This document is an English translation of the original Korean version.

Participant Information Sheet

Study Title	Development and evaluation of a health-promoting meal for late middle-aged women in menopause
Principal Investigator	Prof. Eun-Hee Ha, Department of Preventive Medicine, Ewha Womans University Mokdong Hospital (Coordinating Principal Investigator: Prof. Yangha Kim, Department of Nutritional Science and Food Management, Ewha Womans University)

Your decision to participate in this study is entirely voluntary. You are free to decide whether or not to participate, and you may withdraw at any time without any disadvantage or penalty.

The following information is provided to explain the details of this study, your role if you choose to participate, and the study procedures. Please read this information carefully before deciding whether to participate. It is important that you understand why this research is being conducted and how it will be carried out.

While reading this document, you may ask any questions at any time. Please feel free to ask as many questions as you need in order to make an informed decision. You may also take as much time as you need to review this information and discuss it with your family or others before making your decision. If you have any questions, you may contact the Principal Investigator or study staff at any time.

Do not sign the consent form unless all of your questions have been answered to your full satisfaction.

1. Purpose of the Study

This study will be conducted at Ewha Womans University Mokdong Hospital to evaluate the effects of consuming a “Health-Promoting Meal” on reducing the risk of chronic diseases in late middle-aged women with menopause, and to develop an evidence-based healthy meal plan.

* What is a Health-Promoting Meal?

The Health-Promoting Meal is a specially developed meal box designed to improve the health of middle-aged women. It has been formulated to provide nutrients important for women’s health (e.g., dietary fiber, omega-3 fatty acids, calcium, isoflavones) while limiting nutrients that should be reduced (e.g., calories, carbohydrates, fat).

2. Eligibility and Exclusion Criteria

You may participate in this study if you meet **all** of the following conditions:

1) You voluntarily agree to participate and sign the written informed consent form.
2) You are a woman aged 50 years or older and under 65 years.

3) You reside in Seoul, Incheon, or Gyeonggi Province, where meal delivery is available.
4) Your intake of at least one of the following key nutrients is below the recommended level:
   - Dietary fiber: 18.8 g, Omega-3 fatty acids: 2.0 g, Calcium: 600.0 mg, Isoflavones: 75.0 mg

Even if you meet the above criteria, you may not participate if any of the following apply:

1) You have hypersensitivity to specific foods or ingredients, or have experienced severe food allergy reactions.
2) You have participated in another clinical study within one month prior to the first visit.
3) You have difficulty using a smartphone.
4) The investigator determines that you are otherwise unsuitable for participation in this study.

3. Study Procedures

In this study, late middle-aged women with menopause will first undergo assessments including clinical status, demographic characteristics, anthropometric measurements, vital signs, medical history, and screening tests. If you are eligible, you will be asked to consume the Health-Promoting Meal. In order to develop and evaluate a healthy diet aimed at reducing the risk of chronic diseases, relevant tests will be performed according to the study protocol. A portion of the collected human biological specimens may be used for additional analyses if needed. If such additional analyses are performed after the study has ended, your specimens will be anonymized so that your personal information cannot be identified.

4. Information about the Health-Promoting Meal

The Health-Promoting Meal will be prepared at an institution certified with HACCP (Hazard Analysis and Critical Control Points). The meals will be delivered twice a week for a total of 8 weeks as follows:

- **Every Wednesday:** Meals and snacks for Wednesday–Friday (3 days)
- **Every Saturday:** Meals and snacks for Saturday–Tuesday (4 days)

Each meal consists of rice, a main dish, and side dishes. Snacks and side dishes will be delivered fully cooked, while rice and main dishes will be provided in semi-cooked form. Most ingredients will be pre-prepared, allowing you to complete the cooking within 10 minutes.

Week 1		Mon	Tue	Wed	Thu	Fri	Sat	Sun
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Lunch	Rice	White rice	Black soybean rice	White rice	White rice	White rice	White rice	Black soybean rice
	Main Dish	Seafood soybean paste stew with vegetables	Mapo tofu	Assorted mushrooms with tofu	Braised monkfish	Stir-fried pork with bean sprouts	Soy-braised chicken with yuzu sauce	Soybean paste bibimbap
	Kimchi	Napa cabbage kimchi	Leaf mustard kimchi	Napa cabbage kimchi	Napa cabbage kimchi	Leaf mustard kimchi	Young radish kimchi	Leaf mustard kimchi

Dinner	Rice	Black soybean rice	White rice	Black soybean rice	Black soybean rice	Black soybean rice	Black soybean rice	White rice
	Main Dish	Potato bulgogi	Chicken makhani	Braised beef with dried pollock	Braised pork with pumpkin	Beef stroganoff	Braised hairtail with sweet potato stems	Mango kung pao curry
	Kimchi	Young radish kimchi	White kimchi	White kimchi	Leaf mustard kimchi	White kimchi	Napa cabbage kimchi	White kimchi
Side Dish	Side Dish	Stir-fried anchovies	Soy-braised beans	Spicy stir-fried anchovies	Seasoned perilla leaves	Stir-fried seaweed stems	Candied sweet potatoes	Crispy pollock strips in sauce
Snack	Snack	Black bean soy milk	Low-fat milk	Soy milk	Orange juice	Soy milk	Low-fat milk	Yogurt
Week 2		**Mon**	**Tue**	**Wed**	**Thu**	**Fri**	**Sat**	**Sun**
		Day 1	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
Lunch	Rice	White rice	White rice	White rice	White rice	White rice	White rice	White rice
	Main Dish	Soybean paste stew with beef and fermented soybeans	Nutritious rice bowl with grilled beef patties	Seafood soybean pastes hot pot	Spicy braised pork and tofu stew	Braised Spanish mackerel with pumpkin	Octopus and webfoot octopus hot pot	Boneless monkfish cream stew
	Kimchi	Napa cabbage kimchi	Leaf mustard kimchi	Napa cabbage kimchi	Napa cabbage kimchi	Leaf mustard kimchi	Young radish kimchi	Young radish kimchi
Dinner	Rice	Black soybean rice	Black soybean rice	-	Black soybean rice	Black soybean rice	Black soybean rice	Black soybean rice
	Main Dish	Braised chicken stew with dried radish greens	Chuncheon-style stir-fried chicken	Mushroom salad pizza	Orange Mongolian beef	Rice paper bulgogi wraps	Eggplant and pork belly rice bowl	Spicy stir-fried pork with tofu
	Kimchi	Young radish kimchi	White kimchi	White kimchi	Leaf mustard kimchi	White kimchi	Napa cabbage kimchi	White kimchi
Side Dish	Side Dish	Spicy stir-fried anchovies	Stir-fried mushrooms	Candied sweet potatoes	Stir-fried anchovies	Crispy pollock strips in sauce	Steamed perilla leaves	Seasoned seaweed flakes
Snack	Snack	Low-fat milk	Soy milk	Low-fat milk	Soy milk	Yogurt	Black bean soy milk	Orange juice

* The menu is designed to repeat every two weeks; however, it may be modified in part according to food supply conditions

5. Study Content and Examination Procedures

Participants who meet the eligibility and exclusion criteria will receive the Health-Promoting Meal and consume it for 8 weeks. Blood and urine samples will be collected at Ewha Womans University Mokdong Hospital, and some biological specimens will be analyzed at Ewha Womans University.

The detailed schedule and procedures you will undergo from the beginning to the end of the study are

as follows:

(1) Visit 1 (–2 weeks before start)

At this visit, the study staff will explain the purpose of this research. You will be asked to read this information sheet and sign the consent form. In order to understand your past medical history and current health condition, the following procedures will take place. (Estimated duration: about 1 hour)

※ Please note: At each step, if you do not meet the eligibility or exclusion criteria, further procedures may not be conducted at the discretion of the investigator.

① You will listen to an explanation of the study procedures and sign the consent form.

② You will be assigned a study ID number.

③ You will provide demographic information (e.g., date of birth, residence, age).

④ Your pulse, body temperature, and blood pressure will be measured.

⑤ Your medical history, surgical history, use of medications or health supplements, alcohol consumption, and smoking history will be reviewed.

⑥ You will complete a dietary assessment.

⑦ Your eligibility will be evaluated.

⑧ The date of your next visit will be scheduled

(2) Visit 2 (–1 week)

This visit takes place about one week after the first visit. If you agree to participate in the study, the following procedures will be conducted. (Estimated duration: about 1 hour)

① You will be trained on how to use the **E-diary**, a diet and lifestyle recording program available on a smartphone or computer.

② You will be fitted with a **continuous glucose monitoring (CGM) device** and provided with a personal blood glucose meter (self-monitoring device). You will also receive instructions on how to use both devices.
* After the CGM is attached, there will be a short waiting period of about 5 minutes.

③ The date of your next visit will be scheduled.

* **E-diary**: This is a program designed for you to record your food intake and lifestyle habits during the study using either a smartphone or computer. For smartphones: Available for free download (App Store for iPhone, Play Store for Android). For computers: Accessible via the website (e-diary.co.kr). The study staff will help install the app on your phone and explain how to use it.

* **Continuous Glucose Monitoring (CGM) Device**: This device records your blood glucose every 5 minutes for 6–8 days. It will be attached to an area with little movement, such as your abdomen

or upper buttocks. You can continue your daily activities, including showering, while wearing the device.

* **Self-Monitoring Blood Glucose Device**: During the same 6–8 day period, you will be asked to measure your blood glucose four times a day (before each meal and before bedtime). You will record the time and blood glucose value each time you measure.

(3) Visit 3 (Week 0 / Baseline)

This visit takes place 6–8 days after Visit 2. (Estimated duration: about 2 hours)

※ Please fast for 12 hours prior to this visit.

① You will measure your blood glucose using the self-monitoring device and record the value.

② After 15 minutes, the continuous glucose monitoring (CGM) device will be removed and the self-monitoring device will be collected.

③ Your pulse, body temperature, and blood pressure will be measured.

④ Your height, body composition (InBody test), waist circumference, and hip circumference will be measured.

⑤ Any changes in medication use, dietary supplement intake, alcohol consumption, and smoking status will be reviewed.

⑥ You will complete questionnaires on sleep habits (PSQI) and menopausal symptoms.

⑦ A fasting blood sample (38 mL) and urine sample (30 mL) will be collected for clinical laboratory tests and functional assessments (e.g., blood lipid levels).

⑧ Compliance with diet and lifestyle guidelines will be checked, and you will receive reinforcement education.

⑨ Your dietary and lifestyle survey (food intake and activity level) will be reviewed, and you will complete a dietary quality questionnaire (RFS). The study staff will retrain you on the survey method if needed.

⑩ You will receive guidance on how to consume the Health-Promoting Meal and information regarding meal delivery.

⑪ The date of your next visit will be scheduled.

(4) Visit 4 (Week 7 ± 2 days)

This visit takes place about 7 weeks after Visit 3. (Estimated duration: about 1 hour)

① Compliance with diet and lifestyle guidelines will be checked, and reinforcement education will be provided.

② You will be fitted with a continuous glucose monitoring (CGM) device and provided with a self-monitoring blood glucose device, along with training.
   A. After the CGM is attached, there will be a short waiting period of about 5 minutes.

③ Compliance with diet and lifestyle guidelines will be reviewed again, and you will receive retraining on the guidelines and survey methods if needed.

④ Your compliance with meal intake will be assessed.

⑤ You will receive additional guidance on the consumption and delivery of the Health-Promoting Meal.

⑥ Any adverse events will be checked.

⑦ The date of your next visit will be scheduled.

(5) Visit 5 (Week 8 / End of Study)

This visit takes place 6–8 days after Visit 4. (Estimated duration: about 2 hours)

※ Please fast for 12 hours prior to this visit.

① You will measure your blood glucose using the self-monitoring device and record the value.

② After 15 minutes, the continuous glucose monitoring (CGM) device will be removed and the self-monitoring device will be collected.

③ Your pulse, body temperature, and blood pressure will be measured.

④ Your body composition (InBody test), waist circumference, and hip circumference will be measured.

⑤ Any changes in medication use, dietary supplement intake, alcohol consumption, and smoking status will be reviewed.

⑥ You will complete questionnaires on sleep habits and menopausal symptoms.

⑦ A fasting blood sample (38 mL) and urine sample (30 mL) will be collected for clinical laboratory tests and functional assessments (e.g., blood lipid levels).

⑧ Compliance with diet and lifestyle guidelines will be checked.

⑨ Your dietary and lifestyle survey (food intake and activity level) will be conducted.

⑩ Your compliance with meal intake will be assessed.

⑪ Any adverse events will be checked.

(6) Additional Visits

Additional visits may be scheduled outside the regular schedule if you request re-examination, follow-up for adverse events, or if the investigator determines that it is necessary.

6. Requirements for Participants

The following requirements are in place to ensure your safety and the accuracy of this study.
You will be asked to attend the hospital for necessary examinations according to the study schedule.

① Please keep all scheduled appointments.

② For Visit 3 (Week 0) and Visit 5 (Week 8), you must fast for 12 hours before the visit.

③ While wearing the continuous glucose monitoring (CGM) device (for 6–8 days), you must record: Your meals, activities, and blood glucose values four times per day (before each meal and before bedtime), including the time of measurement.
* For Visit 5 (Week 8), you will also be asked to take photos of your lunch and dinner after eating.
* You may continue your normal daily activities, including showering, while wearing the CGM device.

④ During the study, please follow the dietary and lifestyle guidelines below, while maintaining your usual habits otherwise:
- Eat each meal at approximately the same time each day.
- Consume the provided Health-Promoting Meal according to the recipe for that day, and eat the full portion provided.
- Eat the provided side dishes with lunch or dinner, and consume snacks freely.
  Choose a light breakfast from the examples below:
  Example A: 1 serving of fruit + 1 serving of vegetables + 200 mL milk
  Example B: 1 serving of grains + 1 serving of meat/fish/eggs + 1 serving of vegetables
- If you miss a meal for unavoidable reasons (e.g., eating out), please discard the missed meal rather than substituting.
- Do not share the study meals with family members or others.
- Limit intake of simple sugars (sugar, honey, citron tea, quince tea, fruit juice, processed foods).
- Limit fatty foods (fatty meat, fried foods).
- Limit excessive salt intake.
- Do not consume alcohol.

⑤ Do not participate in other research studies during this trial.

⑥ If you are prescribed medication at another hospital or purchase over-the-counter drugs at a pharmacy, you must inform the study staff at every visit. If sufficient information about a medication you are taking is not available, please consult with the study staff. It is recommended to bring the medication itself, a medication list, or a prescription at each visit.

⑦ If you experience any adverse events, please contact the study staff immediately. You may need to visit Ewha Womans University Mokdong Hospital for further examinations.

⑧ If you visit another department or hospital, you must inform the study staff. You should also inform the treating physician that you are participating in a clinical study. Any results from such visits

should be reported to the study staff as soon as possible.

⑨ If your contact address or phone number changes, please notify the study staff promptly.

7. Experimental Aspects of the Study

The Health-Promoting Meal used in this study is experimental in nature, as its effect on reducing chronic disease risk in menopausal women has not yet been scientifically verified.

8. Potential Risks (Side Effects), Discomforts, and Benefits

If you have known hypersensitivity (allergies) to certain foods or ingredients, or have experienced severe food allergy reactions, you cannot participate in this study.

While wearing the continuous glucose monitoring (CGM) sensor, you may occasionally feel mild discomfort at the site of attachment, but this is usually minor. If you experience unexpected side effects from consuming the Health-Promoting Meal, you may be provided with other medications for treatment, and the meal consumption may be temporarily discontinued. In the case of a serious adverse event (e.g., requiring hospitalization), the study may be permanently stopped.

There are no direct personal benefits expected from your participation in this study. However, the findings may contribute to the development of a healthy diet aimed at reducing chronic disease risk in middle-aged women during menopause.

9. Compensation and Benefits Provided for Participation

You will not need to pay for any study-related tests or medical procedures. If you are eligible and complete participation, you will receive the results of your blood and urine tests, as well as a body composition analysis, allowing you to review your overall health status. However, any unrelated medical expenses such as hospitalization fees or general medical consultations will not be covered by the study.

*** Participation allowance (compensation):** You will receive compensation according to the type and duration of assessments conducted at each visit:

- Visit 1 (–2 weeks): KRW 20,000
- Visit 2 (–1 week): KRW 20,000
- Visit 3 (Week 0): KRW 50,000
- Visit 4 (Week 7): KRW 20,000
- Visit 5 (Week 8): KRW 50,000

If you withdraw before completing the study, compensation will only be provided for the visits you have already completed.

10. Alternative Treatments

If you choose not to participate in this study, you will be informed about other appropriate approaches such as regular exercise and dietary modifications that may help improve health in menopausal women.

11. Expected Duration of Participation and Number of Participants

The expected duration of participation in this study is approximately 8 weeks. If you decide to participate, you will undergo tests and follow-up observations throughout this period.

A total of 60 participants is expected to be enrolled in this study.

12. Compensation and Treatment for Research-related Injury

During the study, the research team will make every effort to ensure your safety. If a serious adverse event occurs, appropriate measures will be taken to minimize its impact. If you experience research-related injury while participating in this study, the Coordinating Principal Investigator will assume legal responsibility and compensation will be provided in accordance with the study's insurance policy and relevant regulations. In the event of an adverse reaction or worsening of a medical condition, you will receive the best available treatment.

13. Restrictions on Participation

Your participation in this study may be discontinued without your consent if any of the following occur:

① You experience a serious adverse event.

② You or your legal representative request that the examinations be stopped.

③ You or the investigator violate the study protocol.

④ You do not comply with the study guidelines.

※ Please refer to Section 6, *Requirements for Participants*.)

⑤ You withdraw your consent to participate.

⑥ You cannot be contacted despite repeated attempts.

⑦ The investigator determines that it is not appropriate for you to continue in the study.

14. New Information Affecting Your Willingness to Participate

Your participation in this study is entirely voluntary. If new information arises during the study that may influence your willingness to continue, you will be informed in a timely manner.

15. Collection, Storage, and Disposal of Human Biological Materials

Responsibility for the management of human biological materials collected in this study rests with the Principal Investigator and the Coordinating Principal Investigator. Access will be restricted to authorized study staff. Blood and urine samples collected will be analyzed on the day of collection and then disposed of according to the institution's internal regulations. However, depending on study results, part of the collected blood may be used for additional biochemical analyses for academic purposes. In this case, samples will be anonymized (coded using a combination of screening number and visit number) and transferred to the Department of Nutritional Science and Food Management, Ewha Womans

University, where they will be stored in a designated freezer and managed in a biological specimen registry.

Storage and secondary use of specimens will follow the preferences you indicated in the Human Biological Materials Consent Form, including the storage period, whether secondary use is permitted, and whether any personal identifiers are included. “Secondary use” means the use of human biological materials for general research purposes. Even when specimens are secondarily used, they will be anonymized to prevent identification of personal information. After the storage period you selected expires, the specimens will be disposed of immediately in accordance with the Waste Control Act, Article 13, regarding standards and procedures for storage, transfer, and disposal. If the study is prematurely or abnormally terminated, disposal will follow the procedures set forth in the Enforcement Regulations of the Bioethics and Safety Act.

16. Voluntary Participation, Withdrawal of Consent, and Handling of Human Biological Materials

You are under no obligation to participate in this study, and refusal to participate will not result in any disadvantage to you. By signing this form, you indicate that you are voluntarily agreeing to participate. Even if you initially consent, you may withdraw your participation at any time at your own free will. If you decide to withdraw, the study staff will ask for your permission to use any data or human biological specimens collected up to that point. If you do not consent, the related data and specimens will be immediately discarded.

17. Confidentiality and Protection of Personal Information

For this study, your personal information will be collected, including personal details (e.g., name, contact information) necessary for study management, and information required to confirm eligibility and evaluate functionality and safety (e.g., date of birth, test results). To protect your privacy, a subject identification code will be used on all study-related documents such as case report forms, and access to your information will be restricted to ensure confidentiality. Collected information will be stored in the document storage room of Ewha Womans University Mokdong Hospital for 3 years after study completion, after which it will be destroyed in accordance with Article 16 of the Enforcement Decree of the Personal Information Protection Act. Any records that could identify you will remain confidential and will not be made publicly available. However, within the scope permitted by law or regulation, your medical records and study data may be reviewed during and after the study-by-study monitors, auditors, the Institutional Review Board (IRB) of Ewha Womans University Mokdong Hospital, and relevant government authorities to verify the conduct of the study and the reliability of the data. In such cases, confidentiality will be strictly maintained. By signing this consent form, you are authorizing such access for monitoring and auditing purposes. If the results of this

study are published, your identity will remain confidential.

18. Information on Participant Rights

This study has been reviewed and approved by the Institutional Review Board (IRB) of Ewha Womans University Mokdong Hospital. If you have any concerns, questions, or issues regarding your welfare or rights as a research participant, or if you wish to consult with someone not directly involved in the study, you may contact the Human Research Protection Center at +82-2-2650-2937.

19. Consent Form Signature

Once all of your questions have been answered to your satisfaction, and you have decided that you would like to participate in this study, you will be asked to sign a separate consent form before beginning study participation.

If you choose to participate, you will receive a copy of both the Participant Information Sheet and your signed consent form.

20. Principal Investigator and Study Contacts

If you would like more information about this study, have any questions or concerns about your rights as a participant, experience any study-related injury, or need to contact the study staff for medical reasons, you may contact:

Principal Investigator: Prof. Eun-Hee Ha
Tel: +82-2-6986-6234
Study Coordinators:
Hye-Min Choi, Research Nurse/ Ye-Ji Choi, Research Staff
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