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Development, implementation, and evaluation of a spiritual health promotion program for mothers of children with acute leukemia based on mobile health: A mixed-methods protocol study

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Abstract:

BACKGROUND: Considering the importance of the spiritual health promotion of Mothers of Children with Acute Leukemia (MoCwAL), designing a native mobile health (mHealth) application that is compatible with the beliefs, values, and cultural context of Iranian society is essential. This study aims to develop a Spiritual Health Promotion Program (SHPP) for MoCwAL based on a mHealth application, including design, implementation, and evaluation.

MATERIALS AND METHODS: This is a sequential exploratory mixed-methods study (qual → QUAN). This study will be conducted in four phases. The first phase includes the development of the content of the SHPP using Ewles and Simnett's (2010) designing pattern. After finalizing the SHPP, at the beginning of the second phase (mHealth application development), a panel of experts will be present. Based on the outputs obtained from this panel, the research team will proceed to design the application. The output of the second phase will be an initial version of the mHealth application. In the third phase, the usability and quality of mHealth application questionnaires will be evaluated. Results will be refined by the expert panel, and the final version of the application will be available. In the fourth phase, the SHPP for MoCwAL based on mHealth will be implemented as a quasi-experimental intervention, and mothers' spiritual health be evaluated.

CONCLUSION: This program can be useful in providing care, education, policy-making, and future research. Providing the SHPP in the form of an application will enable program users to benefit from the many advantages of information technology and will contribute to the expansion of the role of mHealth in the healthcare system and the strengthening of policies related to digital health in the field of chronic diseases.

Keywords:

Children, leukemia, mobile health, mothers, software, spirituality

Introduction

Blood cancer, including acute leukemia, is one of the most common cancers and the second leading cause of death among children and adolescents under the age of 14 in the world, including in the United States and Iran.[1,2] Given the shift from hospital-based care to home-based and family-centered care in pediatric oncology, parents play an active role in caring for

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the child, and children rely on their families for care[3,4] Mothers, as the primary caregivers for their children, are the main source of support and the focal point of the family, having the highest involvement in child care. Therefore, rates of psychological stress and tension in mothers with sick children are significantly high.[5] Multiple studies also suggest a higher prevalence of various psychological disorders in mothers compared to fathers.[3,5]

A spiritual approach is one of the coping strategies used by mothers of children with cancer to reduce their psychological distress.[6] Spiritual care, by enhancing and improving spiritual health, reduces psychological disorders and negative emotions and strengthens positive mental health components. Ultimately, it enhances coping abilities and improves the quality of life (QoL) for mothers of children with cancer facing crises.[7,8] Enhancing the spiritual health of mothers not only has positive effects on mothers themselves but also has potential effects on supporting children in overcoming the numerous suffering caused by cancer.[9] According to studies, mothers are the main source that children seek for alleviating their spiritual stress.[4] Therefore, parents, especially mothers, need to empower their spiritual dimension and improve their spiritual health to identify the needs and spiritual crises of their children and have the ability to provide spiritual care to their children.[10]

Providing spiritual care as part of holistic care is an integral component of nursing practice and nursing care.[10] In this context, one of the concepts that have emerged in nursing literature in recent decades is the concept of spiritual health for better coping and adaptation. There is a significant relationship between spiritual health and the adaptive behavior of mothers with children with cancer, in a way that high spiritual health in mothers facilitates hope and a sense of control over fate and tolerance of the suffering and grief resulting from the child's illness and reduces their feelings of sadness and depression.[11,12]

Given the rapid advancement of technology in the present era, there is a need for nurses to develop Spiritual Health Promotion Programs (SHPPs) using state-of-the-art technologies in user-friendly and family-preferred formats. By utilizing information technology tools and leveraging their potential, the effectiveness of health promotion programs can be enhanced.[13] Furthermore, the global mobile health (mHealth) market report indicates a significant increase in the commercial value of health application, generating wealth and capital growth at a remarkable rate in the past decade.[14,15]

There is no standardized definition of mHealth, but for the purposes of the Global Observatory for eHealth (GOe), mHealth or mobile health is defined as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices".[16] MHealth applications, along with the advancement of smartphone technology, high Internet penetration, and easy mobility of mobile phones, have facilitated patient-centered care in any place and time, revolutionizing traditional healthcare delivery.[17]

Despite the wide range of applications, only 5% of them are related to cancer.[18] Currently, most mHealth applications related to cancer patients primarily focus on the physical aspects and physical symptoms of these patients. At the same time, the spiritual dimension, despite its undeniable importance, has not received much attention. Even international mHealth applications have more extensive content but a limited focus on spirituality.[19,20]

After conducting comprehensive searches in databases and online app stores, researchers did not find a similar application for spiritual health promotion and spirituality among family caregivers, especially Mothers of Children with Acute Leukemia (MoCwAL), in Iran. Considering the importance of enhancing the spiritual health of mothers and the role of life experiences and cultural background in improving the spiritual dimension, designing a native mHealth application that is compatible with the beliefs and values prevailing in Iranian society and aligned with cultural and religious behavior patterns is essential. Given the clinical experiences of the research team, the emphasis on shifting care from hospitals to homes, and the necessity of improving spiritual health, the development of spirituality-centered mHealth applications and investment in the field of mHealth applications are crucial. So, to achieve all the desired study goals, it is necessary to design a multi-phase study which is considered as one of the complex nursing interventions. In complex studies, research questions are too broad to be investigated by a single method (quantitative or qualitative methodology). Given that in a mixed-methods study, the investigator collects and analyzes data, integrates the findings, draws inferences, or even gives rise to meta-inferences using both qualitative and quantitative approaches and methods, it provides a better understanding of the subject being studied than using a single method. Therefore, to provide strong, comprehensive, and deep conclusions and inferences, a mixed-methods approach was chosen in the present study. Therefore, this study aims to develop an SHPP for MoCwAL based on a mHealth application with a mixed-methods design approach, including design, implementation, and evaluation.

Materials and Methods

Study design

This is a sequential exploratory mixed-methods study (qual → QUAN) based on the paradigm of pragmatism. This study will be conducted in four phases including development of the content of the SHPP, mHealth Application development, evaluation of application usability and quality, and program implementation and evaluation. The results of the qualitative and quantitative phases will be integrated into the design of the program. The steps of the present study will be as follows [see also Figure 1].

Phase 1: Development the content of the SHPP

SHPP will be developed using Ewles and Simnett's (2010) designing pattern, comprising determining and prioritizing roles, explicating the aims and objectivities, the mission of the program, selecting the best strategy to achieve goals, identifying resources, and designing evaluation methods and setting an action plan.[21] To formulate the final program in this study, qualitative interviews with stakeholders, a literature review, an expert panel, and a modified classic Delphi technique according to the set goals will be used.

Phase 1-1: *Qualitative study*

Study design and setting, participants and sampling, and inclusion and exclusion criteria are mentioned in Table 1.

Procedure

Some examples of questions that will be asked of mothers in the interview will include: A) From the first time you found out that your child has cancer, what spiritual needs did you feel in yourself? B) What did you do to meet these needs? C) Do you think this solution was effective? D) What spiritual and mystical solutions does your wife use to help relieve himself or help you? The interviews and data collection will continue until data saturation is achieved.

Data analysis will be performed simultaneously with data collection using the conventional content analysis based on the Graneheim and Lundman approach.[22] MAXQDA 10 software (software for qualitative data analysis) will be used to manage the data.

Trustworthiness of qualitative data

Trustworthiness will be achieved using criteria proposed by Guba and Lincoln (1985) including credibility, dependability, conformability, and transferability.[23] By prolonging engagement in the field throughout the research, conducting in-depth interviews using a maximum variation sampling, full explaining of the study to participants, combining several methods of data collection, and checking the accuracy of the researcher's perception through review of a sample of the codes by an outsider observer (peer debriefing) and participants, (member check) credibility will be assured. The researchers will try to increase the transferability by clearly, accurately, comprehensively, and purposefully describing the research process and the study population so that other researchers can do the same. For conformability, the study steps will be accurately recorded so that a thorough audit of the work is possible. An independent researcher will examine both the process and product of the research study to ensure conformability. Researchers will try to explain the whole process of research including data analysis, coding, and related results clearly and in detail by providing examples of how to codify and reach categories so that dependability can be confirmed.

Phase 1-2: *Literature review*

A literature review will be conducted focusing on the spiritual needs and strategies to improve the spiritual health of MoCwAL and programs that provide these needs (SHPP) and related mHealth application in this field. In this phase, searching multiple electronic databases will be conducted, including Ovid, The Cochrane Library, Science Direct, PubMed, Scopus, Springer, ProQuest, EMBASE, CINAHL, and Web of sciences. The review process will begin with the extraction of related keywords by using Mesh and Boolean operators (AND, OR, NOT). Also, Persian databases and Android application store will be searched from ab initio until 2023. The purpose of this phase is to confirm the needs discovered in the qualitative phase or to discover the new needs and categories and to discover the strategies to meet the needs of MoCwAL in related texts. Inclusion and exclusion criteria are mentioned in Table 1.

Phase 1-3: *Experts Panel*

Study design and setting, participants and sampling, and inclusion and exclusion criteria are mentioned in Table 1.

Procedure

The research team will provide a summary of the research methodology and integrated data from the qualitative study and literature review as well as objectives of the panel session. The expert panel will prioritize the needs and strategies. Then, the expert panel will discuss the needs and priority strategies, intervention, and evaluation of the program. They determine the type of strategies to meet the needs of MoCwAL and will present their suggestions. The researcher will record and note the stated topics to design the program.

Phase 1-4: *Modified Classic Delphi Technique*

In the first round of Delphi, based on the results obtained from the qualitative study, literature review, and expert

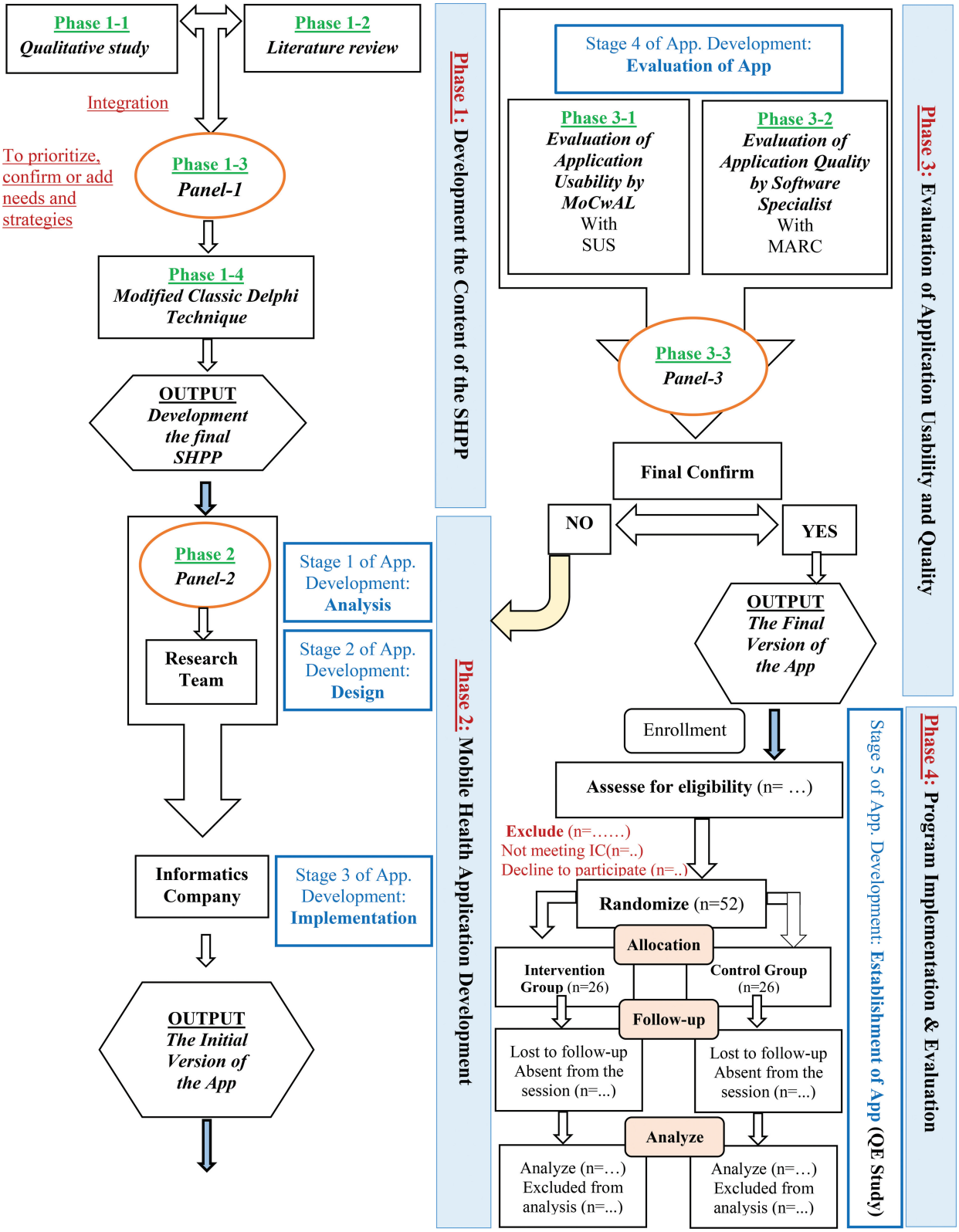

Figure 1: The four phases of a mixed-methods study at a glance

panel, the initial draft of SHPP for MoCwAL will be prepared by the research team. Then in the second round of Delphi, the initial plan prepared to confirm the content will be sent via email to the same specialists participating in the panel meeting. Based on the RAND Appropriateness Method (RAM technique), each component of the initial program is evaluated based on five criteria, "relevance", "intelligibility", "usefulness", "feasibility"

Table 1: Participants, setting, inclusion and exclusion criteria details in four study phases

Phase	Sub-Phase	Study Design	Study Setting	Study Participants and Sampling	Inclusion Criteria	Exclusion Criteria
I	Phase 1-1: Qualitative Study	Semi-structured in-depth individual interviews	Cancer treatment centers [Omid Hospital, Al-Zahra Specialized Chemotherapy Clinic (S)] and MACSA Charity Center (Iranian Center Control and Prevention Cancer) in Isfahan, Iran	MoCwAL, children suffering from acute leukemia, other family members as necessary, physicians, nurses, spirituality experts, and psychologists	All participants: desire to participate in the study, speaking Persian, being a Theist, having Iranian nationality. MoCwAL: age above 18, having a blood relationship with the child. Child: Being Less than 15 years old, having a definitive diagnosis of Acute leukemia (AL). Nurses, Oncologists, Religious experts, and Psychologists: having worked for at least 6 months in oncology-related health centers.	Reluctance to continue cooperation, withdrawal from the study at any stage of the research, and the death of a child with AL
	Phase 1-2: Literature Review	It is mentioned in the article.	It is mentioned in the article.	Not applicable for this section.	Access to the full text of original articles (quantitative, qualitative, and mixed methods), review articles, book reviews, and related Android Application in English or Persian languages regardless of the time limit.	Include Abstracts, short communications, letters to the editors, articles without having access to their full text, and articles in languages other than English and Persian
	Phase 1-3: Experts Panel	Purposive and snowball sampling methods. The number of participants will be at least ten.	Nursing and Midwifery Faculty	Research team, two palliative care specialists, a religious expert, an expert in the field of Application production and medical informatics, an oncology expert, a pediatrician/ an academic member from the pediatric nursing department, a medical education expert, a psychologist, a social worker, and an experienced oncology nurse	Desire to participate in the panel sessions, have sufficient experience and expertise in the considered fields.	Reluctance to participate in panel meetings and failure to attend at least two sessions
	Phase 1-4: Modified Classic Delphi Technique	The same experts of phase 1-3 will be invited.	Nursing and Midwifery Faculty - Email	It is mentioned in the article.	Similar to Phase 1-3	Similar to Phase 1-3
II	All this phase is explained in the article					

Contd...

Table 1: Contd...

Phase	Sub-Phase	Study Design	Study Setting	Study Participants and Sampling	Inclusion Criteria	Exclusion Criteria
III	Phase 3-1: Evaluation of Application Usability	Cross-sectional descriptive study Data collection tool: System Usability Scale (SUS) questionnaire	Similar to Phase 1-1	30 MoCwAL, referring to the study setting, will be recruited in the study using convenience sampling.	Desire to participate in the study, age above 18, having a blood relationship with the child, believing in one of the heavenly religions (being a Theist), having an Android-based smartphone, having the ability to use the Application and having Iranian nationality (self-reporting).	Reluctance to continue cooperation, incomplete questionnaires, The death of a child with AL during study
	Phase 3-2: Evaluation of Application Quality	Cross-sectional descriptive study Data collection tool: Mobile App Rating Scale (MARC) questionnaire	Management and Medical Information Sciences faculty (Department of Management and Health Information Technology) affiliated to IUMS	Three experts, including a health information management expert, a medical informatics expert, and a software engineer, will be recruited in the study using convenience sampling.	desire to participate, having at least three years of work related to electronic health, evaluation of electronic care systems and Application development, and having an Android-based smartphone (self-reporting).	Reluctance to continue cooperation, Incomplete questionnaires
IV	Program Implementation and Evaluation	Pretest–posttest quasi-experimental study Data collection tool: Paloutzian and Ellison Spiritual Well-Being Scale (SWBS)	Similar to Phase 1-1	52 MoCwAL will be allocated randomly into the intervention and control groups.	Similar to phase 3-1	Similar to phase 3-1

and "cost-effectiveness," based on a Likert scale of 1–9. Based on the scores obtained, each action is rated as "appropriate," "uncertain," or "inappropriate." Measures with average scores in the range of 1–3.9 (below 50.9%) are considered as "inappropriate," in the range of 4–6.9 (51–74.9%) as "uncertain," and in the range of 7–9 (above 75%) as "appropriate.".[24,25] The proposed actions that have a "suitable" score (7–9) will be included in the final SHPP. The actions that have an "inappropriate" score (1–3.9) will be omitted, and actions that have an "uncertain" score (4–6.9) score will be re-evaluated in the third round of consensus. In fact, in the third round, which is held in a face-to-face group discussion, the members (experts) are asked to comment on the cases that were not agreed upon by them in the second round. Finally, the necessary corrections should be taken into action based on the experts' feedback to develop the final format of SHPP appropriate to the culture and context of Iran.

Phase 2: Mobile health application development

After finalizing the SHPP, at the beginning of the second phase, a panel of experts consisting of approximately 12 members specialized in the fields of software engineering and medical informatics will be formed as the employer to define the architecture, behavioral characteristics, structural aspects, technical aspects, and user interface features of the application. Based on the outputs obtained from this panel, the research team will proceed to design the behavioral model, structural model, and user interface of the application. The application development process, similar to the Software Development Life Cycle (SDLC), comprises six stages.

This six stages include "Analysis" stage (definition of "Non-Functional Requirements" (NFRS) of the application), "Design" stage (determining the appropriate architecture, user interface, behavioral model design, and

structural model for the application), "Implementation" stage (program coding and application production), "Evaluation of App" stage (testing of the initial version of the application), and "Establishment of App" stage (final application will be installed on end-users smartphones via QE Study). Finally, the last stage of application development is "Maintenance"; this stage is not part of the objectives of the current project.[26,27] In the current research, an object-oriented approach will be used in the analysis and design stages of application development. The design process model will be the V-model. The user interface design of the application will be done using AdobeXD as the environment. Furthermore, the Android Studio operating system will be chosen for application execution.

Phase 3: Evaluation of Application usability and quality

Study design and setting, participants and sampling, and inclusion and exclusion criteria are mentioned in Table 1. The results of this study will be evaluated by the panel of experts who will be held at the end of the third phase, and after confirming its validity, the final version of the application will be available for end users.

Phase 3-1: *Evaluation of Application usability by MoCwAL*

Procedure

The researcher will provide necessary explanations to MoCwAL and then will invite them to participate in this study. After taking informed written consent, the application will be installed on the participants' mobile phones and will be asked to use it for 5 weeks.[28] After the 5 weeks, participants will be asked to complete the System Usability Scale questionnaire (SUS) online (in Google Form format).

Data collection tool and technique

In this phase, the SUS questionnaire will be used. It was developed by John Brooke in 1996. SUS consists of 10 items with a 5-point self-report scale ranging from 1 (strongly disagree) to 5 (strongly agree). There are five positive statements (items with odd numbers) and five negative statements (items with even numbers), which alternate. The total SUS score is calculated by taking one from all the scores on items with odd numbers and subtracting the scores from five for all the items with even numbers. The sum of the 10-item scores is then multiplied by 2.5 to obtain an overall SUS score between 0 (very poor usability) and 100 (excellent usability). The average SUS score is 68. A score of 80.3 or higher means that the application is good and people like the application and recommend it to their friends.[28,29] In Iran, the validity of this questionnaire has been confirmed in the study of Dianat *et al*.[30] (2014); the internal consistency (α = 0.79) and the reliability of the instrument [Intra-class correlation coefficient (ICC) = 0.96] have been obtained optimal.

Statistical analysis

Data will be reported using descriptive statistics in SPSS Version 16 statistical software (SPSS Inc., Chicago, IL).

Phase 3-2: *Evaluation of application quality by software specialists*

Study design and setting, participants and sampling, and inclusion and exclusion criteria are mentioned in Table 1.

Procedure

All the procedure steps will be similar to the procedure of phase 3-1 (only the participants and the questionnaire are different).

Data collection tool and technique

In this phase, the MARS questionnaire will be used. This questionnaire examines the quality of mobile phone application from the point of view of experts. The MARS consists of 29 items including four objective sub-scales engagement (items 1-5), functionality (items 6-9), esthetics (items 10-12), and information quality (items 13-19); it also includes a subjective quality sub-scale (items 20-23).[31] In this study, the Persian version of the questionnaire (MARS-Fa) will be used, the validity of which has been confirmed in the study of Barzegari *et al*.[32] (2022), and its reliability has been confirmed through the test and re-test method (r = 0.94).

Statistical analysis

It will be similar to the statistical analysis of phase 3-1.

Phase 4: Program implementation and evaluation

Study design and setting, participants and sampling, and inclusion and exclusion criteria are mentioned in Table 1.

Procedure

Paloutzian and Ellison Spiritual Well-Being Scale (SWBS) will be completed by the participants (MoCwAL) in a self-report form. In this study, a randomized block design will be used. Randomization will be done using Random Allocation Software. MHealth application will be installed on the participants' mobile phones and will be used for 8 weeks;[33] then SWBS will be completed online. The control group will not receive any intervention during the 8 weeks, but after completing the intervention, if the control group is willing, the SHPP based on mHealth will be provided for them ethically. It is noted that the MoCwOL who will participate in Phase 1-1 (Qualitative study) can participate in Phase 3-1 (Evaluation of Application usability by MoCwAL) or Phase 4 (Program implementation and evaluation), but the MoCwOL who participated in the Phase 3-1 will not be allowed to enter Phase 4.

Data collection tool and technique

In this study, the 20-item SWBS will be used to evaluate spiritual health. Scoring is ordered by a 6-point Likert scale from "strongly disagree," to "strongly agree." The total score of the SWBS can range from 20 to 120 higher scores, indicating higher spiritual health.[34] The results of studies in Iran indicate that the Persian versions of the SWBS have good validity and reliability in assessing spiritual health in the Iranian population. Cronbach's alpha reported greater than 0.85 and 0.82, respectively, in the study of Biglari Abhari *et al.* (2018)[35] and Rezaei (2009).[36]

Statistical analysis

Data analysis will be performed using the SPSS Version 16 statistical software (SPSS Inc., Chicago, IL). A confidence interval of 95% will be considered.

Discussion

Considering the absence of the SHPP based on mHealth for MoCwAL and the predominant focus of existing applications on the physical aspects of the field of cancer, this study is at its most important achievement; therefore, the first comprehensive research in Iran aimed at designing, implementing, and evaluating a family-oriented and specialized SHPP for MoCwAL, taking into account all stakeholders in Iran. Since this program will be designed in line with the structure of the Iranian health system and based on the current needs of a specific target group, it can be considered a native national achievement in the field of digital health. Thus, the current study is a turning point in providing spiritual care to MoCwAL, which will be formulated based on the real needs and experiences in the socio-cultural context of Iranian society, using the consensus of clinical experts through scientific methods and benefiting from experiences available in other global models.

The recommended strategies in the developed program in this study can serve as a guide for improving the spiritual health of mothers of children with cancer for healthcare team members. This program, which will be developed based on a holistic approach and emphasizes innovative technologies, will assist healthcare team members in providing comprehensive care as a professional team. It is expected that this research-oriented product will be well received by the family caregivers of cancer patients, considering the vacancy of this type of application in Iranian society. Therefore, in terms of commercialization, it will be possible to conclude a contract for the sale of this application to the Ministry of Health, NGOs, hospice centers, and centers providing palliative medicine services.

Limitations and recommendations

The Diffusion of Treatment will be a possible limitation in phase 4. In these situations, there is always a possibility that information can spread from individuals in the treatment group to individuals in the control group. To manage this problem, informed written consent will be obtained from the intervention group, stating that the information and program content will not be disclosed or the application will be shared. Also, to ensure that the application is not shared between the intervention and control groups, the "Application locks" technique will be used. Through coding (in the second phase of the study), the protection lock for the application is defined. In this study, application locking will be done using the unique serial number of the user's mobile phone (International Mobile Equipment Identity or IMEI).

Conclusion

The results of this study will provide a better understanding of how to identify the real spiritual needs of MoCwAL, combine qualitative data with the latest available knowledge, and refine the program through the consensus of interdisciplinary clinical experts, aligned with the development of a culturally appropriate program in the context of native Iranian culture in an evidence-based manner. Additionally, providing the SHPP in the form of application will enable program users to benefit from the many advantages of information technology and mHealth. The study results will provide a better understanding of the impacts of enhancing the spiritual health of mothers on them and also on other family members as well as on the treatment process of children. The results of the current study will contribute to the expansion of the role of mHealth in the healthcare system and the strengthening of policies related to digital health in the field of chronic and incurable diseases.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Ethics approval and consent to participate

This protocol study was approved by the Ethics Committee of IUMS (code number: IR.MUI.NUREMA.REC.1402.071). Written informed consent will be obtained from all participants in all four study phases. All participants will be informed that they can withdraw from the study at any time. In the use of textbooks and literature in the review phase of the study, the utmost accuracy and compliance with the principles of literary rights and maintaining trustworthiness will be done in the translation of the materials into the Persian language by mentioning the references.

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Conflicts of interest

There are no conflicts of interest.

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