

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

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<b>Registration date</b> 16/10/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/10/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

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## Contact information

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**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; [lrb-mok@eumc.ac.kr](mailto:lrb-mok@eumc.ac.kr)), ref: EUMC 2020-02-047

**Study design**

Single-arm pre-post interventional study

**Primary study design**

Interventional

**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

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## **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**

[Participant information sheet](#)

**Details**

**Date created**

**Date added**

15/10/2025

**Peer reviewed?**

No

**Patient-facing?**

Yes