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Active and healthy aging in women during early postmenopause

Submission date 27/05/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 01/06/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/07/2023	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

In developed countries like Spain, the number of older people is increasing, and this trend will continue in the coming decades. As a result, the biggest burden of illness and death, as well as the highest social and healthcare costs, will be experienced by people in the later stages of their lives. Just living longer doesn't necessarily mean having a good quality of life. Lifestyle choices and health disparities (e.g., gender inequality) will play a significant role in shaping global health outcomes.

Various institutions, such as the World Health Organization, emphasize the importance of daily physical activity and regular exercise of moderate to vigorous intensity as essential for promoting and protecting health, preventing and managing diseases, and mitigating the effects of aging. However, research shows that a small percentage of adults meet the international recommendations for a healthy and active lifestyle, especially as they get older. This problem is more prominent among middle-aged and older women, who are less likely than men in the same age group to adopt an active lifestyle and to report good health, well-being, and quality of life.

Additionally, women experience a range of biological, psychological, and social changes during menopause. The postmenopausal period can be a time of opportunities for women to improve their health and well-being. The main objective of this research is to identify the key factors that predict a healthy and active lifestyle among middle-aged women. This includes considering physical fitness, cardiometabolic health, mental well-being, and quality of life indicators, as well as exploring different stages and social-cognitive variables proposed in the Health Action Process Approach (HAPA), a theoretical framework for understanding behavior change related to health.

Who can participate?

Postmenopausal women aged between 45 and 65 years old who are willing to voluntarily participate in this research

What does the study involve?

Participants will be eligible based on the inclusion criteria and assigned to one of three study groups:

1. Intervention-Initiators (women who will initiate a multicomponent supervised exercise program accompanied by a HAPA-based intervention for exercise behavior adoption, n=100)
2. Control-Sedentary (sedentary women who will not receive any intervention or change their physical behavior, n=100)
3. Control-Active (women with a regular active lifestyle, n=100)

Measurements of study variables will be conducted at baseline and at postintervention phases, as well as at follow-ups after 3, 6 and 12 months. The predictors of exercise behavior in the different phases or stages of the behavioral change process will be explored and compared within and between groups at each moment of the study to know the factors that determine the initiation and maintenance of healthy active behavior.

What are the possible benefits and risks of participating?
Regular exercise contributes to health and well-being. By participating, women can engage in a sustained active lifestyle. Risks are reduced due to constant supervision and program delivery by experts. Medical insurance on behalf of the study will cover any injury during the exercise program.
The results regarding the study's aims and hypotheses will provide relevant information on issues of great interest in relation to the health and quality of life of women after menopause, specifically in relation to the determinants involved in the adoption of healthy habits such as exercise. This knowledge will help in the design and implementation of successful interventions that fit the needs, opportunities, resources, experiences and circumstances of adult women. Such interventions must combine different action strategies, emphasizing behavioral strategies for health promotion and protection and primary disease prevention, for women’s quality of life improvement. Thus, the findings of this research would make it possible to derive interventions for the promotion of physical activity in postmenopausal women, adjusted to this population, which would contribute to improving the health and well-being of this social group and prevent illnesses, premature mortality and unhealthy aging. These interventions would also contribute to social development and equality between men and women in our community.

Where is the study run from?
University of Granada (Spain)

When is the study starting and how long is it expected to run for?
July 2021 to September 2023

Who is funding the study?
This research is funded by the Ministry of Economic Transformation, Industry, Knowledge and Universities of Andalusia (FEDER/Junta de Andalucía – Consejería de Transformación Económica, Industria, Conocimiento y Universidades (I+D+I Programa Operativo FEDER de Andalucía 2014-2020). Research Project B-CTS-342-UGR20 (2021-23).

Who is the main contact?
Dra. Débora Godoy-Izquierdo, University of Granada (Spain)

Contact information

Type(s)
Principal investigator

Contact name

Dr Débora Godoy-Izquierdo

ORCID ID
https://orcid.org/0000-0002-4294-4232

Contact details
Dept. Personalidad, Evaluación y Tratamiento Psicológico
Facultad de Psicología
Campus Universitario Cartuja, s/n
Granada
Spain
18071
+34 (0)958242331
deborag@ugr.es

Additional identifiers

Protocol serial number
B-CTS-342-UGR20

Study information

Scientific Title
Active and healthy aging: social-cognitive and biomedical predictors of active behavior in postmenopausal women [Envejecimiento activo y saludable: predictores social-cognitivos y biomédicos de la conducta física activa en mujeres en la postmenopausia]

Acronym
AHAWOMEN

Study objectives
Main hypothesis: HAPA stages and variables will be significant predictors of exercise behavior adoption among women in their early postmenopause.
Specific hypotheses:
1. Social-cognitive determinants of intention (motivational factors) and action (volitional factors) within the process of behavior change will be significant predictors of exercise initiation and maintenance, respectively, supporting both the HAPA tenets and the HAPA-based intervention efficacy.
2. Fitness status, physical and mental health status, quality of life and menopausal symptoms burden will interact with HAPA constructs.
3. Other variables (e.g., sociodemographics) will show minimal interactions with the main predictors.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 17/11/2021, Ethics Committee on Human Research of the University of Granada (Comité de Ética en Investigación Humana [CEIH], Vicerrectorado de Investigación y Transferencia. Gran Vía nº 48, 2ª planta. 18071. Granada, Spain; +34 (0)958243008; investigacion@ugr.es), ref: B-CTS-342-UGR20 (2021-23)

Primary study design
Interventional

Study design
Single-center interventional longitudinal prospective multi-design with a randomized controlled study (for intervention and sedentary participants) and a non-randomized controlled study (for intervention/sedentary and regularly active participants)

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Health promotion in generally healthy women in early postmenopause (45-65 years old)

Interventions
Current interventions as of 08/06/2023:
This is a single-center, interventional, longitudinal, prospective, multi-design study with a randomized controlled study (for intervention and sedentary participants) and a non-randomized controlled study (for intervention/sedentary and regularly active participants) with between-group (intervention, sedentary and active participants) and within-subject measures (baseline, post-intervention and 1 to 12-month follow-ups). The "Intention-to-treat" methodology will be adopted. For higher internal and external validity, the main confounders will be controlled for (e.g., matching participants, and counterbalancing measures) to decrease systematic secondary and error variance.

A three-component intervention will be offered:
1. A multicomponent, supervised exercise program with a 3-month duration (12 weeks). The program will be designed and implemented by experts in Exercise and Sport Sciences and Sport and Exercise Medicine, following international recommendations for exercise in middle-aged women. It will include training in aerobic cardio-respiratory fitness, muscle resistance and other fitness functions such as flexibility and balance.
2. A simultaneous intervention for the self-management of behavioral change based on the tenets of the HAPA model will be offered throughout the exercise program period. This intervention has been designed based on previously HAPA-based interventions and is focused on improving the motivational determinants of intention and the volitional determinants for self-regulated action and adherence. Its aim is to increase personal resources for long-term, self-managed adherence to the newly established lifestyle once the supervised exercise program is concluded.
3. A health education and promotion intervention designed and implemented by experts in women’s health. It will be focused on recommendations for a healthier lifestyle during postmenopause, beyond an active lifestyle. This intervention will also be offered on a voluntary basis to the participants in the control groups to equate the study groups in terms of lifestyle after menopause (with the exception of active behavior).

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Intervention Type
Behavioural

Primary outcome(s)
Exercise behavior measured using the self-reported International Physical Activity Questionnaire (IPAQ) at baseline, postintervention and follow-ups

Key secondary outcome(s)
Current secondary outcome measures as of 08/06/2023:
1. HAPA constructs measured using ad-hoc self-reports based on previously published measures (Gholami & Schwarzer, 2014) at baseline, postintervention and follow-ups
2. Menopause-related quality of life measured using the generic 12-Item Short Form Survey (SF-12) and the specific validated Cervantes Scale at baseline, post-intervention and follow-ups
3. Fitness and cardio-respiratory and metabolic health measured using structural (e.g., BMI) and functional (e.g., EUROFIT) indicators at baseline, postintervention and follow-ups
4. Self-reported health status (EQ-SD, Rabin & Charro, 2001) and health-related lifestyle (Pérez-Fortis et al., 2012) at baseline, postintervention and follow-ups
5. Sociodemographic and clinical data measured using a personal data form and medical anamnesis at baseline

Previous secondary outcome measures:
1. HAPA constructs, measured using ad-hoc self-reports based on previously published measures

Gholami & Schwarzer, 2014 at baseline, postintervention and follow-ups
2. Menopause-related quality of life, measured using the generic 12-Item Short Form Survey (SF-12) and the specific validated Cervantes Scale at baseline, post-intervention and follow-ups
3. Fitness and cardio-respiratory and metabolic health, measured using structural (e.g., BMI) and functional (e.g., EUROFIT) indicators at baseline, postintervention and follow-ups
4. Perceived health status and health-related lifestyle, measured using a self-report (e.g., self-reported health status and processes: EQ-SD, Rabin & Charro, 2001); health-related lifestyle: healthy lifestyle indicators, Godoy & Godoy-Izquierdo, 2006) at baseline, postintervention and follow-ups
5. Sociodemographic and clinical data, measured using a personal data form and medical anamnesis at baseline

Completion date
30/09/2023

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 08/06/2023:
For all study groups:
1. Postmenopausal women between 45 and 65 years with no menses for 12 months or more until 10 years of postmenopause, based on Stages of Reproductive Aging Workshop STRAW +10 criteria
2. Providing a signed consent form for voluntary participation
3. Speaking and reading Spanish with proficiency
4. Being in good health for exercising

For intervention and sedentary control groups:
1. Being sedentary, i.e., not exercising on a regular basis, independently of daily physical activity such as walking for transportation, for at least the last 12 months

For the active control group:
1. Exercising on a regular basis reaching international recommended levels for at least the last 12 months

Previous participant inclusion criteria:
For all study groups:
1. Postmenopausal women between 45 and 65 years with no menses for 12 months or more until 10 years of postmenopause, based on Stages of Reproductive Aging Workshop STRAW +10 criteria
2. Non-use of hormone therapy in at least the three months before recruitment
3. Providing a signed consent form for voluntary participation
4. Speaking and reading Spanish with proficiency
5. Not suffering from any severe physical or mental disease that would seriously deteriorate functioning, impede participation in exercise based on medical criteria or introduce bias in responses.

For intervention and sedentary control groups:
1. Not exercising on a regular basis, independently of daily physical activity, e.g., walking for transportation, for at least the last 12 months

For the active control group:
1. Exercising on a regular basis reaching international recommended levels for at least the last 12 months
2. Not being an athlete (i.e., competitive sport) of any performance level

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
45 Years

Upper age limit
65 Years

Sex
Female

Key exclusion criteria
Current participant exclusion criteria as of 08/06/2023:
1. Non-use of hormone therapy in at least the three months before recruitment
2. Not suffering from any severe physical or mental disease that would seriously deteriorate functioning, impede participation in exercise based on medical criteria or introduce bias in responses
3. For active controls, not being an athlete (i.e., competitive sport) of any performance level

Previous participant exclusion criteria:
Does not meet the inclusion criteria

Date of first enrolment
01/12/2021

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
Spain

Study participating centre
University of Granada
Research Group CTS267 Health Psychology & Behavioral Medicine
Mind, Brain and Behavior Research Center [Centro de Investigación Mente, Cerebro y

Comportamiento] (CIMCYC)
C.U. Cartuja, S/N
Granada
Spain
18071

Study participating centre
University of Granada
University Research Institute for Women's and Gender Studies [Instituto Universitario de Investigación de Estudios de las Mujeres y de Género]
Centro de Documentación Científica
C/ Rector López Argueta, S/N
Granada
Spain
18071

Sponsor information

Organisation
University of Granada

ROR
https://ror.org/04njjy449

Funder(s)

Funder type
Government

Funder Name
Consejería de Transformación Económica, Industria, Conocimiento y Universidades

Alternative Name(s)
Ministry of Economic Transformation, Industry, Knowledge and Universities of Andalusia, Ministry of Economic Transformation, Industry, Knowledge and Universities, Consejería de Transformación Económica, Consejería Transformación Eco., Consejería de Transformación Económica, Industria, Conocimiento y Universidades (Junta de Andalucía), Consejería de Transformación económica,Industria, Conocimiento y Universidades, Consejería de Transformación Económica, Industria, Conocimiento y Universidades de la Junta de Andalucía, Consejería de Transformación Ec., Indust., Conocimiento y Univ

Funding Body Type

Government organisation

Funding Body Subtype
Local government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dra. Débora Godoy-Izquierdo (deborag@ugr.es).
The type of data that will be shared: raw data
Timing for availability: 01/07/2023
Whether consent from participants was required and obtained: yes
Comments on data anonymization: data will be anonymized

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		12/07/2023	13/07/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes