ISRCTN11827482 https://doi.org/10.1186/ISRCTN11827482

Development and evaluation of a health-promoting meal for late middle-aged women in menopause

Submission date
12/10/2025

Recruitment status
No longer recruiting

Registration date
16/10/2025

Overall study status
Completed

Last Edited
15/10/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Menopause is a critical transition in a woman's life, characterized by hormonal changes such as increased follicle-stimulating hormone (FSH) and decreased estradiol (E2). These changes often lead to menopausal symptoms, including sleep disturbances and depressive mood, which substantially affect health and quality of life in late middle-aged women. Moreover, this period is associated with an increased risk of chronic diseases, highlighting the importance of appropriate health management and promotion of well-being.
Previous studies have shown that a balanced dietary pattern, with adequate consumption of diverse foods, has positive effects on alleviating menopausal symptoms and preventing chronic diseases in late middle-aged women. In particular, sufficient intake of calcium, omega-3 fatty acids, dietary fiber, and isoflavones has been reported to be closely linked with reducing chronic disease risk in this population.
Therefore, the aim of this study is to develop and implement a health-promoting meal plan enriched with these key nutrients (calcium, omega-3 fatty acids, dietary fiber, and isoflavones) and to evaluate its effects on improving health outcomes among late middle-aged women.

Who can participate?
Women aged between 50 and 65 years.

What does the study involve?
All participants were provided with a health-promoting meal plan for 8 weeks and, their nutritional intake was monitored during the intervention period. Menopausal symptoms, sleep quality, body measurements, blood parameters, continuous glucose monitoring, and plasma and urine metabolomics were assessed before and after the intervention.

What are the possible benefits and risks of participating?
Participants may have benefited from following a meal plan developed to promote health and improve metabolic outcomes. No major risks were reported. Minor risks included slight discomfort or inconvenience from blood sample collection.

Where is the study run from?
Ewha Clinical Trial Center, Ewha Womans University Mokdong Hospital (South Korea)

When is the study starting and how long is it expected to run for?
January 2019 to September 2021

Who is funding the study?
Ewha Womans University and Dr. Kitchen Co., Ltd. (South Korea)

Who is the main contact?
Dr. Yangha Kim
yhmoon@ewha.ac.kr

Contact information

Type(s)
Principal investigator

Contact name
Prof Yangha Kim

ORCID ID
https://orcid.org/0000-0002-7280-7597

Contact details
Department of Nutritional Science and Food Management, Ewha Womans University, 52, Ewhayeodae-gil, Seodaemun-gu
Seoul
Korea, South
03760
+82 2-3277-3101
yhmoon@ewha.ac.kr

Type(s)
Principal investigator

Contact name
Prof Eunhee Ha

ORCID ID
https://orcid.org/0000-0002-4224-3858

Contact details
Department of Environmental Medicine, Ewha Womans University College of Medicine, 25, Magokdong-ro 2-gil, Gangseo-gu
Seoul
Korea, South
07804
+82 2-6986-6013
eunheeha@ewha.ac.kr

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Yoon Jung Park

ORCID ID
https://orcid.org/0000-0001-6999-4996

Contact details
Department of Nutritional Science and Food Management, Ewha Womans University, 52, Ewhayeodae-gil, Seodaemun-gu
Seoul
Korea, South
03760
+82 2-3277-6533
park.yoonjung@ewha.ac.kr

Additional identifiers

Protocol serial number
EUMC 2020-02-047

Study information

Scientific Title
Impact of a tailored meal plan on metabolic health in late middle-aged women: an 8-week pre-post intervention trial

Study objectives
To investigate the effect of a health-promoting meal plan on metabolic health outcomes in late middle-aged postmenopausal women.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/10/2020, Ewha Womans University Mokdong Hospital (1071, Anyangcheon-ro, Yangcheon-gu, Seoul, Republic of Korea, Seoul, 07985, Korea, South; +82 2-2650-2019; Irb-mok@eumc.ac.kr), ref: EUMC 2020-02-047

Primary study design
Interventional

Study design
Single-arm pre-post interventional study

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Late middle-aged postmenopausal women

Interventions
Sixty-one participants underwent the intervention and were provided with a health-promoting meal plan for 8 weeks.
The meal plan was developed by registered dietitians to enrich four major nutrients (calcium, omega-3, fiber, and isoflavone) that showed insufficient intake in late middle-aged women. Meals were supplied as two meals per day (lunch, dinner) and one snack, designed to provide approximately 80% of the estimated daily energy requirement. The meals were provided in the form of meal kits with accompanying recipe cards. Participants were instructed to prepare and consume meals at regular times according to their individual eating schedules, with a simple breakfast being recommended.
Participants were assessed before and after intervention for menopausal symptoms, sleep quality, anthropometric indices, blood parameters, continuous glucose monitoring, and plasma and urine metabolomics.

Intervention Type
Other

Primary outcome(s)
Blood metabolic health markers (glucose and lipid parameters) will be measured at baseline and 8 weeks using standard enzymatic and immunoturbidimetric assays.

Key secondary outcome(s)
1. Menopausal symptoms measured using the Kupperman Index and Pittsburgh Sleep Quality Index (PSQI) at baseline and 8 weeks
2. Hormone levels (estradiol [E2] and follicle-stimulating hormone [FSH]) measured using chemiluminescence microparticle immunoassay and electrochemiluminescence microparticle immunoassay at baseline and 8 weeks
3. Continuous glucose monitoring (CGM) measured using iPro2 (Medtronic Diabetes, Northridge, CA, USA) at baseline and 8 weeks
4. Plasma and urine metabolomics measured using GC-TOF-MS at baseline and 8 weeks
5. Nutritional intake measured using mobile application during 8 weeks intervention period

Completion date
17/09/2021

Eligibility

Key inclusion criteria
1. Women aged >50 and <65 years
2. Subjects with a low intake level of at least one of the target nutrients, below the Korean dietary recommendations (75 mg isoflavones, 2.0 g omega-3 fatty acids, 18.8 g dietary fiber, and 600 mg calcium), as assessed by a 3-day dietary survey (2 weekdays and 1 weekend day)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
50 Years

Upper age limit
65 Years

Sex
Female

Total final enrolment
65

Key exclusion criteria
1. Subjects with hypersensitivity to specific foods or ingredients
2. Subjects with difficulty using smartphones

Date of first enrolment
07/06/2021

Date of final enrolment
01/07/2021

Locations

Countries of recruitment
Korea, South

Study participating centre
Ewha Clinical Trial Center, Ewha Womans University Mokdong Hospital
1071 Anyangcheon-ro, Yangcheon-gu
Seoul
Korea, South
07985

Sponsor information

Organisation
Ewha Womans University

ROR

https://ror.org/053fp5c05

Organisation
Ewha Womans University Mokdong Hospital

ROR
https://ror.org/00ypk0v12

Funder(s)

Funder type
University/education

Funder Name
Ewha Womans University

Alternative Name(s)
Ewha

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Korea, South

Funder Name
Dr. Kitchen Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets are not expected to be made available because participant consent and IRB approval did not cover public data sharing.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			15/10/2025	No	Yes