Original Article

# The Impact of Cardiac Pacemaker Education Provided to Women During Menopause on Quality of Life: A Randomized Controlled Study

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**Abstract**
**Purpose:** In this study, it was aimed to determine the importance of health care by providing training to the women who will be fitted with CIED, by the physician and the midwifery or nurse before the application, to increase the compliance process of the women, to cope with possible problems and to increase the quality of life after the procedure.
**Methods:** This randomized controlled study was carried out between March 2022 and December 2022 in the cardiology clinic of a university health research and application center in Turkey.
The study was carried out with 71 women, 36 in the experimental group and 35 in the control group. Data were collected using the personel information form and the Quality-of-Life Scale (SF-36). The statistical significance level was accepted as $p < 0.05$.
**Findings:** There was a statistically significant difference in the quality of life scale and all sub-dimensions of the women in the experimental and control groups ($p< 0.05$). In addition, in the post-test scores comparison between the scale and all sub-dimensions of the experimental and control groups, the physical functioning sub-dimension ($Z=-3.307$, $p<0.01$), vitality (energy) sub-dimension ($Z=-2.421$, $p<0.05$), and mental health sub-dimension ($Z=-2.142$, $p<0.05$) there was found a significant difference in between.
**Conclucion:** We came up with the idea that education provided by midwifery nurses or physicians to women before the CIED procedure significantly increased the quality of life for women.

**Key Words:** Doctor, Education, Nurse, Midwifery, Pacemaker.

## Introduction

In Turkey, the country's official statistics agency, the Turkish Statistical Institute (TUIK), annually compiles data on deaths that occur in the country broken down by gender and age groups. According to TUIK's data, the most common cause of death among women in Turkey between 2017 and 2021 was cardiovascular disease, accounting for 22.9% of all female deaths, and this rate is higher than that of males. Gender-specific health issues affecting women are often overlooked, especially during menopause and old age, because the health problems women experience

during this period are not typically associated with gender or reproductive issues (Canpolat & Tasti, 2022). Cardiovascular implantable electronic device (CIED) application has been widely performed in recent years as a result of the developments in technology and the increase in the clinical indication rate, and its incidence and prevalence are constantly increasing (Okamura 2014; Raatikainen et al., 2017). According to 2016 data, the rate of CIED implantation in the European Union member countries is almost four times higher than in non-European Union countries, with a total of 500.000 patients implanted throughout Europe. Meanwhile, at the global level, this number reaches 1.25 million every year (Raatikainen et al., 2017).

Novel registry data have emerged with regard to sex-related disparities related to adverse events in Implantable Cardioverter Defibrillator (ICD) implantation. Peterson et al. examined the impact of sex on the safety of ICD-implantation (Bergau et al., 2014). Using the National Cardiovascular Data Registry (NCDR) ICD Registry, data of 161,470 patients were enrolled, of these 27% were female. The overall rate of any adverse event in the entire cohort was 3.6%, with a higher rate in women as compared to men (4.4% versus 3.3%, $P < 0.001$). n particular, women were more likely to experience intraprocedural complications such as lead dislodgements, vessel injuries, pneumothorax, pericardial effusion, or undesirable side effects due to concomitant medication (HR 1.32, CI 1.24–1.39, $P < 0.001$). Also from the NCDR registry, now involving more than 240,000 patients including more than 64,000 women, a risk score of in-hospital adverse events following ICD implantation was derived and confirmed the higher risk of women [Dodson et al., 2014]. The risk–benefit ratio for women is further worsened by a proven higher adverse event rate following ICD implantations (Bergau et al., 2014).

Individuals are unprepared to adapt to CIED-specific care, lifestyle changes (such as activity and nutrition), and regular control programs (Ottawa Heart Institute 2018). Furthermore, they fear feeling dependent on an artificial device, failure of the device, and losing their lives after the procedure (Sharma et al., 2020). In chronic diseases, effective education is given to patients and their relatives about the disease, the treatment applied, and the treatment process relieves the patients' concerns and ensures that the individual takes an active role in their participation in medical decisions. This training also helps them to carry out the disease and treatment compliance process effectively and helps them cope with the current problem (Hadler et al.,2019; Ozpancar 2016). Today, despite the developments in many fields of health sciences, the shortage of health professionals continues. These health professionals aim to improve society's and the individual's health, maintain the current state of well-being, prevent diseases, and regain optimal health levels. It is possible to achieve these goals with the training given to patients and their relatives by professionals, especially and midwifery nurses who spend the most time with patients (Yildirim et al., 2017). Through a good patient education, problems in the process of preventing diseases, restoring health, maintaining health, dealing with the current challenge and compliance with treatment can be reduced ( Ozpancar 2016).

In this study, it was aimed to determine the importance of health care by providing training to the women who will be fitted with ICD, by the physician and the midwifery or nurse before the application, to increase the compliance process of the women, to cope with possible problems and to increase the quality of life after the procedure.

## Methods

**Study Design and Sample:** This randomized controlled study was carried out between March 2022 and December 2022 in the cardiology clinic of a university health research and application center in Turkey.

The sample of the study consists of patients who previously applied to the cardiology clinic and were planned to undergo CIED. The G*Power (3.1.9.4) computer program was used to determine the sample size (Faul et al., 2007). Considering the averages and standard deviations in Koroglu's study, it was calculated that each group should consist of at least 36 patients with an effect size of 0.481, a

significance level of 95%, and a power of 80% (Koroglu 2014). Considering possible losses, the number of samples was increased by 10%, and it was aimed to reach 40 patients for each group. Randomization was determined using the "Researcher Randomizer" program, provided that the number of individuals in the intervention and control groups was equal regardless of the age and education characteristics of the participants. The study included women in the menopausal period who had no communication barriers and were scheduled to receive a CIED. The research went on during the COVID pandemic. While the study was going on, three women from the experimental group and one from the control group lost their lives. The remaining five women (3 from the experimental group and two from the control group) rejected a second interview. The study was terminated with a total of 71 wonen, 36 in the experimental group and 35 in the control group.

**Data Collection Forms**

***Personel Information Form*:** As a consequence of a literature review, it was developed by researchers. It consisted of 15 questions including the sociodemographic and disease-related characteristics of the women.

***SF-36 Quality of Life Scale*:** It was first used by Ware in England in 1987 (Ware et al., 1994). The validity and reliability study of the SF-36 Quality of Life Scale was carried out by Pinar (Pinar, 1995), It was stated that it could be used in chronic diseases. Pinar, the first study of the validity and reliability of the SF-36 Vital Scale, was executed on 180 patients with cardiac, hemodialysis, and diabetes and gave the language and content validity of the instrument by factor analysis and its reliability by the test-retest method. The test-retest reliability coefficients for the SF-36 scales range from 0.83 to 0.92. The scale consists of 8 subgroups and 36 questions, and the subgroups include physical function, physical role difficulty, pain, general health perception, energy/vitality, social function, emotional role difficulty, and mental health. The first 4 of these are reported as physical component scores, and the last four as mental component scores. The total score obtained from the scale is evaluated on a scale between 0-100. The lowest score displays the worst health condition (Pinar 1995).

**Pacemaker Training Manual and Study Procedure:** The training book titled Pacemaker Training Manual was prepared by the researchers in line with the knowledge of the literature (Epstein et al., 2008; Brignole et al., 2013). Before the study, the opinions of 5 experts were consulted for the book's clarity. Three of them were cardiologists, one was a faculty member in midwifery, and the other was a lecturer in the nursing department. The language used in the training booklet is Turkish. The eight-page training booklet contains information about heart health during the menopausal period, an introduction to the cardiac pacemaker, preparation before the procedure, how to insert the cardiac pacemaker, recommendations for living with a cardiac pacemaker, points to consider, and follow-up procedures. Study data were collected through face-to-face interviews with women in the hospital's training hall (by a midwife and a nurse) and in the responsible physician's room. This study was conducted in 3 steps:

***Step 1: Pre-test:*** "Personel Information Form" and "SF-36 Scale" scales were administered to all patients. It took 10-15 minutes to fill out the data collection tools**.**

***Step 2: Pacemaker Training Session:*** The training was provided to the women in the experimental group by a specialist midwife or nurse, and to the women in the control group by two specialist physicians. The interactive training was completed in 30-40 minutes using question-and-answer and demonstration methods. Both training sessions were conducted with the Pacemaker Training Manual.

***Step 3: Post-Test:*** It was performed with women in the experimental (n=36) and control groups (n=35) 1 month after the pacemaker intervention. The SF-36 (post-test) of the patients in both the experimental and control groups was filled, and the specialist physician performed the battery controls.

**Data-analysis:** Data analysis was analyzed in SPSS (Statistical Package for Social Sciences for Windows) version 26.0 package program (IBM Armonk, NY, USA). The normal distribution of continuous numerical data was evaluated using the Shapiro-Wilk test. Pearson chi-square test and Fisher-Freeman-Halton

Exact Test were used to test the homogeneity between the experimental and control groups. Descriptive statistics, including mean, standard deviation, and frequency, were used for the socio-demographic and disease-related characteristics of the participants. The Wilcoxon test was used to determine the difference between repeated measurements, and the Mann-Whitney U test was used to compare continuous quantitative data between two independent groups. The cut-off value of statistical significance was accepted as $p<0.05$.

**Ethics-approval-statement:** Approval was obtained from the Local Non-Interventional Scientific Research Ethics Committee (Date: 21.02.2022 and Approval Code: TUTK-GOBAEK 2022/51). The participants were informed about the purpose of the study following the Declaration of Helsinki, and their written consent was ensured by being invited to participate in the study voluntarily.

## Results

There was no significant difference between the sociodemographic and disease-related characteristics of the women in the experimental and control groups, and it was observed that the groups showed a homogeneous distribution (Table 1). The comparison of the participants' mean quality of life scores before and after the training is shown in Table 2 and Figure 2.

Physical Functioning ($Z=-5.201$, $p<0.001$), Physical Role Functioning ($Z=-4.855$, $p<0.001$), Pain ($Z=-3.237$, $p=0.001$), General Health ($Z=-5.166$, $p<0.001$) of the participants in the experimental group ($p<0.001$), Vitality (energy) ($Z=-5.074$, $p<0.001$), Social Function ($Z=-5.165$, $p<0.001$), Emotional Role Functioning ($Z=-4.379$, $p<0.001$) and Mental Health ($Z= 4.788$, $p< 0.001$).

There was a statistically significant difference between the pre-test and post-test scores for the scales. In the women in the control group, Physical Functioning ($Z=-5.169$, $p<0.001$), Physical Role Functioning ($Z=-4.506$, $p<0.001$), Pain ($Z=-2.861$,$p=0.004$), General Health ($Z=- 5.029$, $p<0.001$), Vitality (energy) ($Z=-4.869$, $p<0.001$), Social Function ($Z=-4.666$, $p<0.001$), Emotional Role Functioning ($Z=-3.638$, $p<0.001$) and Mental Health ($Z=-3.494$, $p< 0.001$).

It was observed that there was a statistically significant difference between the pre-test and post-test scores for the scales (Table 2 and Figure 2).

In addition, in the post-test evaluation between the experimental and control groups, Physical Functioning ($Z=-3.307$, $p<0.01$), Vitality (energy) ($Z=-2.421$, $p<0.05$) and Mental Health ($Z=-2.142$, $p<0.05$) there is a significant difference in between (Table 2 and Figure 2).

## Discussion

In this study, it was observed that the education provided to women in the menopausal period who were planned for CIED implantation significantly improved the post-procedure quality of life in both the experimental and control groups. The increase in post-procedure quality of life was similarly beneficial in both the experimental and control groups.

The importance of patient education given by health professionals in chronic disease management is emphasized in the literature (Krumholz et al., 2002; Erci et al., 2018). Pacemakers, which increase the survival rate, cause physiological and psychological setbacks for individuals.

After the pacemaker implantation application, strict patient follow-up and meeting the patient's follow-up and health education needs are among the factors that increase individuals' physiological and psychological function and quality of life (Shen et al., 2019).

It is observed that patients with permanent pacemakers have problems with their physical functions. Polikandrioti (2021) and Barros et al. (2014) reported low physical functions of patients with pacemakers. In their study, Udo et al. (2013) reported that, according to the results of 7.5 years of observation, the physical functions of patients with pacemakers increased in the first years but then decreased.

**Figure 1. Flow chart of design and recruitment of participants according to 2010 CONSORT statement**

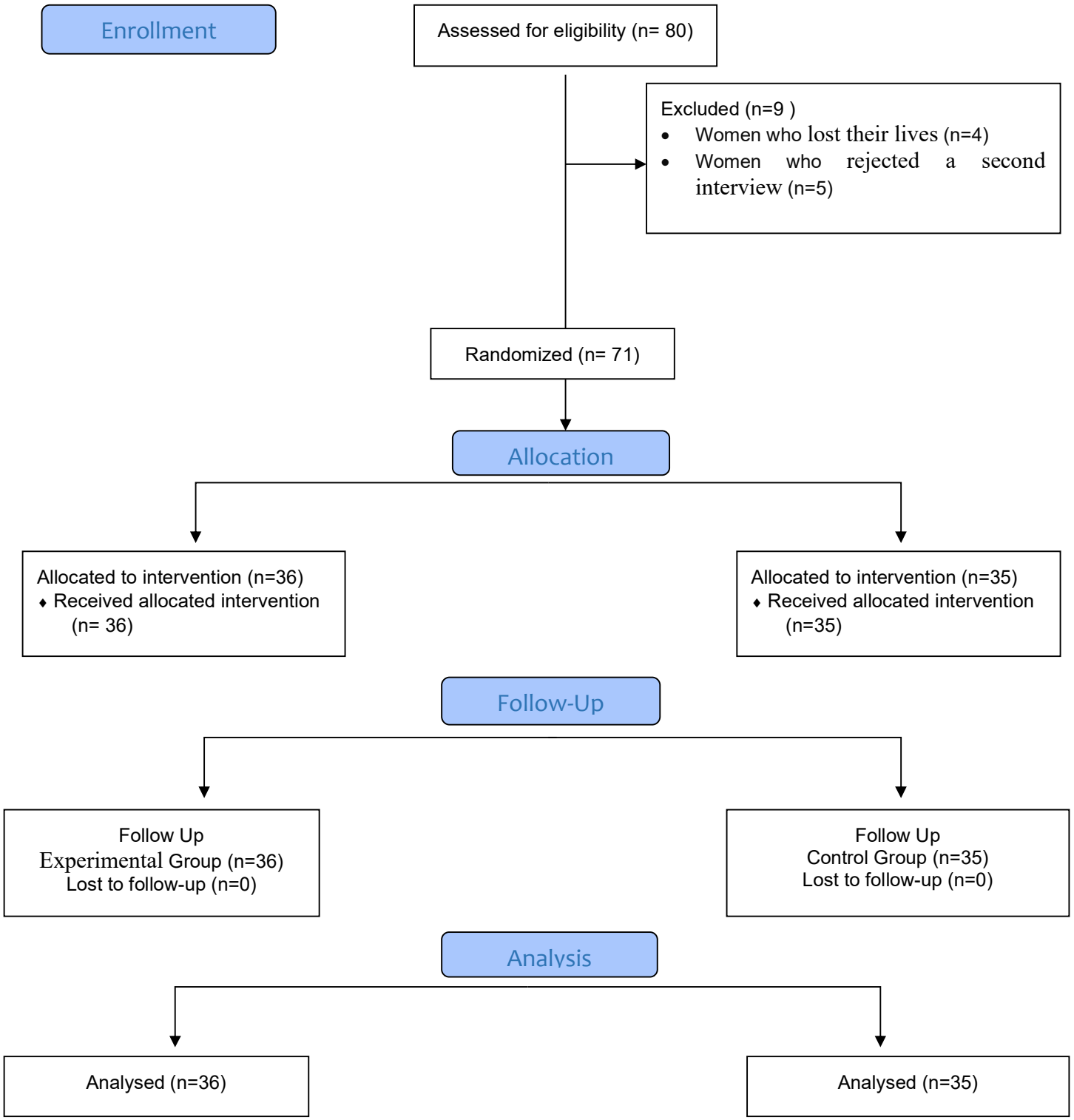
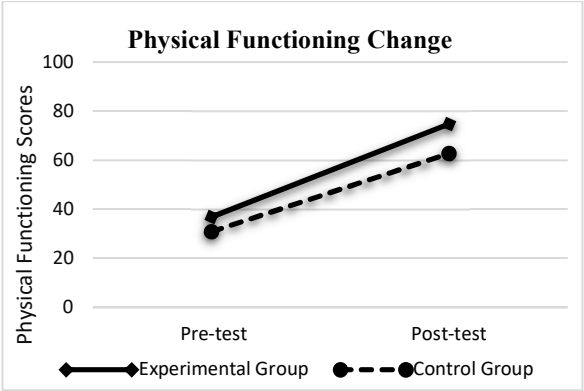
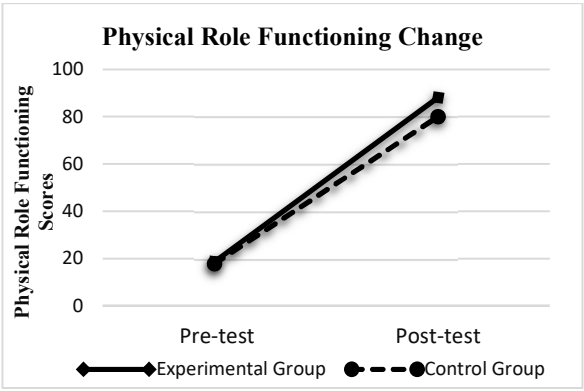


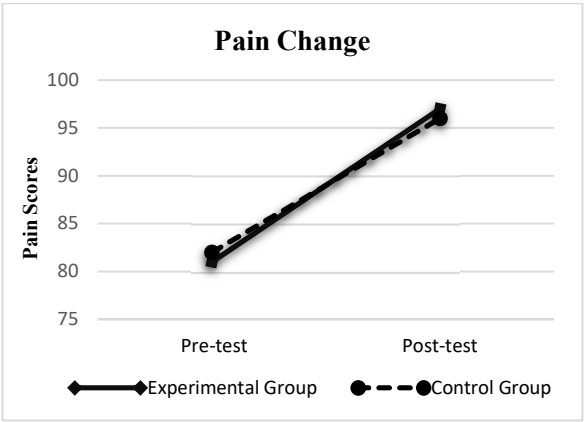
**Table 1:** Characteristics of the participants

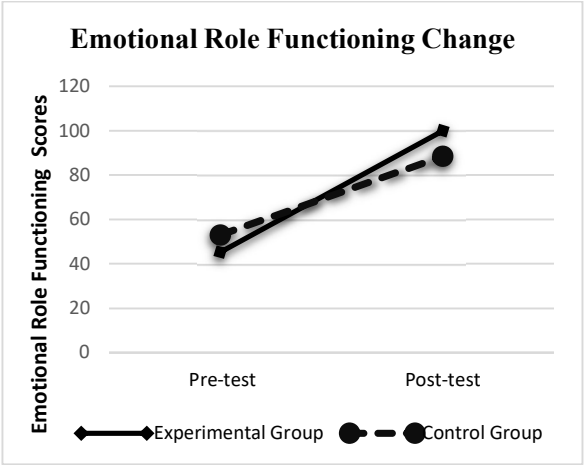
| | Experimental group n (%) / Mean (SD) | Control group n (%) / Mean (SD) | Statistical significance |
|---|---|---|---|
| **Age** | 63.77±10.08 | 63.77±11.35 | Z=0.230* p= 0.818 |
| **Marital Status** | | | |
| **Single** | 11 (69.4) | 6 (17.1) | $X^2$= 1.753** p= 0.185 |
| **Married** | 25 (30.6) | 29 (82.9) | |
| **Educational Status** | | | |
| **Illiterate** | 1 (2.8) | 4 (11.4) | |
| **Primary School** | 23 (63.9) | 19 (54.3) | $X^2$= 2.233*** p= 0.729 |
| **Secondary School** | 3(8.3) | 3 (8.6) | |
| **High School** | 6 (16.7) | 6 (17.1) | |
| **Universty** | 3 (8.3) | 3 (8.6) | |
| **Employment Status** | | | |
| **Worker** | 9 (25.0) | 6 (17.1) | $X^2$= 0,657** p= 0.417 |
| **Nonworker** | 27 (75.0) | 29 (82.9) | |
| **Social Security** | | | |
| **Available** | 35 (97.2) | 31 (88.6) | $X^2$= 2.029** p= 0.154 |
| **Absent** | 1 (2.8) | 4 (11.4) | |
| **Economic Situation** | | | |
| **Income meets expenses** | 11 (30.6) | 10 (28.6) | |
| **Income does not cover expenses** | 8 (22.2) | 14 (40.0) | $X^2$=2.922*** p= 0.238 |
| **Income partially covers his/her expenses** | 17 (47.2) | 11 (31.4) | |
| **Hypertension** | | | |
| **Yes** | 18 (50) | 21 (60) | $X^2$=0.717** p= 0.397 |
| **No** | 18 (50) | 14 (40) | |
| **Diabetes Mellitus** | | | |
| **Yes** | 17 (47.2) | 18 (51.4) | $X^2$= 0.126** p= 0.723 |
| **No** | 19 (52.8) | 17 (48.6) | |
| **Parameters** | | | |
| **EF (%)** | 44.33±14.02 | 43.11±14.09 | Z= -0.256* p= 0.798 |
| **WBC** | 8.66±2.95 | 9.86±2.59 | Z= -1.099* p= 0.272 |
| **Hb** | 12.62±3.33 | 11.64±2.57 | Z= -0.668* p= 0.504 |
| **CRP** | 11.31±12.12 | 17.07±19.25 | Z= -1,035* p= 0.300 |

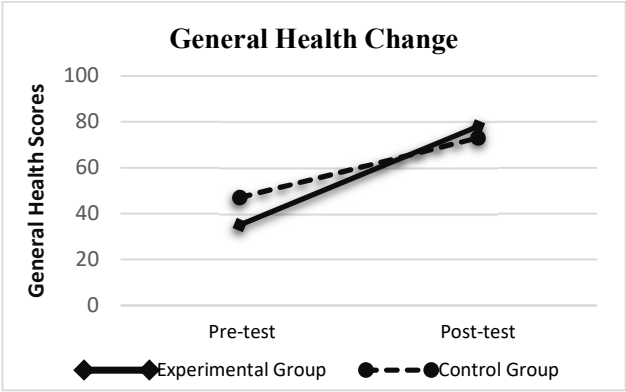
SD: Standard Deviation, *Mann Whitney U test, **Pearson Chi-square test, ***Fisher-Freeman-Halton Exact Test, EF;Ejection fraction, WBC;White blood cell, Hb;Hemoglobin, CRP;C-reactive protein

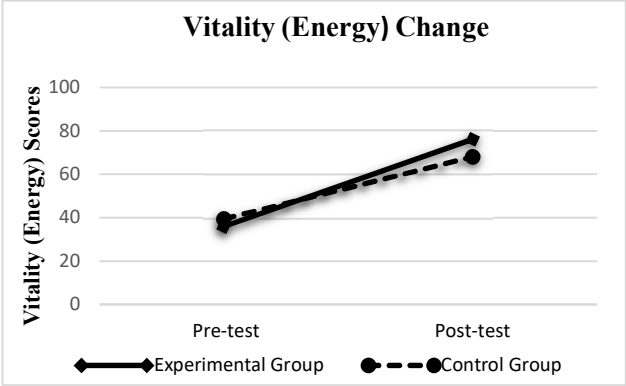

Physical Functioning Change
Physical Functioning Scores
100
80
60
40
20
0
Pre-test
Post-test
Experimental Group
Control Group

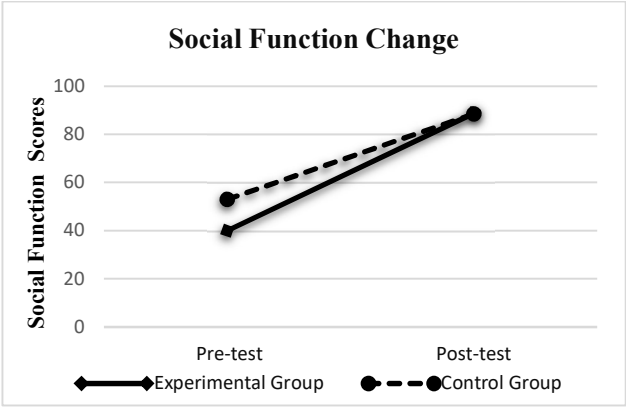

Physical Role Functioning Change
Physical Role Functioning Scores
100
80
60
40
20
0
Pre-test
Post-test
Experimental Group
Control Group


Pain Change
Pain Scores
100
95
90
85
80
75
Pre-test
Post-test
Experimental Group
Control Group


Emotional Role Functioning Change
Emotional Role Functioning Scores
120
100
80
60
40
20
0
Pre-test
Post-test
Experimental Group
Control Group


General Health Change
General Health Scores
100
80
60
40
20
0
Pre-test
Post-test
Experimental Group
Control Group


Vitality (Energy) Change
Vitality (Energy) Scores
100
80
60
40
20
0
Pre-test
Post-test
Experimental Group
Control Group


Social Function Change
Social Function Scores
100
80
60
40
20
0
Pre-test
Post-test
Experimental Group
Control Group

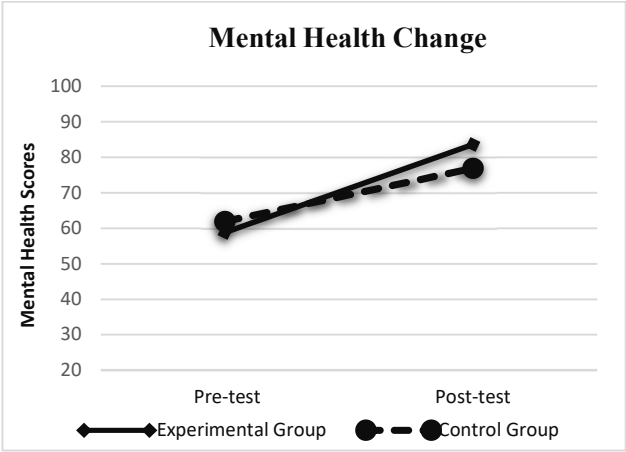

Mental Health Change
Mental Health Scores
100
90
80
70
60
50
40
30
20
Pre-test
Post-test
Experimental Group
Control Group

**Table 2:** Mean differences between scores of the experimental and control groups on Short Form 36 (SF-36)

| Short Form 36 (SF-36) | Mean scores of Short Form 36 (SF-36) | | | | | | Experimental vs. control group comparison |
|---|---|---|---|---|---|---|---|
| | Experimental group | | | Control group | | | |
| | Pre-test mean (SD) | Post-test mean (SD) | Test/p | Pre-test mean (SD) | Post-test mean (SD) | Test/p | Post-test |
| **Physical Functioning** | 36.38±22.53 | 74.72±17.40 | Z=-5.201 P< 0.001[a] | 30.85±19.98 | 62.71±16.86 | Z=-5.169 P< 0.001 [a] | Z=-3.307 **P=0.001[b]** |
| **Physical Role Functioning** | 18.75±37.50 | 88.19±24.99 | Z=-4.855 P< 0.001 [a] | 17.85±38.14 | 80.00±33.65 | Z=-4.506 P< 0.001 [a] | Z=-0.974 P=0.330 |
| **Pain** | 81.59±26.38 | 97.63±8.47 | Z=-3.237 P=0.001 [a] | 82.00±26.83 | 96.85±11.82 | Z=-2.861 P=0.004 [a] | Z=-0.072 P=0.943 |
| **General Health** | 35.30±21.41 | 78.24±15.20 | Z=-5.166 P< 0.001 [a] | 47.97±23.57 | 73.69±16.90 | Z=-5.029 P< 0.001 [a] | Z=-1.086 P=0.27 |
| **Vitality (energy)** | 35.97±21.70 | 76.11±12.36 | Z=-5.074 P< 0.001 [a] | 39.42±15.23 | 68.00±14.91 | Z=-4.869 P< 0.001 [a] | Z=-2.421 **P=0.015 [b]** |
| **Social Function** | 40.00±22.47 | 88.81±11.62 | Z=-5.165 P< 0.001 [a] | 53.07±25.96 | 88.57±10.88 | Z=-4.666 P< 0.001 [a] | Z=-0.426 P=0,670 |
| **Emotional Role Functioning** | 45.37±49.85 | 100.00±0.00 | Z=-4.379 P< 0.001 [a] | 59.04±49.23 | 98.09±7.85 | Z=-3.638 P< 0.001 [a] | Z=-1.445 P=0.149 |
| **Mental Health** | 55.88±19.81 | 83.66±11.56 | Z=-4.788 P< 0.001 [a] | 61.94±16.72 | 76.91±14.35 | Z=-3.494 P< 0.001 [a] | Z=-2.142 **P=0.032 [b]** |

***X*** : Ortalama; SS: Standart Sapma, a: Wilcoxon test, b: Mann–Whitney U-test.

Concalo et al. (2020) determined that patients who lived with their devices for at least one month had the lowest average in physical component scores. Findings from another study (Mode Selection Trial (MOST) study examining 2.010 patients over a four-year follow-up] showed that role functioning and mental health scores remained higher than pre-implantation scores, while physical field scores were comparable to those before (Fleischman et al., 2006). It proved to be comparable. In this current study, contrary to the literature, it was found that post-training physical function levels were significant compared to pre-training in both groups. The physical functions of the patients increased after the education. The increase in the patient's physical functions makes us think that the training given to the patients is effective and that the individuals are prepared for life after the procedure.

When the literature is examined, it is seen that CIED implantation causes discomfort, pain, and limited movement in individuals. This pain negatively impacts the quality-of-life Kamath and Rao.,2015). A study revealed that 23.6% of the patients reported pain and discomfort in the 5-year period following the device intervention (Mickley et al., 1989). In the studies of Polikandrioti (2021) and Snegalatha et al. (2019), it was reported that the pain levels of the patients were high. In this current study, it was found that pain levels were significant compared to pre-training in both groups. The pain levels of the patients decreased after the education (Raatikainen et al., 2017; Polikandrioti 2021).

A study reported that patients 1 year after implantation showed higher values for all SF-36 subscales than pre-implantation values, but overall health scores were lower 4 years after implantation (Udo et al., 2013). Polikandrioti (2021) reported a statistically significant correlation between the general health scores of the patients and the level of knowledge about pacemakers treatment, and the general health scores increased with the increase in the level of knowledge. This current study supports the literature. After the training given by midwifery/nurses and physicians, an increase was observed in the general health scores of the individuals.

A recently published Chinese study reported that the vitality scores of ICD patients were high (Guo et al., 2021). On the other hand, in the randomized controlled web-based intervention (a social learning environment) study conducted with Yardimci and Mert (2019) reported ICD patients, no statistical difference was found between the groups in terms of vitality. In our study determined that after the training given by both nurses and physicians, an increase was observed in the vitality scores of the individuals. It was also found that patients who received training from nurses had higher vitality scores than those who received training from physicians. We think that this is due to the fact that the number of patients per physician globally, as in our country, is higher than desired and the patient education process is disrupted.

When the literature is examined, it is seen that CIED education given to patients increases the social functioning in individuals. In the study of Yardimci and Mert (2019), it was reported that web-based intervention increased the social functionality levels of patients more than control groups. Our study is compatible with the literature and determined that after the training given by both nurses and physicians, an increase was observed in the social functionality levels of the individuals. This result makes us think that the education given in line with the needs of the patients encourages them to participate more in their social lives.

A recent study reported that a statistically significant correlation between the emotional role functioning scores of the patients and the level of knowledge about pacemakers treatment, and the general health scores increased with the increase in the level of knowledge (Polikandrioti., 2021).

However, in the study of Yardimci and Mert (2019), it was reported that web-based education did not make a significant difference in the experimental and control groups. In this current study determined that after the training given by both midwifery/nurses and physicians, an increase was observed in the emotional role functioning scores of the individuals.

ICD patients fear of experiencing shock and running out of battery. These fears affect the mental health of individuals and have an impact on their quality of life (Mert et al., 2012). Training given to patients has positive effects on the mental health of individuals. In the study of Yardimci and Mert (2019), it was reported that web-based education patients had better psychological well-being than standard-care patients. In our study determined that after the training given by both midwifery/nurses and physicians, an increase was observed in the mental health scores of the individuals. It was also found that women who received training from midwifery/nurses had higher mental health scores than those who received training from physicians. It is thought that women' sharing their experiences with health professionals contributes to this improvement.

**Conclusion:** The number of patients per physician worldwide is not at the desired level. The disruption of the patient education process deteriorates the patient's quality of life and increases hospitalization rates. Achieving patient-centered, coordinated patient education and care in CIED patients requires interprofessional collaboration. In light of the results of our study, it is believed that specialized training for midwives and nurses, particularly for women in the menopausal period, in the field of cardiovascular diseases will reduce shortcomings and provide economic advantages for the country in terms of cost-effectiveness. In this context, evaluating our results through comprehensive and multicenter studies and establishing a certification program for midwives and nurses based on supportive findings can be recommended.

**Limitations:** Our study has some limitations; First, this study was designed as a single-center and pilot study. Secondly, no additional surveys were conducted apart from the SF-36 scale as a survey study. It was not compared whether the results were the same with the different quality of life questionnaires. Finally, patients who were fitted with devices such as newly introduced leadless pacemakers and subcutaneous ICD, which are thought to have better quality of life, were not evaluated.

## References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