

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

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Registration date 16/10/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/10/2025	Condition category 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?

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Contact information

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

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

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

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