



THE EFFECT OF NURSING INTERVENTIONS FOR RATIONAL DRUG USE AND RAISING AWARENESS IN OLDER ADULTS: A RANDOMIZED CONTROLLED STUDY PROTOCOL

Tugce SALBUR¹, Busra ALTINEL^{2*}, Ayse CAL³

¹Selcuk University, Institute of Health Sciences, Department of Public Health Nursing, 42130, Konya, Türkiye

²Selcuk University, Faculty of Nursing, Department of Public Health Nursing, 42130, Konya, Türkiye

³Ankara Medipol University, Faculty of Health Sciences, Department of Nursing, 06100, Ankara, Türkiye

Abstract: This article presents the protocol developed for a study investigating the effect of nursing interventions applied to older adults through home visits to raise awareness about rational drug use. This study protocol describes a randomized controlled trial with a parallel group design. Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Statement 2013 checklist will be used in this study. Consolidated Standards of Reporting Trials (CONSORT) flowchart will be followed in the protocol. The research sample will consist of 74 older adults aged 65 and over and living in a rural area in the Central Anatolian Region of Türkiye. The older adults who meet the inclusion criteria will randomly be assigned to the intervention and control groups. Nursing interventions will last seven weeks and consist of individual training, counseling and reminders through home visits. The results will guide interventions to be planned to ensure and maintain rational drug use.

Keywords: Rational drug, Older adults, Awareness, Nursing

*Corresponding author: Selcuk University, Faculty of Nursing, Department of Public Health Nursing, 42130, Konya, Türkiye

E mail: busraaltinel@gmail.com (B. ALTINEL)

Tugce SALBUR



<https://orcid.org/0000-0002-4100-7183>

Received: May 11, 2023

Busra ALTINEL



<https://orcid.org/0000-0002-9491-9012>

Accepted: June 01, 2023

Ayse CAL



<https://orcid.org/0000-0002-2890-156X>

Published: July 01, 2023

Cite as: Salbur T, Altinel B, Cal A. 2023. The effect of nursing interventions for rational drug use and raising awareness in older adults: A randomized controlled study protocol. BSJ Health Sci, 6(3): 439-446.

1. Introduction

Access to and use of drugs is the fundamental right of every individual. However, in order for drugs to be effective in medical treatment, they must be used correctly and regularly (Alp et al., 2018). Rational drug use (RDU) has been defined by the World Health Organization (WHO) as the ability to provide drugs to patients and their communities at the lowest cost in a sufficient time, in doses that meet individual needs and that comply with clinical needs (WHO, 2020). The concept of RDU was first defined at the meeting held in Nairobi in 1985. Practices other than RDU are called irrational drug use (Ekenler and Koçoğlu, 2016). The WHO predicts that more than half of drugs are prescribed, distributed and sold properly, while half of patients do not use drugs correctly (WHO, 2020). Irrational drug use can lead to waste of resources, increased treatment costs, patients' inability to benefit enough from the drug, emergence of antimicrobial drug resistance, and common health problems (Ekenler and Koçoğlu, 2016). Irrational drug use, which is an important public health problem worldwide, is common in older adults (Asma et al., 2014). While irrational drug use affects all age groups negatively, it poses a significant threat to the health of older adults.

Aging is a process with chronological, physiological, psychological and social changes and losses (Soyuer, 2008; Beger and Yavuzer, 2012). The WHO defines aging as a decrease in the ability to adapt to environmental factors (Arslan et al., 2020). The world population is aging as a result of prolonged life expectancy and decreased fertility. Türkiye is also among the countries whose population is aging rapidly (Samancı and Kara, 2018). According to the WHO data, the number of older adults was one billion in 2019. It is estimated that this number will reach 1.4 billion by 2030 and 2.1 billion by 2050 (WHO, 2022). According to the data of the Turkish Statistical Institute (TUIK), while older adults' population was 6,495,239 in 2015, it increased by 22.5% in the last 5 years and reached 7,953,555 in 2020. While the ratio of older adults' population to the total population was 8.2% in 2015, it became 9.5% in 2020 and it is thought that this ratio will be 16.3% by 2040 (TUIK 2021). The rapid aging of the population increases the incidence of chronic diseases, and thus, the use of drugs also increases (Öztürk et al., 2017). One study conducted with the older population in Sweden reported the prevalence of multiple drug use (5 or more) as 44%, and the prevalence of excessive multiple drug use (10 and above) was 11.7% (Morin et al., 2018). Although there is not



enough data about the older population in Türkiye on this subject, one study found that 58.3% of the older population used four or more drugs (Gümüştakım and Başer, 2019). More than half of the drugs in developing countries and a significant proportion of them in developed countries are used irrationally. Parulekar et al. (2016) revealed that individuals in developing countries commonly self-medicate. De Bolle et al. (2008) reported that 70% of individuals take their drugs irregularly, 75.5% use drugs without a doctor's recommendation, 28.6% use drugs for insufficient period of time, 28.3% do not consider the expiration dates of the drugs, 34.9% use drugs without reading drug package inserts, and 24.5% recommend their own medicine to another person. Studies conducted in Türkiye also revealed that irrational drug use is common. Dağtekin et al. (2018) reported the frequency of irrational drug use to be 53.4%. Özen et al. (2018) revealed that 51.1% of people reuse the unfinished drugs at home, and 47.9% of them do not consult any healthcare personnel before reusing the drug.

Irrational drug use, which causes increased mortality and morbidity, reduces the quality of life of older adults. It is considered an important health problem in all countries and as a habit that is difficult to change (Gülmez, 2015; Ekenler and Koçoğlu, 2016). Therefore, it is significant to regulate the treatment of older adults according to the principles of rational drug use. The development of rational drug use in older adults, especially in individuals with chronic diseases using multiple drugs, may reduce the possible adverse effects (Gelal, 2015). In addition, it is very important to investigate and emphasize the rational use of drugs in older adults in Türkiye. Public health nurses have important roles and responsibilities in the prevention of drug use errors in older adults through education, guidance and counseling. It may be beneficial to provide clear and understandable information to older adults/caregivers through planned training and counseling, to allocate sufficient time to these people, and to consider neurological evaluation. Families should be evaluated periodically by public health nurses in terms of drug use, and the awareness of the society about this issue should be raised through effective training programs (Ekenler and Koçoğlu, 2016). Cengiz (2018) found that the education given to hemodialysis patients increased their rational use of drugs.

1.1. Aim of Study

This study aims to investigate the effect of the seven-week nursing intervention to be administered to older adults through home visits on their awareness of rational drug use.

The specific objectives are:

- to analyze the effectiveness of the intervention (training, counseling and awareness-raising nursing practices through home visits) in raising awareness about rational drug use
- to assess the feasibility of the intervention

1.2. Hypotheses

Compared to the control group,

H₁: There is a difference in terms of rational drug use, and

H₂: There is a difference in terms of awareness of rational drug use in the older adults who will be administered the home nursing intervention for rational drug use and awareness development.

2. Materials and Methods

2.1. Study Design

The study is a randomized controlled trial with a parallel group design. It is based on the Standard Protocol Items: Recommendations for Interventional Trials (Chan et al., 2013), and adheres to the Consolidated Standards of Reporting Trials (CONSORT) statement (Moher et al., 2012). The study was registered at ClinicalTrials.gov in May, 2022 (NCT05397847).

2.2. Sample/ Participants

The research population will be people aged 65 and over living in a rural area in the Central Anatolian Region of Türkiye. There are 546 people aged 65 and over in the designated region. According to the sample selection method used when the target population is known, 226 people will be reached using the simple random sample selection method at 95% confidence interval and 5% error margin. Older adults who meet the inclusion and exclusion criteria and agree to participate in the study will constitute the sample of the study (Figure 1).

Inclusion criteria

- Being 65 years or older
- Being able to speak Turkish
- Using at least one regular medication
- Living in the area where the research will be conducted
- Volunteering to participate in the research

Exclusion criteria

- Standardized Mini Mental Test score below 24
- Having any communication problem or medically diagnosed mental illness
- Being bedridden
- Having a neurological disorder

Removal criteria

- Not completing the home visits procedure
- Wishing to withdraw from the study at any stage of the research

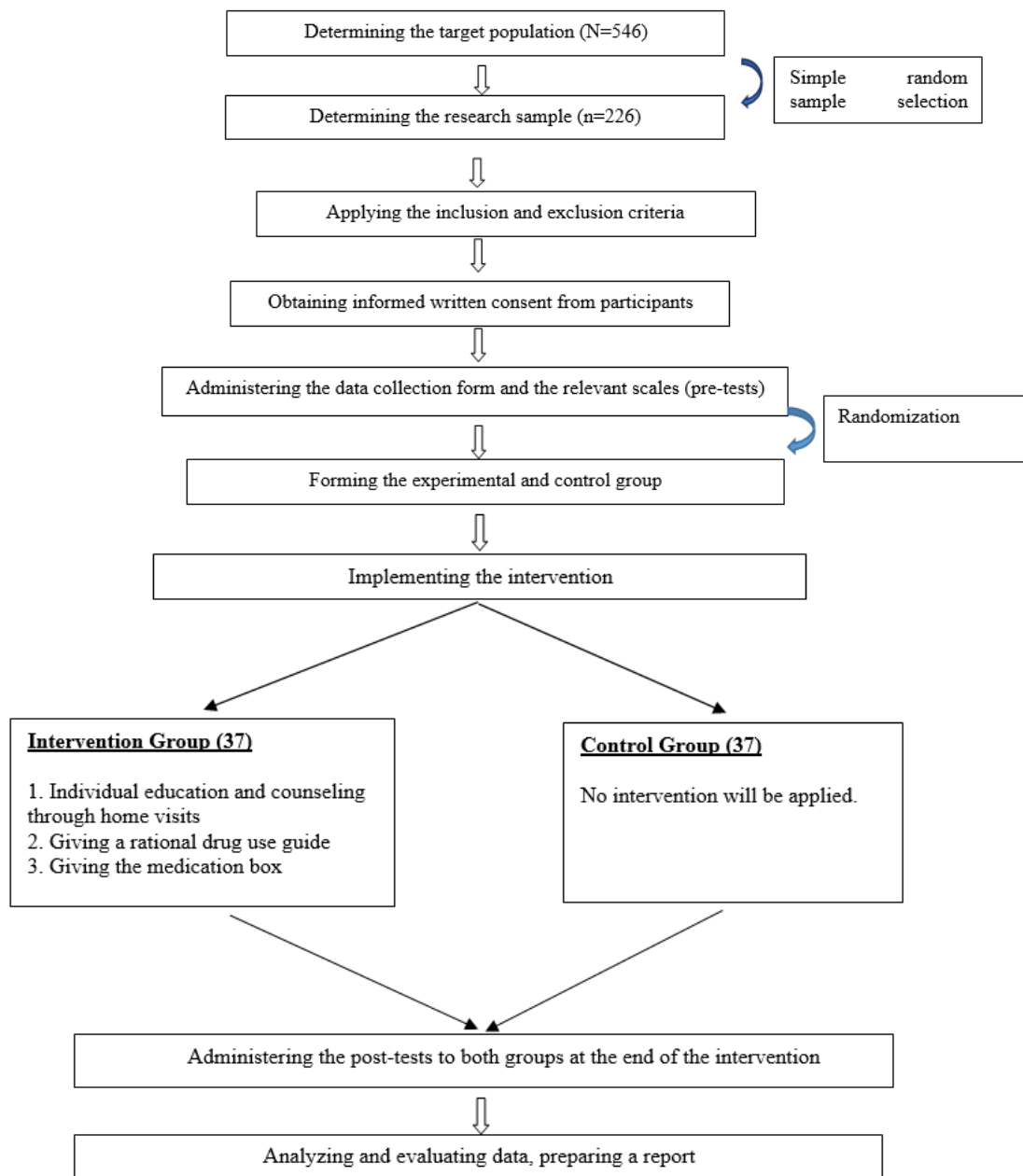


Figure 1. Study flow chart.

2.3. The Sample of the Randomized Controlled Experimental Study

The sample size was calculated on the G* Power program based on the expected effect on the primary outcome, the rational drug use score, and the difference between the two dependent means. In the literature, the effect size of rational drug use was found to be high (0.91) (Park, 2011). Although the effect size was large in the literature, Cohen (1988) recommended that medium effect size (≥ 0.5 of effect size) should be selected for clinical studies (Bindel, 2018). It was determined that 68 older adults should be recruited to reveal the observed difference using the t test, with the effect size 0.8, 80% power, and 5% level of significance. Considering a possible 10% drop out rate, the sample size is expected to consist of 74 older adults.

After the completion of the research, the power and

effect size of the test will be recalculated with the research's own data using the G-Power software program. The primary outcome variables and the data obtained from the Rational Drug Use and Rational Drug Use Awareness Scale will be included in the post hoc power analysis of the study.

2.4. Randomization

Older adults will be randomly assigned to the intervention and control groups. In order to reduce the selection bias and to control the variables that may have an effect on the outcome variables, the participants will be assigned to the experimental and control groups by a statistician other than the researcher, using the simple randomization method. The experimental and control group sets will be created using the research randomizer computer program (Random.org, 2018). It will be ensured that the older adults meet the inclusion criteria

of the study and there are 37 people in each group. Post-tests will be administered by an interviewer to avoid bias.

2.5. Outcome Measures

The outcomes of the study will consist of rational drug use status (primary outcome) and awareness of rational drug use (secondary outcome). Data will be collected using the Participant Information Form, Rational Drug Use Scale, and Rational Drug Use Awareness Scale.

2.5.1. Participant information form

The form was prepared by the researchers in line with the literature (Cooney and Pascuzzi, 2009; Ekenler and Koçoğlu, 2016; Şahin et al., 2018) and consists of 12 questions to determine the basic characteristics of the participants.

2.5.2. Rational drug use scale

The scale was developed by Demirtaş et al. (2018). It consists of 21 questions to assess rational drug use. The answers given to the scale items are scored as follows: Yes-2 points, I don't know-1 point, and No-0 point. The cut-off value of the scale was determined as 34 points. A score of 35 and above can be considered as having knowledge of rational drug use. As the score obtained from the scale increases, the level of knowledge of rational drug use increases. The Cronbach's alpha of the scale was found to be 0.78 (Demirtaş et al., 2018).

2.5.3. Awareness of rational drug use scale (ARDUS)

The scale was developed by Aktaş and Selvi (2019) and consists of 15 items rated on a five-point Likert-type scale. 8 items are reverse-coded. The lowest score that can be obtained from the scale is 15, and the highest score is 75. The Cronbach's alpha of the scale is 0.83 (Aktaş and Selvi, 2019).

2.5.1. Independent Variables

Nursing interventions applied to elderly individuals at home (training through home visits, counseling, giving rational drug use guide, giving medicine box)

2.5.2. Dependent Variables

Rational drug use scale and rational drug use awareness scale mean scores of elderly individuals

2.6. Study Procedure

This study is a randomized controlled study consisting of two groups, an intervention and a control group. The older adults in the experimental group will be given individual education and counseling services through home visits twice, and a rational drug use guide and medication box will be given after the first training as a reminder. The participants in the control group will not receive any intervention. Pre-tests and consent for participation in the study will be completed by the researchers before randomization, and post-tests will be completed by the interviewer during home visits. The study will continue for 7 weeks.

Intervention Group:

Education, counseling and reminder interventions will be implemented in the experimental group. Post-tests will be administered at the end of the 7th week.

Control Group:

The control group will not receive any intervention and the post-tests will be administered at the end of the 7th week. After the post-tests are completed, the rational drug use training given to the experimental group will also be given to the control group. The working procedure has been described below using the CONSORT (Figure 2).

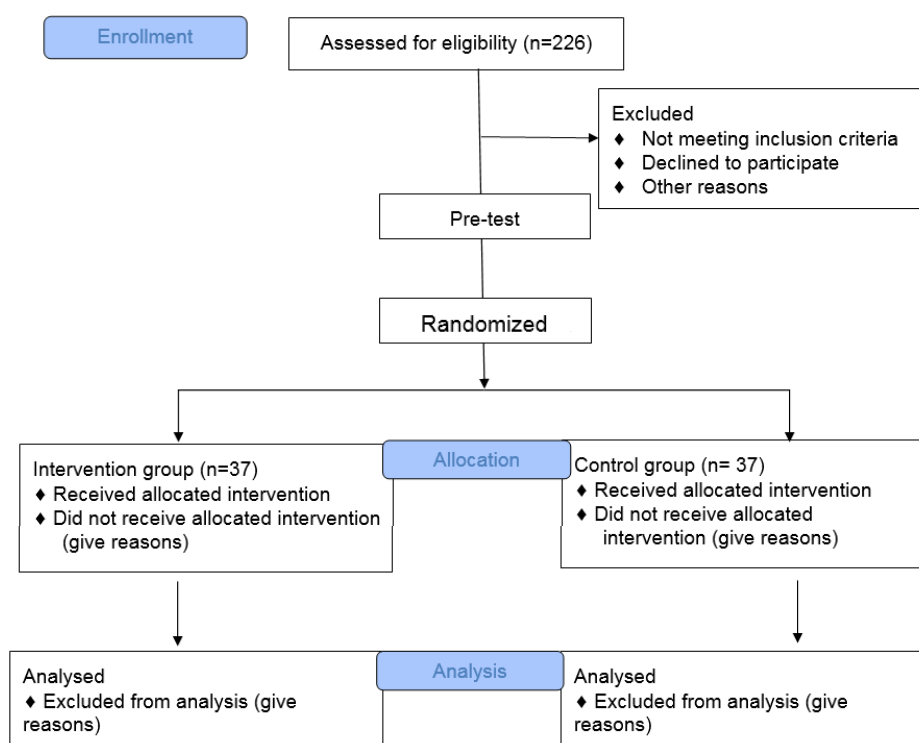


Figure 2. Consolidated standards of reporting trials (CONSORT) flowchart.

2.7. Intervention

Education, counseling, rational drug use guide and personalized medication box will be given to the participants through home visits (Table 1). Education Through Home Visits: In order to increase the rational use of drugs among older adults by improving their knowledge, awareness and control abilities, individual training will be given to elderly individuals twice, at intervals of four weeks, through home visits. It is planned

that the first training will cover the topics of drugs, rational drug use, the importance of rational drug use, and what older adults should do for rational drug use and it will last about 30 minutes. The question-answer method and visual materials will be used in the training. In the second training, the topics covered in the first training will be reviewed in about 20 minutes. Visual materials will be used in the training.

Table 1. Interventions

Interventions		
Date	Intervention/Time	Content
Week 1	-Education (30 min) -Counseling (10-20 min) -Reminders	-Giving the first training -Providing consultancy - Giving the rational drug use guide -Giving a medication box
Week 5	-Education (20 min) -Counseling (10-20 min)	-Giving the second training (Repeating the first training) -Providing consultancy
Week 7	-Post-tests	-Rational Drug Use Scale -Awareness of Rational Drug Use Scale

Rational Drug Use Guide: At the end of the first training, a rational drug use guide including the topics explained will be distributed to the participants. Opinions were received from five experts (a professor, and associate professor, and three assistant professors in the field of Public Health Nursing) to prepared the guide on rational drug use. The quality of the guide was evaluated using the DISCERN, which was developed by Charnock et al. (1999) and which evaluates the quality of training materials providing written information about the treatment options for health problems. DISCERN consists of 16 items and each item is rated from 1 to 5. The 16th item makes a general assessment and thus is evaluated separately. The total score ranges from 15 to 75. Low DISCERN scores show that the quality is poor, while high scores indicate a good quality. DISCERN was translated into Turkish by Gokdogan (2003). The guide was prepared in line with the suggestions.

Medication Box: After the first training, the participants will be given a medication box with 7-day and daily (morning, noon, evening and night) compartments. The box will help older adults not to forget their drugs and to use them regularly. It can be carried in the pocket. Counseling: After the first and second training, counseling services will be provided to the participants on rational drug use.

2.8. Statistical Analysis

The data will be analyzed using the IBM Statistical Package for Social Sciences package program. The conformity of the data to normal distribution will be evaluated with the Kolmogorov-Smirnov test. Sociodemographic variables will be analyzed using descriptive statistics. The significance test of the difference between two independent means will be used to compare the pretest and posttest data of the control

group according to the dependent variables. The Mann Whitney U test will be used for non-parametric data. The dependent groups t test will be performed to compare the pretest and posttest data of the intervention and control groups according to the dependent variables. The Wilcoxon test will be used for non-parametric data. Results will be evaluated at 95% confidence interval and p<0.05 significance level (IBM Corp, 2016).

The intent to treat (ITT) analysis will be conducted due to sample losses after randomization in the data collection process. This analysis is widely recommended to maintain homogeneity between groups in randomized controlled studies. It provides both the continuation of the randomization and the realistic evaluation of the effect of the intervention, even if the individuals in the sample leave the study. The application of the ITT analysis as missing data analysis enables the individuals in the intervention and control groups to be compared in the groups to which they were randomly assigned (Moher et al., 2012).

3. Results and Discussion

This study aims to determine the effect of nursing interventions applied through home visits on the development and awareness of rational drug use in older adults. The findings to be obtained at the end of the study will provide evidence-based data that will help the management of irrational drug use, which is an important problem in the increasing older adult population. It is known that chronic diseases and multiple drug use are increasing in Türkiye and in the world in parallel with the increase in older population (Öztürk et al., 2017; Morin et al., 2018; Gümüştakım and Başer, 2019). The results of national and international

studies have shown that irrational drug use is a common problem (De Bolle et al., 2008; Parulekar et al., 2016; Özen et al., 2018; Dağtekin et al., 2018). For this reason, in recent years, some studies have been encountered in the literature on rational drug use in older adults. However, there is no planned or conducted randomized controlled study including nursing interventions for older adults. This study will be one of the first randomized controlled studies involving nursing interventions on rational drug use in older adults. For this reason, it is thought that the study will make a significant contribution to the literature.

Demographic changes have increased the incidence of diseases in old age and the need for home care services. The purpose of home visit programs is to maintain the health of individuals in their own living spaces, to ensure that they gain autonomy regarding health, to prevent disability and repeated hospitalizations, and it is recommended that services primarily include risky groups (pregnant, child, older population, etc.) (Huss et al., 2008; Aveller and Supplee, 2013). For example, a meta-analysis study examining randomized controlled studies revealed that home visit practices based on clinical examination and system diagnosis reduce the disability burden of older adults (Huss et al., 2008). The cost and clinical effectiveness of home care practices offered by nurses have been demonstrated in studies, and it has been observed that patients' independence can be increased with these practices (Tappenden et al., 2012; Lewin et al., 2013; Cengiz et al., 2019). The implementation of the interventions through home visits in this study will also provide evidence for the need and plans for the integration of home care practices in health services with the changing population projections.

Publication of the study protocol increases research transparency, reduces publication bias, and informs researchers about what studies have been done, which helps prevent duplication and better coordinate research plans. Making study protocols publicly available also has the advantage of disseminating the most up-to-date ideas about study design and data analysis (Ohtake and Childs, 2014). In this protocol, the purpose and type of the planned research, the participant selection and randomization process, the expected outcomes of the research, the research protocol, and the interventions are explained. In addition, the analysis of the data and the ethical compliance of the research are reported in detail according to the Recommendations for Interventional Trials (Chan et al., 2013). When the research is completed, the CONSORT standards used in the reporting of randomized controlled studies will be taken into account (Moher et al., 2012).

5. Conclusion

This study can be an example of nursing care for older adults and can be adapted to other studies. The results to be obtained can guide the interventions to be planned to

ensure and maintain rational drug use. Older adults often need the guidance and support of a caregiver due to the weakening of their cognitive abilities. For this reason, it is recommended to include caregivers in the interventions involving home visits in future studies.

Author Contributions

Percentages of the author(s) contributions is present below. All authors reviewed and approved final version of the manuscript.

%	T.S.	B.A.	A.C
C	35	35	30
D	30	35	35
S		50	50
DCP	85	15	
DAI	50	30	20
L	60	20	20
W	50	30	20
CR	20	40	40
SR		50	50
PM	15	70	15
FA	20	70	10

C= concept, D= design, S= supervision, DCP= data collection and/or processing, DAI= data analysis and/or interpretation, L= literature search, W= writing, CR= critical review, SR= submission and revision, PM= project management, FA= funding acquisition.

Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

Ethical Approval/Informed Consent

This study will be conducted in accordance with the Declaration of Helsinki. Written informed consent will be obtained from the older adults who agreed to participate in the study. They will be informed that they can leave the study at any time and that the study does not pose any harm or risk. The study, Ethics Committee and institutional permission from the District Governor's Office was obtained (approval date: March 30, 2022, protocol code: 2022/27). In addition, after the study is completed in line with the principle of "equality", the participants in the control group will also be given the rational drug use guide and a medication box.

Acknowledgments

This study was supported by Selcuk University Scientific Research Projects (Project no: 22202013). The study was registered at ClinicalTrials.gov in May 2022 (NCT05397847).

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