Research Article

The Effect of Nurse Home-Support Program on Self-Management of Patients Receiving Oral Anticoagulation (Warfarin) Therapy

Jülide Gülizar Yıldırım[1] , Ayla Bayık Temel[2]

[1]Department of Public Health Nursing, İzmir Katip Çelebi University Faculty of Health Sciences, İzmir, Turkey
[2]Department of Public Health Nursing, Ege University Faculty of Nursing, İzmir, Turkey

ORCID IDs of the authors: J.G.Y. 0000-0002-9846-8992; A.B.T. 0000-0001-8727-3279.

ABSTRACT

Aim: Warfarin, which is widely used for preventing thromboembolic events, can cause major and minor side effects. The aim of this trial is to evaluate the effect of nurse home-support program on self-management of patients receiving warfarin therapy.

Method: A randomized, controlled trial was conducted using 36 selected and eligible patients who had 12-month home-visit follow-ups. The bleeding risk score, potential and preventable warfarin-related complications, patients' self-management behaviors, and anticoagulation satisfaction were examined. Data analyses were performed using parametric and nonparametric tests, split-plot analysis of variance, multiple regression analysis, and Bland and Altman plots test.

Results: The bleeding risk score was an effective variable for assessing patient satisfaction (p<0.05). The self-management group demonstrated decreased bleeding risk at the end of the trial. The Duke Anticoagulation Satisfaction Scale mean score represents a statistically significant improvement in the self-management group (p<0.05). Patients' self-management behaviors improved significantly in the self-management group compared to the control group (p<0.05). The number of international normalized ratio values within the target range was significantly higher in the self-management group (174/432) than in the control group (82/432). The self-management group showed significant reductions in both thromboembolic events.

Conclusion: This trial demonstrated evidence that use of nursing home care is effective in developing self-management behaviors, improving patient satisfaction, and preventing complications in patients receiving warfarin therapy. This model could be easily adopted and implemented by home care services and health organizations.

Keywords: Nursing care, self-management, warfarin

INTRODUCTION

Warfarin is the most widely prescribed oral anticoagulant for patients with clinical risk of developing thromboembolism such as in atrial fibrillation (AF) and mechanic heart valve replacement (Kılıç et al., 2017; Kılıç et al., 2019; Yıldırım, 2013). In countries like the United Kingdomand Turkey, oral anticoagulation therapy (OAC) management is maintained using traditional hospital-based outpatient care (Fitzmaurice, Murray, Gee, Allan & Hobbs, 2002; Yıldırım, 2013). In recent years, warfarin outpatient clinics led by nurses have been organized for patients in several countries. Recent studies have demonstrated the effectiveness of nurses who successfully used patient-centered support programs and clinical protocols in primary and secondary health care as an alternative model of care for managing these types of patients receiving warfarin (Ansell, Jacobson, Levy, Völler & Hasenkam, 2005; Fitzmaurice et al., 2002; Hua et al., 2011; McBane et al., 2005; Ruiz-Nodar et al., 2012). Self-management of OAC-involving patients measuring their own international normalized ratio (INR) values, directly using point-of-care (POC) testing devices, and managing their warfarin doses-facilitates the patients' decision-making and responsibility, monitoring of symptoms and complications, and management of medications and dietary needs (Beyth, Quinn & Landefeld, 2000; Yıldırım, 2013). In randomized controlled trials (RCTs), examining patient self-management (PSM) strategies (medication management, dietary management, self-testing, self-monitoring, and follow-up complications) has consistently shown an increased proportion of INR values in the therapeutic range and

decreased rates of thromboembolic events (Beyth et al., 2000; Clarkesmith, Pattison, Khain & Lane, 2017; Fitzmaurice et al., 2002; Fitzmaurice et al., 2005; Hua et al., 2011; McBane et al., 2005; Völler et al.,2004). To date, there is no study in Turkey that enables the self-management of patients receiving warfarin therapy by supporting nurse home visits with the cooperation of hospital outpatient clinics.

The aim of this trial is to evaluate the effect of nurse home-support program on the self-management of patients receiving oral anticoagulation (warfarin) therapy**.**

Hypothesis

The following hypothesis was tested in the study at the end of the nursing home follow-up (12 months) and support program:

H_1: The anticoagulation satisfaction is higher in the PSM group than in the control group.
H_1: Target INR level is higher in the PSM group than in the control group.
H_1: The incidence of complications is lower in the PSM group than in the control group.

METHOD

Study Design

This study was a randomized controlled trial.

Sample

Universe and eligibility criteria for participants

The trial was conducted in the Cardiology and Cardiovascular Surgery outpatient clinics of a University Hospital in Izmir, Turkey, between January 2013 and January 2015. Patients who had received OAC for at least 6 months, were diagnosed with AF and mechanic heart valve replacement, were over the age of 18 years, and had high-risk bleeding scores of ≥3 compliance (Pisters et al., 2010) were defined as eligible for participating in the study. Patients who had mental problems, insufficient vision and manual dexterity, were physically unable to perform daily routines (bedridden patients), were over the age of 80 years, were hospitalized for a long time, had unstable heart failure and unstable arrhythmia, were diagnosed with cancer, and had cognitive disorders were defined as fulfilling the exclusion criteria. The eligible patients (186 patients) who could be included in the sample group were identified from clinical records. Of the total of 186 patients who were invited to take part in the trial, 52 accepted to be volunteers and participated in the study, and 16 of 52 patients decided to withdraw from the trial.

Sample Size

The trial sample size was calculated using statistical power analysis and G*Power software program (Version 3.1.9.2, Franz Faul, University of Kiel, Kiel, Germany) to provide 80.0% of confidence, α level of 0.05, and effect size estimates of 0.71 before the random assignment between medium and large effects (Leech, Barrett & Morgan, 2008). In total, 28 patients as the sample size estimation were found to be satisfactory according to the statistical power analysis.

Randomization

A total of 36 eligible patients fulfilled the preliminary requirements for study entry. Before they signed the informed consent form, they were advised that they could be assigned to a trial or a control group according to three criteria: age (<65 years and >65 years), clinical indications (target INR ranges, 2.0–3.0 and 2.5–3.5), and treatment duration (<2 years and ≥2 years). CONSORT guidelines were followed for reporting RCTs (CONSORT group, 2010) (Figure 1). Of the 36 patients, 18 were assigned to the trial group (PSM) and 18 patients were assigned to the control group (optimal routine care) using stratified and block randomization techniques and a computer program (Research randomizer, 1997). The trial group received nurse home-support program and follow-up besides routine hospital treatment, and the control group received only routine hospital treatment (Figure 1). Both groups were found to be
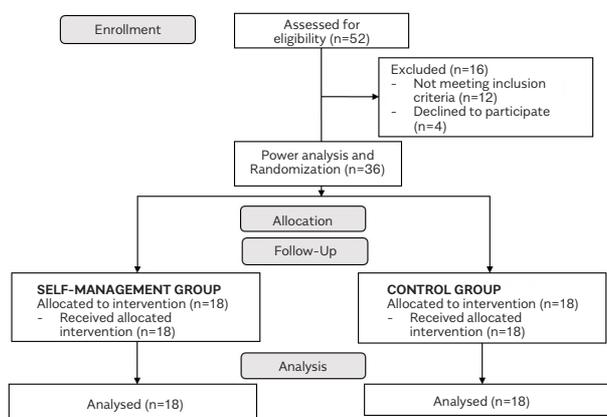

Figure 1. Eligibility and random assignment of the patients' CONSORT diagram

homogenous according to number, age, and gender, as well as clinical indications and treatment duration (p>0.05).

Self-management behaviors (such as INR measurements, compliance with medication management), frequency of complications, HAS-BLED bleeding risk score, Duke Anticoagulation Satisfaction Scale (DASS) score, and perception of general health level were defined as the dependent variables in the study.

Instruments

In the pre-study intervention period of the trial, the data were collected from both groups using a sociodemographic form, patient and illness history forms, DASS (Yıldırım & Bayık-Temel, 2014), and HAS-BLED (Hypertension, Abnormal Renal/Liver Function, Stroke, Bleeding History, Labile INR, Elderly, and Drugs/Alcohol Usage) score (Pisters et al., 2010). DASS was developed by Samsa et al. (2004), and the validity and the reliability of the Turkish version of DASS were implemented by Yıldırım and Bayık-Temel (2014). DASS, which has a three-factor structure (limitations, hassles and burdens, and positive impacts), consists of 25 items using a 7-point Likert-type scale, which assesses the requirements and the perceptions of the patient receiving OAC. The high scores indicate worse patient satisfaction. Cronbach's alpha was found to be 0.91, content validity index was 0.99, test-retest reliability was 0.98, and confirmatory factor analysis showed an acceptable level of compliance (Yıldırım & Bayık-Temel, 2014). The HAS-BLED score is the recommended score in the ESC guidelines (Vahanian et al., 2013) for evaluating bleeding risk, developed by Pisters et al. (2010). A high HAS-BLED score (≥3) is indicative of the need for regular clinical follow-up but should not be used per se as a reason for stopping OAC. The bleeding risk score, referred to as HAS-BLED, calculates seven clinical indications (hypertension, abnormal renal/liver function, stroke, bleeding history or predisposition, labile INR elderly (>65 years), and use of drugs/alcohol concomitantly). Using a questionnaire, the patients were asked to evaluate their general health perception (GHP) by responding in a Likert-type format based on 4 points, ranging from 4 signifying very good health to 1 signifying poor health. For the PSM group, the physical examination form, the INR test follow-up chart, and medication records were also used. In the trial, the obtained data were used to identify targets for the support program before the study (INR target range, GHP, HAS-BLED, and DASS mean score), and these parameters effect sizes were calculated in the pre and post monitoring study period. According to the study by Fitzmaurice et al. (2005), the effect sizes of the INR target range increased to 27% with a 2% increment in the post monitoring of the trial. The researchers demonstrated for the PSM group how to check INR by using coagulometer POC meters. Thus, INR testing was undertaken using coagulometer POC meters, and regular external quality control tests were performed. A sub-analysis of the data was carried out to compare the results of coagulometer and laboratory testing. A Bland-Altman plot analysis revealed that the strong correlation between coagulometer and laboratory INR results (Bland & Altman, 2003) in the pre-study period and the mean values of INR for coagulometer and laboratory tests, respectively, were determined as the pre-monitoring in the first month, r=0.99 (0.28±0.14, INR, 0.02–0.50, 95% confidence interval (CI), 0.22–0.36, p<0.001) and in the second month, r=.98 (0.22±0.14, INR, -0.05–0.5), 95% CI, 0.15–0.29, p<0.001). Two follow-up results of INR values illustrated a good overall agreement between the two techniques and consequently demonstrated that patients could safely use an coagulometer at home (Heiss, 2013).

Data Collection

In the pre-study period, the PSM group provided venous blood samples in the blood center when the patients arrived at the hospital to control laboratory INR values on appointment days of the pre-monitoring months, and INR test results were achieved within a maximum of 4 hours (Beyth et al., 2000; Fitzmaurice et al., 2005). In the meantime, the PSM patients were trained to monitor their INR values at home, and they were receiving OAC on successful completion of training; during the training sessions, the researchers supervised their potential and success in using near patient POC testing device, namely, the coagulometer. In the clinic, the patients ensured that they could check their INR values with the coagulometer by sampling capillary blood from their fingers (Völler et al., 2004).

Implementation of Education Program

The PSM group used the individualized planned education program, which was conducted in pre monitoring, covered theoretical and practical training aspects, and aimed at gaining the self-management behaviors in OAC patients such as medication and

dietary management, self-testing, and self-monitoring considering cognitive, affective, and psychomotor goals. The individualized planned education program for PSM was implemented from 8 hours to 12 hours for each patient. The education kit, which was prepared by the researchers, was used during the education sessions. This kit covered patient education guide (Yıldırım, 2013), patients' personal health record notebook, medication list, INR test follow-up chart with traffic light methods, video film, and reminders (prescription and emergency card, magnet, calendar, and pillbox).

The education kit, which was used by nurse researchers during the education sessions such as patient education guide (Yıldırım, 2013) and patients' personal health record notebook, consists of medication list, INR test follow-up chart with traffic light methods, video film, and reminders (prescription and emergency card, magnet, calendar, and pillbox). Some education techniques used during the education sessions were INR test demonstration and motivational interviewing (MI) technique (Rollnick, Miller & Butler, 2008).

In the study period, the direction of the determined goals and targets and the planned educational program were continued for the PSM group by implementing home visits. The PSM group benefited from the patient's support program at home and was monitored under the supervision of a hospital physician. During home visits, the researchers benefited from the MI technique and the 5A model (Ageno et al., 2012; Rollnick et al., 2008). The MI technique is a client-centered approach that helps the individual discover the dilemma that the individual is experiencing and resolve the problem in the setting of behavioral change (Rollnick et al., 2008). The researchers tried to strengthen the motivation of the individuals using reflective listening, summarizing, confirming, and exchanging conversation in accordance with the flow of the viewers. The 5A model, which was developed by Whitlock, Orleans, Pender, and Allan (2002), can be used by the health staff to facilitate evaluation and implementation in behavioral change. In the 5A model, the patient's behaviors can be evaluated using the following steps: ask, assess, advice, assist, and arrange. The objectives of the individual activity plan were established, and the obstacles in reaching this goal were evaluated, together with the patient, regarding how the individual solved the problem, the ways in which the goal was reached, the level

at which and when the target would be applied and when the patient achieved the target. For the study period, the patients were advised to perform the INR tests every 2 to 3 weeks, or weekly if a dose adjustment was made, or when unexpected INR results or suspicious test results were obtained (Fitzmaurice et al., 2002; Völler et al., 2004).

The control group received routine hospitalized care by visiting the outpatient clinic for INR monitoring and adjustment of warfarin dosage in the hospital. The control group was interviewed at the hospital only two times (pre and post monitoring). The control group's INR and venous blood test results were collected in the laboratory. During the study period, the INR values and the complications of the study groups were recorded by the investigator from the clinical registry for each month; if the records were not available, the principal investigator conducted a telephone interview with the patient.

Statistical Analysis

The data analysis was performed using Statistical Package for the Social Sciences 22.0 (IBM SPSS Corp.; Armonk, NY, USA). The descriptive characteristics were displayed with percentage, number, and mean values. By considering the distribution normality of the data, the Wilcoxon signed-rank (Z value), t-tests, Mann Whitney U test, mixed designed method (split-plot analysis of variance), McNemar's test, $χ^2$ test, and multiple regression analysis were applied (Leech et al., 2008). MedCalc Statistical Software version 16.4.3 (MedCalc Software bvba, Ostend, Belgium) was used for Bland and Altman plots analysis (Bland & Altman, 2003). The results showed 99% of the reliability interval, and the level of significance was considered as $p<0.01$ (Bland & Altman, 2003; Leech et al., 2008).

Ethical Considerations

Ethical approval was obtained from the University Clinical Research Ethics Committee (Appr. No.1723/78, Date: 05.10.2012) and the written consent was obtained Cardiology and Cardiovascular Outpatient clinics. A written informed consent form was obtained from all of the patients.

RESULTS

The patients' characteristics are shown in Table 1. The mean ages of the patients were 62.27±12.36 years (range, 31–79 years). The patients who were living alone in the PSM and control groups were

found to be 5.6% and 11.1%, respectively. In both groups, 72.2% of the patients received support from their spouses. The patients' health history was examined; pre monitoring of the trial, 52.8% of the total patients had a prior minor or major hemorrhage in his/her health history. Bruising complaint (66.6%) was more common than bleeding (52.8%).

Bleeding Risk

While the trial group patients' pre-monitoring bleeding risk mean score was high (3.33±0.49), the post-monitoring bleeding risk mean score decreased (2.0±0.77; p<0.001). Pre-monitoring mean scores in the control group were 3.61±0.78; however, their post-monitoring scores showed a statistically mean-

Table 1. Characteristics of patients (N=36)

Sociodemographic Characteristics	Self-Management Group (n=18) n (%)	Control Group (n=18) n (%)	χ^2	p
Age groups, years				
31–44 (Young adult)	2 (11.1)	1 (5.6)	0.65	0.89
45– 64 (Middle adult)	8 (44.4)	9 (50.0)		
65 –74 (Young old)	3 (16.7)	4 (22.2)		
≥75 (Middle old)	5 (27.8)	4 (22.2)		
Gender				
Men	8 (44.4)	9 (50.0)	0.00[a]	>0.99
Women	10 (55.6)	9 (50.0)		
Marital status				
Married	15 (41.7)	16 (44,4)	1.03	0.60
Single/divorced	3 (8.4)	2 (11.1)		
Education				
Literate	1 (5.6)	2 (11.1)	3.09	0.38
Primary-secondary school	8 (44.4)	12 (66.7)		
High school	5 (27.8)	2 (11.1)		
University level	4 (22.2)	2 (11.1)		

[a]Chi-squared test with Yates continuity correction,χ^2: Chi-squared test

Table 2. Distribution of Duke Anticoagulation Satisfaction Scale pre- and post-monitoring test results (N=36)

DASS point average	Self-management group (n=18) M±SD	Control group (n=18) M±SD	Significance test t (p)[a]
Pre monitoring	108.50±20.30	90.30±20.70	2.66 (0.012)
Post monitoring	66.30±22.40	94.0±25.70	-0.35 (0.002)
Significance test t (p)[b]	6.91 (<0.001)	-1.39 (0.184)	
Group[c]		t=3.50	p=0.015
Time		t=33.54	p<0.001
Group * time		t=47.52	p<0.001

[a]Two independent sample t-test; [b]paired sample t-test; [c]variance analysis of repeated measures; M±SD: Mean±standard deviation; *group and time interaction.

ingless difference (3.72±0.89; p>0.05). According to the multiple regression analysis results, the regression model is considered a well-established model since the Durbin-Watson value was 1.758. The correlation between the DASS post-monitoring mean score and the independent variables was 0.685. The 46.9% alteration in the DASS mean score was associated with gender, GHP, and HAS-BLED score (r^2=0.469). When the linearity of the relationship was assessed, it was statistically quite significant and linear (F=2.909; p<0.001). The HAS-BLED bleeding score has been identified to affect the post-monitoring DASS mean scores linearly (p<0.05); however, GHP and gender were not found to be statistically meaningful (p>0.05).

Perception of General Health Status and Satisfaction of Treatment

In the pre-monitoring stage, the results showed that in the PSM and control groups, the GHP average scores were 2.89±0.90 and 2.67±0.91, respectively

Figure 2. Comparison of an average of pre- and post-monitoring test scores of DASS in the patient self-management and control groups

(Z=−1.16, p>0.5). The PSM group perceived GHP as higher (4.06±0.64) according to the control group (2.39±0.85) in post monitoring (U=-4.52, p<0.001). The perception of treatment satisfaction was assessed using the DASS and pre- and post-monitoring results shown in Table 2 and Figure 2. In the post-monitoring stage, the PSM group's DASS average score was decreased (66.30±22.4) during the study period follow-up (t=6.91, p<0.001). The DASS mean score was determined as 80.13±27.63 (33-148, 95% CI, 70.79-89.49) with the 0.76 effect size for this trial in both groups. Repeated measures variance analysis was performed to determine whether there is a difference between DASS pre- and post-monitoring mean scores in both groups. The variances were found to be homogeneous for each monitoring value (pre monitoring, p=0.887; post monitoring, p=0.564) in both groups. According to the Pillai's trace test analysis, the group (t=3.50, p=0.015), time (t=33.54, p<0.001), and group x time (t=47.52, p<0.001) revealed a statistically significant difference in terms of the interaction of the test results.

Monitoring INR Test Levels

Patients had controlled INR levels when their warfarin doses were changed routinely between 20 days and 30 days. The frequency of the INR test was found to be high (r=−376, p<0.05) for each patient in the PSM group (15.4 times INR measurement, 3.8 times/week) according to the control group (12.8 times INR measurement, 3.2 times/week). The PSM group's time in therapeutic range (TTR) was significantly higher (40.3%; 174/432; 95% CI, 39.3–41.3) than the control group (19%; 82/432; 95% CI, 18.0–19.96) (Table 3). In the PSM group, 216 of the POC readings were either subtherapeutic TTR (6.5%) or supratherapeutic TTR (3.2%). In the control group, 25.3% of these patients had subtherapeutic TTR
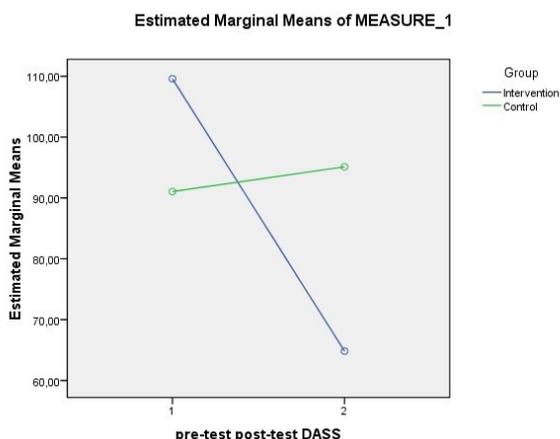
Table 3. Distribution of target and outside the target INR levels in the patient self-management and control groups during the study period (12 follow-up periods)

INR levels in the target range and outside the target range during the study (12 follow-up sessions)*	Self-management group (n=18)	Control group (n=18)	
	n (%)	n (%)	Total (N=36)
Poorer therapeutic INR range (outside target INR range)	42 (19.4)	134 (62.0)	176 (40.7)
Therapeutic INR range (target INR level)	174 (80.6)	82 (38.0)	256 (59.3)
Total	216 (100.0)		432 (100.0)

*36 patients performed a total of 432 INR measurements in 12 follow-up sessions per month.

and 15.4% had supratherapeutic TTR. The results revealed a statistically significant difference in both groups: INR target, 2.0–3.0 and 2.5–3.5 (χ^2=81.15, p<0.001).

Monitoring Complications

During the study period, the patients experienced minor hemorrhagic events such as gum and nose bleeding in the PSM (four patients) and control (seven patients) groups, whereas in the control group, there were reports of one stroke and three major hemorrhagic events (gastrointestinal bleeding). When the relative risk index was examined for thromboembolic events and bleeding complications, the relative risk (RR) index was 0.45 (95% CI, 0.30–0.68; Z=3.78, p<0.01) between the PSM and control groups.

DISCUSSION

The HAS-BLED score estimates the risk of minor or major bleeding events (Pisters et al., 2010; Ruiz-Nodar et al., 2012). At the beginning of the research, HAS-BLED showed that the patients were at high-risk in terms of bleeding (Ruiz-Nodar et al., 2012) and that there were also other possible risks in the study. The bleeding risk score decreased in both groups (2.86±1.99), and the target behaviors were attained. This reduction in the HAS-BLED score can also be interpreted as the effect of the patient support program and the positive change in the patients' self-management behaviors. One study has shown that bruising and bleeding events affect the quality of life in a negative manner, creating stressors in the individuals and increasing the patients' problems with OAC (Samsa et al., 2004).

The GHP is an important factor in ensuring that the behavioral change associated with the individual's health is maintained and that the patient's self-treatment responsibility is gained by acquiring preventive health behaviors (Ageno et al., 2012; Heiss, 2013; Yıldırım & Bayık-Temel, 2014). After the implementation of the support program, the PSM patients improved their GHP by developing positive behaviors related to self-management (e.g., INR levels remained in the target range, information, and researcher support). In the studies conducted, the quality of life was highly perceived by the patients who were followed by the health professionals who, in turn, reported that the patients' TTR intervals were higher and that they could manage their behaviors (Fitzmaurice et al., 2002; Garcia-Alamino et

al., 2010). The patient's training increases his/her knowledge and skill, motivates active participation in his/her own care, achieves independent decision-making competence, and increases the ability to cope with problems. Thus, patients can make their own observations and, if necessary, consult their physician/nurse to perform self-management. A situation that occurs in the individual's general health behavior can positively or negatively affect the performance of the behavior (Ageno et al., 2012).

When the patients' perception of satisfaction with anticoagulation treatment was assessed, the PSM group showed a highly significant (p<0.001) increase in treatment satisfaction after the support program compared to the control group. In the PSM group, the increase of treatment satisfaction is related to the self-management behaviors developed by the support program to cope with the patients' problems, to improve the GHP level, and thus to increase the quality of life and satisfaction of the treatment. In the studies conducted by Yıldırım and Bayık-Temel (2014) and Samsa et al. (2004), the PSM and the control patients were compared and higher satisfaction of anticoagulation therapy (85.02±25.13 and 55.0±17.6) was observed in the trial group. In our study, the DASS mean score was found to be at the target value and there was high confidence in both groups.

Adjusting medication dosage is important, so warfarin patients are advised to check the INR levels by using directly POC testing devices or laboratory testing (Hua et al., 2011; McBane et al., 2005). When the INR level is out of range (subtherapeutic TTR or supratherapeutic TTR range during warfarin therapy) and if major and minor side effects are frequently encountered, the quality of life of patients is negatively affected (Ansell et al., 2005; Kılıç et al., 2019; Yıldırım, 2013). RCTs showed an increased proportion of warfarin therapeutic range decreases of thromboembolic events (Ansell et al., 2005; Beyth et al., 2000; Clarkesmith et al., 2017; Fitzmaurice et al., 2002; Fitzmaurice et al., 2005; Hua et al., 2011; Völler et al., 2004). In this study, the INR percentage time in the range confidence interval was higher in the PSM group (40.3%) than in the control group (19%). At the end of the study, the percentage of the target interval for both groups was found to be 59.3% (256/432). The TTR was reported as 49.5% in the warfarin–TR study (Kılıç et al. 2017). The INR target range has been detected in a much larger

target than the specified target (27%). Beyth et al. (2000) in their research found that the therapeutic INR range was 56% in the PSM group and that it was 32% in the control group. Ansell et al. (2005) found that the TTR remained within the INR interval (88.6% in the PSM group and 68% in the control group). In the study conducted by Fitzmaurice et al. (2002), there were no significant differences in INR control (per cent time in the range: intervention, 74%; control, 77%). But in our study, improvements in the PSM group clearly demonstrated the effect of the support program in terms of the extent to which the INR values during the 3-month monitoring period remained in the target range.

The rates of potential adverse warfarin-related complications between the groups consisted of three events that occurred in the presence of subtherapeutic INR values, including minor bleeding and bruises. When the INR level was outside the target range during warfarin therapy, the patients' quality of life was adversely affected with the major (e.g., major bleedings, embolism) and minor (e.g., mild bleedings, bruises, hematuria) complications (Ansell et al., 2005; Heiss, 2013; Kılıç et al., 2017; Kılıç et al., 2019; Yıldırım & Bayık-Temel, 2014; Yıldırım, 2013). There were more life-threatening major complications reported in the control group, especially major bleeding and stroke events. Relative risk efficacy and small value of 1 indicate decreased risk, whereas values greater than 1 indicate increased risk. The PSM group lived 0.45 times with fewer complications than the control group. Our study findings are consistent with the findings of the trial. Garcia-Alamino et al. (2010) detected similar relative risk effects (0.47). Not resembling the findings of the research, Völler (2004) found a lower risk effect (0.33), and in other studies, the risk effect was found to be greater (1.11 and 0.83) than those shown in our trial, respectively (Clarkesmith, 2017; Fitzmaurice et al., 2005).

Study Limitations
Patients who were receiving warfarin for at least 6 months, only patients with AF and heart valve replacement therapy, and adults (>18 years and <85 years old) were included in this study.

As this study is in its experimental design stage, the evidence could be generalized for this group. Also, possible limitations include small sample size and high HAS-BLED scores, which may have increased the rate of complications. Additionally, another limitation was that the patients who resided in the provincial center and were easy to reach were chosen for the trial group.

CONCLUSION AND RECOMMENDATIONS
This RCT demonstrated that for a selected population, PSM is a safe primary care management for patients receiving OAC. Additional studies are needed to elucidate whether this model of care is suitable for a larger population.

PSM was superior to routine care, and it was easily implemented by the patients if they were properly trained and if this was the method preferred by the patients. At the end of the trial, in the PSM group, the risk of bleeding decreased; however, the bleeding risk did not change in the control group; the incidence of the complications was less, and the GHP level was better in the PSM group. When the PSM group receiving nurse home-support program and the control group under the hospital treatment were compared according to their performing self-management, the anticoagulation satisfaction and the target INR level were found to be higher in the PSM group.

It is recommended that "anticoagulant patient monitoring nurse-led clinics" could be organized where nurses can follow up with the patients and advise and motivate the patients to receive warfarin therapy for self-management and use POC devices at home using INR charts/algorithms. In these units, in-charge nurses should be trained with in-service training programs and certificate programs. Training programs for warfarin patients can be applied in the form of individual or group training. The education program can be arranged according to the needs of the patients, considering the characteristics of the patient group. The education kit materials (guide, video film, etc.) and reminders (e.g., magnet, pillbox) could be recommended for use for patients receiving anticoagulant therapy.

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