducted at three stages: Before the intervention, immediately afterward, and 1 month later. The results will be compared between the two groups.

CONCLUSION: To support or enhance the psychological well-being of parents with infants born with congenital malformations, there will be a pressing need for tailored interventions. This family-centered intervention, designed for all parents facing similar challenges, has the potential to significantly enhance their psychological resilience. We anticipate that implementing this intervention will lead to notable improvements in psychological outcomes, particularly in mitigating the effects of anger and PTSD, as individuals adopt effective coping strategies and adjust to their new circumstances.

Keywords:

Anger, congenital abnormality, family-centered nursing, infant, parent, post-traumatic stress disorder

Introduction

Congenital anomalies, also known as birth defects, encompass a range of structural, functional, or metabolic disorders found in newborns, and are primarily rooted in prenatal factors, such as genetic mutations, chromosomal abnormalities, hereditary traits, environmental exposures, or nutritional deficiencies.[1,2] These anomalies represent a significant global health issue, contributing to perinatal and neonatal mortality, even in high-income countries, such as the United States and Western Europe, where their impact has risen as infectious disease-related deaths decline.[3] Notably, approximately 13% of neonatal intensive care unit (NICU) admissions are linked to congenital anomalies, underscoring their substantial role in infant mortality rates.[4] The World

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Health Organization (WHO) reports that around 8 million babies worldwide are born with birth defects annually as of March 2022.[5] Despite advances in prenatal screening technologies, such as ultrasound, which enhance fetal anomaly detection, many expectant parents face unexpected emotional and psychological challenges when a congenital anomaly is diagnosed after birth.[6]

The birth of a child with a congenital anomaly often places parents under immense stress, due to the demands of managing their infant's condition, prolonged hospitalizations, and the uncertainty surrounding prognosis. These stressors can lead to significant impacts on the parents' quality of life, emotional well-being, and caregiving abilities, increasing their risk of psychosocial difficulties.[7,8] Parents of infants with congenital abnormalities often endure mental and emotional distress, particularly during their hospitalization in specialized care units, where the complexities of treatment and care may strain parental coping mechanisms and exacerbate feelings of uncertainty.[9-11] Consequently, these challenges may strain the parent-child bond and contribute to adverse parental responses to stress, including anxiety, fatigue, and PTSD, with mothers being particularly susceptible.[5,8,12,13] PTSD following childbirth trauma, characterized by symptoms like fear, helplessness, and sleep disturbances, can persist for extended periods, affecting daily functioning.[14]

Research indicates varying prevalence rates of postnatal stress disorder globally, with mothers of infants hospitalized in NICUs experiencing heightened vulnerability.[15] Indeed, up to 30% of parents with infants affected by congenital anomalies report symptoms of PTSD, with factors, such as the stress of caregiving, medical procedures, perceived lack of control, and emotional distress contributing to its occurrence.[15,16] Overall, the birth of a baby with a congenital anomaly amplifies parental stress levels and jeopardizes mental well-being, potentially influencing the quality of caregiving and parent-child interactions.[17,18]

Active involvement in newborn care and bolstering parental roles are pivotal in mitigating parental stress.[17] Family-centered care, an innovative healthcare approach emphasizing collaboration between patients, families, and healthcare providers, facilitates active parental participation in caregiving decisions, thereby empowering them to contribute meaningfully to their baby's care journey.[19-21] First introduced in 1987, this method for planning, implementing, and evaluating healthcare is based on mutually beneficial partnerships between caregivers, patients, and families, rooted in the principles of empowerment. Numerous studies highlight the positive effects of family-centered care on psychological outcomes, including reduced anxiety, improved quality of life, increased satisfaction, enhanced self-efficacy, and boosted self-esteem.[8,22,23] However, some research indicates that this approach may not always yield beneficial results, suggesting that alternative treatments might be necessary in certain cases.[24] Despite its benefits, family-centered care remains underutilized, often due to inadequate communication and information sharing with families, which undermines their sense of control in stressful situations.[25]

In NICUs, where nurses prioritize newborn monitoring and care, parents may feel hesitant or unable to express their needs, potentially impeding optimal child care.[26]

This study aims to address this gap by examining the impact of a family-centered care intervention on reducing the psychological distress experienced by parents of infants born with congenital anomalies. By empowering parents to take a more active role in their child's care, this intervention has the potential to mitigate the adverse psychological outcomes associated with such births.

Materials and Methods

Study objective

The aim of the present study is to determine the impact of a family-centered care program on psychological outcomes, such as aggression and PTSD.

Hypotheses

1. H1: The mean score of changes in PTSD in parents of infants with congenital anomalies differs between the control and intervention groups after the intervention.
2. H1: The mean score of changes in aggression in parents of infants with congenital anomalies differs between the control and intervention groups after the intervention.
3. H1: The mean scores of PTSD and aggression, controlling for demographic and confounding variables (level of adaptation, level of stress in the NICU, perceived social support of parents), differ between parents of infants with congenital anomalies in the intervention and control groups.

Study design

This study employs a multicenter, single-blind, research protocol for a prospective controlled clinical trial, utilizing a parallel group design with a 1:1 ratio. The research took place within university-affiliated hospitals and adhered to established standards, including the SPIRIT guideline for interventional trials and consolidated standards of reporting trials statement for social and psychological interventions (CONSORT-SPI).[27,28] Approval for the project was obtained from the University of Medical

Sciences under the scientific code 3401281, and registration with the IRCT.IR system was completed under registration code IRCT20220605055080N1. The study is scheduled to occur across several hospitals associated with the University Hospital between 2022 and 2024. The researcher does not have knowledge of group assignments. This study will be conducted in three phases. Phase one will involve selecting participants and performing initial assessments, which will take approximately 1–2 days. Phase two will focus on the intervention, which will be carried out in four stages over a period of 2 weeks. Phase three will consist of a follow-up conducted 1 month after the intervention's completion.

During the follow-up phase, if the patient remains hospitalized, they will be visited in the hospital. If the patient has been discharged, arrangements will be made for them to complete the questionnaire in person. If in-person completion is not feasible, the questionnaire will be administered via phone, with a research team member filling it out on their behalf. This process will be considered in the data analysis.

The study will include a pre-test, a second test immediately after the intervention, and a third test conducted 1-month post-intervention.

Study framework

The theoretical framework for this study is based on understanding the impact of family-centered care on psychological outcomes in parents of infants with congenital anomalies. It integrates elements from stress and coping theory, family systems theory, and health promotion models. The framework identifies key variables and their interrelationships to explain how family-centered care can mitigate stress, enhance coping, and improve psychological outcomes [Figure 1].

Additionally, the study framework conforms to the community, intervention, comparison, outcomes, and type of study (PICOS) criteria. Accordingly, our study will involve parents of infants with malformations as the target population. We will implement a family-centered care program as our intervention, while the control group will receive standard care. The outcomes under examination will include measures of anger and PTSD. The study will employ a randomized controlled trial design.

Criteria for study inclusion: Inclusion criteria entail voluntary participation, a PTSD score exceeding 24, parents with infants having any congenital abnormality necessitating hospitalization in the PTSD department, literacy, and the absence of any parental mental disorder. Exclusion criteria comprise instances, such as infant death during the intervention, congenital abnormalities requiring emergency surgery, infant discharge during the intervention, additional stressful events occurring during the study, and parental absence or non-participation in one or more sessions. Additionally, dissatisfaction and unwillingness of the infant's family to continue cooperating with the researcher throughout the study will serve as exit criteria.

Sampling

Sample size determination was performed using statistical analysis and G*power 3.1.9.4 software. Each group, control, and intervention, comprised 34 individuals. Calculations were based on an α error probability of 0.05, an effect size of 0.7, Power (1-β error probability) of 0.8, and an allocation ratio N2/N1 of 1. Accounting for a 10% attrition probability, the final sample size was established at 37 individuals for each group.

Randomization and allocation

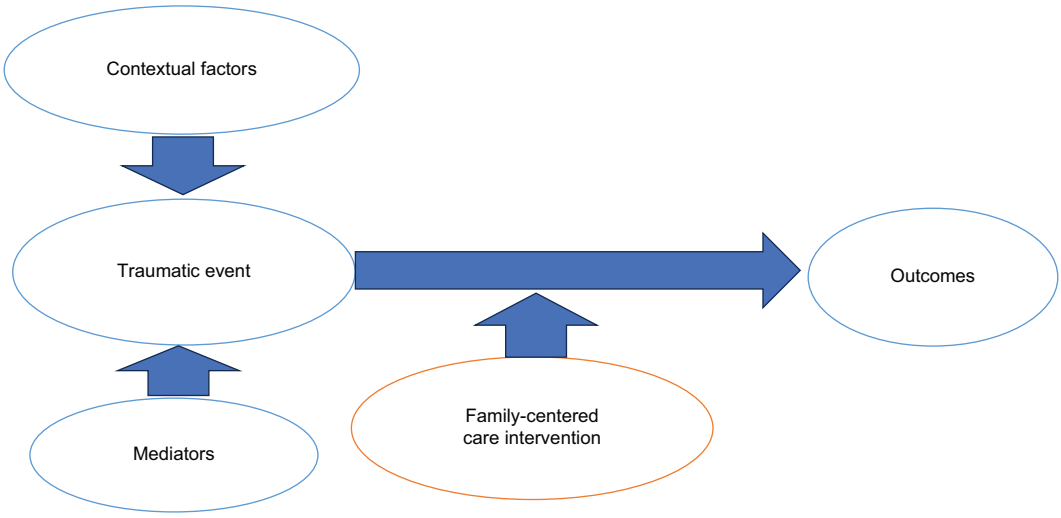
Study participants will be selected through non-proportional stratified random sampling from parents of infants with abnormalities hospitalized in the NICU who meet the inclusion criteria. This methodology involves dividing the research population into two or more subgroups based on the type of infant abnormality, followed by random sample selection from each subgroup. While members within each subgroup will share similarities, differences will exist between the subgroups. The random allocation software (RAS) will be employed to allocate samples. The participants' CONSORT flowchart is depicted in Figure 2. Based on the software output, which determines the group assignment for each sample and the number of patients with abnormalities to be included in each group, sampling will continue until the required sample sizes are achieved.

Blinding: Both participants and the statistician will be blinded to the case. To ensure blinding and mitigate the researcher's influence, equal time will be allocated to both groups, and the researcher will remain unaware of the allocation process.

Intervention

Routine care for the control group includes the mother's physical presence next to the baby, answering questions upon inquiry, breastfeeding education, and restricted visitation by the baby's father.

The intervention group will participate in a family-centered educational support program consisting of four stages: sharing knowledge, enhancing self-efficacy, boosting self-esteem, and evaluation. These daily sessions for parents aim to educate them on how to care for infants with abnormalities, encourage active participation in



Key Components	Definition
Contextual factors	Socio-demographic details: Parental age, education, occupation, economic status, number of children, etc.
	Baby's characteristics: Gestational age, weight, gender, mode of delivery.
	Parental profiles: Level of involvement, birth order of the child, external support received by the family.
	Cultural and religious factors: Influences on parental coping and stress.
Mediators	These intermediate variables are affected by the intervention. They include coping mechanisms, perceived social support, parental stress, traumatic event impact, and anger expression.
Family-centered care intervention	This intervention is the core of the study, designed to affect the mediators and, through them, the psychological outcomes. It includes knowledge sharing, self-efficacy enhancement, self-esteem enhancement, and evaluation.
Psychological outcomes	The main outcomes of interest are aggression, PTSD, stress levels, and quality of life.

Figure 1: Conceptual framework

infant care, facilitate communication and mutual support among partners, and offer psychological guidance on coping with the stresses associated with having infants with abnormalities in the NICU. The training sessions will be conducted face-to-face, combining instruction, counseling, and support. They will last between 45 min and 1 h and will be followed by practical application at the bedside. FK, AN, and FV will facilitate these sessions, and parents will have access to the researcher's contact number for further guidance and to address any questions or concerns they might have [Table 1].

Results

The study outcomes will be assessed based on various parameters, including socio-demographic details, information regarding the baby's characteristics (such as gestational age, weight, gender, and mode of delivery), and parental profiles (such as age, education, occupation, economic status, number of children, parental involvement, birth order of the child, and any external support received by the family).

Additionally, the questionnaire will cover inquiries concerning the perceived type of abnormality in the baby, how the mother learned about the fetal abnormality, timing of disclosure to the parents, method of informing the father, and parental experiences upon learning about the baby's abnormality (anatomically) on the first day.

Data collection will involve structured interviews with the parents, self-report measures, and

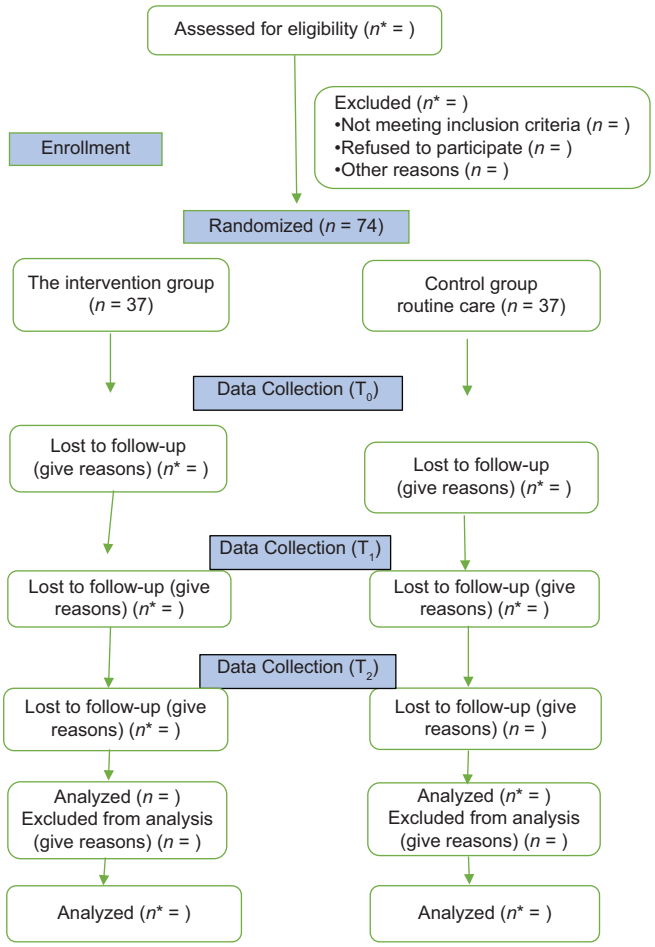


Figure 2: Consolidated standards of reporting trials (CONSORT) flow diagram of participants (*The value of "n" will be determined upon conducting the study, as this is a protocol.)

review of the baby's medical records. Before the intervention, participants will complete the COPE Brief, parental stress questionnaire in the neonatal intensive care unit (PSS-NICU), Revised Weiss and Marmar Event Impact Scale (IES-R), Spielberger Trait-State Anger Expression Inventory (STAXI-2), and Multidimensional Scale of Perceived Social Support (MSPSS).

The sequence of questionnaire administration will be as follows: Parents will receive information about the research protocol during follow-up visits, and upon their consent to participate, they will complete the IES-R questionnaire. If the score exceeds 24, participants will be enrolled in the study after providing informed consent and will be assigned to either the intervention or control group based on the allocation schedule.

Follow-up assessments will occur immediately and one-month post-intervention, during which participants will complete the IES-R Scale and the STAXI-2 questionnaire again.

Data collection instruments

In the present study, data will be collected using a questionnaire consisting of six sections:

- *Demographic profile form*
- *COPE brief*: This instrument, developed by Cooper *et al*., is based on Lazarus' stress psychology theory. It comprises 28 items distributed across 14 subscales representing a variety of coping strategies. These strategies fall under two main dimensions: Problem-oriented and emotion-oriented coping. Problem-oriented coping strategies include active coping, planning, use of instrumental support, acceptance, positive reframing, humor, and religion. Emotion-oriented coping strategies encompass emotional support, venting, denial, substance use, distraction, and self-blame. The questionnaire's reliability and validity have been established by Cooper *et al*., (2008)[29] who reported Cronbach's alpha coefficients of 0.84 for problem-oriented coping, 0.72 for emotion-oriented coping, and 0.75 for dysfunctional coping. Additionally, Mirlashari[30] obtained a Cronbach's alpha coefficient of 0.72 in a study involving 80 mothers of premature infants hospitalized in the NICU.
- *Parental stress questionnaire in neonatal special care unit (PSS-NICU)*: This questionnaire, developed by Miles *et al*. (1993),[31] evaluates parental stress in the neonatal special care unit across three scales: Caregiver environment, appearance and behavior of the baby and special treatments, and parent-baby relationship and parental role. The tool consists of 38 items, with scores ranging from 0 to 170, where higher scores indicate higher levels of stress. Reliability and validity have been confirmed through previous studies.[32]
- *IES-R scale:* This questionnaire, designed by Weiss and Marmar in 1997, assesses dimensions of mental distress experienced in response to traumatic events, including avoidance, intrusive thoughts, and hyperarousal. It comprises 22 items scored on a Likert scale ranging from 0 to 4. The reliability and validity of the questionnaire have been established in previous studies.[33,34]
- *Spielberger state-trait anger expression inventory (STAXI-2):* This questionnaire, developed by Spielberger, assesses state anger across various dimensions, including angry feelings, verbal and physical expression of anger. It consists of 57 items scored on a 4-point Likert scale. Reliability and validity have been confirmed by previous studies.[35,36]
- *Multidimensional scale of perceived social support (MSPSS):* Developed by Zimet and colleagues in 1988, this scale measures perceived social support from family, friends, and significant others. It comprises 12 items rated on a 7-point scale. Reliability and validity have been established by previous studies.[37,38]

Table 1: Summary of a family-centered care program in four steps

Step	Objectives	Content	Presentation Method
Step 1: Knowledge sharing	- Identify the role of parents in improving the baby's health - Increase awareness and understanding of congenital malformations. - Introduce resources and services from support providers.	- Discuss parental roles and challenges in caring for babies with abnormalities - Provide information on congenital abnormalities - Increase knowledge about available support resources.	- Lectures - Q and A sessions - PowerPoint presentations - Educational booklets - Hands-on experience at the baby's bedside
Step 2: Self-efficacy enhancement	- Improve knowledge, skills, and readiness in infant care. - Boost parents' confidence and control in managing infants with abnormalities. - Enhance communication skills and adaptability. - Reduce care-related stress.	- Improve readiness and confidence in care based on abnormality type. - Educate on strategies for maintaining parental health. - Increase knowledge of baby care techniques.	- Lectures - Q and A sessions - Counseling and phone follow-ups - Practical training at the newborn's bedside
Step 3: Self-esteem enhancement	- Learn to care for and handle a baby with abnormalities. - Boost confidence and control over newborn care. - Enhance readiness in caring for newborns.	- Enhance preparation and confidence in newborn care based on abnormality type. - Provide instruction on maintaining and enhancing parental health. - Increase understanding of baby care.	- Lectures - Observation of caregiving behavior - Parental support - Q and A sessions
Step 4: Evaluation	- Summarize and review previous session topics.	- Evaluate participants' understanding through oral questioning. - Assess self-efficacy. - Request demonstration of two skills.	- Oral questioning - Self-efficacy assessment - Skills demonstration

Data analysis

Descriptive statistical methods, including measures such as mean, standard deviation, median, frequency, ratio, minimum, and maximum, will be applied. The independent *t*-test and analysis of covariance will be utilized to compare the two groups across three different measurement points. When analyzing variables with a normal distribution, the Mann-Whitney U test will be employed for comparing quantitative data between the two groups without a normal distribution. For normally distributed variables, the paired *t*-test will be used for intergroup comparisons. Conversely, the Wilcoxon rank test will be utilized to compare variables with a non-normal distribution between groups. In instances of missing data, multiple imputation and maximum likelihood methods will be utilized. An intention-to-treat (ITT) analysis will be conducted to maintain the randomization effect and minimize attrition bias. Furthermore, Pearson and regression tests will be employed to explore the relationship between demographic variables and the intervention process. Finally, qualitative data from structured interview questions will be analyzed using conventional content analysis.

Ethical considerations

This research was initiated in accordance with the principles outlined in the Declaration of Helsinki and commenced after receiving written approval from the ethics committee of Isfahan University of Medical Sciences, under code number IR.MUI.NUREMA.REC.1401.067, as well as obtaining written permission from the hospital. Subsequently, a detailed explanation of the research methodology was provided to the parents, and written informed consent was obtained from them to participate in the study. Parents were also informed that they had the right to withdraw from the study at any stage if they chose not to continue their participation.

Discussion

The birth of a baby with congenital abnormalities can pose significant psychological challenges for parents, including feelings of anger, grief, and post-traumatic stress.[39,40] Family-centered care has the potential to alleviate these burdens by fostering unity within the family and reducing the stress associated with such crises.[25] This approach is especially critical during the period when parents first become aware of the abnormality and during childbirth, as it can help prevent complications. However, if the baby requires admission to the NICU, the challenges may intensify, further exacerbating the family's crisis.[41,42] Parents of babies hospitalized in the NICU often experience heightened emotional and mental distress, leading to increased tension, feelings of hopelessness, fatigue, depression, and anxiety. These emotional strains can severely impact their quality of life and hinder the development of a healthy parent-child relationship.[43,44]

Family-centered care plays a pivotal role in empowering parents to navigate challenges such as aggressive treatments, lack of involvement in caregiving, and uncertainty about their role or difficulty in interacting with

the baby. By addressing these issues, family-centered care has the potential to enhance outcomes for these parents, fostering self-care and reducing stress.[19] This article outlines the protocol of a randomized, multicenter trial aimed at investigating the impact of a family-centered care program on psychological outcomes, including aggression and PTSD. Given the scarcity of scientific evidence regarding the influence of family-centered care on psychological consequences, such as anger and PTSD, the findings of this study are anticipated to contribute valuable insights to this field.

Research strengths, weaknesses, and limitations

Strengths:

Clear protocol: The study design is well-defined, with a structured approach including multiple phases and specific objectives for each phase.

Randomization: The use of randomization and stratified sampling helps in minimizing selection bias and ensures a representative sample of participants.

Family-centered approach: The design emphasizes family-centered care, which is known to positively impact both parents and infants, aligning with best practices in neonatal care.

Comprehensive data collection: The study collects data at multiple points (pre-test, post-intervention, and follow-up), providing a robust dataset for analysis.

Transparency: Efforts will be made to present the data clearly and comprehensively, enhancing the reliability and credibility of the findings.

Weaknesses:

Implementation complexity: The study design involves multiple phases and detailed procedures, which could lead to complexities in implementation and potential inconsistencies.

Resource intensive: The comprehensive nature of the study design may require substantial resources and coordination, which could impact feasibility and scalability.

Limitations:

Attrition risks: The study may face challenges with participant retention, particularly if follow-up is required over an extended period, potentially affecting the completeness of the data.

Control group challenges: If the control group receives standard care, there may be variability in the quality of care, which could influence the outcomes and comparability between groups.

Measurement constraints: The accuracy of the results may be affected by limitations in the measurement tools used for assessing psychological outcomes and the effectiveness of the intervention.

Potential biases: Results might be influenced by biases in self-reporting or observational assessments, which could affect the accuracy of the outcome.

Generalizability issues: Findings may be specific to the study population and setting, potentially limiting the generalizability of the results to other contexts or populations. One of the primary factors potentially influencing the research outcomes is the stress induced by the NICU environment, which is further compounded by economic factors, insurance coverage, perceived support levels, and coping mechanisms for parental stress. To address these challenges, the study will measure these factors at the outset and use appropriate statistical methods to mitigate their impact. Additionally, cultural and religious factors may affect the research implementation process. Although efforts will be made to minimize their influence through enhanced interaction, detailed explanations of the research procedures, provision of privacy, and encouragement of active participation in infant care, complete control over these factors may not be entirely feasible.

Future studies could explore strategies to better manage these confounding variables, such as incorporating longitudinal designs to assess the long-term effects of family-centered care and examining the impact of additional support interventions tailored to specific cultural and economic contexts.

Conclusion

Parents experiencing psychological challenges following the birth of a baby with congenital malformations often hesitate to seek help or address their issues, sometimes due to unawareness. This research will aim to establish a pathway to assist these individuals in confronting this adversity, aligning with health policy benchmarks that emphasize the importance of mental health support and family involvement in neonatal care.

Implementing a family-centered care program will serve as a crucial intervention in NICUs to meet these benchmarks by:

1. *Enhancing parental engagement*: By involving parents more deeply in their infant's care, the program will promote greater parental control and reduce stress,

which is consistent with policies advocating for patient and family engagement.
2. *Providing mental health support*: Addressing psychological outcomes, such as anger and PTSD will align with health policies that recognize the need for comprehensive mental health support for families dealing with neonatal health challenges.
3. *Reducing health disparities*: By offering targeted interventions for parents of infants with congenital malformations, the study will contribute to reducing health disparities and ensuring equitable care, a key health policy goal.

Future health policies could be informed by the findings of this study, advocating for the integration of family-centered care practices into standard NICU protocols. This will ensure that parents receive the necessary support and training, ultimately leading to improved psychological outcomes and fostering a more resilient healthcare system.

However, no studies focusing on family-centered intervention and its implementation techniques for parents of infants with abnormalities have been identified, rendering this article unique in this regard. The findings of this study will provide guidance for healthcare professionals to implement effective family-centered care for parents of infants, ultimately contributing to improved psychological outcomes and aligning with health policy benchmarks aimed at enhancing family involvement and mental health support in neonatal care.

Ethical approval and consent to participate

This research received approval from the Ethics in Research committee of the Research and Technology Vice-Chancellor of Isfahan University of Medical Sciences, documented with the registration number IR.MUI.NUREMA.REC.1401.067. Furthermore, it was registered with the Iranian Registry of Clinical Trials (IRCT) under the identifier IRCT20220605055080N1 on August 27, 2022. Following the referral to the hospital, the necessary ethics code was acquired, and coordination was established with the relevant authorities. Subsequently, a comprehensive explanation of the research methodology was provided to the parents, leading to written informed consent from the parents.

Consent for publication

All authors hereby give their consent for the publication of "Study Protocol: The effect of a family-centered care program on the psychological outcomes of births with congenital malformations," including any associated materials, figures, or data. We understand that the manuscript will be made publicly available and may be accessed by individuals worldwide.

Acknowledgement

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Author's contributions

FV, AN and FK all contributed to various aspects of the research, including design, implementation, result analysis, and manuscript writing, MT: Result analysis, ZH: Design, and manuscript writing.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Conflicts of interest

There are no conflicts of interest.

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