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Design and evaluation of a multi-theory model-based intervention to promote childbearing intentions among Iranian single-child women: A mixed-methods protocol

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Abstract

Background: The total fertility rate (TFR) has dropped to below the replacement levels in numerous countries, which necessitates new educational approaches and behavioral models to encourage a more positive societal view of childbearing. The present research aims to design, implement, and evaluate an intervention based on the multi-theory model (MTM) aiming at boosting childbearing intentions among Iranian single-child women of reproductive age.

Methods: This mixed-methods study, designed in three phases, will first explore childbearing intentions qualitatively through in-depth interviews, with the resulting data analyzed using a directed content analysis based on the MTM. Second, the themes identified from this phase will then be used to develop and psychometrically validate a new measurement tool. Third, a field trial will be conducted to implement and evaluate an MTM-based educational intervention. Data will be collected with the validated tool both pre- and post-intervention, with follow-ups at three, six, and nine months to assess pregnancy outcomes. The effectiveness of the program and participant feedback will be analyzed via descriptive statistics, paired t-tests for within-group comparisons, and repeated measures analysis of variance (ANOVA) for between-group differences over time. All statistical analyses will be performed using SPSS version 22.

Conclusion: This study represents the first known application of the MTM to investigate childbearing intentions among single-child women. Developing and assessing a culturally-adapted intervention has the potential to boost individuals' childbearing intentions and generate evidence for guiding reproductive health policies in settings experiencing a decline in fertility.

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Introduction

The total fertility rate (TFR) has decreased in various developed and developing nations. In Iran, recent data indicate that the TFR fluctuated, rising from 1.8 children per woman in the early 2010s to 2.01 children by the middle of the decade, before dropping to 1.7 children at the decade's end (1,2). The TFR has fallen below the replacement level over the last two decades (3). An aging crisis looms over many societies, posing a significant and multifaceted challenge that will likely affect all aspects of life (4). Today's families also hold different views and desires concerning childbearing (5). The development of reproductive health intervention programs necessitates a renewed focus on educational strategies, with the design process guided by a specific conceptual framework (6). Implementing behavioral models appears to be an effective strategy for encouraging couples to have children and experience parenthood (7). Childbearing behavior is a social phenomenon influenced by a complex interplay of individual and environmental factors (8). The actual reproductive functioning is further influenced by economic, social, and cultural factors (9). Environmental influences specifically encompass social pressures, dominant socio-cultural norms, and the extensive availability of family planning services (10). Furthermore, significant others and peers who are parents exert social pressure that can influence an individual's intention to have children (11). Additionally, the availability of and support from relatives for informal childcare has been shown to be a significant factor in increasing the probability of pregnancy and childbirth (12).

The MTM of health behavior change was introduced by Professor Manoj Sharma in 2015 (13) to address the shortcomings of conventional theories like the health belief model (HBM) and the theory of planned behavior (TPB), especially concerning the maintenance of long-term behavioral changes. The MTM provides a comprehensive framework for behavior change by integrating cognitive, emotional, volitional, and environmental factors. This approach is designed to initiate and sustain health behaviors among various populations (14), and its novelty is particularly useful for tackling complex areas like reproductive health.

Key constructs for initiating behavior are as follows:

Participatory dialogue: A process of weighing the perceived advantages over disadvantages of change.

Behavioral confidence: The conviction an individual has in their own ability to successfully conduct the behavior.

Changes in the physical environment: Enhancements to the availability and accessibility of required resources.

For sustaining behavior, MTM focuses on:

Emotional transformation: Leveraging feelings to drive objective-oriented behavior.

Practice for change: Cultivating consistent and supportive habits.

Changes in the social environment: Establishing and preserving supportive social networks (Figure 1).

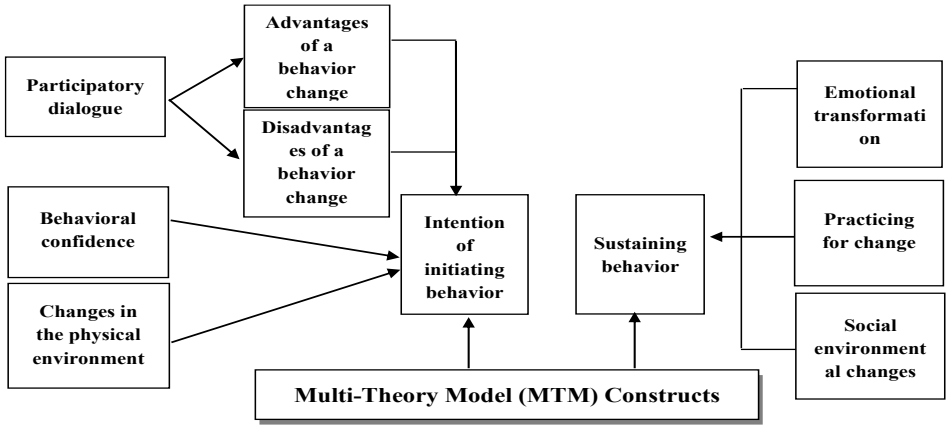

Figure 1. Schematic representation of the multi-theory model

The MTM is a promising framework for initiating and maintaining new health behaviors, such as childbearing (13). It has been used in several studies (15-17) and combines insights from different behavioral theories, making it adaptable for various contexts, especially in resource-limited settings. Despite its potential, the model is still being researched further (13).

Having children is seen as an investment affected by several factors, such as the associated costs, benefits, and the mother's specific situation (18).

While the MTM has been extensively applied to various health-related behaviors, including smoking cessation, physical activity, and nutrition, its use in understanding childbearing intentions is quite restricted. To date, only one conceptual paper has investigated this model in a fertility context (14). Although the MTM has shown its efficacy in predicting and altering health behaviors (13), its application to childbearing contexts has yet to be documented, both in Iran and internationally.

To design successful programs that encourage childbearing, it is crucial to acknowledge and respect cultural sensitivities, along with local social norms and customs, since these elements are critical to a program's effectiveness (19). Therefore, a thorough investigation is needed to improve procreative behaviors and create targeted local interventions, because reproductive decisions are highly dependent on context and are influenced by deeply ingrained social and cultural standards (20).

To our knowledge, a thorough systematic review of the literature reveals no prior research that has applied the MTM specifically to the fertility intentions of single-child women of reproductive age, either in Iran or globally. This study, therefore, utilizes the MTM's comprehensive framework to perceive behavioral change, adopting a culturally-adapted approach that is suitable for the unique social and cultural environment of Iran. A new questionnaire will be developed and psychometrically validated to precisely measure childbearing intention, using the theoretical framework of MTM as the first instrument of its kind for this specific purpose. Unlike standard global tools, the current research will focus on creating a context-specific measurement. Furthermore, the intervention will uniquely involve men in educational sessions with their wives, acknowledging the crucial role of spousal participation in reproductive choices. The results of this study are anticipated to address key research deficiencies, provide a more profound understanding of childbearing behaviors, guide effective population policies, and improve reproductive health initiatives. This exploratory mixed-methods research seeks to develop, execute, and assess an educational MTM-based intervention, conducted in three consecutive phases among single-child women of reproductive age.

Methods

The present study employs an exploratory mixed-methods design and is structured into three distinct phases. Phase 1 involves a qualitative study to create a questionnaire derived from the constructs of the MTM. Phase 2 focuses on validating the researcher-developed instrument. Finally, Phase 3, an intervention package will be developed using the insights from the previous phases and the MTM framework. A subsequent field trial intervention program will then be implemented and evaluated to determine any changes in pregnancy intention. The mean scores of the MTM constructs will be utilized to assess this change (Figure 2).

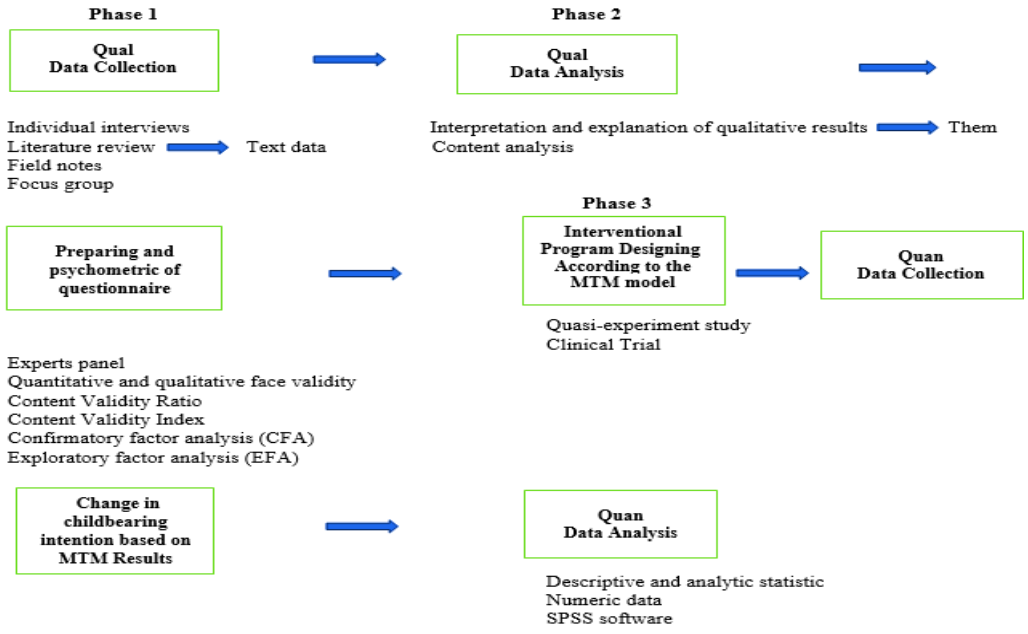

Figure 2. Study phases and methodological flow diagram

Phase 1

Study design and participants

To our knowledge, no Iranian or international researcher has designed a questionnaire that assesses childbearing intentions using the MTM constructs. Consequently, for Phase 1 of this study, we will conduct qualitative research, including a literature review and interviews. The interview guide will feature questions derived from each MTM construct to develop a preliminary version of the questionnaire, which will then be administered to participants.

The study will involve single-child women with the capacity to contribute to population replacement levels. This specific demographic was selected because they are at a key point where decisions about family size can still be influenced. Furthermore, this group is more likely to benefit from educational programs designed to increase their desire to have more children.

This phase focuses primarily on examining the experiences of single-child women. The participation of their spouses is scheduled for Phase 3, specifically during the intervention.

This population is considered the ideal target for the intervention due to their potential receptiveness to behavior change. Women will be selected from comprehensive healthcare centers in Yazd, Iran, using a purposive sampling method.

In the qualitative phase of this study, participants will be single-child women of reproductive age who are literate. Key inclusion criteria are a willingness to participate and the ability to articulate their experiences related to childbearing. A purposive sampling strategy with maximum variation will be employed to ensure a wide range of perspectives are captured.

Women who are unwilling to participate or who withdraw their consent during the interview process will be excluded from the study.

In the qualitative phase of this study, all ethical principles pertinent to qualitative research will be meticulously adhered to. Key among these are the requirement for informed consent, which will be obtained either in writing or verbally based on participant preference, and a clear articulation of the study's objectives. Furthermore, voluntary participation will be ensured, and participants will be guaranteed the right to withdraw from the study at any point without any form of retribution. To ensure a tranquil, non-judgmental, and confidential atmosphere, all interviews will be conducted in private rooms located within comprehensive health centers. Participants will be informed that audio recordings will be accessible only to the interviewer and that they have the right to pause or terminate the recording at any time. To guarantee complete anonymity, no identifying information will be collected, and all transcripts will be assigned a pseudonym or code. Audio recordings will be promptly and permanently deleted following transcription. The resulting transcripts will be stored in a secure manner, adhering to both national and institutional ethical guidelines for qualitative research. A summary of the interview findings will be made available to participants upon request. These protocols are implemented to guarantee the protection of participants' privacy, autonomy, and safety throughout the research process.

Sample size

The sampling process will continue until both data saturation and deep data are achieved.

Data collection process

In this study, following the acquisition of all necessary permits and ethical approvals, and the coordination required for researchers' access to the designated research centers, a preliminary discussion will be conducted to provide participants with an initial verbal overview of the study. Subsequently, their consent will be obtained for both the conduct and recording of the interviews. Participants for these interviews will be chosen from the target group through a combination of purposive and convenience sampling methods.

In the initial session, participants will receive a comprehensive overview of the study, including the voluntary nature of their involvement, the confidentiality of all data collected, and their right to withdraw from the study at any time. The interviews will begin with a general, open-ended question concerning mothers' experiences with childbearing and subsequent pregnancies. Subsequent interview questions will be structured around the MTM. The primary objective of these interviews is to focus on and elicit detailed accounts of the participants lived experiences. With the participants' consent, each semi-structured interview will be audio-recorded and transcribed immediately afterward. The transcription process will involve listening for several times to ensure accuracy and to capture non-verbal communications. During the interviews, the interviewer will also take notes to document important non-verbal cues, such as the participant's tone of voice, pauses, and points of emphasis. The interviews are scheduled to be held at designated comprehensive health centers. Attempts will be made to ensure the interviews are conducted in an appropriate, bias-free environment. In line with the principle of skepticism in qualitative research, the researcher will maintain a neutral stance, not allowing preconceived hypotheses or ideas to influence the interview questions or subsequent analysis. The initial interview guide will be developed based on a review of relevant literature and expert consultation, with the MTM constructs serving as the guiding framework. An open-ended, guiding question like *"What is your opinion on childbearing?"* will be posed to initiate the interview and clarify the main issues. The interview will proceed with subsequent questions tailored to the participant's responses. To ensure clarity and gain deeper insights, follow-up questions will be asked based on the information provided, and probing questions like *"Can you explain further?"* or *"Can you provide an example?"* will be utilized. Simultaneously with the interview, the key points raised by the interviewees will be documented. This will help summarize the main discussion points at the end of each interview session and confirm their meaning with the interviewee. If any ambiguity emerges after the interview has been transcribed, the interviewee will be contacted for clarification, and the new information will be added to the transcript. Data collection will continue until thematic saturation is achieved. This is defined as the point at which no new concepts or themes emerge from the data, and all relevant areas have been comprehensively addressed. The interviews will be independently analyzed by two researchers who are not involved in the study. The anticipated duration for each interview is between 40 to 50 minutes.

Data analysis

A theory-driven approach to qualitative text analysis is best accomplished through the directed qualitative content analysis method, as proposed by Hsieh and Shannon (2005). This study will employ this method alongside a deductive approach (21). The recorded interviews will be transcribed verbatim on the same day they are conducted. The transcripts will then be imported into the MAXQDA2020 software. The qualitative data analysis will proceed concurrently with data collection, guided by the methodology proposed by Granheim and Landman (2004) (22).

This process of data analysis, following data collection, consists of five stages:

1. Interviews are transcribed verbatim and reviewed repeatedly to establish a general comprehension.
2. The text is segmented into condensed semantic units.
3. These units are abstracted and assigned codes.
4. Codes are categorized into subthemes by comparing their similarities and differences.
5. Themes are then identified as representing the underlying content of the text. The research team will repeatedly review the interviews to acquire a comprehensive understanding of the textual data. Once the analysis and semantic units are identified, the data will be independently coded by two analysts. Any discrepancies will be resolved through discussion and deliberation until a consensus is reached. If a disagreement remains, a third expert (Either a supervisor or a qualitative consultant) will be consulted to make a final decision.

The process begins with a comparison of initial codes, and similar codes are subsequently organized into subcategories. These subcategories are then placed within main categories, with continuous comparative analysis to ensure their relevance and similarity. This process is iterative; with each new interview, the codes and categories are refined, and the research team maintains a close connection to the data throughout the analysis.

Validity and reliability

In this study, the reliability of findings will be enhanced through several methodological strategies, including employing maximum diversity in participant selection, allocating sufficient time for data collection, conducting in-depth interviews at various times and locations. Additionally, to further ensure rigor, we will combine several data

collection methods, such as individual interviews and field notes. Moreover, participant reviews and a comprehensive, continuous record of researcher decisions and activities will be used to increase confidence in the study's conclusions. To improve the transferability of the findings, the research results will be shared with several individuals who have similar characteristics to the participants who were absent from the study, allowing us to assess the similarities between the study's conclusions and their personal experiences. Following data collection and preliminary analysis, we will use Lincoln and Guba's criteria (23) to ensure the quality and authenticity of the results.

Credibility

The credibility of the data-referring to the extent that research findings are viewed as believable by participants-will be ensured through several methodological strategies. These include conducting interviews with a maximum diversity of participants and employing continuous data comparison throughout the research process. To ensure representativeness, diversity will be emphasized across diverse dimensions, including age, occupation, educational level, socioeconomic status, marriage duration, and childbirth history. A purposeful sampling strategy will be used to ensure the inclusion of a diverse group of women, representing a wide range of socioeconomic statuses, age groups, and reproductive histories. Concerning the review of participants, if any statements made during the interview are unclear to the researcher or if the participant's intended meaning is not fully understood, those statements will be revisited several times, and clarification will be requested from the participant. Furthermore, procedures like summarizing and categorizing the data will be performed continuously to guarantee the accuracy and comprehensiveness of the analysis (24).

Dependability

This refers to the degree to which other researchers can verify the findings. To achieve this, we will share the transcripts of certain interviews, coding, and identified categories with other experts. Additionally, by replicating similar conditions with individuals outside the study, we will assess the accuracy of the research process. Furthermore, peer review or validation of the collected data will be carried out with other experts and researchers experienced in qualitative research. The coding process will be reviewed by two supervisors and advisors, distinct from the qualitative method advisor, experienced in qualitative studies. Their diverse perspectives will ensure a robust and well-rounded evaluation. Additionally, the research team will enhance the study's reliability through ongoing collaboration with participants, which includes collecting and validating information from them (25).

Confirmability

To guarantee the findings' consistency under similar conditions, the accuracy of the coding process will be verified through the involvement of the research team and experts. The research results should show that they are based on real evidence and data, rather than just the researcher's personal opinions or interpretations. To bolster the credibility of this study's findings, the research team employed a rigorous process of expert review and repeated re-examination of the interview data. Feedback from the research team, colleagues, and external experts was utilized to ensure the accuracy of the coding process. Furthermore, the interviews, codes, and derived categories were systematically reviewed and validated by several experienced qualitative research professors (26).

Transferability

This section addresses the transferability of the data, which refers to the extent to which the findings can be applied to similar contexts. To achieve this, a comprehensive and accurate description of the research process, participant statements, and analysis methods will be provided, enabling other researchers to apply the methodology in comparable settings. Furthermore, to enhance the transferability of the findings, the study will explore the experiences of the key participants and ensure that the sample represents a diverse range of ages, educational backgrounds, cultures, and social contexts. The diversity of data sources enhances the transferability of the findings to other contexts. Furthermore, to ensure the research method is replicable in similar situations and thus guarantee the transferability of the results, we will review the study with colleagues to confirm its stages. A detailed and comprehensive description of the research process will also be provided, including participants' statements and the procedures for data analysis (26,27).

After completing the final analysis and theme identification, a questionnaire titled "the MTM-Based Childbearing Intention" will be developed. The items for this questionnaire will be formulated by integrating the findings from the data analysis, the concepts derived from the themes, and a thorough literature review. Additionally, the formulation will be guided by an analysis of the frequency of recurring words and the established MTM constructs. The initial version of the questionnaire will then be created, with items scored on a Likert scale. Subsequently, a psychometric analysis will be conducted to reduce and refine the designed statements.

Phase 2

At this stage, the researcher-developed questionnaire, which was compiled based on the MTM constructs, will undergo validation. This process is comprised of several distinct parts.

Face validity

Sample size

For this phase, the questionnaire will be administered to 10 experts in relevant fields, including health education and promotion, reproductive health, psychology, and demography. Additionally, 5 to 10 women from the target population will be recruited using a convenience sampling method to assist in this process.

Qualitative face validity

Sample size

To establish qualitative face validity, researchers will conduct face-to-face consultations with 5 to 10 women from the target population at designated health centers. The purpose of these consultations is to gather participant feedback on three key aspects: Clarity (Understanding and interpreting the questions), appropriateness (Relevance and suitability of the questions for measuring the intended constructs), and ambiguity (Identification and subsequent resolution of any confusing or unclear items). Based on the feedback received, necessary modifications will be made to the questionnaire items.

After making any necessary adjustments to the questionnaire items, quantitative face validity will be conducted.

Quantitative face validity

Sample size

For this phase, the questionnaire will be sent via academic email to a panel of 10 experts specializing in relevant fields, including health education and promotion, reproductive health, psychology, and demography.

Quantitative face validity will be assessed to eliminate inappropriate phrases and determine the importance of each item using the impact score method.

Each item will be assessed using a 5-point Likert scale, ranging from 5 (Very important) to 1 (Not important at all). Only items with a mean score of 1.5 or higher will be selected for subsequent analysis (27). Furthermore, a concerted effort will be made to ensure that all questionnaire items are written in a correct style and have a logical sentence structure. These items will be subject to review by the research team, and their feedback will be incorporated. To further enhance the validity of the questionnaire, expert opinions on its content will also be solicited during the content validity assessment.

Content validity

Qualitative content validity

Sample size

Beginning on October 10th, a questionnaire will be disseminated to experts via their institutional email addresses. They will be requested to provide revisions for each item, with a specific focus on syntactic structure, appropriate diction, and adherence to grammatical conventions. The problematic items will then be revised based on the feedback received.

Quantitative content validity

We will quantitatively assess content validity using the content validity ratio (CVR) and the content validity index (CVI). To do this, we will ask at least 10 specialists, experts, or consultants to review the questionnaire. They will be instructed to evaluate each item's appropriateness using the following three-point scale: "Essential," "useful but not essential," or "not essential."

For a panel of 10 experts, the minimum acceptable CVR according to Lawshe's table is 0.70. This value determines the acceptability of individual items. The CVI will be calculated based on the simplicity, relevance, and clarity of the items. If an item's CVI score is low, it will be reviewed and revised to improve its accuracy and clarity. Should the score remain low after revision, the item may be removed. Additionally, any item that fails to meet the required CVR will be excluded from the questionnaire, subject to the research team's approval.

Construct validity

The structural validity of the instrument will be assessed using factor analysis. This statistical technique is widely recognized as a powerful method for variable reduction and simplifying complex datasets. Factor analysis serves two distinct purposes: exploratory and confirmatory. Exploratory factor analysis (EFA) is used to identify and categorize the underlying factor structure of items based on their intercorrelations, a process that may or may not align with a specific theoretical framework. Conversely, confirmatory factor analysis (CFA) aims to test and validate a theoretical model of relationships between items and their corresponding factors that the researcher has specified in advance.

Sample size

The recommended sample size for this analysis is 5-10 participants per item of the proposed instrument. Some researchers also deem three samples per item as sufficient, as long as the percentage of variance and factor loading is above 0.8. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity will be utilized.

The sample size needed for establishing construct validity will be determined using the rule of thumb of 5 to 10 participants per item (27). Since the final number of items will be finalized after the qualitative stage, an initial sample of 300 to 400 participants is planned. A systematic random sampling method will be employed to select participants from Iran's Integrated Health System (SIB).

Reliability

The reliability of a research instrument refers to the extent to which it yields consistent results when used for repeated measurements under the same conditions (28).

Internal consistency

To determine the scale's reliability, we'll assess its internal consistency using Cronbach's alpha and McDonald's omega. A coefficient of 0.70 or greater is considered an acceptable indicator of reliability. Since the instrument employs a Likert scale, it is essential to evaluate the homogeneity of its items to ensure internal consistency (29). We will calculate Cronbach's alpha for the entire scale and for each dimension individually.

Stability reliability

The intraclass correlation coefficient (ICC) will be employed to assess the questionnaire's test-retest reliability, a key measure of its stability. A ICC value exceeding 0.80 suggests a satisfactory level of consistency between the two administrations. In this context, the Spearman-Brown prediction formula is a widely used method for estimating the correlation between the scores from the two tests (27).

Sample size

To assess the reproducibility of the questionnaire using a test-retest method, a cohort of 30 participants will be re-administered the questionnaire after a two-week interval. Additionally, Pearson's correlation coefficients will be computed to evaluate the relationship between the different sections of the questionnaire (30).

Phase 1 of the study, which encompasses conducting interviews, data analysis, coding, and the development of the preliminary questionnaire, is projected to last approximately 3 months. The subsequent psychometric evaluation is estimated to take around 4 months. Upon successful completion of these stages and confirmation of the questionnaire's validity and reliability, the research will advance to Phase 3.

Phase 3

This phase of the research is a quantitative investigation that entails the implementation of an intervention program. The primary objective is to evaluate and measure any subsequent changes in the childbearing behavior of women of reproductive age.

This study will be a randomized interventional parallel field trial, utilizing a two-group design (Intervention and control) to evaluate the effectiveness of the intervention program. Following an explanation of the research objectives and the acquisition of informed consent, all participants will complete a demographic information form and a researcher-made questionnaire based on the MTM model constructs at three time points: Baseline (Pre-intervention), and again one and three months after the intervention's conclusion.

Participants and research setting

The research will be conducted in a comprehensive health center in Yazd. To ensure a representative sample with cultural, economic, and social similarities, four of these centers will be selected from the north, south, east, and west of the city. Subsequently, two centers will be randomly assigned to the intervention group, and the remaining two will be assigned to the control group.

Participants

The selection of participants will be based on predefined criteria and will be proportional to the number of single-child women within each comprehensive health center.

Inclusion criteria

This study requires participants to meet several specific criteria. They must be literate and of childbearing age, have no intention of becoming pregnant before the study begins, have a single and only spouse, have one child, and maintain an active marital and sexual relationship. Participants must also have access to a mobile phone and social media networks, and have no medical contraindications for pregnancy (Such as Class 4 heart disease, use of teratogenic drugs for conditions like epilepsy or rheumatoid arthritis, and a history of malignancies).

Exclusion criteria

The following are considered grounds for participant exclusion: A confirmed pregnancy before or during the intervention, the participant or their spouse not providing consent, or the participant withdrawing from the study at any point.

Researcher procedure

After acquiring the necessary ethical approval and clinical trial code number (IRCT20170802035446N3, registered on 2024-10-18 and last updated on 2025-04-02), and armed with a formal letter from the Deputy of Research and Technology at Shahid Sadoughi University of Medical Sciences, Yazd, Iran, the researcher will visit the pre-selected comprehensive health centers. Upon arrival, the researcher will introduce themselves, provide a clear explanation of the research process and its objectives, and then proceed with a purposive sampling method. The sample size for the intervention group will be determined at the beginning of this phase.

Sample size

The sample size was estimated based on the attitude score toward childbearing from the study by Ansari Majd et al. (31). Using G*Power software, with a significance level (α) of 0.05, a power of 0.8, and an effect size (d) of 0.6, an initial estimate of 45 participants per group was determined. To account for a 10% non-cooperation rate and the use of cluster sampling, a design effect of 1.5 was applied, which resulted in a final sample size of 50 participants per group.

$$n \geq \frac{(1+k)}{k}\frac{(z_{1-\frac{\alpha}{2}}+z_{1-\beta})^2}{d^2}+\frac{z_{1-\frac{\alpha}{2}}^2}{2(1+k)}$$

K is the ratio of the control group to the intervention and is equal to one. d is the effect size and is equal to 0.6.

Recruitment process

Eligible single-child women will be identified and their contact details will be retrieved from the SIB system. They will be contacted by telephone and invited to participate in the study. Prospective participants who consent to be involved will be provided with comprehensive information regarding the study's objectives, procedures, confidentiality protocols, and their right to withdraw at any time. They will also be notified about the nature of the field trial and their random assignment to either the intervention or control group. Contact information will be collected for coordination purposes, and a link to the informed consent form will be provided to the couples. This research will be conducted in accordance with the principles of the Declaration of Helsinki.

Allocation and concealment mechanism

Participants will be assigned to either the intervention or control groups through block randomization, utilizing a block size of 4. The random

sequence will be generated by a researcher who isn't involved in either participant recruitment or data collection. Although the randomization.com website may be used for practical purposes to assist in implementing the block randomization, the independent researcher's generation of the random sequence will be the primary method of allocation. Each participant will be given a unique study ID. The allocation sequence will be kept confidential in sequentially numbered, opaque, sealed envelopes, which will be opened only after the participants have completed their baseline assessments.

Blinding

Given the nature of the educational intervention, achieving blinding of both participants and instructors is impractical, as their awareness of group assignments is inherent to the study design. Nevertheless, to mitigate potential assessment bias, the individuals responsible for collecting and analyzing the outcome data will be kept blinded to the group allocations.

Interventions

Pre-Test phase: A questionnaire, developed by the researcher and grounded in the constructs of the MTM, will be disseminated to all participating women through an internal messaging network, enabling them to self-report their responses.

Educational intervention

This intervention will involve at least 4 sessions, each lasting 45-60 minutes (32) (Table 1). The sessions will be held in person, twice a week, for 50 women from two comprehensive health centers. The participants will receive their education at their respective centers.

Table 1. Details of the content presented in the sessions

Session	Educational objectives	Session content
1	**Participatory dialogue and Behavioral confidence**	**Participatory dialogue:** - Introduction and welcome, and outlining the objectives of the study - Creating a joint group in an internal messaging network for session notifications, sharing educational materials, and enabling question-and-answer through voice messages and private chats with the researcher - Advantages of childbearing: Individual, family, social, and religious advantages - Disadvantages of childbearing: Potential challenges and problems - Discussing the dangers of an aging population and the future of society and the country, etc. **Behavioral confidence:** - Strengthening confidence in decision-making regarding childbearing and parenting - Enhancing couples' self-efficacy and self-confidence - Recalling positive experiences from raising a previous child, etc.
2	**Changes in the physical environment and emotional transformation**	**Environmental changes:** - Informing about accessible centers and services, including free midwifery consultations before and during pregnancy - Informing about benefits, laws, and government support for mothers, such as assistance for pregnant mothers in child care at work centers, remote work options - Introducing free centers for pregnancy tests, affordable ultrasound centers - Informing about the opportunity to attend online classes if mothers wish to continue their education, etc. **Emotional transformation:** - Using religious teachings, such as the belief that raising a righteous child is an approved act and a divine blessing, and a form of enduring charity - Not being alone in old age - The positive emotional impacts of having children on the family, such as the care children will provide to their parents in the future. - The impact of childbearing on individual growth and family stability. - The impact of childbearing on marital satisfaction. - Parental personality transformation, responsibility, self-satisfaction, and avoiding regret in old age due to having multiple children, etc.
3	**Practice for change and changes in the social environment**	**Social changes for childbearing:** - Social and family impacts of having more children - Introducing and inviting successful women with multiple children to join the target group to speak, to encourage mothers to have children, to serve as role models, and to offer guidance on how to manage work, life plans, and childbearing - Strategies for establishing effective communication with healthcare providers and obtaining advice from them, as well as from spouses and families (Themselves or their partners), to help with child care. **Practice for change:** - Strengthening the ability to say "no," problem-solving skills, and helping identify challenges and find possible solutions to overcome barriers to childbearing - Training on how to handle potential social interference, pressures, and expectations from others regarding the number of children in the family.
4	**Participation, support, and childbearing planning**	- The role of men during their wife's pregnancies and choosing the right time for pregnancy according to scientific evidence, and the consequences of delayed pregnancy and secondary infertility. - Support and participation in shared life responsibilities. - Division of tasks and responsibilities, division of household chores and child care. - Emotional support for the wife: Psychological support during pregnancy - Increase in prosperity and blessings: The impact of childbearing on prosperity and blessings. - Access to welfare and healthcare facilities: Information on the latest government support for childbearing - Changing mindsets and strengthening joint decision-making. - Psychological and social disadvantages of being an only child. - Education on joint decision-making: Strengthening cooperation and participation in decisions. - Cultural and social impacts of childbearing: The influence of public culture and the role of the media. - Managing expenses: Teaching the culture of contentment and financial management for childbearing. - Teaching problem-solving skills and stress management: Coping with stress and life challenges. - Creating supportive and social networks: The importance of support networks and introducing counseling centers. - Teaching how to plan financially for childbearing: Economic planning and saving for the future of the child. - Teaching parenting skills: Child-rearing and how to deal with parenting challenges.

The intervention content will be designed based on an analysis of findings from the qualitative phase, a comprehensive literature review, and the pre-test results, with a consistent focus on the MTM framework. A draft of these materials will be submitted for review and validation to a panel of experts specializing in reproductive health, health education, and clinical psychology. Their feedback will inform subsequent revisions to guarantee the materials are accurate, culturally appropriate, and practically applicable. The intervention program, supervised by esteemed professors and delivered by Ph.D. students, will consist of a variety of educational activities. These activities, which include lectures, group discussions, instructional videos, pamphlets, book introductions, practical training, and brainstorming sessions, are specifically designed using insights from interviews, pre-tests, and the MTM model to focus on childbearing.

Given the crucial role men play in childbearing decisions and their influence on women's childbearing intentions, the fourth training session will involve husbands to enhance their awareness and engagement. This initiative aims to equip men to better support their wives and contribute to informed decision-making. Spousal support can mitigate women's stress, bolster their psychological security, and ultimately improve the quality of decisions related to childbearing.

The core of this research is to alter women's attitudes and behaviors. Consequently, the study's assessment instruments, such as questionnaires and qualitative evaluations, are crafted exclusively for female participants, who are required to complete them. Conversely, men are not obligated to complete these tools. The influence of male involvement will be gauged indirectly via women's self-reports and qualitative analysis. Spouses of male non-participants will not be excluded from the study.

To enhance accessibility, women will be encouraged to share essential knowledge with their husbands, and a video recording will be made available for men who cannot attend. To ensure high-quality instruction, prominent psychology and fertility specialists will be invited to deliver crucial scientific and practical education. The number of sessions may be increased based on participant feedback to meet educational needs.

Communication and support

The designated internal messaging platform facilitates the distribution of session announcements and educational resources, while also providing participants with the capability to engage in private correspondence with the researcher via text or voice messages. Additionally, reminders for each session's homework assignments will be disseminated through SMS notifications.

Control group procedures

Participants assigned to the control group will be provided with standard or routine care from the comprehensive health center throughout the study period.

Post-test and outcomes

The primary outcome of this study will be the modification of pregnancy intention behavior. This includes changes in the mean scores of the constructs related to initiating behavior change (Participatory dialogue, behavioral confidence, and change in the physical environment). It also encompasses changes in the mean scores of the constructs for maintaining and sustaining behavior change (Emotional transformation, change in the social environment, and practicing for a change). The term behavioral intention is defined as the initiation of childbearing, which involves completing the pre-pregnancy care form at a health center, beginning folic acid supplementation, and discontinuing contraceptive use.

The secondary outcome will be the occurrence of pregnancy.

All participants (Both the intervention and control groups) will complete the questionnaire for a second time at one month and again at three months following the conclusion of the intervention. To ensure consistency, researchers will conduct follow-up assessments on pregnancy occurrences via telephone calls at three, six and nine -months post-intervention.

Due to ethical considerations, the educational materials and training package will be made accessible to the women in the control group and their spouses through a virtual network after the final follow-up. Furthermore, any questions they may have will be addressed.

Statistical analysis

Quantitative variables will be summarized by their mean and standard deviation, while qualitative variables will be described using frequencies and percentages. The Shapiro-Wilk test will be used to determine if the quantitative data are normally distributed. If the data do not follow a normal distribution, non-parametric tests (Such as the Mann-Whitney U test or the Wilcoxon signed-rank test) will be employed. For inferential statistics, within-group comparisons will be analyzed using a paired t-test or the Wilcoxon test, whereas between-group comparisons will be analyzed with an independent t-test or the Mann-Whitney test. To compare outcomes across the different time points (Baseline, one month, and three months post-intervention), a repeated measures analysis of variance (ANOVA) will be utilized. In cases where the data do not meet the assumptions for ANOVA, the Friedman test will be used as a non-parametric alternative. If the analysis reveals significant differences, post-hoc Bonferroni correction will be applied to the pairwise comparisons to control. Finally, effect sizes will be calculated and reported, using Cohen's d for t-tests and partial η^2 for the ANOVA results, to quantify the magnitude of the observed effects. Potential confounding variables (Such as age, duration of marriage, and socioeconomic status) will be statistically controlled through the use of analysis of covariance (ANCOVA) or various regression models. To address missing data, the technique of multiple imputations will be employed. All statistical analyses are planned for execution using SPSS version 22 (IBM Corp., Armonk, NY), with a predetermined significance threshold of $p < 0.05$ to establish statistical significance.

Discussion

To comprehend the psychological and social factors influencing childbearing intention, a theoretical framework is necessary to explain this complex behavioral shift within a reproductive context. For studying childbearing and fertility, an effective theory must merely concentrate on the target behaviors, possess strong predictive power grounded in empirical evidence, be economical, and contain modifiable constructs. Additionally, it should be executable across diverse cultures and be applicable to both short- and long-term behavioral changes at the individual, group, and community levels (13). The HBM serves as a valuable framework for comprehending the interplay between personal beliefs and perceptions in shaping reproductive health behaviors. This model has proven effective in illuminating factors that influence childbearing counseling, which could help in overcoming obstacles and fostering healthy family development (27). Consistent with the central tenets of the HBM, prior studies have underscored that both knowledge and the perceived risk of infertility are crucial factors in encouraging behaviors that optimize fertility (33).

The TPB is a prominent theoretical framework that has been widely utilized in the study of fertility intentions. For instance, a particular study demonstrated that an educational intervention based on the TPB's principles led to significant positive changes in the attitudes, perceived behavioral control, and fertility intentions of single-child women (34).

Despite some successful outcomes, not all TPB-based interventions have been effective. For example, one study found that a structured educational program rooted in TPB principles failed to produce significant changes in attitudes, subjective norms, perceived behavioral control, or childbearing intentions. This suggests that broader sociocultural, economic, and religious factors exert a powerful influence on fertility behaviors. Therefore, educational interventions by themselves may be insufficient to change behavior unless these wider contextual factors are also taken into consideration (35).

A validated instrument, specifically designed for the Iranian context, was developed to assess childbearing intentions, thereby supporting applications of the TPB (36).

Based on the TPB, behavioral intention is primarily shaped by an individual's attitudes, subjective norms, and perceived behavioral control (34). Numerous intervention studies have shown that TPB-based educational programs can culminate in significant improvements in attitude scores among women (37). For example, research in Italy found that these three TPB components were strongly linked to fertility intentions, though they did not always translate into actual fertility behavior, highlighting the widely recognized intention-behavior gap (38).

Consistent with these observations, evidence from Iranian studies indicates that attitudes and subjective norms are crucial determinants of fertility intentions, playing a central and significant role in childbearing decision-making (39).

Other models like the transtheoretical model (TTM) and PRECEDE-PROCEED have also demonstrated effectiveness, though they are less commonly used. For example, a TTM-based educational program led to a notable improvement in childbearing decision-making scores among Iranian women, even with minimal progression across the stages of change (31). Additionally, a recent multimedia field trial targeting single-child women showed a significant rise in positive fertility motivation just six weeks after the intervention. This finding underscores the crucial influence of both environmental and behavioral factors in shaping childbearing intentions (40).

In total, childbearing is fundamentally a social act molded by broader societal structures (8). A socio-cognitive lens reveals that people learn behaviors not just from their own lives, but also by watching and emulating others (41). Therefore, beyond personal choices, reproductive decisions are heavily influenced by economic, social, cultural, and environmental factors (9).

While established theoretical frameworks, including the HBM, TPB, TTM, PRECEDE-PROCEED, and ecological models, have offered significant insights into fertility behavior, they each have limitations when addressing its complex, multidimensional nature. Consequently, a MTM that synthesizes cognitive, volitional, and environmental constructs-drawing on and supported by prior empirical research-could offer a more comprehensive and actionable approach. These integrated models are especially valuable for developing effective interventions tailored for individuals, interpersonal networks, and communities, particularly in low-resource contexts (13).

In contrast to single-theory frameworks, the MTM is uniquely structured to encompass both the initiation and the ongoing maintenance of behavior change, a capability essential for establishing durable fertility-related behaviors. Its demonstrated applicability across culturally diverse and resource-limited contexts further substantiates its value for reproductive health interventions focused on strengthening childbearing intentions.

In this study, we applied the MTM to investigate the childbearing intentions of single-child women. This approach deals with limitations found in existing theoretical frameworks and interventions. Future studies should focus on assessing the efficacy of MTM-based interventions and comparing them to traditional models. This will help identify the most effective strategies for promoting changes in reproductive behavior and establish best practices.

Conclusion

This research introduces a culturally-adapted and theoretically-grounded intervention designed to encourage childbearing among Iranian couples using a three-phase, mixed-methods approach. The initial qualitative phase informs the creation of the intervention, which is subsequently assessed in a field trial. A mixed-methods design is considered suitable due to the intricate and multifaceted nature of childbearing behavior.

The current research, while facing limitations like restricted generalizability and a dependency on qualitative data during its early phases, presents significant strengths. These include a diverse sampling methodology and the rigorous validation of the MTM constructs. A notable contribution is the creation of a new questionnaire, “the Childbearing Intention Questionnaire,” as an MTM-based framework. This instrument could serve as a valuable resource for future studies and strategic planning within the field of reproductive health.

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Ethical statement

The present study received approval from the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran (IR.SSU.SPH.REC.1403.069). Prior to participation, all individuals will provide written informed consent. Furthermore, verbal consent will be obtained before any audio recording takes place. The research's goals and methodology will be explained to participants, and their privacy and anonymity will be guaranteed before the interviews are conducted.

Conflicts of interest

No conflict of interest.

Author contributions

Conceptualization: T.M.S.; Data curation: M.B. and F.M.; Methodology/Formal analysis/Visualization: T.M.S., M.SH., and F.M.; Project administration: S.S.M.M.; Writing - Original draft: T.M.S.; Writing - Review and Editing: T.M.S. and M.SH. All authors actively participated in all stages of preparing the manuscript and approved the final version of the manuscript.

Data availability statement

Not applicable.

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