A Study on the Efficacy of Spirituality-Based Intervention on Spiritual Well Being of Patients with Leukemia: A Randomized Clinical Trial

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Abstract
Background: Leukemia is the most common malignancy in young adults that has a life-threatening nature which increases the patients' spiritual needs, leading to emergence of spiritual crises. However, evidences indicate that spiritual needs of patients and their spiritual well-being are not emphasized among health care personnel. According to the cultural, religious and social backgrounds as well as contradictory findings in studies, this study intends to determine the effects of a spiritual-based intervention on spiritual well-being of patients with leukemia.

Methods: This randomized clinical trial was conducted at Sayyed-Al-Shohada Hospital (Isfahan, Iran) in 2012-2013. We randomly divided 64 adult patients with leukemia into experimental and control groups. In the experimental group, a spiritual-based intervention that included supportive presence and support for religious rituals was implemented for three days. Both groups completed the Palutzian and Ellison Spiritual Well-being Questionnaire before and after the intervention. Data was analyzed using ANCOVA, chi-square, the Mann-Whitney U-test, and paired and independent t-tests in SPSS (Version 18, SPSS Inc., Chicago, IL).

Results: There was a significant difference in the scores of the experimental group before and after the intervention ($P<0.001$). This difference was absent in the control group. According to ANCOVA results, the mean score of spiritual well-being after spiritual-based intervention in the experimental group was more than the mean score of spiritual well-being in the control group. This result was statistically significant ($P<0.001$, $F=63.303$)

Conclusion: Our spiritual-based intervention promoted the spiritual well-being of patients with leukemia. Therefore, in cases of refractory diseases such as leukemia, nurses should apply a holistic care approach with emphasis on spirituality-based intervention.

Keywords: Iran, Leukemia, Nursing, Spirituality
Introduction

Among all various types of cancers, leukemia is the most common malignancy in young adults. This cancer has the greatest mental and emotional impact among all cancers.\(^1\)

The America Cancer Society reported an estimated 52,380 new cases of leukemia and 24,090 deaths from leukemia in 2014.\(^2\) A report of the National Cancer Registration stated that leukemia, with 3,461 cases (4.7%), was the seventh most prevalent cancer out of ten most common cancers based on the total numbers of Iranian men and women in 2009.\(^3\)

Leukemia is a prevalent cancer in Isfahan (a city in central Iran) and responsible for 13% of total cancer mortalities.\(^4,5\) In 2007, the prevalence of leukemia among the male and female population in Isfahan was 8.48 and 4.72 patients per 100,000 inhabitants, respectively.\(^6\)

Leukemia changes the life of an individual in all aspects - physical, psychological, social, spiritual, economical and family.\(^7\) The threatening nature of leukemia significantly increases the spiritual needs of patients\(^8\) and may produce a type of spiritual crisis.\(^9,10\) Spirituality is an important phenomenon which has widely attracted the attention of psychologists and mental health professionals over the past few decades.\(^11\) According to available literature, spirituality is a strong predictor and promoter of psychological health.\(^12\) Previous studies have suggested that spirituality can increase the patients’ resistance against a mental health crisis following diagnosis and treatment of cancer.\(^13\) Spiritual interventions have also been found to help prevent and improve a range of physical illnesses and cope with chronic pain and death.\(^14-18\)

Spiritual needs often go unaddressed by health care professionals who have little training in the provision of spiritual care and may not feel comfortable assuming this role.\(^19\) Numerous studies validate that a strong sense of spiritual well-being (SWB) in cancer patients is associated with better quality of life and less psychological distress.\(^20-23\)

Research suggests that because of the strong relationship between psychological and SWB, these concepts should be referred to as psychospiritual functioning.\(^20\) In an attempt to minimize problems and enhance patients’ quality of life as well as cope with this disease, many patients with cancer turn to religion to fulfill their spiritual needs.\(^9,24,25\)

Spiritual well-being is well-recognized as a factor that affects patients’ quality of life, quality of care, and satisfaction.\(^26,27\) There is evidence that supports the fact that the patients’ spiritual needs are associated with a better quality of care, higher hospice utilization, and less aggressive care at the end of life.\(^27\)

Spiritual well-being can be an important resource for individuals and the families of individuals who struggle with serious or chronic illnesses. Frequently, when individuals are faced with adversities, including serious and life-threatening conditions (such as breast cancer), they turn toward a higher power or religion as a way of coping.\(^28\)

There is an increasing interest in the role and importance of spirituality in the context of health, illness, and healthcare practice.\(^29\) Empirical studies have shown that SWB is associated with various health measures. For example, Ellison and Smith (1991) have found that individuals who score high in SWB also tend to score high on psychological and relational scales. Hammermeister et al. (2005) reviewed a vast range of literature and concluded that SWB had a positive influence on most aspects of health. Mohan, et al. (2007) found significant positive correlations between the measures of SWB and psychological well-being among adolescents.\(^30\)

Two smaller scale studies with more homogenous cancer patient populations (i.e., malignant melanoma only, breast cancer only) suggested that nearly 85% to 90% of the patients have reported that they are spiritual or that spirituality is important in their lives.\(^31,32\)

Therefore, it is necessary to recognize spiritual care as a nursing component and nurses should assist patients with a holistic approach to acquire
and maintain health, physical, mental and spiritual recovery,33,34 and combine spirituality with care in leukemic patients has remained a need for research.33

Despite the fact that religiosity and spirituality have been described as the most commonly used 'complementary therapies' by individuals with cancer,35 no published research has examined the efficacy of spirituality-based intervention on SWB of patients with leukemia or other types of cancer; only a few studies have been undertaken in other diseases. The results reported by Delaney and Barrer,33 Warber et al.36 and Kennedy et al.37 showed a significant positive correlation between spirituality-based intervention and SWB in cardiac patients. In contrast, Blumenthal et al. reported few evidences that spirituality, frequency of going to church or praying was correlated with cardiac complications or mortality following acute myocardial infarction in depressed patients or those with little support.38

Despite the increase in knowledge regarding the necessity for spiritual care, there is no unique agreed method about its use for cancer patients, in particular those with leukemia. The higher concentration on physical parameters of patients with leukemia in physiologic crisis has led to less emphasis on spiritual needs. While a patient requires spiritual needs and meets them at the time of hospitalization, nurses can assist patients with a holistic approach to acquire and maintain health in addition to physical, mental and spiritual recovery.33,39,40 Hence, this study is an attempt by the researcher to use the results obtained from Iranian cultural, religious and social backgrounds in conjunction with various worldwide reports regarding spiritual care located through a comprehensive library search, and comments of experts and professionals to develop a spiritual-based intervention and review the impact of its implementation on SWB of patients with leukemia.

Due to the lack of a similar study in terms of the effects of spirituality-based intervention on SWB of patients with leukemia and contradictory results of previous research, we designed and implemented a spiritual-based intervention and evaluated its effects on SWB of patients with leukemia admitted to the Intensive Care Unit at Sayyed-Al-Shohada Hospital (Isfahan, Iran) in 2012-2013.

**Materials and Methods**

This was a two-group double-phase single blind clinical trial that had a pre- and post-test design; spiritual care was the dependent variable and SWB was the independent variable. Subjects were diagnosed with leukemia and admitted to the intensive care unit at Sayyed-Al-Shohada hospital (Isfahan Oncology Health Center) Isfahan, Iran. Inclusion criteria included a definite diagnosis of leukemia by a hematologist and patients who were undergoing chemotherapy, radiotherapy or surgery. Additional inclusion criteria were: consent to participate, Shiite, 18 years of age and older, native Iranians and Persian-speaking. Exclusion criteria included patients unaware of their disease, mental retardation, blindness, deafness or active mental diseases (schizophrenia, paranoia and obsession). In addition, subjects were excluded in case of unwillingness to continue the study, any indications that prevented the patient from participating or transfer of the patient to another hospital. We randomly allocated participants to the experimental and control groups (n=32 per group) using envelopes that contained numbers from a table of random numbers. Sampling lasted for six months.

Data were collected through a two-part questionnaire. The first part assessed demographic and disease-related data and contained questions that pertained to age, sex, education, marital status, employment, type of leukemia, type of treatment and elapsed time from diagnosis. The second part comprised the Palutzian and Ellison Spiritual Well-being Questionnaire (SWB Questionnaire).

The Spiritual Well-being Questionnaire (Paloutzian and Ellison, 1982; Ellison, 1983; Reviewed by Boivin, Kirkby, Underwood, and Silva, 1999) is a 20 item, self-assessment instrument that consists of two subscales, one
that represents the vertical religious well-being (RWB) dimension and the other represents the horizontal existential well-being (EWB) dimension. Each subscale contains ten items. Each item is rated on a six-point Likert type scale, with answer options that range from ‘strongly disagree’ (1) to ‘strongly agree’ (6). Examples of items are ‘I believe that Allah loves me and cares about me’ and ‘I feel that life is a positive experience’. The RWB subscale had an alpha reliability of 0.77 and the EWB subscale had an alpha reliability of 0.78. This standard questionnaire was applied in Iran by Seyed Fatemi et al. with an alpha reliability of 0.82.

Despite the widespread use of the SWB Questionnaire in studies and confirmation of its validity and reliability, in the present study we examined the reliability of this questionnaire in leukemic patients in a pilot study conducted by Musarezaie. The Pearson correlation coefficient was 0.955 for the RWB subscale, 0.935 for the EWB subscale and 0.945 for the total according to the test re-test method with a two-week interval. The results showed satisfactory reliability in patients with leukemia.

Based on the scores obtained, the SWB scale has been divided into three levels: low (20-40), moderate (41-99), and high (100-120). The scale is easily understood, requires 10 to 15 minutes to complete and has clear scoring guidelines. It is nonsectarian and can be used in a variety of religious, health, and research contexts. The SWB scale has been used in over 300 research endeavors, and has consistently demonstrated its validity and reliability in measuring spiritual health.

After obtaining an introduction letter from the School of Nursing and Midwifery, the researcher referred to the management of Sayyed-Al-Shohada Hospital and began sampling after an explanation about the study objectives was provided to the authorities. Following informed consent from subjects, the researchers (a man for male patients and a woman for females) visited the patients’ rooms and implemented the spiritual-based intervention. The selected patients were reassured about data confidentiality and their access to the final results. The study was conducted in full conformance with the principles of the Declaration of Helsinki. Participants read and understood the information necessary to make an informed decision about their voluntary participation. This research was approved by the Ethical Review Committee of Isfahan Faculty of Nursing and Midwifery. The research fellow was briefed by the researcher. Implementation and planning of spiritual care was performed by the research fellow under supervisor of the researcher.

The SWB questionnaire was completed before the intervention and at the end of the third day by an unaware co-researcher who received a brief explanation by the researcher before the beginning of the study. The planning and implementation of the spiritual-based intervention was closely monitored by the main researcher. Based on a previous study by Moeini and the average hospital stay of patients with leukemia, the study subjects in the experiment group received spiritual care at 16:00-20:00 for three days, for a total of 12 hours per patient.

The planned spiritual-based intervention included two major components of supportive presence and support for religious rituals. The researcher supported the patients through encouraging them to express their feelings, needs and concerns through verbal and non-verbal communication, providing them with a detailed description of the disease and its therapeutic process, and responding to their questions by holding their hands while talking, touching them using a supportive approach, and active listening. The researcher avoided any prejudgments about the patient’s appearance, accent and behavior, particularly at admission. In all stages of the intervention, patients were called by their name for respect and to preserve their dignity.

In order to support religious rituals, patients were provided a packet that contained a prayer rug, rosary and a veil for women. Patients were also informed about their free access to an MP3 player and earphones to listen to the Quran, prayers and
azan. Reading of the Tawasol Prayer and Quran at the patient’s bedside was also implemented by a clergyman.\textsuperscript{40,45}

Data analysis was conducted through SPSS software for Windows version 18.0 (SPSS Inc., Chicago, IL, USA) and descriptive as well as inferential statistical methods (ANCOVA, chi-square, Mann-Whitney U-test, paired and independent t-tests).

\section*{Results}

The mean age of the participants was 41.68 (17.17) years in the experimental group and 41.56 (13.45) years in the control group. According to the results of the chi square test the two groups had no significant differences (statistically both groups were identical) in terms of sex ($P=0.79$), marital status ($P=0.14$), employment ($P=0.43$), type of leukemia ($P=0.49$) and type of treatment. The Mann-Whitney U-test showed that both groups had no significant difference in terms of education ($P=0.86$). Findings indicated there was no significant difference (statistically both groups were identical) in terms of elapsed time from diagnosis ($P=0.96$) and age ($P=0.97$). Table 1 lists patients’ demographic information.

The results of the independent t-test in the experimental and control groups prior to the study showed no significant differences in terms of mean scores of the existence dimension ($t=0.26; P=0.79$), religious dimension ($t=0.16; P=0.84$), and total score ($t=0.08; P=0.47$) of SWB. However, the independent t-test showed a statistically significant relationship between the experimental and control groups after the spiritual-based intervention in terms of mean scores of the existence dimension ($t=0.26; P=0.79$), religious dimension ($t=0.16; P=0.84$), and total score ($t=0.08; P=0.47$) of SWB.

The results of the paired t-test showed no significant differences before and after the study in terms of mean scores of the existence dimension ($t=2.26; P=0.11$), religious dimension ($t=1.39; P=0.17$), and total score ($t=2.39; P=0.09$) of SWB. However, the paired t-test showed a significant difference before and after the spiritual-based intervention in terms of mean scores of the existence dimension ($t=4.15; P<0.001$), religious dimension ($t=2.38; P=0.02$), and total score ($t=3.87; P=0.001$) of SWB. Table 2 shows a comparison of the mean SWB scores between the experimental and control groups.

\begin{table}[h]
\centering
\caption{Demographic characteristics of the study subjects with leukemia.}
\begin{tabular}{|l|l|l|l|l|l|}
\hline
\textbf{Variable} & \textbf{Category} & \textbf{Experimental group} & \textbf{Control group} & \textbf{Statistical indicators} \\
 & & \textbf{Frequency} & \textbf{Percentage} & \textbf{Frequency} & \textbf{Percentage} & \\
\hline
Gender & Male & 19 & 59.4 & 20 & 62.5 & $N^2 = 0.79$ \\
 & Female & 13 & 40.6 & 12 & 37.5 & $P=0.07$ \\
\hline
Educational level & Illiterate & 5 & 15.6 & 6 & 18.8 & \\
 & Less than high school & 15 & 46.9 & 16 & 50.0 & $Z = -0.17$ \\
 & High school graduate & 11 & 34.4 & 5 & 15.6 & $P=0.86$ \\
 & College degree & 1 & 3.1 & 5 & 15.6 & \\
\hline
Marital status & Single & 10 & 31.2 & 5 & 15.6 & $N^2 = 2.18$ \\
 & Married & 22 & 68.08 & 27 & 84.4 & $P=0.14$ \\
\hline
Employment status & Employee & 0 & 0 & 2 & 6.2 & \\
 & Worker & 5 & 15.6 & 2 & 6.2 & \\
 & Self-employed & 8 & 25 & 7 & 21.9 & $N^2 = 5.9$ \\
 & Retired & 1 & 3.1 & 1 & 3.1 & $P=0.43$ \\
 & Housekeeper & 7 & 21.9 & 11 & 34.4 & \\
 & Other & 11 & 34.4 & 9 & 28.1 & \\
\hline
Leukemia type & AML & 22 & 68.8 & 18 & 56.2 & \\
 & ALL & 7 & 21.9 & 8 & 25 & $N^2 = 2.39$ \\
 & CML & 2 & 6.2 & 2 & 6.2 & $P=0.49$ \\
 & CLL & 1 & 3.1 & 4 & 12.5 & \\
\hline
\end{tabular}
\end{table}

\begin{thebibliography}{99}
\bibitem{40} \textsuperscript{40} Azan. Reading of the Tawasol Prayer and Quran at the patient’s bedside was also implemented by a clergyman.\textsuperscript{40,45}
\bibitem{45} Data analysis was conducted through SPSS software for Windows version 18.0 (SPSS Inc., Chicago, IL, USA) and descriptive as well as inferential statistical methods (ANCOVA, chi-square, Mann-Whitney U-test, paired and independent t-tests).
\end{thebibliography}
For comparing the mean scores of SWB of the two groups after intervention, we used ANCOVA (Analysis of covariance) with control of SWB as the covariate variable before intervention. According to ANCOVA results, the mean SWB score after spiritual-based intervention in the experimental group was significantly more than the mean SWB score in the control group ($P<0.001$, $F=63.303$; Table 3).

### Discussion

The results showed that with the random allocation method no statistically significant differences existed between the two groups before intervention in terms of demographic characteristics, type of leukemia, and terms of elapsed time from diagnosis. The statistical test also confirmed the random allocation of the study subjects.

The results showed that after the intervention there was a significant difference in existence, religious and total score of SWB in patients with leukemia in the experimental and control groups. The current study confirmed study results reported by Warber et al. where there was a significant difference between SWB of the two groups after spiritual–based intervention ($P=0.025$). Study results by Wachholtz and Pargament that aimed to review the impact of spiritual meditation, secular medication and relaxation on spiritual and psychological outcomes in the U.S. showed that after the intervention a significant difference existed between the three groups in SWB ($P=0.01$; $f=2.4$). This result also supported our findings.

The results showed that the SWB score had a significant difference in the experimental group before and after intervention. In line with the results of the present study, the results reported by Delaney and Barrer aimed to review the impact of spiritual care (music/guided visualization) on mental/spiritual results of cardiac patients. Their results showed that mean scores of SWB before and after intervention had a statistically significant difference ($P<0.05$).

A study by Kennedy et al. aimed to review spiritual-based intervention on spirituality and health of patients. In their study, a significant difference existed in SWB of patients before and after intervention in the test group ($P<0.05$), which supported the present study's results.
Additionally, in support of the findings of the present study, Jorna et al. reviewed the impact of a holistic health program on women’s physical activity and mental health and SWB. The results of their study showed a significant difference in SWB of the test group before and after intervention \((P=0.009)\).46

In a study conducted by Moeini et al. in Iran, the results have indicated a significant increase in SWB patients after spirituality-based intervention.43 Therefore, implementing this spiritual-based intervention by nurses can be effective for SWB of patients with leukemia. This intervention can be an appropriate method to improve their SWB.

**Conclusion**

Given the results of the present study, spiritual-based interventions similar to the current study's spiritual program can lead to a significant increase in the SWB’s leukemia patients. Optimum SWB can serve multiple functions in long-term adjustment to cancer such as maintenance of self-esteem, provision of emotional comfort and hope, and providing a sense of meaning and purpose. Hence, it is necessary for the treatment team to assess and improve the SWB of patients. Meanwhile the role of nurses is emphasized. Nurses can be effective in meeting spiritual needs and improving SWB. It is strongly recommended that in leukemia patients, applying a holistic care plan based on spiritual care development and education of patients should be taken into consideration in order to improve patients’ SWB.

The findings of this study had limitations. One of the most important limitations of the present study was that the researcher found no published research that examined the efficacy of spirituality-based intervention on SWB of patients with leukemia or other types of cancers which made it difficult to support the findings. Low numbers of eligible patients (low sample size) with leukemia was the most important limitation of this study which decreased the generalization of present study’s findings. In particular, the physical and psychological situations of this inadequate number of patients were other major issues encountered by the researchers. Short-duration implementation of the intervention (as a student thesis) was another limitation. Implementing interventions with higher number of spiritual care sessions and longer follow-up on a greater number of patients would lead to more reliable conclusions.

According to the findings of this study, we suggest the impact of spiritual-based intervention on SWB and spiritual distress of patients with other types of cancers should be evaluated. Furthermore, experiences of patients from spiritual care and barriers to provide this care in the hospital should be studied.

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**Conflict of Interest**

No Conflict of interest is declared.

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