


Study to improve the quality of life in perimenopausal women from the community pharmacy. Research protocol pilot study – m+45

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KEYWORDS

Menopause, community pharmacy, intervention, quality of life, perimenopause

ABBREVIATIONS

CEICA: Research Ethics Committee of the Autonomous Community of Aragón
HRQoL: Health-Related Quality of Life
ICH: International Conference on Harmonization
LOPD: Ley Orgánica de Protección de Datos (Organic Law on Data Protection)
MRS: Menopause Rating Scale
MSL: Menopause Symptoms List
MSQL: Menopause Specific Quality of Life
WHO: World Health Organization
SBP: Systolic Blood Pressure
SPFA: Professional Pharmaceutical Care Service
UBE: Indicate units of beverage
UQOL: Utian Menopause Quality of Life Score
WHQ: Women's Health Questionnaire
ZAP: Personalized Attention Zones

ABSTRACT

The menopause is a stage in a woman's life, characterised by oestrogen and progesterone deficiency, which can cause a series of symptoms of varying intensity among women. When they appear, their quality of life can be affected to a greater or lesser extent, so it is important to identify them and intervene by offering appropriate solutions. There are different validated scales, although in recent years the Menopause Rating Scale (MRS) has been one of the most widely used in global research.

Taking into account the healthcare work of the community pharmacist, it is appropriate to suggest a project to measure the perception of quality of life in women aged from 45 to 64 years before and after a structured intervention to assess its impact on general wellbeing.

A study was proposed in community pharmacies that were randomly distributed into intervention and control groups. The study was offered to women who came to collect medication related to this stage or requested information or recommendations as long as they signed the informed consent form and did not suffer cognitive or language difficulties that would not allow them to understand the study. Two questionnaires were carried out on the first visit, which were repeated on the second visit, after 3 months, as well as a third, only on the second visit, on sources of information. The intervention group received on the initial visit, after data collection, health education and recommendations of commercially available products related to the characteristic symptoms.

INTRODUCTION/JUSTIFICATION

Menopause is a physiological period in a woman's life, progresses with age, and is conditioned by the hormonal changes that occur during it. The World Health Organisation (WHO) defines it as the permanent cessation of menstruation, determined retrospectively after 12 consecutive months of amenorrhea, without pathological causes and as a result of the loss of ovarian follicular activity. The age of presentation is between 45 and 55 years, with an average age of around 51 years [1]. Estrogen and progesterone deficiency, more or less abruptly, can lead to the onset of a series of symptoms of varying intensity from one woman to another. These range from asymptomatic women to severe symptoms with a major impact on quality of life.

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In addition to menopause, there are other terms that are also used during this stage. The menopausal transition and/or perimenopause is the period of time in a woman's life that extends from the onset of hormonal changes and clinical symptoms until one year after the last menstrual period. Perimenopause usually lasts about seven years but can be extended up to fourteen years [2]. It is impossible to predict when a woman will begin to experience menopause, although there is some correlation with demographic, health and genetic factors [3,4]. And although the biological changes associated with menopause are universal, there are notable variations in women's personal experience, also between different cultures and in the way these changes affect their quality of life [5]. The interaction between genetics, which will determine the number of oocytes present at the time of birth, the environment, influenced by cultural and socio-economic aspects that will determine cultural level, type of diet, smoking or not, and exercise, will contribute to their occurrence [6].

The most frequent symptoms of this early stage are heavy bleeding and the onset of hot flashes. Subsequently, in the short term, hypoestrogenism produces vasomotor and psychological symptoms (anxiety, depression, irritability, etc.). In the medium term, menopause causes genitourinary atrophy which increases the incidence of urinary tract infections. Many women also experience a decrease in sexual desire, either because they are unaware of this stage or because of problems associated with it, such as vaginal dryness and/or dyspareunia. Finally, there is an increased risk of osteoporosis and increased cardiovascular risk, which poses an additional health risk for women over the age of 65 [7]. Health-related quality of life (HRQoL), on the other hand, has been defined as "the subjective assessment of the influence of current health status, health care and health-promoting activities on the ability to achieve and maintain a level of overall functioning that allows one to pursue valued life goals and that is reflected in one's general well-being" [8].

The most commonly used specific scales to assess the quality of life of menopausal women are: Blatt and Kuperman's Menopause Index, the Women's Health Questionnaire (WHQ) [9], the Qualifemme, the Menopause Rating Scale (MRS) [10], the Menopause Specific Quality of Life (MSQOL), the Utian Menopause Quality of Life Score (UQOL), the Menopause Symptoms List (MSL) [11], the MENCAP of Cuenca and the Cervantes Scale. All of them, in different ways, assess the impact of the symptoms associated with the transition to menopause in order to identify the needs of each woman.

Most of the studies that have been carried out on quality of life in peri- and/or menopausal women have been developed in gynecological or nursing consultations. Thus, in Spain, in 2015 a study was published by several gynecologists who analysed the quality of life of meno-

pausal women with the Cervantes Scale and concluded that: menopausal women can improve their quality of life with treatment with hormone therapy and isoflavones, the Cervantes Scale being a very useful clinical tool for assessing changes [12].

In 2016, through the SÍSIFO program [13], a study was conducted to assess the control of cardiovascular risk factors in obese menopausal women after following a structured program of dietary education and physical exercise, and it was concluded that the application of this program improved the parameters related to cardiovascular risk in the women studied. After the intervention, weight decreased (4.4 ± 2.3 kg), systolic blood pressure (SBP), lipid profile and glycaemia improved, in addition to an improvement in quality of life, dietary habits and physical exercise. Another article was published in the Zarzuela hospital in Madrid in 2020 in which it was evaluated, using the Cervantes scale, that women who choose to use hormone therapy for menopausal symptoms have a worse quality of life than those who do not initiate it [14].

Although the Cervantes scale, in its short version, is a valid questionnaire for measuring the quality of life of women in the peri- and menopausal stage, the SEFAC Women's Health working group has investigated new scales with a more international projection in order to compare results and advance in the study of women's quality of life after the onset of perimenopause. Therefore, after a literature search of published works [15-18], mainly at European and Latin American level, the MRS has been selected because it is a scale widely used worldwide, with translations available in 25 languages. It was initially developed in 1992 in Germany by the Berlin Centre for Epidemiology and Health Research [16]. It was designed to measure the severity of symptoms related to menopause and ageing in women aged 45-64 years [16,17]. It is also used as a screening tool to identify women who require referral to a medical specialist as a result of severe menopausal symptoms [18]. That is, it assesses the symptoms and complaints of older women in different conditions and in different cultures, the severity of symptoms over time, and measures changes before and after the use of postmenopausal replacement therapy [16].

The use of the MRS in recent years by many researchers and in various parts of the world has been an important advance that makes it possible to objectify and compare the clinical effects of this stage in various populations [19-21]. Thus, the REDLINC42 group conducted a large study using the MRS scale to assess the quality of life of middle-aged Latin American women, involving 8,373 women aged 40-59 years in 18 cities in 12 Latin American countries. A marked deterioration in the quality of life of Latin American menopausal women was found, determined by a generally high prevalence of high total MRS scores. However, there are differences between countries,

such as Chile with 80.8% of values recorded as moderate to severe; Ecuador with 60.1%; Peru with 51.6%; Colombia 48.3%, among others, with the Latin American average being 55.4%.

In Spain in 2011, the MRS scale was used by nursing professionals in the province of Murcia, and it was concluded that the outcome of going through this stage is conditioned by the personal assessment of the different aspects, both positive and negative as well as neutral, that women experience. Therefore, a holistic view of the menopause is the most appropriate, as resources such as health education improve the personal experience [22]. Subsequently, in 2022, in Almería, the MRS scale was applied to postmenopausal women and moderate total symptomatology was observed, as well as in the somatic-vegetative and urogenital domains. After the intervention, they concluded that adherence to the Mediterranean diet and physical exercise reduced somatic-vegetative and psychological symptomatology, respectively [23].

It should not be forgotten that it is usually women in this age range who go to the community pharmacy and that the proximity and accessibility of the pharmacist often makes them the first health professional with whom they come into contact. It is therefore necessary for community pharmacies to offer peri- and/or menopausal women comprehensive care to improve their health and well-being, knowing which aspects can affect their quality of life the most; it was therefore considered appropriate to conduct a study on the perception of the quality of life of these patients, before and after our structured intervention, to assess the impact of the intervention, since there are not many experiences in this regard in community pharmacies. In addition, it is a good time to propose smoking cessation in women smokers and nutritional services for a balanced and adequate diet.

APPLICABILITY OF THE RESULTS

It is hoped that pharmacists will incorporate care for women in the perimenopausal period (45–64 years) as one of the professional services offered in Community Pharmacy. On the other hand, it is hoped that the pharmaceutical intervention, consisting of health education on the improvement of hygienic dietary habits and pharmaceutical indications, will prove efficient to improve the quality of life of women between 45 and 64 years of age. These are activities for which the community pharmacist, in collaboration with other health professionals, with the appropriate training, is perfectly qualified and which form part of the competences recognised by law.

OBJECTIVES

Main objective:

To assess whether pharmaceutical intervention improves symptoms and quality of life in perimenopausal women, as measured by the MRS scale.

Specific objectives:

- To assess the intensity of climacteric symptoms using the MRS scale, before and after the pharmaceutical intervention.
- To determine the frequency (present or not present) of each of the symptoms contained in the MRS scale in the women surveyed.
- To identify and analyse whether socio-demographic variables influence the health habits and quality of life of the study population.
- To identify the perception of the quality of life of perimenopausal women between 45 and 64 years of age regarding the dimensions of quality of life: somatic domain, psychological domain and genitourinary syndrome.
- To analyse the sources of information consulted by the participants to find out about aspects related to the menopause.
- To record the health decisions related to menopause that occurred during the study period.
- To list the sources that influence women's health decisions.

MATERIAL AND METHODS

Study design:

Prospective longitudinal quasi-experimental study with intervention and control groups conducted in community pharmacies in Spain, which agreed to participate in the study, from 1 December 2023 to 30 April 2024.

Study population:

Women aged 45 to 64 years attending participating pharmacies in the period from 1 December 2023 to 30 April 2024.

Inclusion criteria:






- Women aged 45 to 64 years who went to the community pharmacy requesting information or recommendation on any of the symptoms of this stage included in the MRS questionnaire.
- Women aged 45 to 64 years who went to the community pharmacy to pick up their prescribed medication for any of the symptoms of this stage included in the MRS questionnaire.
- Women aged 45 to 64 years who went to the community pharmacy and voluntarily requested to participate in the study.

Exclusion criteria:

- Women who did not sign the informed consent form.
- Women with cognitive or language difficulties that did not allow them to understand the study.

Variables:

Primary variable (Figure 1): Score obtained in the (MRS) [14]
 The score obtained in MRS will be used as the main variable. It will be expressed as average ± standard deviation,

Which of the following symptoms apply to you at this time?	None	mild	moderate	severe	extremely severe										
															
	0	1	2	3	4										
SOMATIC DOMAIN															
Hot flashes, sweating (episodes of sweating)															
Heart discomfort (unusual awareness of heart beat, heart skipping, heart racing, tightness)															
Joint and muscular discomfort (pain in the joints, rheumatoid complaints)															
Sleep problems (difficulty in falling asleep, difficulty in sleeping through the night, waking up early)															
PSYCHOLOGICAL DOMAIN															
Depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings)															
Irritability (feeling nervous, inner tension, feeling aggressive)															
Anxiety (inner restlessness, feeling panicky)															
Physical and mental exhaustion (general decrease in performance, impaired memory, decrease in concentration, forgetfulness)															
UROGENITAL DOMAIN															
Sexual problems (change in sexual desire, in sexual activity and satisfaction)															
Bladder problems (difficulty in urinating, increased need to urinate, bladder incontinence)															
Dryness of vagina (sensation of dryness or burning in the vagina, difficulty with sexual intercourse)															
<table border="1"> <tr> <td>Somatic domain 0 - 16 points</td> </tr> <tr> <td> </td> </tr> </table>		Somatic domain 0 - 16 points		<table border="1"> <tr> <td>Psychological domain 0 - 16 points</td> </tr> <tr> <td> </td> </tr> </table>		Psychological domain 0 - 16 points		<table border="1"> <tr> <td>Urogenital domain 0 - 12 points</td> </tr> <tr> <td> </td> </tr> </table>		Urogenital domain 0 - 12 points		<table border="1"> <tr> <td>Total 0 - 44 points</td> </tr> <tr> <td> </td> </tr> </table>		Total 0 - 44 points	
Somatic domain 0 - 16 points															
Psychological domain 0 - 16 points															
Urogenital domain 0 - 12 points															
Total 0 - 44 points															

Source: Heinemann LA, Potthoff P, Schneider HP. International versions of the Menopause Rating Scale (MRS). Health Qual Life Outcomes. 2003; 1:28

Figure 1 Menopause Rating Scale (MRS)

although the responses to each of the items, the total score and the score by domains will also be expressed in N (%).
(Figure 2)

MRS total score (11 items):

- 0: no deterioration in quality of life.
- 44: maximum deterioration in quality of life.

MRS domain score (3 domains):

- Psychological domain (4 items):
 - 0: total absence of psychological symptomatology.
 - 16: maximum presence of psychological symptomatology.
- Somatic domain (4 items):
 - 0: total absence of somatic symptoms.
 - 16: maximum presence of somatic symptoms.
- Urogenital domain (3 items):
 - 0: total absence of urogenital symptoms.
 - 12: maximum presence of urogenital symptoms.

Socio-health variables: (Figure 3)

- Age: years.
- Level of education: no education/primary/secondary/university.
- Relationship: steady partner/occasional partner/single.
- Last menstrual period: month and year.
- Hysterectomy: partial/total/radical; date.
- Diseases: high blood pressure/dyslipidaemia/thyroid/obesity/diabetes/osteoporosis/other (name).
- Smoker: YES/NO/ex-smoker.
- Alcohol: never/almost never/ 1-3 times a month/at least

once a week/every day. Indicate units of beverage (UBE)

- Caffeine: YES/NO.
- Physical exercise: YES/NO. Which one? Name. Time? Minutes/week.
- Medication: name by active substance of the medicines prescribed in electronic prescriptions. In addition, all those who were using without medical prescription, health product or medicinal plants were included.

Variables sources of information on health: (Figure 4)

- Have you looked for information about this stage? (majority choice): menopause/diet/exercise/dietary supplements/I have not looked for information.
- Where (majority choice): internet/books/pharmacist/doctor/friends or relatives/not looking for information.
- When you look for information on the internet, you do so from official sources (majority choice): health portals/Ministry sources/patients' associations/I do not look for information on the internet/ I do not know which are the official sources.
- Have you visited a doctor, gynecologist, midwife since the first appointment of the study: primary care doctor/gynecologist/midwife/ I have not visited any of them.
- Have you used any new medication or food supplement to relieve menopausal symptoms in the last 3 months (it is recommended to consult MRS to remember what each domain refers to): for psychological/somatic/urogenital domain/I have not used any.
- Who told you: pharmacist/internet search/primary care physician/gynecologist/midwife/friends or family members/I have not used any.

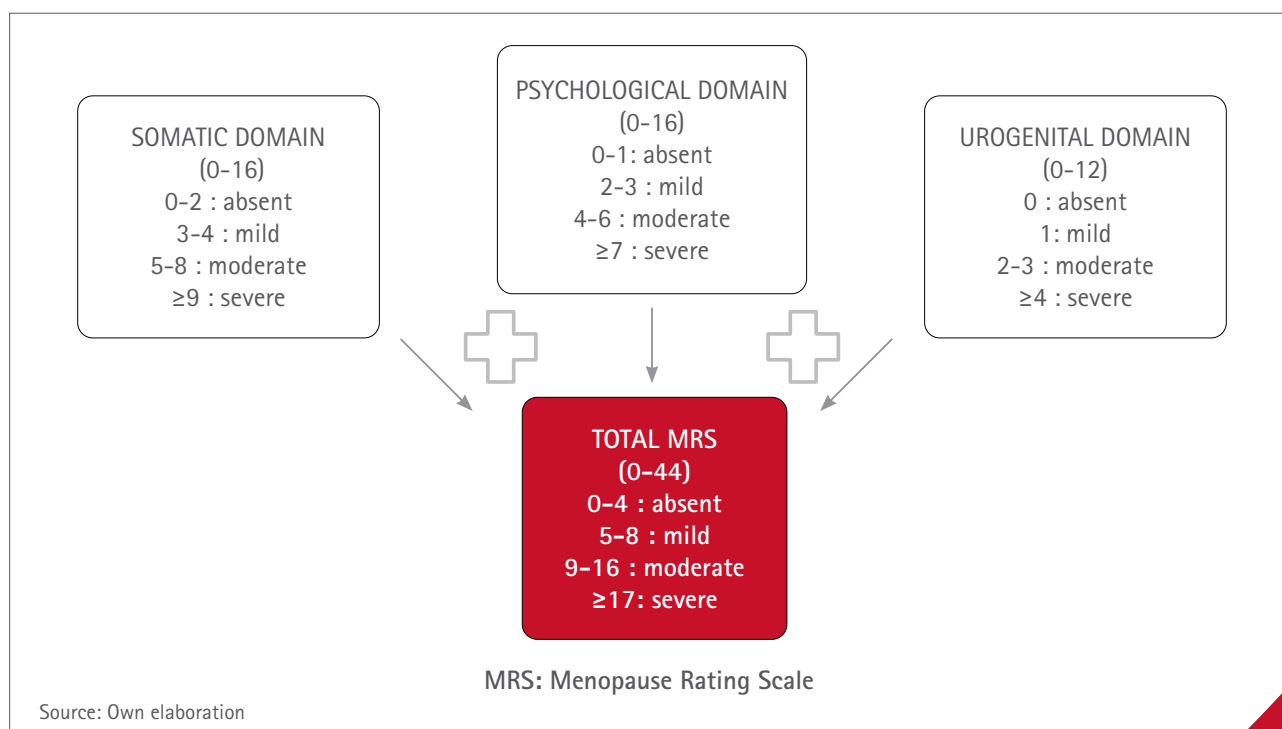


Figure 2 Assessment of the Menopause Rating Scale (MRS) questionnaire. Affect on quality of life

SOCIAL AND HEALTH VARIABLES		
Date:	Participation code:	Age (Years):
Studies: <ul style="list-style-type: none"> • No studies • Primary 	<ul style="list-style-type: none"> • Secondary • University 	
Relationship <ul style="list-style-type: none"> • Stable couple 	<ul style="list-style-type: none"> • Eventual couple 	<ul style="list-style-type: none"> • No partner
Last menstruation (month and years):		
Hysterectomy (month and year) ¹ <ul style="list-style-type: none"> • Total • Partial 	<ul style="list-style-type: none"> • Radical • No 	
Previous gynecological diseases:		
Other diseases: <ul style="list-style-type: none"> • Arterial hypertension • Dyslipemia • Other: 	<ul style="list-style-type: none"> • Thyroid • Obesity 	<ul style="list-style-type: none"> • Diabetes • Osteoporosis
Smoking <ul style="list-style-type: none"> • Yes 	<ul style="list-style-type: none"> • No 	<ul style="list-style-type: none"> • Smoker
Alcohol (indicate units of alcohol) ² : <ul style="list-style-type: none"> • Never/almost never • 1-3 times a month 	<ul style="list-style-type: none"> • At least once a week • Every day 	
Caffeine <ul style="list-style-type: none"> • Yes 	<ul style="list-style-type: none"> • No 	
Physical exercise <ul style="list-style-type: none"> • Yes Which one? Time (minutes /week):	<ul style="list-style-type: none"> • No 	
Medications		
1. Hysterectomy: removal of the uterus. It can be partial , only the upper part of the uterus; total , complete uterus and cervix; radical , complete uterus, cervix and upper part of the vagina. In all cases, ovaries and fallopian tubes may or may not be removed. (Hysterectomy [Internet]. OASH; December 29, 2022. Available from https://womenshealth.gov/a-z-topics/hysterectomy 2. 1SBU= 10 gr alcohol = 250 ml beer; 100 ml wine; 30 ml spirits https://espanol.womenshealth.gov/a-z-topics/hysterectomy Source: Own elaboration		

Figure 3 Socio-health variables questionnaire

QUESTIONNAIRE SOURCES OF INFORMATION
<ul style="list-style-type: none">• Have you searched for information about this stage? (majority choice)<ul style="list-style-type: none">a) On menopauseb) About dietc) About exercised) Food supplementse) I have not looked for information
<ul style="list-style-type: none">• Where (majority choice)<ul style="list-style-type: none">a) Internetb) Booksc) Pharmacistd) Doctore) Friends or relativesf) I have not looked for information
<ul style="list-style-type: none">• When you search for information on the Internet, do you do so from official sources?<ul style="list-style-type: none">a) Health portalsb) Ministry sourcesc) Patient associationsd) I do not search for information on the Internete) I don't know which are the official sources
<ul style="list-style-type: none">• Have you visited the doctor, gynecologist or midwife since the first appointment of the study?<ul style="list-style-type: none">a) Primary Care Physicianb) Gynecologistc) Midwifed) I have not visited any of them
<ul style="list-style-type: none">• Have you used any new medication or dietary supplement to alleviate menopausal symptoms in the last 3 months) (it is recommended to consult MRS to remember what each domain refers to)<ul style="list-style-type: none">a) For psychological domainb) For somatic domainc) For urogenital domaind) I have not used any
<ul style="list-style-type: none">• Who has indicated it to you?<ul style="list-style-type: none">a) Pharmacistb) Internet searchc) Primary Care Physiciand) Gynecologiste) Midwifef) Friends or relativesg) I have not used any

Figure 4 Questionnaire of health information source variables

Source: Own elaboration

Procedure (Figure 5)

The participating pharmacies were randomly distributed into intervention and control groups, ensuring that they had similar characteristics in terms of opening hours or type of community pharmacy (rural/urban/semi-urban). They were assigned a fixed code correlated to their inclusion as research pharmacies, which was included in the identification codes of the participants.

- Study offer

At the time of dispensing, the community pharmacist randomly offered participation in the study to all women who met the inclusion criteria. Those who accepted went to the personalized attention area or an appointment was scheduled according to availability.

- Information sheet and informed consent

At the first appointment, the pharmacist handed the information sheet to the participants and the informed consent form was signed, prior explanation of the same, and they were considered to be included in the study. This is where the participation code assigned to the participants

was written down, which consisted of a number correlative to their inclusion in the study, a letter according to the group to which the pharmacy was assigned, I intervention and C control, and, finally, the number assigned to the research pharmacy (e.g., 2C3 would be the code of the third woman included in the control group of research pharmacy number 2).

The informed consent is the only document where the personal data and the participation code are listed, becoming the one used from now on to collect the study data.

INITIAL interview

- Completion of the questionnaire on socio-health variables and healthy habits and MRS (Figure 1 and 3). Estimated duration 10 minutes.
 - The assigned participation code was noted.
 - The responses corresponding to each variable were coded and the total MRS questionnaire score and in each of the 3 domains evaluated by the questionnaire were assessed (Figure 2).
 - Depending on the group in which the participant was included, intervention was performed or not.

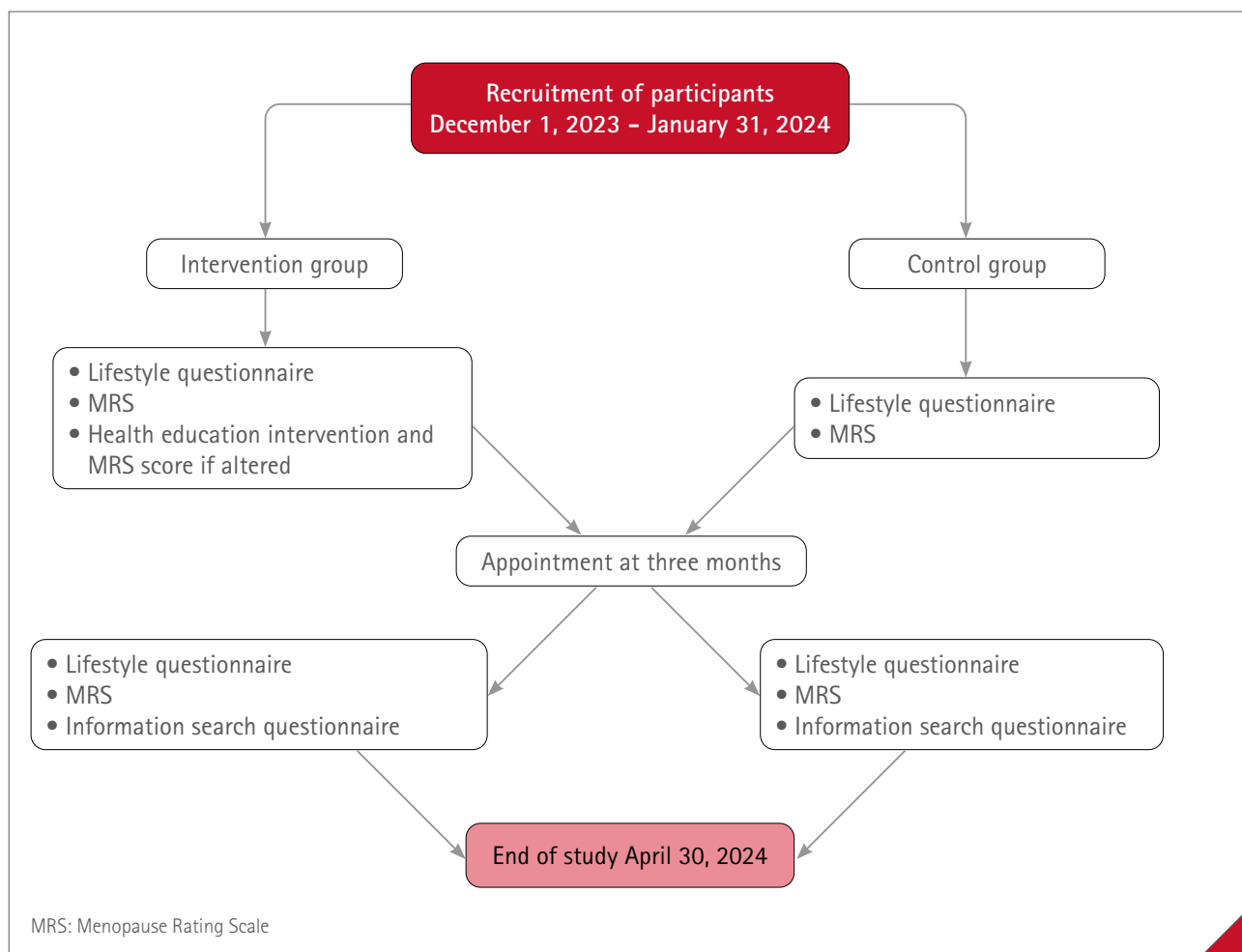


Figure 5 Working algorithm

Source: Own elaboration

Pharmaceutical intervention. Estimated duration 10 minutes.

Participants included in the intervention group were provided with:

- Health education that included a brief presentation defining the difference between menopause and perimenopause, changes that occur at this stage and associated symptomatology assessed on the MRS. Brief advice related to diet and exercise useful for the menopausal transition was also provided.
- Information on the existence of marketed health products and/or food supplements that show evidence in the areas involved in order to improve women's quality of life.

If necessary, referral to another professional pharmaceutical care service (SPFA) was offered, such as smoking cessation or blood pressure monitoring, in those community pharmacies that perform them as part of their care work, free of charge. In addition, referrals were made to the gynecologist or other health professionals when necessary. The intervention performed was recorded.

- Written health education was provided, reflecting the information transmitted verbally (**Figure 6**).
 - Follow-up interview (3 months after the initial interview) Estimated duration 10 minutes. It was scheduled by telephone contact.



Figure 6 Intervention group infographic

- Completion of the questionnaire on socio-health variables and healthy habits and MRS (Figure 1 and 3).
 Check for possible changes in the questionnaire on socio-health variables and healthy habits and MRS 3 months after the first visit.
- Completion of the questionnaire on information search and sources consulted (Figure 4).

Both groups were asked about information search and sources consulted.

ETHICAL CONSIDERATIONS

The study was developed in accordance with the standards of Good Clinical Practice of the International Conference on Harmonization (ICH E6) for a study of these characteristics. The autonomy of the participants was respected in all cases, following the ethical principles of the current Declaration of Helsinki and the Organic Law 3/2018, of 5 December, on Personal Data Protection and guarantee of digital rights.

The registration sheets will remain guarded in the collaborating pharmacies complying with high-level security measures for this purpose, complying with the provisions of the Data Protection Act for files with a high level of security (LOPD). The recorded data were subjected to a process

of data coding and dissociation and were dumped into an Excel® sheet prior to their communication to the research team, so that they could never have knowledge of identifying or identifiable data of the patients.

The collaborating pharmacist adequately informed the patients, verbally and in writing (Figure 6), of the purpose and characteristics of the study, indicating to them that their participation was free and voluntary, and that they could discontinue their participation at any time, requesting their written consent and assuring them of the absolute confidentiality of the data, which were pseudo-anonymized for analysis.

The project was approved by the Research Ethics Committee of the Autonomous Community of Aragón (CEICA) on 22 November 2023, with reference CI PI23/474.

CHRONOGRAM

The project was carried out in 14 community pharmacies, divided into 7 in the intervention group and 7 in the control group, in various Spanish autonomous communities. The interviews were carried out in the personalized attention zones (ZAP) of each pharmacy with total confidentiality.

Table 1 shows the chronogram of the project from the bibliographic search to the publication of the results.

Table 1 Timeline

TASK	2023												2024						
	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7		
Bibliographic search	■	■	■																
Study design	■	■	■	■	■														
STADA grant documentation and presentation	■	■	■																
Drafting of intervention group material				■	■														
Documentation and presentation to SEFAC's scientific committee					■														
Documentation and evaluation by CEIC Aragón						■	■	■											
Contact, selection and training with collaborating CFs								■	■										
Research development									■	■	■	■	■	■					
Statistical processing													■						
Analysis of results														■	■				
Final report writing														■	■	■			
Presentation at congresses														■	■	■			
Publication of results															■	■	■		

Source: Own elaboration

Table 2 Economic analysis. Breakdown of expenses

TASK	AMOUNT
Writing the research protocol	300 €
Contact and selection of collaborating pharmacists	100 €
Training of collaborating pharmacists	100 €
Statistical processing	1.000 €
Publication of the protocol in the journal Community Pharmacists	500 €
Publication of results in international journal	3.000 €
TOTAL	5.000 €

Source: Own elaboration

ECONOMIC ANALYSIS

The research project is financed by the IX Stada-Sefac Grant for research in pharmaceutical care in the amount of 5,000 euros. The items into which the expenses are broken down are listed in **Table 2**.

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