**ORIGINAL ARTICLE** 

# The Nurse-Led Telephone Follow-Up on Medication and Dietary Adherence among Patients after Myocardial Infarction: A Randomized Controlled Clinical Trial

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#### Abstract

**Background:** Adherence to dietary and medication regimen plays an important role in successful treatment and reduces the negative complications and severity of the disease. Therefore, the present study aimed to investigate the effect of nurse-led telephone follow-up on the level of adherence to dietary and medication regimen among patients after Myocardial Infarction (MI).

**Methods:** This non-blinded randomized controlled clinical trial was conducted on 100 elderly patients with MI who had referred to the cardiovascular clinics in Shiraz. Participants were selected and randomly assigned to intervention and control groups using balanced block randomization method. The intervention group received a nurse-led telephone follow-up. The data were collected using a demographic questionnaire, Morisky's 8-item medication adherence questionnaire, and dietary adherence questionnaire before and three months after the intervention. Data analysis was done by the SPSS statistical software (version 21), using paired t-test for intra-group and Chi-square and t-test for between groups comparisons. Significance level was set at<0.05.

**Results:** The results of Chi-square test showed no statistically significant difference between the intervention and control groups with respect to their adherence to dietary and medication regimen before the intervention (P>0.05). However, a statistically significant difference was found between the two groups in this regard after the intervention (P<0.05). The mean differences of dietary and medication adherence scores between pre- and post-tests were significantly different between the two groups. Independent t-test showed these differences (P=0.001).

**Conclusion:** The results of the present study confirmed the positive effects of nurse-led telephone follow-up as a method of tele-nursing on improvement of adherence to dietary and medication regimen in the patients with MI.

Trial Registration Number: IRCT201409148505N8

KEYWORDS: Adherence; Follow-up; Myocardial infarction; Nurse

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#### INTRODUCTION

Coronary Artery Diseases (CADs), which have been consistently ranked among the most common Cardiovascular Diseases (CVDs), are the leading cause of mortality and morbidity in both developed and developing countries.<sup>1,2</sup> CADs account for 21% of mortality and morbidity worldwide in both men and women.<sup>3,4</sup> In Iran, also, CAD is the leading cause of mortality and morbidity and almost 138,000 Iranians die due to such diseases annually. Almost 50% of such deaths occur due to Myocardial Infarction (MI).<sup>5</sup> According to the report published by World Health Organization (WHO), approximately 14 million people globally die due to MI. However, recent surgical and pharmaceutical interventions have reduced the mortality resulting from MI. Yet, prognosis of patients with acute MI is still poor.6

Patients' adherence to treatment regimen, especially dietary and medication regimen, is one of the disease-related behaviors which can predict successful treatment and reduce the severity of the disease and its complications.<sup>7</sup> Adherence to treatment regimen is especially of utmost importance in patients with CVDs.<sup>8</sup> Patients often have challenge with dietary modifications, especially with heart-healthy dietary pattern, and their adherence to the prescribed regimens not appropriate after discharge.<sup>9</sup> Moreover, patients with MI are commonly advised to take lots of medications for long periods of time to reduce the complications, morbidity, and mortality.

Despite health care providers' advice, medication and dietary adherence is still poor among the patients with MI that can increase the risk of disease recurrence and rehospitalization. Moreover, 48% of all readmission in patients with MI are due to lack of adherence to dietary and medication regimen.<sup>10</sup> Accordingly, it is essential for clinicians and caregivers to encourage the patients to adhere to appropriate methods which modify the risk factors of CVDs.<sup>11</sup>

Nurses also play a vital role in increasing the patients' adherence to treatment regimen

and improvement of their clinical outcomes.<sup>10</sup> Furthermore, they can significantly contribute to providing the patients with information about their disease and its symptoms as well as MI-related subjects such as lifestyle, medications, nutrition, physical activities, and stress management which can definitely help them make better decisions about lifestyle modifications in the post-discharge period.<sup>12</sup> Therefore, providing patients with training and consultation is highly recommended as an essential part of nursing care.<sup>13</sup> Nurses' optimal selection of the type of nursing education and consultation is of great importance in this regard; it can lead to patients' adherence to treatment regimen, delay progression of the disease, and reduction of the disease-related complications.14

Nowadays, information and communication technology is widely used to alleviate the limitations of health care systems and for better patient care.<sup>15</sup> It seems that electronic management of chronic diseases is an effective method which helps to obtain reliable information, empowers the patients, affects their attitudes and behaviors, and potentially improves their medical conditions.<sup>16</sup>

Tele-nursing, which is a part of electronic health (e-Health), has provided the possibility to deliver nursing care and conduct nursing practice through communication devices, such as movies, Internet, and telephone, among which telephone is more available and widely used by the majority of individuals.<sup>17</sup> It is a very helpful and cost-effective method to assess the patients' out-of-hour care needs and to reduce the frequency of check-ups.<sup>18</sup> Using telephone not only reduces the costs and facilitates access to effective healthcare, but it also improves the relationship between patients and healthcare providers. It can eliminate the barriers associated with time and place, as well.<sup>19</sup> Weekly or monthly telephone conversations of nurses with patients and providing consultations can be considered a promising healthcare approach that can increase the positive outcomes of the treatment and improve management of patients' health conditions.<sup>20</sup>

Research has shown that telephonedelivered interventions could improve self-efficacy among patients with chronic obstructive pulmonary disease.18 It also could significantly decrease emotional distress and improve functional status and mental impression (quality of life) in patients suffering from breast cancer.<sup>21,22</sup> Besides, telephone-based interventions could result in clinically important reductions in hospital readmissions among adults with asthma.<sup>23</sup> Several studies in Iran have also reported that such interventions could improve the patients' quality of life after pacemaker implantation,<sup>24</sup> reduce readmissions in patients with heart failure,<sup>25</sup> reduce glycosylated hemoglobin, and play an effective role in controlling the glycemic level.<sup>26</sup> However, no comprehensive studies have been performed in Iran on the use of telephone follow-up interventions for providing healthcare to patients with MI. Therefore, the present study aimed to investigate the effect of nurse-led telephone follow-up on medication and dietary adherence among patients after myocardial infarction.

### MATERIALS AND METHODS

This study was a non-blinded randomized controlled clinical trial (IRCT201409148505N8). After obtaining approval from the Ethics Committee of Shiraz University of Medical Sciences (Ethics Committee Approval Number: CT-93-7089), we recruited 100 elderly patients with MI who had referred to the cardiovascular clinics affiliated to Shiraz University of Medical Sciences, Shiraz, southwest Iran from June to December 2014.

Based on a similar study conducted by Mok et al.  $(2013)^9$  and using MedCalc statistical software (power: 90%,  $\alpha$ : 0.05, and loss rate=20%), a 100-subject sample size was determined for the study (50 subjects in each group).

$$n = \frac{2(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 S^2}{(\mu_1 - \mu_2)^2}$$

From patients with diagnosis of myocardial infarction referred to heart clinics affiliated to Shiraz University of Medical Sciences, 100 patients who met the inclusion criteria were selected by convenient sampling method. The participants were randomly assigned to an intervention and a control group using block randomization method. To provide balance between the groups and prevent selection bias, a random sequence of 2 or 4 block sizes was applied (Figure 1).

The inclusion criteria of the study were first-time MI, confirmed diagnosis of MI by a cardiologist, being under treatment, ability to speak and understand Persian, after at least 2 months from the onset of the disease, Left Ventricular Ejection Fraction (LVEF)  $\geq$ 30%, having access to a telephone, not suffering from any severe and life-threatening diseases (approved by physician), and having ability to perform daily routine activities. On the other hand, the exclusion criteria of the study were unwillingness to participate in the study, not answering the telephone for more than three consecutive times, and need for coronary artery bypass surgery.

After providing the patients with information regarding the study objectives and procedure, their written informed consents were obtained and their anonymity and confidentiality were guaranteed. The data were collected using a demographic questionnaire, Morisky's 8-item Medication Adherence Questionnaire (MAQ), and dietary adherence questionnaire before and three months after the intervention. Demographic data included age, gender, blood pressure, weight, height, marital status, education level, occupation, smoking status, and history of underlying medical conditions such as diabetes, hypertension, and hyperlipidemia.

Dietary adherence was assessed using dietary adherence questionnaire for patients with MI that is a part of dietary adherence questionnaire for patients with cardiovascular diseases. This self-report questionnaire was developed to assess the patients' dietary and medication adherence. This questionnaire



#### **CONSORT Flow Diagram**

Figure 1: Design and protocol of the study

consisted of 13 items. The total score of the questionnaire could range from 0 to 46, with higher scores reflecting better adherence to the regimen. In addition, scores 0 -15.3, 15.3-30.6, and 30.6- 46 represented poor, intermediate, and high adherence levels, respectively. Ziaee et al. (2011) verified the validity and reliability of the Persian version of the scale by content validity and test-retest methods, respectively (r=0.86).<sup>27</sup>

Adherence to medication regimen was examined by 8-item MAQ scale. The total score of the scale could range from 0 to 8, with scores <6, 6 to <8, and 8 reflecting low, average, and high levels of adherence, respectively. The scale's reliability and validity were assessed by Morisky et al. (2008).<sup>28</sup> At first, the questionnaire was translated into Persian and its face and content validities were confirmed with corrective feedback from 8 professors in the field of nursing. Besides, its Cronbach's alpha coefficient was calculated as 0.95.

Initially, the participants' blood pressure (BP), height, and weight were measured by the

researcher. Then, the participants and one of their close relatives with whom they lived were trained by the researcher on the importance of adherence to dietary and medication regimen in a one-hour session.

The participants in the intervention and control groups received a training booklet, attended an initial training session, and received routine healthcare services such as check-up or screenings by the designated physician. Additionally, the participants of the intervention group received a threemonth nursing telephone consultation and follow-up. In this study, nurse-led telephone follow-up included phone calls for 12 weeks with patients and providing opportunities for counseling and education about diet, medications and clinical manifestations of myocardial infarction and helping the patients to identify the benefits and barriers of behavioral modifications and encouraging them for observance of treatment regimen.

The researcher's cell phone number and a call schedule were given to the patients. The schedule included two contacts per week during the first four weeks, one contact per week during the second four weeks, and one contact every two weeks during the third four weeks. The average duration of each call was at least 15 minutes and the researcher was available for contact 24 hours a day in case of any questions or problems.

The content of telephone conversations generally included the researcher's selfintroduction, inquiring about the patient's general health condition, giving healthcare advice, informing the patients about nutrition and medication, assessing the patients' level of adherence to dietary and medication regimen, evaluating the behavioral objectives agreed upon by the patients and the researcher, reinforcing health behaviors, terminating the call with the words of encouragement, and arranging the next contact. During the telephone conversation, the researcher emphasized compliance with the plans and agreements made during the training session, evaluated the existing barriers, and proposed possible solutions to the patient's problems. The researcher also tried to involve the patients' family members in the process of follow-ups during the telephone contacts. According to similar studies,<sup>9,25,26</sup> the questionnaires were completed again by the participants three months after the intervention.

The collected data were analyzed using the SPSS statistical software, version 21. Chi-square and t-test were used to compare demographic variables based on the quantitative or qualitative nature of the variables and to ensure the homogeneity of the groups. Intra-group comparisons were performed by paired t-test whereas independent t-test was used for inter-group comparisons before and after the intervention. The significance level was set at <0.05.

# RESULTS

This study was conducted on 100 patients with MI in the age range of 58.31±1.032 years. The majority of the participants were female (54%) and married (84%), and had primary school

education. The results of independent t-test and Chi-square test showed no statistically significant difference between the intervention and control groups with respect to quantitative and qualitative demographic characteristics (Table 1). In other words, the two groups were homogenous in terms of age, sex, BP, weight, height, marital status, education level, occupation, smoking status, and history of any underlying diseases such as diabetes, hypertension, and hyperlipidemia.

The results showed no statistically significant difference between the intervention and control groups as to pre-test dietary adherence scores. The results of paired t-test showed no significant difference between the pre-test and post-test mean scores of dietary adherence in the control group (P=0.096). However, a significant difference was observed in the intervention group in this regard (P=0.001). The mean differences of dietary adherence scores between pre- and post-tests were 0.82 (SD=3.14) and 17.46 (SD=56.12) for the control and intervention groups, respectively. The result of independent t-test showed a significant difference between the two groups in this regard (P=0.001) (Table 2).

The results also indicated no significant difference between the intervention and control groups in terms of pre-test mean scores of medication adherence. The results of paired t-test showed no significant difference between the pre-test and post-test of medication adherence scores in the control group (P=0.084), while a significant difference was observed in the intervention group in this regard (P<0.05). The mean differences of pretest and post-test scores were 4.08 (SD=0.367) and 0.34 (SD=0.192) in the intervention and control groups, respectively. The results of independent t-test showed a significant difference between the two groups in this regard (P=0.001) (Table 2).

In the pre-test, the majority of the participants in both groups reported poor dietary adherence level (more than 80%), but in post-test the majority of the patients in the intervention group (62%) reported a

Group Variable		Intervention group (N=50)		Control group (N=50)		P value*
		Frequency	Percentage	Frequency	Percentage	
Sex	Male	27	54%	19	38%	0.160
	Female	23	46%	31	62%	
Marital status	Married	39	78%	45	90%	0.171
	Widowed-Divorced	11	22%	5	10%	
Education	Primary education	36	72%	33	66%	0.666
level	Diploma or higher education	14	28%	17	34%	
Occupational	Employee	5	10%	7	14%	0.184
status	Retired	15	30%	13	26%	
	Self-employed	12	24%	14	28%	
	Homemaker	18	36%	16	32%	
Characteristics		Mean±SD		Mean±SD		P value**
Age (Year)		58.92±9.64		57.70±10.64		0.140
Weight (kg)		68.46±10.06		73.40±11.24		0.230
Height (cm)		163.54±8.20		165.68±7.84		0.186
Systolic blood pressure (mmHg)		$130.80{\pm}14.35$		129.00±14.32		0.146
Diastolic blood pressure (mmHg)		82.40±7.30	82.40±7.30		80.00±8.63	

Table 1: Characteristics of participants in intervention and control groups

\*Chi-square test; \*\*independent t-test

**Table 2:** Comparison of the intervention and control groups regarding the mean score of adherence to dietary and medication regimen before and after the intervention

Time		Pre-test	Post-test	Mean difference	Paired t-test
Group and variable		Mean±SD	Mean±SD	Mean±SD	P value
Adherence to	Intervention group	13.46±7.26	30.92±10.86	17.46±56.12	0.001
dietary regimen	Control group	$12.90 \pm 5.38$	13.72±6.63	0.82±3.41	0.096
	Between group: P	0.662	0.001	0.001	
Adherence to	Intervention group	3.16±2.43	7.24±1.53	4.08±0.367	0.001
medication	Control group	2.8±2.49	3.14±2.69	0.34±0.192	0.084
regimen	Between group: P	0.467	0.003	0.001	

high level of dietary adherence while in the control group the majority of patients (82%) still had poor dietary adherence in posttest. The results of Chi-square test showed a statistically significant difference between two groups with respect to their adherence to dietary regimen after the intervention (P<0.001) (Table 3).

Similarly, the majority of the participants reported a poor medication adherence level in the pre-test, but after the intervention the majority of the patients in the intervention group (68%) reported a high level of medication adherence. No significant improvement was reported by the participants of the control group in this regard. The results of Chi-square test showed a statistically significant difference between the two groups with respect to their adherence to medication regimen after the intervention (P < 0.002) (Table 3).

Overall, the study findings demonstrated that the level of dietary and medication adherence improved significantly in the participants of the intervention group who had received the nurse-led telephone follow-up intervention.

#### DISCUSSION

The results of the present study confirmed the positive effects of tele-nursing intervention on improvement of adherence to dietary and

Time and group		After interventi	After intervention		Before intervention	
Variable and level of adherence		Intervention	Control group	Intervention	Control group	
		group (N=50)	(N=50)	group (N=50)	(N=50)	
		F (%)	F (٪)	F (%)	F (%)	
Adherence to	Poor	40 (80)	43 (86)	5 (10)	41 (82)	
dietary regimen	Moderate	7 (14)	5 (10)	14 (28)	7 (14)	
	Good	3 (6)	2 (4)	31 (62)	2 (4)	
	P value	0.726		0.001		
Adherence to	Poor	37 (74)	39 (78)	5 (10)	36 (72)	
medication	Moderate	9 (18)	6 (12%)	11 (22)	8 (16)	
regimen	Good	4 (8)	5 (10)	34 (68)	6 (12)	
	P value	0.683		0.002		

**Table 3:** Comparison of the intervention and control groups regarding the level of adherence to dietary and medication regimen before and after the intervention

medication regimen in the patients with MI. The points of special interest in the results were the changes occurred in the adherence to dietary regimen in the intervention group; their adherence level increased from poor in the pre-test to high in the post-test after receiving the intervention. However, no significant difference was observed between the dietary adherence level in the preand post-test phases in the control group.

Likewise, tele-nursing intervention could positively affect the patients' adherence to medication regimen. The medication adherence level increased from poor in the pretest to high in the post-test in the intervention group after receiving tele-nursing intervention. However, no significant difference was found between the medication adherence level in the pre- and post-test phases in the control group.

Our findings were supported and confirmed by the results of other studies. One of them reported that tele-nursing follow-up could improve dietary adherence in patients with MI.<sup>9</sup> In another study, a twelve-week telephone follow-up intervention resulted in positive changes in post-MI lifestyle.<sup>29</sup> A similar study revealed that nurse-led telephone follow-up could improve diabetes diet adherence and decrease glycosylated hemoglobin levels among the patients with type 2 diabetes mellitus.<sup>26</sup> Likewise, the results of a study on the patients with psychological disorders revealed that telephone consultation could improve medication adherence and reduce the referral rate to emergency department.<sup>30</sup> The results of another study that compared the effects of educational intervention based on adult learning theory with and without telenursing on self-management in adult with epilepsy showed that patients who received telephone follow-up in addition to education had a better self-management.<sup>31</sup>

The effect of nursing follow-up counseling by telephone on blood pressure and self-care behaviors of patients with hypertension was investigated in a clinical trial. The results showed that the intervention had consistently positive effect on the patients' systolic blood pressure control, but it couldn't improve the patients' adherence to treatment and life style modification. Researchers emphasized the necessity of long term and regular follow-up for enhancing the patients' self-care behaviors in chronic conditions.<sup>32</sup>

During hospitalization, patients with MI usually do not receive effective trainings on the dietary and medication regimen due to their short-term accessibility. Therefore, they might have inadequate knowledge about the regimen and suffer from lack of self-control and self-confidence in the post-discharge period.<sup>6,13</sup> Moreover, disconnection from healthcare centers may increase the risk of poor adherence to medication regimen which, in its own turn, may worsen the symptoms of the disease. Therefore, it is important to provide the patients with training and consultation after discharge.33

Hence, telephone-delivered follow-ups and consultation can be applied as a useful method for self-assessment, monitoring, making decisions, and providing patients with the necessary advice.<sup>17,18</sup> On the other hand, it enables the patients to have a better contact with their healthcare providers at times of need.<sup>34</sup> Overall, tele-nursing intervention could improve the patients' adherence to medical regimen and reduce the symptoms of their disease.

Telephone follow-up and consultation create an opportunity to provide need-based trainings for the patients, which is not possible through other training methods such as text messaging. The results of one study showed the effect of sending information to patients with hypertension through short text messages on their BP and compliance with therapy. They observed no significant differences between the intervention and control groups in terms of the mentioned variables after six months.35 Such results could be due to failure in providing faceto-face training, the fixed content of training subjects sent by short message system for all patients, and the fact that such educational messages were not tailored to the patients' training needs. Hence, short text messages cannot replace a verbal communication since in telephone-delivered consultation healthcare providers talk with patients and answer their questions, but the text messages which are sent to all patients have a fixed content.

Tele-nursing refers to the use of information technology in providing care to patients. It is designed based on the care needs of the patients when a large physical distance exists between the patient and the healthcare provider.<sup>17,18</sup> Such method is commonly applied for the patients with chronic diseases or those who live in rural areas with transportation difficulties.

Moreover, constant encouragement and advice given by the nurses to patients and their family members can increase the patients' independence and self-care skills. Also, establishing a care-based network after discharge can not only solve the patients' caring problems, but it can also decrease the rate of their referral to medical centers.<sup>34</sup> Considering the nurses' limited time and the tension of the patients admitted to cardiac intensive care units, it may be difficult to provide face-to-face training well. Therefore, applying tele-nursing, which is time- and cost-effective, is highly recommended.

The limitations of the current study were its small sample size and short follow-up period. Therefore, further studies with larger sample sizes and longer follow-up periods are recommended to obtain more evidence on the positive effects of tele-nursing on the patients' adherence to treatment.

# CONCLUSION

As to the prevalence of MI, effects of this disease on individuals' lives, and importance of adherence to treatment to control and prevent the disease and reduce its symptoms, nurses should find better methods to improve the patients' adherence to treatment. It can be concluded from the present study findings that tele-nursing could improve and modify adherence to medication and dietary regimen among the patients with MI. It is recommended that health care providers especially nurses use the potentials of telenursing for improving the patient's self-care.

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