Development and Psychometric Assessment of the Need Assessment Tool for Women with the Experience of Pregnancy Termination due to Fetal Anomalys

Abstract

Introduction: Fetal anomaly, especially when results in pregnancy termination, is a great challenge for pregnant women. Pregnancy termination can have a great somatic, mental and social impact on women and their families. On the other hand women who experience pregnancy termination due to fetal anomaly have not yet received proper attention and support by researchers and health policy makers. The aim of the present study is to explain the experience of women who underwent pregnancy termination due to fetal anomaly and to develop and assess the psychometric properties of a specific tool to assess the needs of these women.

Materials and methods: This sequential explanatory mixed method study which will be conducted in two phases. The first phase is a qualitative study based on purposeful sampling among women with the experience of pregnancy termination due to fetal anomaly and their spouses, midwives, gynecologists and forensic medicine specialists in Rasht, Iran. Subject recruitment will be continued till reaching data saturation. Data collection is performed based on semi-structural interview and record field notes. Data will be analyzed simultaneously using qualitative content analysis method. The draft of the need assessment of women with the experience of pregnancy termination due to fetal anomaly questionnaire will be prepared based on the findings of the first phase as well as literature review. The questionnaire will then be finalized based on evaluations in an expert panel. The face and content validity as well as reliability of the questionnaire will be performed after generating questionnaire items. Construct validity will be assessed using the exploratory factor analysis through a descriptive cross-sectional study on women with the experience of pregnancy termination due to fetal anomaly. Sample size is calculated based on the required sample size for factor analysis for identifying the factors of the questionnaire. Therefore data will be collected from health and treatment centers based on simple random sampling. Data will be analyzed using descriptive and inferential analyses.

Conclusion: The developed questionnaire in this sequential explanatory design study can be used in the interventions, supporting and curative programs of the Ministry of Health and Medical Education for women with the experience of pregnancy termination due to fetal anomaly.

Keywords: Tool development; Psychometric properties; Need assessment; Pregnancy termination; Fetal anomaly; Mixed methods study

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Introduction

Pregnancy is a pleasant experience and is accompanied with unique psychosomatic changes in women. The recent progress in diagnostic technologies in the field of reproductive medicine has led to provision of a variety of screening tests for fetal anomaly (1). Fetal anomalies are defined as all genetic and structural anomalies at ovum fertilization or during the intra-uterine development (2). Fetal anomalies approximately occur in 2-3% of pregnancies (2). The prevalence of fetal anomalies varies in different populations and range from 1.07% in Japan to 4.3% in Taiwan (3).

Fetal anomaly creates a great challenge for pregnant mothers to choose between continuation of pregnancy and elective termination of pregnancy or empirical fetal treatment in specific cases. Decision to terminate pregnancy is hard and complicated and the limitations in the diagnosis of fetal anomalys increase the complexity of decision making. Mothers have a crucial role in the decision making for pregnancy termination and thus the grief after pregnancy termination due to fetal anomaly is widely different from the grief after abortion or fetal death (4).

Regardless of the somatic, psychological and social outcomes, women who experience pregnancy termination due to fetal anomaly have been neglected in supportive systems by researches and health policy makers. Unfortunately, no study has yet been conducted in Iran on this issue. Considering the various consequences of pregnancy termination due to fetal anomaly, it is necessary to have a need assessment instrument for women with the experience of pregnancy termination due to fetal anomaly based on the cultural characteristics of this population in Iran. This need assessment tool is necessary for further actions in fundamental and universal support systems. An eminent pregnancy health service should consider the special needs of this population reflecting the individual, cultural, religious and ethical characteristics of the target population. The aim of this study was to determine the experience of women who chose to terminate their pregnancy due to fetal anomaly and to design and assess the psychometric properties of a need assessment tool.

Specific objectives

- To identify the needs of women with the experience of pregnancy termination due to fetal anomaly
- To define the items of the need assessment tool for women with the experience of pregnancy termination due to fetal anomaly
- To assess the psychometric properties of the need assessment tool for women with the experience of pregnancy termination due to fetal anomaly

Materials and methods

This study will be conducted based on a sequential explanatory mixed method. Primarily a qualitative study will be conducted in order to obtain local information related to needs of women with the experience of pregnancy termination due to fetal anomaly. The need assessment tool for women with the experience of pregnancy termination due to fetal anomaly will be designed based on the findings of the qualitative study and literature review. Face validity, content validity and reliability of the need assessment tool will be assessed after identifying the questionnaire items.

Phase 1: Qualitative study

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The study subjects in the first phase of the study were women with the experience of pregnancy termination due to fetal anomaly, their spouses, midwives, gynaecologists and forensic medicine specialists who were willing to participate in the study.

Data collection method:

Women with the experience of pregnancy termination due to fetal anomaly and their spouses will be selected using purposeful sampling based on the maximum variation sampling for age, education level, social and economic status as well as gestational age at pregnancy termination. Selection of the other subjects including midwives, gynaecologists and forensic medicine specialists will be performed using purposeful sampling based on maximum variation sampling for years of work experience. The Rasht Health and Treatment Centers were chosen for data collection for the first phase due to the ease of access to subjects.

Data collection

Data will be collected based on in-depth and semi-structured interviews along with field note records. Interviews will be conducted in the comfortable location for subjects and will be recorded using the Moving Picture Experts Group layer 4 (MP4) recorder. Data collection will be continued till reaching the data saturation.

Data analysis

Data will be analysed using conventional content analysis. The data will be collected by researcher using systematic sampling by performing simultaneous interviews and field recording. Transcripts will be recorded and sentences and phrases will be coded. Then themes and classes will be obtained from the coded phrases.

Trustworthiness, credibility, transferability and confirmability measurements will be performed to verify the accuracy of the collected data. Credibility will be assessed using the proper time allocation, continuous interaction in data collection and triangulation in data collection methods including in-depth interviews, filed note recording and selection of the subjects based on the maximum variation method.

To assess the correctness of data collection and the generated codes data will be reviewed by contributors. Expert opinion will be used to ensure that the collected data reflect subjects' ideas. Transferability will be assessed by introducing the findings of the interviews to individuals who did not participate in the study but have similar characteristics to study subjects to see whether they find an agreement between their experience and the findings of the study.

Phase 2: Quantitative study

In the second phase of the study items and phrases will be identified based on the findings of the previous phase of the study as well as a comprehensive literature review. Then the psychometric properties of the questionnaire will be assessed.

Reliability assessment of the instrument

Content validity, face validity and construct validity will be assessed for the instrument. The content validity will be assessed using qualitative and quantitative methods. The qualitative method includes the opinion of an expert panel (10-15 experts in questionnaire design, reproductive health specialists, gynaecologists and forensic medicine experts). The panel will assess the questionnaire

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in terms of grammar, use of proper wording, correct placement of phrases and the necessity and importance of the phrases as well as appropriateness of scoring. Content validity will be quantitatively assessed using content validity ratio (CVR) and content validity index (CVI) (5, 6).

The CVR is measured based on the opinion of the expert panel. Each expert is required to rate questions based on a 3-point Likert scale (extremely important to include in the instrument, might be important to include in the instrument and should not be included). The CVR is then calculated based on the following equation, where n_g refers to the number of the experts who rated the question as important and N refers to the total number of experts.

$$CVR = \frac{n_E - \frac{N}{2}}{\frac{N}{2}}$$

The critical values for CVR are available based on the number of experts who rated the questions (Table 1). Questions with calculated CVR below the critical value will be excluded.

Table 1: Critical values for CVR based on the number of experts

Number of experts	CVR	Number of experts	CVR	Number of experts	CVR
5	0.99	11	0.59	25	0.37
6	0.99	12	0.56	30	0.33
7	0.99	13	0.54	35	0.31
8	0.75	14	0.51	40	0.29
9	0.78	15	0.49		
10	0.62	20	0.42		

The CVI will be assessed based on the method described by Waltz and Basel (6). Each expert has to rate the items based on a 4-point Likert scale in terms of relevance, clarity and ease of understanding. Item level CVI (I-CVI) will then be calculated for each item while the scale level CVI (S-CVI) will be calculated for the whole questionnaire. For this purpose the I-CVI will be calculated based on the following equation:

$$\text{CVI} = \frac{\text{Number of experts who scored the item as 3 or 4}}{\text{total number of experts}}$$

An item will be considered suitable if the calculated CVI is higher than 0.79. The item will require revision if the CVI falls between 0.70 and 0.79. The item is considered not acceptable and should be removed if the CVI falls below 0.70. The S-CVI will then be calculated by obtaining the average of all I-CVIs. The acceptable cut-off for S-CVI is 0.9 (7).

The face validity of the instrument will be assessed using qualitative and quantitative measures. At first, the questionnaire will be filled by 10 women with the experience of pregnancy termination due to fetal anomaly regarding the clarity, ease of understanding and comprehension of the items. Furthermore the questionnaire will be assessed by a group of experts including reproductive health specialists, gynecologists and midwives in order to improve the face validity. The item impact method will be used to quantify the face validity of the questionnaire (8). For this purpose each item

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will be scored using a 5-point Likert scale in terms of its significance, where score 5 indicates very important, 4 somewhat important, 3 moderately important, 2 of little importance and 1 not important.

Then the questionnaire will be reviewed by 20 women with the experience of pregnancy termination due to fetal anomaly. Face validity will then be calculated based on the following equation and the identified important items for the target group will remain in the questionnaire. An item will be considered valid if the item impact score is greater than 1.5. The item will be deleted in case the calculated item impact is lesser than 1.5 (8).

Item impact score= frequency (%) × importance

Reliability assessment:

The reliability of the questions will be assessed after the face and content validity assessment and the items with inappropriate reliability will be excluded from factor analysis. The internal consistency will be used for the assessment of reliability (9). In order to assess the internal consistency the Cronbach's alpha will be calculated (10). For this purpose, the questionnaire will be filled by 20 women with the experience of pregnancy termination due to fetal anomaly and the Cronbach's alpha will be calculated using the statistical package for social sciences (SPSS) software. The cut-off for the acceptance of reliability is the Cronbach's alpha greater than 0.70 (11).

The internal consistency will be assessed by test-retest method (9). For this purpose the questionnaire will be filled by 20 women with the experience of pregnancy termination due to fetal anomaly twice with a 2 week interval. The reliability will then be assessed using the Pearson correlation coefficient between the two tests.

Construct validity assessment of the instrument:

The exploratory factor analysis will be used to assess the construct validity of the questionnaire.

Study design:

In this part of the study a cross-sectional study will be carried out in order to assess the psychometric properties of the questionnaire.

Study population and study sample

The study population in this phase of the study will be women with the experience of pregnancy termination due to fetal anomalies who refer to Rasht Health and Treatment centers.

Inclusion criteria

- Willingness to participate in the study and share their information and experiences
- Iranian citizenship
- Ability read and write and comprehend the questions
- Pregnancy termination should take place earlier than one year from data collection

Exclusion criteria

- Refusal to participation in the study
- Incomplete questionnaires due to missing answers or multiple answers for one question will be excluded

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Sampling method

In this phase of the study subjects will be allocated based on convenience sampling. Considering the fact that the required subjects should exceed the number of questionnaire items in factor analysis, therefore; the required sample size for factor analysis is reported to be 3 to 5 subjects per each questionnaire item. Therefore, the sample size will be identified based on the number of variables.

Materials and methods

Heath and Treatment centers will be selected after obtaining the required permission from the Ethical Committee of Rasht University of Medical Sciences and the Department of Health of the Rasht University of Medical Sciences. Data collection will take place in the allocated centers based on convenience sampling and subjects who meet the inclusion criteria will be interviewed by the researcher and informed about the purpose of the study and the anonymity of their responses to questions. Subjects will then be asked to sign a written informed consent prior to participation in the study. Data collection tool for this phase of the study will be the need assessment questionnaire which is designed and validated in the previous phase of the study and literature review. This questionnaire will comprise of two sections and will be filled by subjects in the form of a self-report.

Data analysis

Descriptive and inferential analyses will be performed using the SPSS software. The maximum acceptable error (type 1 error) for the analyses is 5%.

In this phase of the study and after completion of data collection the Kaiser-Meyer-Olkin (KMO) test will be performed to assess the sampling adequacy prior to performing the factor analysis. Based on the acceptability of the KMO test, factor analysis will be performed using the correlation matrix. The Eigen value and Scree plot will be utilized to identify the number of factors.

Ethical approval:

Written informed consent is taken from each participant. The Ethics Committee of the Isfahan University of Medical Sciences in Isfahan, Iran approved the protocol of this study (ethics code: IR.MUI.Rec.1396.30206)

Discussion

Pregnancy termination due to fetal anomaly experience can be studied from various dimensions. Identification of the multidimensional needs of women with this experience is the key factor in the successful care and support for women and their family. Although the psychological impacts of pregnancy termination due to fetal anomaly has been studied before but the specific needs and the required support for this population has not yet fully determined. This study aims to identify the needs of women with the experience of pregnancy termination due to fetal anomaly and to design and validate a national tool based on the cultural characteristics of these women using a sequential explanatory mixed method. This study also aims at the production of a need assessment tool which could be applicable to larger populations. Sequential explanatory mixed method is an established research method for topics, for which there is a scarcity of data. Sequential explanatory mixed is also a known method for the assessment of the experience of subjects. Sequential explanatory mixed is a two-phase study where the findings of the first phase (qualitative study) forms the foundation for the second phase (quantitative study). Sequential explanatory mixed method is

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generally related to design and assessment of a newly designed tool, design and assessment of the statements of a new theory, identifying unknown variables and in-depth identification and assessment of the prevalence of a phenomenon (14). Therefore, the use of sequential explanatory mixed method with both qualitative and quantitative components seems rational to achieve the aims of this study. It is estimated that the findings of this study can serve as a basis for interventions and support and management programs for women with the experience of pregnancy termination due to fetal anomaly. Furthermore, the Ministry of Health and Medical Education and related organizations who are responsible for the health of women can use the findings of the current study in policy making, education planning and improving the reproductive health of women with the experience of pregnancy termination due to fetal anomaly.

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