STUDY PROTOCOL

Design, validation, and Evaluation of the "Mumapp" Virtual Clinic Application and its Effect on Quality of Life in Mothers with Maternal Near Miss: An Exploratory Mixed-Method Study Protocol

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Abstract

Background Maternal near miss refers to women who nearly die from severe complications during pregnancy, childbirth, or within 42 days postpartum, facing significant physical, psychological, and social challenges. It is essential to offer effective, practical, and affordable solutions to meet the needs of these mothers. This study aims to design and validate the "Mumapp" virtual clinic application and assess its impact on the quality of life for mothers who have experienced maternal near miss.

Methods This study employs a mixed-methods exploratory design in three phases. The first phase involves a qualitative content analysis study to explore the experiences of women and healthcare providers regarding maternal near miss, identify their needs, and gather data on their expectations for follow-up care via a virtual clinic after hospital discharge. The second phase focuses on developing a virtual clinic application called "Mumapp," incorporating the needs identified from the qualitative findings and a thorough literature review. The third phase consists of a quasi-experimental, single-group pretest–posttest study designed to evaluate the impact of the Mumapp application on the quality of life of mothers who experienced maternal near miss, with assessments conducted at baseline, 3 months, and 6 months post-intervention.

Expected Results The qualitative findings will define the content and functions of a validated Mumapp prototype. The quasi-experimental phase will provide preliminary estimates of changes in quality of life at three and six months, together with information on application utilization and feasibility.

Discussion This protocol describes a user-centered virtual clinic designed to address an important gap in structured post-discharge care for maternal near-miss survivors. The study will generate preliminary evidence on the feasibility and potential value of digitally supported, individualized follow-up.

Keywords Life quality, Maternal health, Mobile applications, Morbidity, Quality of life

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1 Introduction

Background

The World Health Organization (WHO) defines "MNM" as a condition where a woman nearly dies but survives a serious maternal complication during pregnancy, childbirth, or within 42 days of completing pregnancy. These women have survived severe maternal complications or "life-threatening conditions.[1] MNM mothers experience long-term negative physical problems due to organ dysfunction and psychological and emotional effects, such as anxiety, isolation, depression, and trauma during childbirth.[2] Their family members and infants are also affected by these negative outcomes.[3,4] Following a delay in resuming sexual activity, there is a higher prevalence of sexual problems among such mothers.[5] Sometimes, after a baby loss, the mother should be followed up for a longer time for a subsequent pregnancy.[6] Women experience physical and psychological problems such as fear, frustration, disempowerment, and shock during the immediate emergency, and symptoms of anxiety, alienation, and flashbacks are experienced during recovery.[7-9] Despite the global prevalence of MNM cases being 18.67[10] and 3 per 1,000 live births in Iran,[11] and the cumulative effect of its complications in the long run, the current irregular follow-up may not provide a complete picture of their primary care after discharge from the hospital. Implementing integrated care, including physical, psychological, social, and spiritual aspects for women, can help reduce the burden of pregnancy complications on millions of women worldwide.[12] Due to the physical, psychological, economic, and socio-cultural problems that these mothers face, many sources emphasize the need for special care and support for them.[13] Psychological interventions have been shown to significantly reduce postnatal depression among at-risk women.[14] These interventions include programs and policies such as home visits by health professionals, peer support provided over the telephone, interpersonal psychotherapy, and counseling.[14,15] A study conducted in 2016 in the United Kingdom recommended routine application of counseling and other methods to support MNMs and prevent post-traumatic stress disorder and postpartum depression. Serious gaps exist where women are not receiving appropriate maternity care, and there is growing concern about the increasing level of morbidity among childbearing women globally.[16] One recent strategy designed to close the global equity gap around access to high-quality maternity care involves a system redesign of large-scale changes to offer all women access to advanced facilities with high-quality pregnancy and post-partum care.[15] There have been calls for "Beyond the numbers"[17] or "rethinking maternal health"[18] and the importance of women's health is not overlooked by anyone. However, they lack access to reliable resources or medical personnel.[19] New technologies can improve patients' ability to access supportive information and enable them to receive counseling, treatment, and support.[20] As is evident in other healthcare technologies, these tools may enhance women's ability not only to manage their own health, but also to participate in healthcare with their professionals during this critical period of life.[21] This study aims to develop the Mumapp application, a smartphone virtual clinic for MNM mothers. The clinic connects them with a specialized medical team, offering personalized advice based on their specific needs. By providing accessible and convenient support, Mumapp helps mothers overcome challenges without the burden of costly and time-consuming travel for physical and mental health issues.

Objectives

The general goal of the first phase (qualitative) is to elucidate mothers, spouses, and other health providers' understanding and experiences of MNM and to extract their needs and expectations from a virtual clinic.

The general goal of the second stage is to design a virtual clinic related to the MNM challenge based on the results of the first stage and the literature review.

The general objective of the third stage (quantitative) is to determine the effect of the implementation of the Mumapp virtual clinic on the mother's quality of life.

2 Methods

Study Design

The current study utilizes a mixed-methods approach with an exploratory model. The study consists of three sequential phases:

Phase 1: Qualitative study

Phase 2: Development and validation of the Mumapp virtual clinic

Phase 3: Quasi-experimental evaluation of the intervention

Study Setting

Following approval from the Ethics Committee, sampling will occur in referral hospitals with intensive care wards and comprehensive health service centers in Mashhad City, where most high-risk pregnancies and severe maternal morbidities are treated.

Participants

Phase 1 Participants

The sampling will be purposive to ensure maximum diversity. For healthcare providers, maximum diversity

will be sought regarding their years of work experience, clinical specialty, and organizational role. Participants will be selected to represent a wide range of variation in terms of socio-demographic and clinical characteristics, including maternal age, level of education, occupational status, parity, socioeconomic status, and the specific type of near-miss event. After stating the research objectives and obtaining informed consent, mothers will be included in the study, with interviews scheduled at convenient times and locations. Mothers willing to share their experiences of MNM events or organ failures and their impacts on life will be selected for interviews. Additionally, the study will include the husbands of these mothers to describe their life conditions following the MNM incident. Additionally, key informants and service providers, including midwives, gynecologists, university professors, healthcare providers, ICU nurses, and maternal health policymakers, will be interviewed.

Inclusion Criteria

The inclusion Criteria in this study are mothers who have experienced life-threatening conditions according to the WHO[1] including those suffering from the following organ failures (severe preeclampsia, eclampsia, severe postpartum hemorrhage, blood transfusion of more than five units, septic shock, cardiovascular dysfunction, respiratory dysfunction, renal dysfunction, coagulation/hematological dysfunction, hepatic dysfunction, neurological dysfunction), and uterine dysfunction (hysterectomy due to uterine hemorrhage or infection).

Exclusion Criteria

Mothers who, for any reason, do not wish to continue participation in the study will be excluded.

Phase 1: Qualitative Study

Qualitative data will be collected using in-depth semi-structured interviews with open-ended questions. Each interview will last approximately 40–60 minutes. An interview guide will be developed based on the literature review before data collection begins. The research team will use predetermined questions while asking additional probing questions according to participants' responses. The interviews aim to uncover participants' understanding of and experiences with MNMs, as well as the challenges they face post-hospital discharge. Husbands will be asked about the negative changes they experienced in their lives, while service providers will discuss the challenges they perceive from participants' unmet needs, and suggestions for addressing these issues. During the interview, the researcher will obtain the participant's permission to record the session using an audio recorder. Non-verbal cues, such as tone of voice, facial expressions, and posture, will also be noted. The interview's time and location will be documented, taking place in a quiet setting of the participant's choice, which may include their home, workplace, or other suitable environments. At the end of the interview, the participant will be thanked, and the possibility of a follow-up interview will be discussed. Data collection and analysis will occur simultaneously, allowing for immediate verbatim transcription after each session. Sampling will continue until data saturation is reached, meaning no new codes emerge.

Qualitative Data Analysis

MAXQDA software will be utilized for data analysis. A conventional qualitative content analysis approach will be adopted to analyze the data. The main advantage of this approach is obtaining direct information from a study without imposing preconceived categories or theories.[22] The data will be analyzed based on a qualitative content analysis method introduced by Graneheim and Lundman.[23] This method allows for extracting not only the explicit content of the texts but also their implicit content with varying degrees of abstraction. We will use four criteria to evaluate the accuracy of the qualitative data (Credibility, Dependability, Confirmability, Transferability).[24]

Phase 2: Development of the Mumapp Virtual Clinic

To develop the virtual MNM clinic, codes should be derived based on maternal needs and challenges, through interviews and literature review. These identified needs are then validated by participants. Subsequently, solutions are proposed, taking into account participant feedback and input from relevant experts. This validation process is carried out through a nominal group. The categorized needs will form the content of the Mumapp virtual clinic, accessible to both mothers and the medical team's panel. The Mumapp platform comprises a smartphone application for mothers and a secure web-based dashboard for healthcare professionals. Mothers can enter relevant clinical information, complete standardized assessments (including the Family Support [25] and DASS-21 scales[26]), receive automated feedback, access educational resources, and request or schedule virtual consultations. Authorized healthcare professionals can review the mothers' medical history and assessment results through the dashboard and provide individualized recommendations. All electronic data and communications will be encrypted and accessible only to authorized personnel.

Phase 3: Quasi-experimental Evaluation

A quasi-experimental, single-group pretest-posttest study will be conducted to evaluate the impact of the 'Mumapp' virtual clinic on the quality of life of mothers with maternal near-miss in Mashhad, Iran. Participants will be recruited through purposive sampling from healthcare centers.

After providing written informed consent, eligible mothers will complete the SF-36 at baseline and receive access to the Mumapp virtual clinic for six months. During the intervention, participants may use the application's self-assessment, educational, appointment-booking, and virtual consultation functions. Quality of life will be reassessed with the SF-36 at three and six months after enrolment.

Intervention

The intervention is six months of access to the Mumapp virtual clinic described in Phase 2. Participants will receive individualized digital follow-up care based on their clinical information, assessment results, and consultation needs.

Outcome Measures

Primary Outcome

The primary outcome is quality of life, measured using the 36-Item Short Form Health Survey (SF-36). The primary outcome will be assessed at baseline and at three- and six-month follow-ups.

Secondary Outcomes

Secondary outcomes include:

- Mothers' utilization of the virtual clinic
- Psychological assessment using DASS-21
- Family support assessment
- Individualized follow-up through virtual consultation

Sample Size

The sample size was estimated using G*Power software (version 3.1.9.4). Based on a t-test, means - difference between two dependent means (matched pairs) analysis, with an alpha of .05, a power of .90, and a predicted medium effect size (dz = 0.52) derived from similar postpartum quality of life literature, a minimum sample size of 41 participants was determined to be sufficient to detect statistically significant changes.

Recruitment

Eligible mothers will be identified in healthcare centers affiliated with Mashhad University of Medical Sciences. Women meeting the eligibility criteria will receive verbal and written information regarding the study. After providing written informed consent, participants will be enrolled in the intervention and complete baseline assessments before beginning the six-month follow-up period.

Data Collection and Management

Qualitative and quantitative data will be collected during their respective study phases. Interviews will be audio-recorded with permission, transcribed verbatim, and supplemented by field notes. Standardized questionnaires will be administered at baseline and at three and six months. All study records and data transferred through Mumapp will be securely stored, encrypted, and accessible only to authorized research personnel.

Statistical Analysis

Qualitative data will be analyzed using MAXQDA software according to the conventional content analysis approach proposed by Graneheim and Lundman.

Quantitative data will be analyzed using SPSS version 26, and the significance level will be set at a two-sided p-value < 0.05. Continuous variables will be summarized using means and standard deviations. Categorical variables will be presented as frequencies and percentages. To evaluate the effectiveness of the Mumapp intervention over time (from baseline to 3-month and 6-month follow-ups), a Linear Mixed-Effects Model (LMM) or Generalized Estimating Equations (GEE) will be employed. These models will allow for the assessment of mean changes in quality-of-life scores while adjusting for potential confounding variables such as maternal age, education level, and baseline family support.

Patient and Public Involvement

This study protocol involves near-miss mothers participating in a qualitative interview during the first phase and engaging with the researcher through a virtual clinic as part of a clinical trial in the third phase.

3 Expected Results

The qualitative phase is expected to identify the post-discharge physical, psychological, social, and informational needs of maternal near-miss survivors. These findings will inform the content and functions of a validated Mumapp prototype. The quantitative phase will estimate changes in SF-36 scores over six months and generate preliminary evidence on the feasibility, utilization, and potential effectiveness of this virtual-clinic model.

4 Discussion

According to Standard Six of the WHO's guidelines for maternal and neonatal care, it is essential to provide emotional support and empowerment to every woman, as well as her family and companions.[27] Integrating care that addresses the physical, psychological, social, and spiritual aspects of women can alleviate the burden of pregnancy complications for millions of women globally.[12] The current irregular follow-up of mothers with newborns has raised concerns about the cumulative impact and long-term adverse effects, as it may not provide a comprehensive overview of their primary care

post-hospital discharge.[28] A 2018 study by Furniss et al.in New Zealand suggests the need for tailored programs to alleviate the mental and physical burden experienced by these mothers, emphasizing the importance of planning, implementation, and evaluation.[29] Gathering information from mothers with newborns before hospital discharge, based on their backgrounds, can facilitate social-psychological support and enable regular, periodic follow-ups, helping to address their concerns and reduce their burdens.[30] Given that these mothers are discharged from the hospital under challenging circumstances, they often grapple with their own problems and those of their families, underscoring the necessity for a comprehensive plan.[2]

In today's technology-driven world, electronic devices like cell phones and tablets have become indispensable in daily life.[31] With remarkable advancements in medical technology related to pregnancy and childbirth, applications and websites now encompass all facets of human existence, including pregnancy.[32,33] It's rare to find a pregnant woman these days who isn't aware of her health status.[32] As a result, motherhood has become an increasingly lucrative and popular topic worldwide; this is due to the quality, reliability, and effectiveness of telemedicine methods in lifestyle and healthcare, and in reducing anxiety and stress.[31] However, despite the recommendations of some studies on progress and innovation in smartphone technology to develop comprehensive and appropriate programs for postpartum care,[34] no mobile application-based virtual clinic addressing MNM or childbirth complications has been developed to date.

The sequential design strengthens the intervention by grounding its content in the lived experiences of mothers and the perspectives of families and healthcare providers before evaluating preliminary outcomes. This user-centered approach may improve the relevance, acceptability, and practical usability of the virtual clinic for long-term maternal follow-up.

Maternal near-miss survivors may experience persistent physical, psychological, social, and financial consequences after hospital discharge. By providing need-based, remote, and potentially lower-cost follow-up, Mumapp may help reduce barriers to continued care and support recovery. Its effectiveness, however, must be established through the planned evaluation.

A major strength of the protocol is the involvement of mothers, spouses, healthcare providers, and policymakers in developing a need-based digital intervention. The sequential mixed-method design may enhance the clinical relevance and contextual suitability of Mumapp. Important limitations include purposive recruitment, a single-group quasi-experimental design, the absence of a concurrent control group, potential selection and attrition bias, and limited generalizability beyond the study setting. Therefore, any observed changes should be interpreted as preliminary rather than causal evidence.

5 Conclusion

This protocol describes the development, validation, and preliminary evaluation of Mumapp, a virtual clinic for maternal near-miss survivors. By translating qualitative evidence into a user-centered digital intervention, the study seeks to establish a feasible model for individualized post-discharge follow-up. Findings from the single-group evaluation will inform the design of larger controlled studies and future implementation strategies.

Declarations

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Artificial Intelligence Disclosure

No AI tools were used in the preparation of this article.

Authors' Contributions

Sedigheh Abdollahpour, Sanaz Mollazadeh, and Talat Khadivzadeh contributed to the design of the protocol. Sedigheh Abdollahpour, Talat Khadivzadeh contributed to the implementation and analysis plan. Sedigheh Abdollahpour, Sanaz Mollazadeh, and Talat Khadivzadeh have written the first draft of this protocol article, and all authors have critically read the text and contributed with inputs and revisions.

Availability of Data and Materials

Not applicable.

Conflict of Interest

The authors declare that they have no competing interests.

Consent for Publication

Not applicable.

Ethical Considerations

Written informed consent will be obtained from all participants before enrolment. The study protocol has been approved by the Ethics Committee of Mashhad University of Medical Sciences (Approval No. IR.MUMS.REC.1401.094). All study procedures will be conducted in accordance with the Declaration of Helsinki and relevant ethical guidelines. The study has been registered in the Iranian Registry of Clinical Trials (IRCT20220712055438N1). The findings of this study will be disseminated through publication in peer-reviewed journals and presentation at national and international scientific conferences.

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