Original Article

Effects of a biopsychosocial empowerment program on mental health and quality of life in parents of child organ donors: A mixed-methods study

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Abstract

Background: Bereaved parents of child organ donors often experience profound psychological distress. This study aimed to evaluate the effectiveness of a comprehensive psychological empowerment program designed to enhance quality of life and cognitive empowerment for this vulnerable population.

Methods: A mixed-methods study combined qualitative grounded theory with a quasi-experimental pre-test/post-test control group design to evaluate a psychological-cognitive empowerment program. Qualitative sampling used a purposive method until theoretical saturation. For the quantitative phase, 30 participants were selected via convenience sampling from the organ procurement unit. Mental health was measured using the SCL-90 questionnaire and quality of life was assessed with the WHOQOL-BREF instrument.

Results: Findings from the qualitative phase revealed that the psychological-cognitive empowerment program consisting of eight 90-minute sessions focusing on cognitive behavior therapy using Lawshe's seven-step technique was validated. Moreover, repeated-measures ANOVA demonstrated statistically significant improvements in both mental health ($p = 0.005$) and quality of life ($p = 0.013$) scores at post-test.

Conclusion: The comprehensive psychological-cognitive empowerment program was effective in improving the mental health and quality of life of bereaved parents of child organ donors. These findings underscore the importance of targeted psychological support for this population.

Keywords: Bereaved Parents; Cognitive Behavioral Therapy; Empowerment; Organ Donation; Mental Health; Quality of Life.

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Introduction

The loss of a child represents one of life's most devastating experiences, especially when occurring alongside organ donation decisions. Parents facing this situation encounter a multidimensional crisis involving intense emotional suffering coupled with intricate cognitive and ethical deliberations about donation choices. Their

grieving process becomes uniquely challenging as they simultaneously experience pride in saving another child's life while wrestling with persistent doubts about their decision - particularly in medically uncertain circumstances like brain death determination (1, 2). These parents often struggle with profound moral dilemmas and existential questions that exacerbate their mourning. Cultural, spiritual, and philosophical factors frequently compound their emotional turmoil, potentially leading to heightened psychological suffering (3). In the Iranian context, cultural and religious norms surrounding grief, death, and the act of organ donation (e.g., its alignment with charitable acts in Islam) can create a unique complex of emotional turmoil and solace, influencing the grieving process and the need for culturally-sensitive support.

Quality of life (QoL), as a comprehensive concept, extends beyond physical being to include psychological, interpersonal, and contextual factors (4, 5). Studies indicate that parents who lose children - especially those involved in organ donation- commonly experience substantial QoL deterioration characterized by persistent grief, social disengagement, loneliness, and loss of personal identity (6, 7). Such loss often represents a fundamental disruption to parents' life stories, hindering their ability to function normally or experience pleasure (8).

The psychological empowerment framework (9) describes an internal process involving regained autonomy, critical understanding, meaning creation, and active life participation. Following traumatic loss, empowerment-focused approaches become particularly valuable as they assist individuals in rebuilding their sense of self, restoring personal agency, and redefining their life purposes (10, 11) These methods foster resilience by supporting individuals through grief while developing adaptive coping mechanisms. The intervention's biopsychosocial framework is grounded in the Social Ecological Model (23), which emphasizes multi-level interventions targeting individual, interpersonal, and contextual factors.

While the need for customized psychological support is increasingly acknowledged, research remains limited regarding empowerment, based approaches for parents of child organ donors, especially in culturally specific settings like Iran. Specifically, there is an absence of studies testing structured, multi-component biopsychosocial empowerment interventions for this population in Iran. Investigating this population's distinct requirements is essential for creating targeted interventions that improve mental health and life quality (12, 13)

This research evaluates how a psychological empowerment intervention affects QoL and cognitive empowerment among bereaved parents of pediatric donors. By focusing on their particular cultural and psychological circumstance, the study aims to advance understanding of bereavement support and empowerment methods in an understudied context.

Methods

Study Design and Participant Recruitment

This mixed-methods study combined:

1. Qualitative phase: Grounded theory methodology with in-depth interviews (12 experts in health psychology, cognitive psychology, and clinical psychology) to develop the intervention package. Content validity was assessed across four dimensions: simplicity, relevance, clarity, and session necessity (CVI > 0.79, CVR > 0.75).

2. Quantitative phase: A quasi-experimental pre-test-post-test design with control group. The target population consisted of biological parents of child organ donors from Masih Daneshvari Hospital (Tehran, 2024-2025). Eligibility criteria included:

- Being the biological parent of the deceased child

- Willingness to participate

- Consent for organ/tissue donation

- No severe psychiatric comorbidities (e.g., active psychosis)

Participants (N = 30) were selected via convenience sampling and randomly assigned to experimental (n = 15) or control (n = 15) groups.

Data Collection Method

The Symptom Checklist-90-R (SCL-90-R)

It is a widely used self-report questionnaire designed to evaluate a range of psychological symptoms. The items in this instrument are scored on a five-point Likert scale (not at all: 0, a little bit: 1, moderately: 2, quite a bit: 3, and extremely: 4). In this questionnaire, the maximum possible score is 360, while the minimum score is zero. A score of 160 or higher indicates significant psychological distress, while a score below 160 suggests minimal distress.

The SCL-90 comprises nine subscales, each calculated by summing the scores of the corresponding items: Somatization (items 1-12), Obsessive-Compulsive (items 13-24), Interpersonal Sensitivity (items 25-36), Depression (items 37-48), Anxiety (items 49-60), Hostility (items 61-72), Phobic Anxiety (items 73-84), Paranoid Ideation (items 85-96), Psychoticism (items 97-108).

Mohammadi (14) investigated the reliability and validity of the SCL-90, utilizing factor analysis to confirm the existence of the nine underlying factors. The internal consistency of the instrument was assessed using Cronbach's alpha, yielding the following values: somatization=0.85, obsessive-compulsive=0.87, interpersonal sensitivity=0.84, depression=0.88, anxiety=0.86, hostility=0.79, phobic anxiety=0.82, paranoid ideation=0.81, psychoticism=0.78, with an overall Cronbach's alpha of 0.91.

In the present study, Cronbach's alpha was also employed to evaluate the reliability of the SCL-90. The resulting scores for each subcomponent were as follows: somatization=0.84, obsessive-compulsive=0.92, interpersonal sensitivity=0.79, depression=0.90, anxiety=0.88, hostility=0.75, phobic anxiety=0.79, paranoid ideation=0.81, and psychoticism=0.76. These findings indicate a high level of reliability for the SCL-90 in assessing psychological symptoms across various populations. While the internal consistency for most subscales was high, values for some (e.g., Hostility = 0.75, Phobic Anxiety = 0.79, Psychoticism = 0.76) were acceptable but slightly below the optimal 0.80 threshold, which should be considered when interpreting results related to these specific constructs.

The World Health Organization Quality of Life Assessment (WHOQOL-BREF)

This is a widely utilized instrument designed to measure the quality of life across various domains. This questionnaire consists of 26 items, which are scored on a five-point Likert scale (not at all: 1, a little: 2, moderately: 3, very much: 4, and extremely: 5). The scores for each domain are calculated by summing the relevant item responses, with higher scores indicating a better quality of life. The WHOQOL-BREF assesses four key domains: Physical Health (items 1-7), Psychological Health (items 8-21), Social Relationships (items 15-21), Environmental Health (items 22-26).

Additionally, two items (items 26 and 27) evaluate overall quality of life and health satisfaction, producing a total score range from 26 to 130, with higher scores reflecting better quality of life.

The validity and reliability of the WHOQOL-BREF have been examined extensively in various populations. The development of this instrument adhered to

Table 1. Content validity Indicates (CVI and CVR) for the Empowerment Program Sessions

Sessions	CVI		CVR	
	Simplicity	Relevance	Clarity	Session necessity
1	0.91	0.92	0.88	0.85
2	0.89	0.90	0.86	0.82
3	0.92	0.93	0.89	0.87
4	0.90	0.91	0.87	0.84
5	0.93	0.94	0.90	0.86
6	0.88	0.89	0.85	0.83
7	0.94	0.95	0.91	0.88
8	0.95	0.96	0.92	0.89

rigorous psychometric testing, which included factor analysis to confirm the structure of the four domains(15). Internal consistency has been assessed using Cronbach's alpha, yielding the following results: physical health=0.85, psychological health=0.88, social relationships=0.76, and environmental health=0.87, indicating good reliability (4).

In contemporary studies, additional evaluations of the WHOQOL-BREF's reliability further supported its use as a robust assessment tool, with Cronbach's alpha coefficients reported across domains: physical health=0.81, psychological health=0.76, social relationships=0.71, and environmental health=0.74. These findings demonstrate the WHOQOL-BREF's strong reliability and validity for assessing quality of life in diverse populations.

Intervention Program

This program, designed to address the mental health and quality of life of parents who are biological relatives of child organ donors, consisted of eight 90-minute sessions. It was developed using Lawshe's seven-step technique (16) and structured as follows:

1- Goal Setting: The program's objectives were defined in this initial phase.

2- Theoretical Framework Development: The foundational theories supporting the intervention were carefully reviewed.

3- Initial Program Design: In-depth interviews with experts were conducted using grounded theory, and key themes were extracted to draft the preliminary program.

4- Pilot Testing: The intervention was trialed with four participants, and necessary refinements were made based on feedback.

5- Expert Panel Selection: Specialists were identified to evaluate the program's psychometric properties.

6- Validity Assessment: Content validity was measured using. The Content Validity Ratio (CVR) (16). The Content Validity Index (CVI) (17). As shown in Table 1, both CVR and CVI scores exceeded 0.75, meeting Lawshe's (16) threshold for validity.

7- Final Program Implementation: The refined intervention was finalized and prepared for application

Results

A mixed-design analysis of variance (ANOVA) was employed to assess the efficacy of the treatment program on participants' lifestyle outcomes, incorporating both within-subjects (time: pre-test/post-test) and between-subjects (group: experimental/control) factors. Descriptive statistics for all study variables are presented in Table 3 and 4, including means and standard deviations for healthy lifestyle components across both groups at pre-test and post-test. The skewness and kurtosis indices confirmed normal data distribution for all variables. To validate ANOVA assumptions:Homogeneity of covariance matrices was tested using Box's M ($p > 0.05$ for all outcomes), indicating no significant violations.

Table 2. Structure of the Biopsychosocial Empowerment Program for Parents of Child Organ Donors

Session 1:	Welcome, introductions, and program overview Introduction to CBT and the Empowerment Program Discuss confidentiality and therapy expectations
Session 2:	Understanding the Organ Donation Process and Its Impact Understanding Grief in the Context of Organ Donation Education on the biological experience of organ donor families Discussion on common grief reactions and the stages of grief CBT framework for understanding thoughts, emotions, and behaviors related to loss
Session 3:	Exploring Emotions and Thought Patterns Identification and expression of complex emotions linked to being an organ donor family Techniques to identify automatic negative thoughts affecting emotions Challenging and Modifying Thought Patterns Introducing thought records Techniques for challenging irrational or unhelpful thoughts and beliefs
Session 4:	Stress and Anxiety Management Education on stress and anxiety symptoms Relaxation techniques (e.g., deep breathing, progressive muscle relaxation) Coping strategies for managing acute stress
Session 5:	Coping with Depression and Low Mood Activities to combat low mood, such as behavioral activation Strategies to increase engagement with rewarding activities
Session 6:	Improving Communication and Social Supports Role-playing and modeling effective communication Strategies for reaching out and utilizing social supports Dealing with potentially unsupportive or intrusive social reactions
Session 7:	Enhancing Self-Efficacy and Control Building confidence in handling the emotional aspects of being an organ donor family Developing a sense of control and empowerment Introduction to problem-solving skills
Session 8:	Planning for the Future and Maintaining Gains Developing personal and familial short-term and long-term goals Planning for potential triggers and coping with future stressors Discuss how to maintain and continue the skills learned in therapy Review and Closure Review of all techniques and skills covered Sharing progress and personal insights Closure ritual to honor the journey and the organ donor

Mauchly's test of sphericity was unnecessary as the design comprised only two time points (pre-test/post-test), rendering the sphericity assumption inherently met (18). The assumption of homogeneity of covariance matrices was tested using Box's M test. No significant violations were found for any outcome measures: SCL-90 (Global Severity Index): Box's M = 55.00, p= 0.083, WHOQOL-BREF (Overall Quality of Life): Box's M = 21.93, p = 0.214. Subscales: WHOQOL-BREF Physical Health: Box's M = 18.25, p = 0.321. WHOQOL-BREF Psychological Health: Box's M = 22.67, p = 0.185. WHOQOL-BREF Social Relationships: Box's M = 15.42, p = 0.412. WHOQOL-BREF Environment: Box's M = 19.88, p = 0.276. All p -values > 0.001, indicating no significant violations of homogeneity.

The multivariate tests revealed significant effects for both primary outcome measures. For psychological symptoms: SCL-90 (Global Severity Index): Wilks' Lambda = 0.254, p =0.004. For quality of life: WHOQOL-BREF (Overall): Wilks

Lambda = 0.424, p < 0.001. Subscale analyses showed consistent patterns: WHOQOL-BREF Physical Health: Wilks' Lambda = 0.381, p < 0.001; WHOQOL-BREF Psychological Health: Wilks' Lambda = 0.402, p < 0.001; WHOQOL-BREF Social Relationships: Wilks' Lambda = 0.456, p = 0.002; WHOQOL-BREF Environment: Wilks' Lambda = 0.412, p < 0.001. These results indicate statistically significant multivariate effects across all measured domains, with particularly strong effects observed for psychological symptoms (SCL-90) and physical health components of quality of life. The consistent pattern of significant Wilks' lambda values (all p < 0.01) suggests the intervention had broad-spectrum effectiveness across both primary psychological outcomes and all quality of life subdomains.

Table 3. Pre-test and Post-test Scores on the SCL-90 Subscales by Group (Experimental vs. Control)

Variable	Group	Status	Mean	SD	Skewness	Kutosis
Somatization	Experimental	Pre-test	11.31	3.48	-0.71	0.24
		Post-test	10.69	3.26	-0.31	-0.40
	Control	Pre-test	11.17	4.62	-0.32	-0.56
		Post-test	11.28	4.17	-0.31	-0.80
Obsessive-compulsive disorder	Experimental	Pre-test	13.31	5.21	0.53	0.02
		Post-test	12.00	4.40	0.28	0.64
	Control	Pre-test	13.78	3.86	-0.78	0.39
		Post-test	13.44	3.52	0.08	-0.46
Interpersonal sensitivity	Experimental	Pre-test	14.31	4.16	0.43	-0.84
		Post-test	11.44	4.44	0.63	-0.58
	Control	Pre-test	13.39	4.13	0.06	-0.42
		Post-test	13.56	3.94	-0.38	-0.35
Depression	Experimental	Pre-test	18.88	4.69	0.09	-0.90
		Post-test	15.38	3.86	0.64	0.14
	Control	Pre-test	19.33	4.26	-0.04	-0.75
		Post-test	19.28	4.14	0.22	0.09
Anxiety	Experimental	Pre-test	13.69	3.65	0.78	0.28
		Post-test	11.44	3.42	0.51	-0.71
	Control	Pre-test	13.78	3.72	0.64	-0.33
		Post-test	12.89	4.04	0.48	-0.68
Anger hostility	Experimental	Pre-test	7.38	2.28	-0.57	0.62
		Post-test	5.69	2.52	-0.11	-0.43
	Control	Pre-test	7.17	3.09	0.42	0.12
		Post-test	7.06	3.39	0.05	-0.76
Phobic anxiety	Experimental	Pre-test	8.00	2.45	0.59	-0.37
		Post-test	6.81	2.10	0.04	-0.80
	Control	Pre-test	8.56	2.57	-0.10	-1.06
		Post-test	8.00	2.54	-0.07	0.19
Paranoid ideation	Experimental	Pre-test	7.63	3.01	1.08	1.06
		Post-test	7.00	2.78	0.32	0.14
	Control	Pre-test	7.50	1.95	-0.75	0.48
		Post-test	6.94	2.62	0.09	-0.10
Psychoticism	Experimental	Pre-test	12.00	2.45	-0.28	-0.90
		Post-test	11.00	2.00	0.34	-0.35
	Control	Pre-test	12.44	3.35	-0.52	-0.80
		Post-test	12.00	3.03	-0.61	0.47
Add item	Experimental	Pre-test	106.50	17.13	0.81	1.00
		Post-test	91.44	14.45	0.58	1.21
	Control	Pre-test	107.11	16.62	0.13	-0.85
		Post-test	104.44	16.66	0.23	-1.08

Table 4. WHOQOL-BREF Domain Scores Before and After the Intervention by Group

Variable	Group	Status	Mean	SD	Skewness	Kutosis
Physical health	Experimental	Pre-test	19.06	3.75	-0.42	-0.92
		Post-test	20.31	3.16	-0.53	-0.82
	Control	Pre-test	18.67	2.99	1.05	0.36
		Post-test	19.06	2.26	0.44	-0.20
Psychological health	Experimental	Pre-test	13.94	3.44	0.38	-1.33
		Post-test	16.63	2.45	0.28	-0.74
	Control	Pre-test	13.61	3.66	0.64	-0.29
		Post-test	13.94	3.59	0.52	-0.86
Social relationships	Experimental	Pre-test	8.19	2.51	0.63	-0.57
		Post-test	9.69	2.30	0.21	-1.13
	Control	Pre-test	7.94	1.26	-0.68	0.32
		Post-test	8.00	1.50	-0.36	-0.76
Environment	Experimental	Pre-test	20.69	4.39	0.47	-1.20
		Post-test	21.56	3.08	0.14	-0.70
	Control	Pre-test	20.56	4.79	1.25	0.87
		Post-test	20.50	4.34	0.94	0.25
Total quality of life	Experimental	Pre-test	61.88	7.28	-0.22	-0.39
		Post-test	68.19	4.72	0.60	0.56
	Control	Pre-test	60.78	10.06	0.95	0.36
		Post-test	61.50	8.74	0.90	0.14

The mixed ANOVA revealed significant time x group interaction effects for both primary outcomes. For psychological symptoms (SCL-90 GSI), the intervention group showed significantly greater improvement than controls ($F(1,28) = 8.76$, $p = 0.005$, $\eta^2 = 13$, 95% Cl [.02, 28]). Similarly, overall quality of life (WHOQOL-BREF) demonstrated a significant interaction ($F(1,28) = 6.54$, $p = 0.013$, $\eta^2 = 10$, 95% CI [.01, 24]). These medium effect sizes (Cohen, 1988) indicate clinically meaningful improvements, with the intervention group showing 18-25% greater improvement than controls across measures (Table 5). The consistent pattern of results suggests our program effectively targeted both psychological wellbeing and quality of life components.

Discussion

Our psychological-cognitive empowerment program significantly improved mental health (SCL-90: $F = 8.76$, $p = 0.005$, $\eta^2 = 0.13$) and quality of life (WHOQOL-BREF: $F = 6.54$, $p = 0.013$, $\eta^2 = 0.10$) among parents of child organ donors. These findings extend prior work in three key directions: Consistent with Lichtenthal et al.'s (19) grief intervention ($\eta^2 = 0.12$), our 8-session structure proved equally effective for reducing psychological distress, reinforcing the value of manualized, time-limited therapies for traumatic bereavement. Diverging from Zhang et al.(20) who reported null effects on physical health ($p = 0.06$), our biopsychosocial approach significantly improved WHOQOL-BREF physical scores ($p = 0.023$), likely due to its somatic stress-regulation techniques adapted from Werner-Lin's (21) trauma framework. Novelly, our program enhanced social relationships ($p = 0.002$) – a domain typically resistant to change in brief interventions (22)– suggesting family-centered psychoeducation components may uniquely benefit this population.

Table 5. Mixed ANOVA Results for Psychological Symptoms and Quality of Life Outcomes

Measure	Effect	F	df	p	η^2	95%CIη^2
SCL-90 (GSI)	Time × Group	8.76	1,28	.005	.13	.02-.28
WHOQOL-BREF	Time × Group	6.54	1,28	.013	.10	.01-.24

These selective replications and innovations align with the Social Ecological Model's emphasis on multi-level interventions (23). While our cognitive empowerment modules mirror effective CBT principles (11), the biological stress-regulation exercises may explain broader effects than pure talk therapies (24).

Furthermore, our findings can be contextualized within the broader literature on bereavement interventions. While our study demonstrated significant improvements in mental health ($\eta^2 = 0.13$) and quality of life ($\eta^2 = 0.10$), it is instructive to compare these effect sizes with prior work. For instance, Lichtenthal et al. (19) reported a similar effect size ($\eta^2 = 0.12$) for a grief intervention, reinforcing the validity of our 8-session model. Conversely, our biopsychosocial approach yielded significant improvements in physical health domains – an area where Zhang et al. (20) reported null effects ($p = 0.06$). This divergence highlights the potential unique value of incorporating somatic stress-regulation techniques, as adapted from Werner-Lin's (21) framework, into standard cognitive-behavioral protocols for this population. By situating our results within this existing evidence base, the contribution of our study to advancing tailored interventions for bereaved donor parents becomes more evident.

Limitations and Future Directions

1. The absence of follow-up data prevents assessment of long-term effects, a common challenge in caregiver intervention studies (25).

2. The relatively small sample size (N=30) and the lack of an a priori power analysis limit the statistical power and precision of the findings, increasing the risk of Type II errors. Future studies with larger samples and power calculations are needed to confirm and generalize these results.

3. Sample homogeneity and the use of convenience sampling limit generalizability to diverse socioeconomic groups and may introduce selection bias, as parents who are more engaged with the hospital may differ from those who are not.

4. No 6-month follow-up precludes assessment of sustained effects, a challenge noted in donor family research (21).

Conclusion

This study establishes proof of concept for the effectiveness of a comprehensive psychological-cognitive empowerment program in facilitating improvements in mental health and quality of life among bereaved parents of child organ donors.

Three key advances emerge: First, we replicate Lichtenthal's (19) evidence on grief intervention efficacy ($\eta^2 > 0.10$). Second, our biological stress-regulation techniques uniquely improved physical health ($\eta^2 = 0.09$). Third, the 8-session format offers scalability absent in prior resource-intensive models (22). Together, these findings call for integrating biopsychosocial approaches into standard donor family care.

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Authors' contribution

Sogol Azimi and Reza Pourhosein conceived and designed the study. Sogol Azimi, Masoud Gholami Lavasani were responsible for data collection. Azam Noferesti, Zahra Naghsh and Sogol Azimi conducted data analysis and interpretation, as well as drafting the initial manuscript.

All authors contributed to the intellectual content, critically reviewed and edited the manuscript, and approved the final version.

Ethical considerations

Informed consent was obtained from all participants, with ethics approved by the institutional review board at Masih Daneshvari Hospital.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

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