



# Quality of Life Outcomes of Iranian Traditional Medicine Health Measures Instruction (Hefzalsehe): A Clinical Trial

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Received 2018 December 20; Revised 2019 February 19; Accepted 2019 February 26.

## Abstract

**Background:** The sedentary lifestyle violates health status and has negative impacts on the quality of life with subsequently numerous diseases.

**Objectives:** The current study aimed at evaluating the quality of life outcomes of Iranian traditional medicine (ITM) health protection measures instruction (traditionally named Hefzalsehe meaning that the essential lifestyle recommendations to maintain health and well-being based on ITM).

**Methods:** The current randomized, controlled trial aimed at examining the quality of life outcomes of ITM health protection measures instruction (Hefzalsehe) in individuals in Tehran, Iran in 2017. At the same interval, the experimental group was trained virtually and traditionally for the ITM health protection measures; whereas the control group was not. Subsequently, the Persian version of the short-form 12 quality of life questionnaire (SF-12) standardized in former studies was applied to measure the effect of Hefzalsehe instruction on the quality of life of 101 subjects randomly assigned to two demographically-matched groups.

**Results:** Significant improvement was observed in physical functioning (19.12 vs. -20.5;  $P < 0.001$ ), role constraints due to physical problems (42.16 vs. -34;  $P < 0.001$ ), bodily pain (16.67 vs. -11;  $P < 0.001$ ), general health (14.71 vs. -12.5;  $P < 0.001$ ), vitality (12.55 vs. -2;  $P < 0.001$ ), social functioning (18.14 vs. -12;  $P < 0.001$ ), role constraints due to emotional problems (35.29 vs. -16;  $P < 0.001$ ), and mental health (14.51 vs. -4.2;  $P < 0.001$ ) in the experimental group compared with the control group.

**Conclusions:** The current study indicated positive effects of education and Hefzalsehe instruction on the quality of life parameters.

**Keywords:** Quality of Life, Health Belief Model, Hefzalsehe, Iranian Traditional Medicine

## 1. Background

In Iranian traditional medicine (ITM), prevention of diseases is considered as the priority (1). Based on Avicenna's point of view, it is necessary to consider treatment by three methods: change in the six essentials of life, the employment of medications, and manipulation (2). It is observed that lifestyle modification is a reasonable method in primary healthcare to lessen weight, blood glucose level, belly fat amount, and psychological distress (3). Numerous epidemiological researches show that the primary approach of the intervention is lifestyle modification, which could be used without inevitability of medical treatment as lifestyle modification may result in constructive consequences on metabolic diseases (4). Lifestyle modification including physical activity and control of eating

habits are focused meticulously on ITM. For instance, numerous factors regarding foodstuff and its quality are concentrated by ITM scientists including MIZAJ status, demographic characteristics, and gastrointestinal condition of the individual, as well as the quality of foodstuff (5).

Hefzalsehe is the ancient name of modern preventive medicine mainly based on ITM, which is one of the methods of maintaining health based on MIZAJ status as well as lifestyle modification. The concept of health from Avicenna perspective is in accordance with the balance among organs function. Hefzalsehe is a set of instructions, including instructions on eating and drinking (consumption of foodstuff considering MIZAJ), sleep and awakening (sleep time, environment, and sleeping behavior), physical activity and rest (exercise and its types, rest, work and

its effect on the body), nutrition and disposal of waste materials (sweating and the importance of cupping), the weather (the influence of the weather and various seasons on the body and body adjusting to each season), and mental states (controlling anger, coping with sadness, excitement, and joy). Although these lifestyle modifications are similar to traditional principles of traditional medicine, ITM provides these strategies with regard to each individual's physical characteristics. One of the basic strategies to improve the quality of life is to educate lifestyle modification based on the ITM that should be considered as the World Health Organization defined health as a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity (1-6). Although such approaches are similar both in lifestyles relied on traditional and modern medicines, these approaches in ITM are presented with regard to temporal and personal characteristics of each individual; hence, the ITM has a comprehensive performance. For example, a review observed that the furthestmost resolution to prevent and control diabetes, such as proper diet, weight loss, physical activity, and lifestyle modification, is almost identical in both traditional and modern medicines (6). Several studies, such as that of Mahdizadeh et al., revealed that health education programs, which are in accordance with health acceptance models, are applicable in encouraging health awareness and perceptions of cognitive and healthy lifestyle performances in adolescents (7). To the best of authors' knowledge, there is lack of evidence of assessing the quality of life following Hefzalsehe education. Therefore, the current study aimed at evaluating the effect of Hefzalsehe education on the quality of life by standardized short-form 12 quality of life questionnaire (SF-12).

Findings of former studies proposed that the SF-12 is a reliable and valid instrument to measure health related quality of life in Iranian population (8).

## 2. Objectives

The current randomized, clinical trial aimed at evaluating the effects of Hefzalsehe (healthcare guidelines based on ITM) education on the quality of life in a population in Tehran, Iran in 2017.

## 3. Methods

The study was also registered at Iranian Registry of Clinical Trials (registration No. IRCT20190109042302N1). The inclusion criteria were: individuals with no documented history of any chronic diseases and willingness

to participate in the study. Patients with a history of any long-standing disease, which required medication or hospital admission, were excluded. The participants were randomly selected and then assigned to the control and intervention groups using simple random allocation method. Subjects were randomly selected from database of insured individuals covered by Iranian Health Insurance Organization. Individuals were randomly selected from 1 to 100. Randomization was performed using a computer-generated randomization slope (Arcus Quickstat, Cambridge, United Kingdom) with simple random allocation method. Randomization numbers were assigned consecutively in an order in which subjects were enrolled using statistical analysis of SPSS software version 21.0 (SPSS Inc., Chicago, IL, USA).

Totally, 150 subjects were required; however, 101 cases were included due to the loss to follow-up. Educational material was extracted from ITM texts and then, based on the health belief model, a curriculum was designed according to the ITM in order to educate Hefzalsehe. The 1st and the 2nd sessions took totally four hours. The detailed curriculum of Hefzalsehe education was on the following subjects: introduction, eating and drinking, rest, sleeping, disposal of waste, and mental health. Along with educational program, 364 Telegram messages were sent to participants to keep their knowledge up to date.

The educational content was based on the booklet of Hefzalsehe for Behvarz, published by the Iranian Ministry of Health and Medical Education and the textbooks of the ITM. The subjects were assigned to groups of maximum 10 subjects and then face-to-face training was performed in two sessions based on the provided content in eight hours. Education was performed by two trainees of traditional medicine (last-year medical students who participated in the ITM program at Shahed University, Tehran, Iran).

Subsequently, for six months instruction was given using social media as well as telephone conversation. Quality control team regularly followed up the subjects in order to check their access to social media. The primary outcome of the study was to evaluate the quality of life of the subjects before and six months after the intervention. Quality of life in the current study was evaluated using the standardized SF-12 questionnaire including 12 items on the quality of life. The short-form of the quality of life questionnaire (SF-36) is a 36-item instrument widely used by various studies. However, SF-12 is a self-reporting questionnaire with 12 items and eight subscales (i.e., physical functioning (PF), role constraints due to physical problems (RP), mental health (MH), role constraints due to emotional problems (RE), energy/vitality (VT), social functioning (SF), bodily pain (P), and general health (GH)). In this questionnaire,

lower scores represent lower quality of life. The study protocol was approved by the Ethics Committee of the University. All the subjects signed the informed consent form and they were assured of the confidentiality of their information. Furthermore, it was explained that there is no medical or surgical intervention in the study. Participants confirmed that they gave the consent arbitrary with the right to refuse or withdrawal. The case and control groups were matched for age, gender, and level of education. Descriptive statistics (mean, standard deviation, frequency, and ratio) and inferential statistics (chi-squared, Independent *t*-test, the Mann-Whitney, Dependent *t*-test, Paired-samples *t*-test, and the Wilcoxon tests as well as Spearman correlation coefficient) were used in the current study based on normality or non-normality of data assessed by the Kolmogorov-Smirnov test. *P* value < 0.05 was considered as the level of significance. Sample size calculation determined 50 subjects in each group.

#### 4. Results

The initial sample size in the current study was 150, of whom 101 were finally enrolled in the study (Figure 1). Both groups were homogenous in terms of mean age (the intervention group =  $38.72 \pm 9.78$  versus the control group =  $40.1 \pm 9.74$  years, *P* = 0.514), gender (male percentage in the intervention group = 45% versus the control group = 54%, *P* = 0.428), educational level (academic education percentage in the intervention group = 73% versus the control group = 70%, *P* = 0.761), and occupational status (housewife percentage in the intervention group = 15% versus the control group = 28%, *P* = 0.250). According to the results shown in Table 1, the experimental group in all aspects of the quality of life had a significant increase compared with the control group, especially in physical problems, while there were no significant changes in the control group. The correlation between change score (post-pre) of subscales and total score of quality of life in the two groups are presented in Table 2. Accordingly, most subitem quality of life changes were significantly seen in the intervention group, but such relationship was less observed in the control group.

#### 5. Discussion

Significant improvement was observed in physical functioning, role constraints due to physical problems, bodily pain, general health, vitality, social functioning, role constraints due to emotional problems, and mental health in the experimental group compared with the control group. The validity and reliability of SF-12 were confirmed in previous studies to assess general community

health status (9, 10). The current study aimed at evaluating the effect of Hefzalsehe education on the quality of life using SF-12.

In the lifestyle derived from ITM, paying attention to all aspects of life summarized in six principles of eating and drinking, sleeping and awakening, moving and staying, preserving the required materials and disposing of waste, climate, and mental state is of great importance (2). Based on this lifestyle, paying special attention to individual's temperament plays a pivotal role in maintaining the balance among different organs to such an extent that previous studies showed the better performance and function of individuals with good adherence to ITM and its lifestyle rather than modern medicine (11).

The results of the current study showed a significant difference in physical aspect, including physical functioning, role constraints due to physical problems, physical pain, life expectancy, vitality, and social performance, between the intervention and control groups following the lifestyle education to the intervention group based on ITM (Hefzalsehe), which was consistent with the findings of the study by Razavi et al., showing that lifestyle education was effective in reducing the risk factors of coronary artery diseases (12) and the results of the study by Loveman et al., on the clinical efficacy of type 2 diabetes education, which reported a significant improvement in metabolic control or quality of life as well as other mental parameters in the patients receiving such educations (13).

The results of several other studies including the study by Xu et al., in China on the effect of education on blood pressure (14), and the study by Coker et al., (15) on the effect and role of education in the promotion of health in the learners, were also consistent with the findings of the current study in terms of physical aspect.

The results of the current study also showed a significant difference between the intervention and control groups in psychological aspect following the education of lifestyle to the intervention group. The results were in agreement with former researches showing a significant difference between the groups in the psychological and physical aspects, which indicated that the lifestyle introduced in the current study could affect these aspects of life as well (13).

Thoroughly, the results of physical and mental health assessments showed a significant difference in the quality of life between the intervention and control groups. Since the results of the current study were consistent with those of previous studies (16), it can be concluded that the health-promoting lifestyle, developed based on ITM, introduced in the current study could improve the quality of life in the study participants. The study by Najafimanesh et al.,

**Table 1.** Quality of Life and its Subscales at the Beginning and End of the Study in Both the Study Groups

Variable, Group	Before		After		Diff.	P Value	P Value
	Mean	SD	Mean	SD			
<b>Physical functioning</b>							< 0.001
Intervention	57.84	30.20	76.96	24.92	19.12	< 0.001	
Control	63.00	22.15	42.50	22.73	-20.5	< 0.001	
<b>Role constraints due to physical problems</b>							< 0.001
Intervention	37.25	44.55	79.41	34.89	42.16	< 0.001	
Control	56.00	42.43	22.00	38.01	-34	0.104	
<b>Bodily pain</b>							< 0.001
Intervention	53.43	23.99	70.10	21.81	16.67	< 0.001	
Control	58.00	20.48	47.00	19.97	-11	< 0.001	
<b>General health</b>							< 0.001
Intervention	31.37	17.92	46.08	18.96	14.71	< 0.001	
Control	35.50	16.04	23.00	12.21	-12.5	< 0.001	
<b>Vitality</b>							< 0.001
Intervention	40.78	16.47	53.33	18.62	12.55	< 0.001	
Control	45.20	13.28	43.20	13.01	-2	< 0.001	
<b>Social functioning</b>							< 0.001
Intervention	54.41	18.51	72.55	16.77	18.14	< 0.001	
Control	61.00	16.87	49.00	20.18	-12	0.008	
<b>Role constraints due to emotional problems</b>							< 0.001
Intervention	51.96	47.92	87.25	29.74	35.29	0.003	
Control	53.00	44.50	37.00	36.15	-16	< 0.001	
<b>Mental health</b>							< 0.001
Intervention	60.39	15.23	74.90	13.17	14.51	< 0.001	
Control	57.60	12.22	53.40	13.34	-4.2	< 0.001	
<b>Physical component summary</b>							< 0.001
Intervention	44.98	24.72	68.14	20.85	23.16	< 0.001	
Control	53.13	19.85	33.63	17.22	-19.5	0.013	
<b>Mental component summary</b>							< 0.001
Intervention	51.89	20.27	72.01	15.04	20.12	< 0.001	
Control	54.20	15.71	45.65	14.58	-8.55	< 0.001	

**Table 2.** The Correlation Between Change Score (Post-Pre) of Subscales and Total Score of Quality of Life in the Two Groups<sup>a</sup>

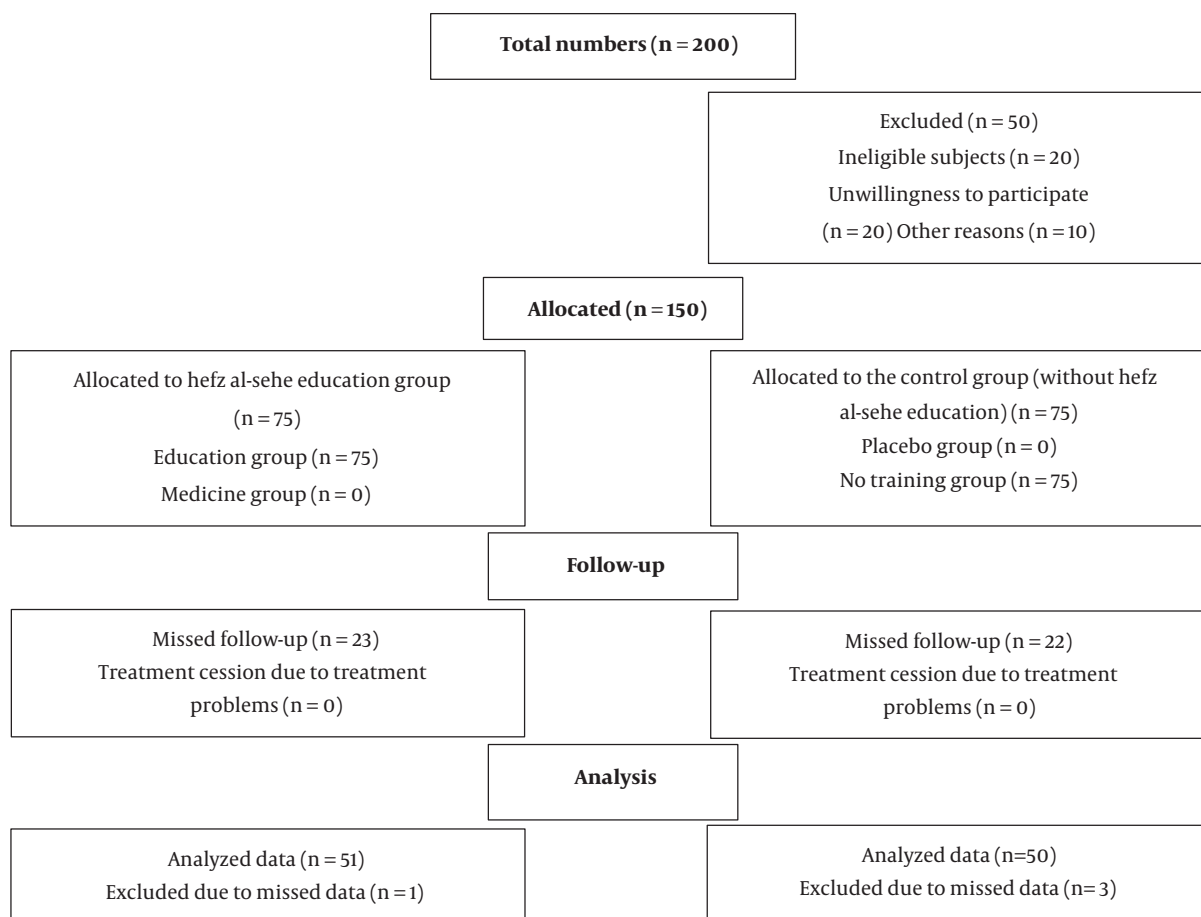
	PF	RLP	BP	GH	VT	SF	RLE	MH	PCS	MCS
PF		0.235	0.468 <sup>c</sup>	0.418 <sup>c</sup>	0.314 <sup>b</sup>	0.358 <sup>c</sup>	0.032	0.401 <sup>c</sup>	0.709 <sup>c</sup>	0.254
RLP	0.564 <sup>c</sup>		0.244	0.231	0.156	0.257	0.257	0.191	0.785 <sup>c</sup>	0.313 <sup>b</sup>
BP	0.572 <sup>c</sup>	0.402 <sup>c</sup>		0.277 <sup>c</sup>	0.194	0.422 <sup>c</sup>	0.357 <sup>b</sup>	0.406 <sup>c</sup>	0.602 <sup>c</sup>	0.469 <sup>c</sup>
GH	0.664 <sup>c</sup>	0.634 <sup>c</sup>	0.575 <sup>c</sup>		0.155	0.191	0.344 <sup>b</sup>	0.330 <sup>b</sup>	0.596 <sup>c</sup>	0.381 <sup>c</sup>
VT	0.157	-0.049	-0.127	0.030		0.154	0.299 <sup>b</sup>	0.419 <sup>c</sup>	0.287 <sup>b</sup>	0.559 <sup>c</sup>
SF	0.287 <sup>b</sup>	0.163	0.057	0.503 <sup>c</sup>	-0.059		0.241	0.533 <sup>c</sup>	0.422 <sup>c</sup>	0.542 <sup>c</sup>
RLE	0.071	0.169	-0.002	0.113	-0.147	0.169		0.344 <sup>b</sup>	0.326 <sup>b</sup>	0.890 <sup>c</sup>
MH	0.081	0.257	-0.069	0.113	0.287 <sup>b</sup>	0.110	-0.022		0.429 <sup>c</sup>	0.642 <sup>c</sup>
PCS	0.804 <sup>c</sup>	0.912 <sup>c</sup>	0.661 <sup>c</sup>	0.817 <sup>c</sup>	-0.006	0.265	0.136	0.179		0.474 <sup>c</sup>

Abbreviations: BP, bodily pain; GH, general health; MCS, mental component summary; MH, mental health; PCS, physical component summary; PF, physical functioning; RLE, role constraints due to emotional problems; RLP, role constraints due to physical problems; SF, social functioning; VT, vitality.

<sup>a</sup>The intervention group (upper diagonal), the control group (lower diagonal).

<sup>b</sup>P value < 0.05.

<sup>c</sup>P value < 0.01.



**Figure 1.** The study flowchart

found relationships between type D personality and quality of life (17); however, since the current study did not assess the mental status of the participants, it should be considered as a limitation and may shed light on future studies to subdivide cases into personality types.

On the other hand, it was observed that lifestyle modifications may remain positive effects on quality of life in healthcare workers, as reported in the study by Kasani et al. (18). The current study results also indicated that lifestyle education and Hefzalsehe instruction may improve the quality of life parameters. Future studies, for example, may examine the effect of education on socioeconomic status. Authors published a paper on the effect of education on the reduction of treatment costs in insurance organizations in a domestic Persian language journal. The results revealed that Hefzalsehe education could be considered as a proper way to control the cost of treatment in insurance organizations (19).

One of the main limitations of the present study was the small sample size. Furthermore, the findings were not based on longitudinal data. Future investigations with the cohort study design may shed light on more conclusive results. In spite of these limitations, the strengths of the study—i.e., a homogenous population and clinical trial setting, made the findings particularly unique. The rationale of our study was the clinical evaluation of principles of traditional medicine in Iran as the pioneer study. To our knowledge, there was no similar study so far on the same methodology

### 5.1. Conclusions

The results of the current study showed that in case of training and adherence to healthcare maintenance guidelines based on the ITM, health status can be enhanced in various physical and mental aspects, and as a result, the quality of life can also be improved.

## Footnotes

**Clinical Trial Registration Code:** The study was registered at Iranian Registry of Clinical Trials (Reg. No. IRCT20190109042302N1).

**Conflict of Interests:** The authors declared no conflict of interest.

**Ethical Approval:** The current study was approved by the Medical Ethics Committee of Shahed University on 31 May 2017 (code No. IR.Shahed.REC.1396.28).

**Funding/Support:** There was no funding/grant for the current study.

**Patient Consent:** Informed consent was obtained from participants.

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