**The present study has already been registered and approved in the Iranian clinical trial site with number (**the Iranian Registry of Clinical Trials under the number IRCT20150731023423N12 **,** 2018-11-06).

**Despite this, the protocol was also completed by the World Health Organization platform.**

**Project summary**

|  |  |
| --- | --- |
| Title | The effect of spiritual counseling on improving of the quality of life among pregnant women: A randomized control trials |
| Background | Physical and psychological changes during pregnancy affect the social and physical performance, as well as the quality of life (QoL) of pregnant women. There is a gap in the effectiveness of spiritual-based interventions in the culture and context of Iran on health-related QoL in women with the first pregnancy |
| Methodology | Parallel Randomized control trial- Not blinded  Intervention: Spiritual counseling was held in 8 sessions+ routine care  Control: routine care |
| Study Duration | Expected recruitment start date=2018-11-11  Expected recruitment end date= 2019-02-22 |
| Study centers | Two childbirth preparation centers in Zanjan city, Iran |
| Objectives | To examine the effect of spiritual counseling on the quality of life (QoL) of women with the first time pregnancy |
| Number of Subjects | 60 randomized patients in two arms; Treatment and Control |
| Main Inclusion  Criteria | **Inclusion Criteria**  Living in Zanjan city  Gestational age 20-24 weeks  Willingness to participate in the study  Lack of any psychiatric disorders or use of psychiatric drugs  the Edinburgh Depression Inventory  Score ≤10  the Cohen Perceived Stress 18 to 36  Having a normal pregnancy with a singleton fetus  **Exclusion criteria**  Having any medical or obstetric complication  Being absent more than two counseling sessions  No access to telephone follow up |
| Outcome | Quality of life among pregnant women  Measure: Health related Quality of life(SF-36) |

**General information**

|  |  |
| --- | --- |
| Protocol title | The Effectiveness of Spirituality Counseling on Quality of Life in First Time Pregnant Women |
| protocol identifying number | 32031 |
| Name and address of the sponsor/funder. | Dr Alireza Shoghli  Address: Azadi Blvd, Zanjan University Of Medical Sciences, Zanjan. Postcode No: 4515613191, Tel: +98 24 3314 8300 |
| Name and title of the investigator(s) who is (are) responsible for conducting the research, and the address and telephone number(s) of the research site(s), including responsibilities of each. | Maleki Azam, PhD in Maternal & Child Health  Address 1: Gavazang Road, Zanjan University Of Medical Sciences, Zanjan, Iran, Tel: +98 24334206519  Address2: Azadi Square ,Jomhori Eslami St , Social Determinants of Health Research Center, Zanjan University of Medical Sciences, Zanjan, Iran, Phone: 024-33156141  Fax: 024 – 33424770, Postal code: 4515613191, Email: malekia@zums.ac.ir & malekia41@yahoo.com. ORCID : https://orcid.org/0000-0001-7888-1985  the research site |
| Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the research | Social Determinants of Health Research Center, Zanjan University of Medical Sciences, Zanjan, Iran.  Name of recruitment center:  Childbirth Preparing Class at Imam Hussein Hospital & Ayatollah Mousavi Hospital of Zanjan, Iran |

**Rationale & background information**

Pregnancy is a physiological phenomenon in the women's life. Physical and psychological changes during pregnancy can affect the social and physical performance, as well as the quality of life (QoL) of pregnant women (1). According to the World Health Organization (WHO), health-related QoL refers to the physical, psychological, social, and spiritual dimensions of individuals’ well-being (2). Furthermore, QoL of pregnant women could be affected by many factors (3, 4). On the other hand, poor pregnancy QoL is associated with adverse pregnancy outcomes (5, 6) . Spirituality and religiosity are known as an important components of health and well-being(7). Childbearing is one of the ideal condition for enriching spirituality(8). Spirituality is defined as sensitivity or attachment to religious values, or to things of the spirit as opposed to material or worldly interests(10).

In Iran, spiritual care has not routinely included in prenatal care program, while in recent years, valuable results from the implementation of interventions based on religion and spirituality in improving anxiety, depression and coping with stress has been reported(11, 12). However, there is a gap in the effectiveness of spiritual-based interventions in the culture and context of Iran on health-related QoL in women with the first pregnancy. Given the importance of spiritual care and the presence of limited studies in this field, this study aimed to determine the effect of spiritual counseling on improving of the QoL of women with the first time pregnancy.

**References (of literature cited in preceding sections)**

References can also be listed at the end of Part 1.

**Study goals and objectives**

Primary objective: To determine the Effectiveness of Spirituality Counseling on improving Quality of Life in First Time Pregnant Women

**Study design and setting**

This parallel randomized control trial was carried out on 60 first time pregnant women who referred to two childbirth preparation centers in Zanjan city, Iran in 2018-19.

Inclusion criteria consisted of living in Zanjan city, gestational age of 20-24 weeks, willingness to participate in the study, lack of any psychiatric disorders or use of psychiatric drugs, obtaining scores ≤10 according to the Edinburgh Depression Inventory, scores 18 to 36 based on the Cohen Perceived Stress Questionnaire, and having a normal pregnancy with a singleton fetus.

Exclusion criteria were the presence of any medical or obstetric complication during the study period, being absent more than two counseling sessions, and no access to telephone follow up.

**Methodology**

Pregnant women who met the inclusion criteria and signed the informed consent form were allocated into two intervention and control groups using randomized a block size of four. To ensure the concealment of the sequence of enrolment, an opaque sealed envelope system was used (19). Envelope preparation and random allocation sequencing were performed by a person not involved in the research process. In the present study, participants & researcher were not blinded only outcome assessors were blinded. The research process is showen in fig1.

Intervention

The counseling sessions were designed in accordance with the study by khoda Karmari et al. and the method suggested by Richard and Bergin's.

According to the guidelines of the Iranian Ministry of Health, routine childbirth preparation classes were held from the 20th week of gestation every two weeks until the 32nd week of gestation. The sessions focused on making the mothers familiar with the different stages of pregnancy from fertilization to delivery, personal hygiene, nutrition, mental and physical changes during pregnancy, pregnancy risks, childbirth planning, postpartum health, breastfeeding, and child care. However, no spiritual counseling was provided.

The control group only received routine care. A spiritual counseling were integrated with routine care in the intervention group. Spiritual counseling was held in 8 sessions, as a group counseling (8-10 people) for 4 weeks (2 sessions per week for 45 minutes) at preparation classrooms. The main topic of counseling were reported in table 1.

Each session was started with a focus on breathing exercise or the sacred name like "Allah". Next, the counselor provided a description of the subject of the meeting and encouraged the mothers to express emotions, needs, concerns and thoughts on pregnancy. At the same time, the counselor guided the participants to increase their knowledge to choose the appropriate remedy for emotional reactions during pregnancy and pay attention to spiritual aspects of life. Further advice was given as homework. At the end of each session, explanations and summaries was provided and the women discussed about the topic. The counseling was conducted by a midwife that familiar with counseling approaches under the supervision of a clinical psychologist.

Outcomes

The outcome of this study was prenatal QoL of the first time pregnant women. Data were collected using the SF-36 as a standard questionnaire of QoL, which was completed by the groups before and two months after the intervention.

Data collection instruments

*Demographic*

It included personal information of woman's age, education, occupation and spouse’s occupational status.

Health-related quality of life (HRQoL) -*SF-36*

It is a health-related QoL (HRQoL) questionnaire as a multidimensional measure of health status for self or interviewer administration. It is widely used in clinical research and is a reliable and valid measure of health-related QoL in different populations(22, 23). It measures the perceptions of health-related QoL in 8 domains of Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Role-Emotional, Social Functioning and Mental Health. Responses are scored on a 5-point scale, that are transformed into a score of 0–100 with higher scores indicating better functioning or well-being. Validity and reliability of The Farsi version of the questionnaire have been assessed by Montazeri et al. (23).

**Safety considerations**

All participants in the study (intervention and control) received routine care, and the intervention, which was in the form of training and counseling, was integrated with the content of the routine care. It was held only the intervention group. The educational intervention did not have any harm to the participants and it was always possible to cancel the study for all participants**.**

**Follow-up**

The participants in both groups were 20 to 24 weeks pregnant, with the difference that the intervention group received 8 counseling sessions twice a week. The follow-up period was two months for two groups.

**Data management and statistical analysis**

The sample size of the present study was calculated 30 pregnant women in each group.The statistical analysis was performed using the SPSS software version 16. Descriptive statistics were employed to describe demographic data. The chi-square test was used to compare the demographic characteristics between the groups. The Kolmogorov-Smirnov test revealed that the scores of the QoL and its components had normal distributions. Therefore, to compare total scores and all areas between and within the groups in pre- and post-intervention, the independent t-test and paired samples t-test were applied, respectively. The risk of having a low QoL was estimated using the linear regression model. The level of significance was p< 0.05. We did not have missing in follow up period.

**Quality assurance**

The counseling was conducted by a midwife that familiar with counseling approaches under the supervision of a clinical psychologist. A standard questionnaire was used for data collection.

**Expected outcomes of the study**

The spiritual aspects of pregnancy and childbearing are often neglected in prenatal care. Integration of midwifery led counseling with the spiritual approach for improving quality of life of pregnant women is necessary**.**

**Dissemination of results and publication policy**

Azam Maleki is the lead in publication will be acknowledged in publications.

**Duration of the project**

Expected recruitment start date=2018-11-11

Expected recruitment end date= 2019-02-22

**Problems anticipated**

The long duration of each session could lead to the exhaustion of mothers. However, the women were allowed to have rest and walk for a few minutes during the sessions. .

**Project management**

This study was one part of the MSC thesis of M.K,M. The conception, design of the study, and data collection process were undertaken by M.K,M and A.M was the supervisor who also contributed to the design of the study and reporting of the results. K.A and S.F as the second supervisors contributed to all the stages of the study. Analysis, interpretation, and reporting were supervised by S.F and A.M. All authors contributed to the drafting and revising of the article and are in agreement with final version of the manuscript to be submitted to the journal; they also meet the criteria of authorship. S.F was one of the colleagues, but unfortunately he is not alive.

**Ethics**

This study was a part of MSc thesis and approved by the Ethics Committee of the Vice Chancellor for Research of Zanjan University of Medical Sciences, Iran, with the approval number IR.ZUMS.REC.1397.024. All procedures of the study were in accordance to the protocol of the regional ethical research committee and with the declaration of Helsinki 1964. After informing the study's purposes, written consent were obtained from all women. They were informed that their participation were voluntary, confidential, and anonymous, and were apprised of their right to withdraw from the research at any time**.**

**Informed consent forms**

The consent form is set in Persian.

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Research protocol: part 2

**Budget**

**Competing interests**

No potential conflict of interest relevant to this article was reported

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curriculum vitae of Azam Maleki

<https://scholar.google.com/citations?hl=en&user=2bczHUMAAAAJ>

Table 1 Details of the intervention

|  |
| --- |
| Counselling content |
| The first session was to meet the participants and researcher, to explain the aim, the rules, and brief full program, providing pre-test.  Talking about concept of quality of life, self-concept in pregnancy, and checking misconceptions.  Assessing attitudes and beliefs of the pregnant women on spiritual issues, the role of god and religious in her life.  Listening to positive statements of participants based on reading the holy book, and spiritual issues in overcoming or felling calm in stressful situations. |
| Listening to the physical and mental problems, worries, fears, ambivalence sense in early pregnancy and her actions in daily life.  Focus on human creation discuss concerning the status of women in the continuity of creation  Talking about the spiritual aspects of the pregnancy and childbearing.  Focus on the concept of trust, resort, patience, kindness.  Blessings of God and the role of it in reinterpreting concept of pregnancy and overcoming the worrisome symptoms of pregnancy.  Book therapy / listening to Qur'an voices for 10 min.  Strengthening individuals' inner hope and powers for coping with pregnancy and childbearing.  Encourages to create a daily spiritual space of time or place at home. |
| Encouraging to express their feeling after/ during creating a daily spiritual space.  Talking about the experience of participating in religious programs or doing spiritual issues.  Discuss to the effect of spiritual's beliefs on eating habits on the fetus, taking care of oneself in pregnancy.  Encouraging to refer to people who create a positive sense or comfortable with them.  Book therapy / listening to Qur'an voices for 10 min.  Listening to The "Nature's Music" the sound of birds, rivers and waterfalls…  Illustration and slowly moving tone using meditation relaxation technique along or with listening to relaxing music |
| Discuss the strategy of prayer therapy to reduce the worrisome symptoms of pregnancy related to pregnancy and increase hope  Express the pleasure and responsibility of being a mother from the point of view of the Quran" Divine Responsibility Reward"  Teaching relaxing muscles with deep breathing for getting rid of the stress. Repeat twice daily for 10 to 15 minutes |



**CONSORT 2010 Flow Diagram**

## Follow-Up

Analysed (n= 30 )  
 Excluded from analysis (give reasons) (n= )

## Analysis

Analysed (n=30 )  
 Excluded from analysis (give reasons) (n= )

Lost to follow-up (give reasons) (n=0 )

Discontinued intervention (give reasons) (n=0 )

Lost to follow-up (give reasons) (n= 0 )

Discontinued intervention (give reasons) (n=0 )

## Enrollment

Allocated to intervention (n= 30 )

 Received allocated intervention (n= 30 )

 Did not receive allocated intervention (give reasons) (n= 0 )

## Allocation

Allocated to intervention (n=30 )

 Received allocated intervention (n=30 )

 Did not receive allocated intervention (give reasons) (n= 0 )

Randomized (n= 60 )

Excluded (n8ons (n= 86 )

Assessed for eligibility (n= 146 )