

Validation of a Health Promotion Program for Infertile Couples with Unsuccessful Treatment: A Delphi Study

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Abstract

Background: Designing a health promotion program for infertile couples with unsuccessful treatment can play an important role in promoting their health in physical, social, psychological, and spiritual dimensions. There are different techniques for validation of programs. In this study, the Delphi technique was used to validate a health promotion program developed for infertile couples with unsuccessful treatment.

Purpose: Validating the health promotion program for infertile couples with unsuccessful treatment using the Delphi technique.

Methods: In this study, three rounds of Delphi were conducted with attendance of 17 specialists in different fields to validate the content of a health promotion program, which was developed based on a grounded theory study, review of literature, and focus group discussion. The selection of specialists was done by purposive and snowball sampling. In the first round of Delphi, the experts were asked to give feedback on the program draft. After analysis of the first round data and adding the new suggestions, in round two, members were asked to grade the value of statements based on the Likert scale to state their agreement. In the third round, the discussion on disagreements and reaching consensus was accomplished.

Results: The program was validated by all participants with 6 main themes and 45 strategies including the stakeholders' awareness and attitude (11 strategies), fair financial participation (4 strategies), improving the executive process (6 strategies), psychological and counseling support (11 strategies), resolving legal, managerial, religious and ethical challenges (6 strategies), and logistic facilities (7 strategies) at a consensus level of at least 70%.

Conclusions: The validated program proposes clear and functional strategies for implementation of a health promotion program for infertile couples with unsuccessful treatment.

Background

Infertility has been considered as a turbulent crisis of life for couples (1). Today, assisted reproductive techniques (ARTs) are more common and their use is increasing. A significant number of couples, who cannot naturally have children, seek the assisted reproductive techniques (2). Specialists recommend a variety of treatments for these couples, such as medication, surgery, and assisted reproduction (3). There are increasing numbers of infertility treatment centers and specialists in this field (4). Success rate for assisted reproductive techniques has improved significantly, but only 35% of couples have had pregnancy with these methods (5). Therefore, many couples experience unsuccessful treatment (6). These unsuccessful efforts can lead to acute clinical depression and other problems (7). Psychological, physical, economic, and social pressures resulting from infertility treatment cause infertile patients to discontinue treatment before they become tired of other treatment options (8).

Since the infertility treatment often focuses on the medical and technical aspects of infertility, some emotional and social aspects, such as psychological distress have not been given much attention. It should be noted that physical infertility treatment alone is often not enough, but paying attention to psychological needs of infertile couples is an essential part of the success of infertility treatment (9). In this regard, the research team in the previous study designed a health promotion program following the need assessment of infertile couples after exposure to unsuccessful treatment. Health promotion planning includes designing a series of ongoing activities to achieve one or more strategies for creating changes in behavioral, environmental, and legal perspectives at the social level to improve the health status of a particular group in society (10). It is necessary to validate the content in order to examine the impact of a program in wider studies(11).

Among types of validation, the content validation is the most important type of licensed programs (12). Content validation is a qualitative type of validation in which the concept scope is clear, and the judgment clearly represents the scope (Derast, quoted in Belan, 1989) (13). Content validation methods are known as judgmental methods, in which the measurement tools are judged and examined. Specialists' judgment is used to determine the content validity (13, 14). Bakas et al. (2009) conducted a study with an aim to validate the content of Telephone Assessment and Skill-Building Kit (TASK) program as an 8-week follow-up program based on an individual assessment of the care needs of patients with heart attack. During the development of this program, its components were validated by ten specialists in terms of accuracy, ease and acceptance ((15)). Delphi technique is a validation technique of program content (16). In previous studies, Delphi technique was also used to validate health promotion programs (11–13, 15, 17). Delphi technique is an organized process in which questionnaires or rounds are used to collect data or feedback. The rounds are held until the group reaches a consensus (17, 18). Despite the fact that the collective judgment of specialists seems mental in this technique, it is more valid than individual statements because it produces more objective results (19). A main reason for the popularity of this technique is that it involves a large number of people in different places with different specialties, and thus, the dominance of one or more individuals over the consensus process is avoided (18). A basic feature and benefit of using the Delphi process is that the individuals' names are not disclosed. In this way, the influence of dominant individuals, which may affect the process of data collection and analysis, decreases (17). The present study was derived from a doctoral thesis that first designed a health promotion program for infertile couples with unsuccessful treatment in Iran, and the program was then validated using Delphi method in three rounds.

Method

After designing the Health Promotion Program, it was validated by 17 specialists using the Delphi technique from June 26 to December 6, 2018. Four key activities in the Delphi technique include identifying the problem, selecting experts, determining the group size, and performing Delphi rounds (20).

To identify the problem, Delphi questionnaire was designed by the research team based on the content of the Health Promotion program using the Grounded theory study, review of quantitative and qualitative

texts, and a focus group discussion. The selection of specialists was performed by purposive and snowball sampling. The Delphi questionnaire was sent to them via e-mail or print of the questionnaire in person; and they were asked to review the written content and express their views on the strategies. The responses returned via e-mail, SMS, phone call, and face-to-face visits were reviewed and summarized. The summary report was re-sent to specialists who were allowed to change their own answers according to the report.

Participants were selected at five stages of preparation for selection, population determination by name, introduction of other specialists, ranking the specialists, and invitation of specialists. At the preparation stage for the selection, the disciplines and centers related to the research topic were identified, including the infertility center directors, gynecologists, reproductive health specialists, faculty members, center staff, and infertile couples. In fact, qualified people with a background in the issue were invited to Delphi study. At the population determination by name, the names of individuals who were identified at the first stage, were written. At the stage of introducing other specialists, we contacted the specialists listed at the previous stage; and a list of other specialists was identified by them. At the ranking stage, the identified specialists were ranked. At the invitation stage, higher level specialists were invited after ranking.

In Delphi technique, the number of participants is usually less than 50 and often between 15 and 20 (21). In the present study, 13 specialists (a gynecologist, three reproductive health specialists, three faculty members of midwifery, four masters of midwifery, and two bachelors of midwifery) as well as five participants with unsuccessful infertility treatment (a master of midwifery and her husband who was a traditional medicine specialist, a bachelor of midwifery and her husband, a master of law, and a nurse practitioner with a doctorate degree) were invited to participate in Delphi rounds. 17 out of 18 participants completed the study, and a bachelor of midwifery did not participate in the third round.

In the first round, the Delphi questionnaire was started based on strategies derived from the program and closed-ended and open-ended questions. Members were asked in the Delphi questionnaire to answer the closed-ended questions, review the texts and focus group in the qualitative section of study; and mention the gaps or other opportunities affecting the design of the health promotion program if there were not included in the questionnaire. After receiving the answers, the researchers converted the collected data into a fully organized questionnaire. The questionnaire was used as a research tool for the second round of data collection. In the round, the program was referred to specialists who were asked to examine the content in three fields, clarity (clarity of content and no ambiguity), validity (connection of details of the program with the subject) and usability (the feasibility of implementing the program in infertility centers of Iran) and express their opinions in open-ended responses to the program.

In the second round, each Delphi method participant received the second questionnaire, and was asked to rate the items summarized by the researchers based on the data provided in the first round according to the Likert scale (weak with a score of 1–3, medium with a score of 4–6, and high with a score of 7–9). On this basis, it might be necessary for Delphi method participants to use a ranking scale in order to create initial priorities among the items; hence, the issues of agreement and disagreement could be

identified (22) and a space could be created to identify new ideas, correct, interpret, eliminate and explain their strengths and weaknesses. In some cases, participants were even asked to express their reasoning and prioritization of options. In this round, the panel members' motivation for higher participation increased because they received feedback from their answers and were eager to determine the quality of their colleagues' answers (23). During this round, members participating in the Delphi Method expressed their levels of agreement on the program strategies using the Likert scale.

In the third round, each Delphi member received a questionnaire including cases and rankings summarized by researchers in the previous round, and they were asked to reconsider their views and judgments or state their reasons for non-consensus (22). Here, new predictions were provided by ranking the comments; and statistical summaries of answers were prepared. From this round on, members reconsider their responses and those of others; and the process was repeated until all new ideas were presented and the strengths and weaknesses of all opinions were identified. In this round, statements of the previous round were presented along with a summary of other findings in the group. In this round, the group members could change their opinions according to opinions of other group members (23). It should be noted that number of Delphi repetitions in the degree of consensus were largely depended on the researchers and could be from 3 to 5 (22).

During this round, members of the Delphi method received a questionnaire, including cases and rankings summarized by researchers in the previous round, and were asked to reconsider their opinions and judgments, reconsider their answers and those of others, and explain their reasons for disagreement. It should be noted that the Delphi method continued for three rounds until reaching a consensus in the present study, and finally the consensus views were presented as a final plan. In results of studies, a different range of consensus level from 51–100% was reported (24). In the present study, the consensus level was considered to be at least 70%. The consensus level of each statement was obtained in a way that the maximum number of members, who responded to one of the Likert numbers, was divided by the total number of members participating in Delphi method; and the resulting number was multiplied by 100.

Results

The program was confirmed with 6 main themes and 45 items including the stakeholders' awareness and attitude (11 strategies), fair financial participation (4 strategies), improving the executive process (6 strategies), psychological and counseling support (11 strategies), resolving legal, managerial, religious and ethical challenges (6 strategies), and logistic facilities (7 strategies) as follows:

A. Stakeholders' awareness and attitude

- 1. Preparing a training package proportional to the target group (self-learning) in CDs, Pamphlets, educational pamphlets, and booklets**
- 2. Holding individual counseling sessions (face to face)**
- 3. Holding group counseling sessions (explanatory workshops)**
- 4. Establishment of continuous answering centers (24 hours) as websites, Interactive Voice Response (IVR), and the availability of face-to-face response units.**
- 5. Creating a patient and mobile training unit**
- 6. Holding communication workshops with the patient for all treatment staff**
- 7. Holding training courses for specialized personnel to update them (inside or outside Iran)**
- 8. Defining educational competence for service providers**
- 9. Creating specialized fields in master's and doctoral degrees for infertility counseling**
- 10. Setting up virtual sites to inform and provide advice to infertile couples due to the widespread use of virtual networks**
- 11. Holding classes for the families of infertile couples**

B. Fair financial participation

1. Proportion of insurance support services through interaction with insurance companies (in the form of placing patients in different levels of support)
2. Proportional financial coverage of special target groups
3. Covering the relevant expenses through interaction with donors and non-governmental organizations
4. Allocating the low-interest or interest-free loans for special target groups

C. Improving the executive process

1. Development, promotion, documentation and information of relevant executive processes (how to receive services, interaction with insurance companies)
2. Preparing an electronic file for patients or online software
3. Establishing the referral systems
4. Invisible supervision and control of specialists by relevant authorities can help improve communication with patients.
5. High supervision is necessary in some private centers for surgery and non-indicative procedures.
6. Developing rules and regulations, and imposing them firmly for medical errors in infertility

D. Psychological and counseling support

1. Creating a field of psychological counseling in the center
2. Proper communication with patients by all staff
3. Creating counseling and follow-up of patients after unsuccessful treatment in the form of how to continue or discontinue treatment and alternative methods
4. Focus on acquiring communication skills when hiring work forces
5. Continuation of communication workshops for all people involved in patients' status
6. It is necessary to create appropriate training classes for staff of centers to learn and repair them and respect the men's dignity.
7. The necessity of a psychological and scientific (combined) counseling center to guide about the continuation of treatment.
8. Providing advice for unsuccessful infertile people for appropriate alternatives
9. Passing counseling courses by staff to learn how to advise infertile couples
10. Hiring personnel who have completed additional courses to work in infertility treatment units
11. Hiring staff who have also experienced infertility.

E. Resolving legal, managerial, religious and ethical challenges

1. Observing the patient's privacy
2. Eliminating the unnecessary operations and tests (final protocol decision by a committee consisting of two center specialists and a staff aware of the patient's treatment and morale)
3. Focus of all services in the center as consulting departments, laboratory, pharmacy (supply without restrictions of drugs) and centralization
4. Developing the inter-sectoral and interdisciplinary cooperation
5. Preparing a map of center and presenting it to the client on arrival
6. Hiring the friendly staff at the beginning of the client's arrival

F. Logistic facilities

1. Increasing the employment of skilled specialists, midwives, and nurses
2. Requesting to improve the queuing system of centers
3. Possibility of temporary accommodation for patients of other cities
4. Possibility of short-term hospitalization
5. Creating a research field in the center
6. Research on new treatment options
7. Establishing the pregnancy care centers in infertility centers

The first round started on 26/7/2018 and continued until 29/9/2018. The first stage analysis was performed after collecting the questionnaires on 6/10/2018. The cases suggested by the individuals were examined and the items of the second round of Delphi were added. At this stage, the amount of agreement on all above sentences was greater than the median 5.

The second round started on 7/10/2018 and continued until 28/10/2018. The second stage analysis was performed after collecting the questionnaires on 30/10/2018. The cases suggested by individuals were examined and were added to the third round items of Delphi. Results of the second Delphi round were expressed as median and mean, and the phrase "Not respecting the dignity of infertile men in some medical centers" was identified and eliminated as an insignificant index.

The strategy of "formulating firm rules and regulations and implementing in medical errors in infertility" was added and revised. All participants confirmed most of the items. The main statistics used at this stage included central sizes (mean and median).

The third round started on 31/10/2018 and continued until 6/12/2018. The second stage analysis was performed after collecting the questionnaires on 29/11/2018. The comments were ranked, new predictions were presented, and statistical summaries of the responses were prepared. Members reviewed their responses and those of others, and the process was repeated until new ideas were achieved and the strengths and weaknesses of all opinions were identified. In this round, the statements of the previous round were presented with a summary of other findings in the group. In this round, no item was deleted or added, and the members were discussed face-to-face with 6 panel members.

Discussion

The present study, which was conducted by Delphi method, examined the content validity of the health promotion program for infertile couples with unsuccessful treatment. The study confirmed six main themes, namely stakeholders' awareness and attitude, fair financial participation, improving the executive process, psychological and counseling support, solving legal and managerial, Sharia and ethical challenges, and logistics facilities.

Zahmatkeshan et al. (2019) conducted a cross-sectional descriptive study with an aim to design the infertility monitoring system. Data were collected from infertility clinics around the world and some reputable sites such as the WHO. In order to decide on the data elements, the Delphi technique was utilized using a questionnaire including data elements distributed among 12 specialists, including a reproductive endocrine gland and infertility fellow, six obstetricians, two biological reproduction specialists, two urologists, and a social medicine specialist. Using a 5-point Likert scale, the questionnaire was divided into two categories: managerial and clinical. The above study reported the criteria that can be used to ensure the quality of infertility care (25). In the present study, a 9-point Likert scale was used and the validity of the health promotion program was approved.

In addition to specialists, infertile couples also participated in the present study. Dancet EA. et al. (2013) in their study on six dimensions of infertility care quality (26) and Den Breejen E.M. et al. (2013) in their study on the development of guide-based indices in patient-based fertility care (27) used the Delphi technique according to the consensus of specialists' and patients' views (26, 27)

In the present study, Delphi questions included the structured questions from grounded theory study, review of quantitative and qualitative texts, and focus groups, as well as open-ended questions that were modified versions of Delphi technique. The method aimed to maximize the response rate in the first round and ensure that important issues were selected, otherwise it was likely to be eliminated by experts, as well as increasing the likelihood of reaching a consensus more effectively. This method has been also used in other studies (28, 29).

In Dancet's study, the gynecologists, embryologists, counselors, nurses/ midwives, and patients participated in three Delphi rounds. Ranking the quality dimensions was important in terms of safety, effectiveness, patient-centeredness, productivity, timeliness, and fairness, respectively (29). In the present study, the gynecologists, university professors, reproductive health doctors, midwives, and patients participated in three rounds, and 6 health promotion programs were approved by Delphi method. In the Delphi technique, selecting the right people is the most important step in the whole process because the quality of results depends directly on it. Since the Delphi technique focuses on extracting expert opinions over a short period of time, the selection of individuals generally depends on the expertise in a particular field. However, it includes non-specialists and enthusiasts (20). The number of Delphi repetitions in the degree of consensus largely depends on the researchers and can be from 3 to 5 (22).

A strength of the present study was the selection of specialists in various fields, some of whom had executive posts in various centers and cities, most of them were academics, and some experienced unsuccessful treatment. Furthermore, the health promotion program was first designed for infertile couples with unsuccessful treatment in Iran according to the researchers' review of various sources; and its content validity was performed using the Delphi technique. The limitation of study was the lack of interaction between members that was also a limitation of Delphi technique.

Conclusions

It seems that implementing the validated health promotion program in infertility treatment centers could provide special services for infertile couples with unsuccessful treatment and lead to promotion of health in this vulnerable group in the society. In the present study, clear and functional strategies were proposed to achieve a health promotion program for infertile couples with unsuccessful treatment in fertility centers.

Abbreviations

ARTs

Assisted reproductive techniques

TASK

Telephone Assessment and Skill-Building Kit

WHO

World health organization

Declarations

Ethics approval and consent to participate:

The present study was approved in the Local Research Ethics Committee, Mashhad University of Medical Sciences, Mashhad, Iran (Code: Research Ethics Committee.1395.120.)

Consent for publication: *Not applicable*

Availability of data and material: *Supplementary files were uploaded.*

Competing interests: *The authors declare that they have no competing interests.*

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Authors' contributions:

SEZ has made substantial contributions to the conception, design of the work; interpretation of data; and has drafted the work. RJhas made substantial contributions to interpretation of the data; and revision of the manuscript. SMMBand MA have made substantial contributions to the design of the work; and substantively revised it. All authors read and approved the final manuscript. RLR has made substantial contributions to the conception, design of the work; interpretation of data; and substantively revision of the manuscript.

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