

## **RESEARCH PROTOCOL**

**Chrono-Nutrition Application: The Effect of Fiber Jelly on Blood Glucose Response, Postprandial Satiety, and Weight Loss in Overweight Women**

**NCT NUMBER/ID: Not Assigned Yet**

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# INFORMED CONSENT FORM

## Title of the Study

**Chrono-Nutrition Application: The Effect of Fiber Jelly on Blood Glucose Response, Postprandial Satiety, and Weight Loss in Overweight Women**

## Principal Investigator

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Faculty of Sports Science and Health

Universitas Negeri Surabaya

## Sponsor / Research Institution

Universitas Negeri Surabaya, Indonesia

## Introduction

You are being invited to participate in a research study. Before you decide whether or not to take part, it is important that you understand why the research is being conducted and what your participation will involve. Please take time to read the following information carefully. You may ask questions at any time.

Your participation in this study is **completely voluntary**.

## Purpose of the Study

The purpose of this clinical nutrition study is to evaluate the effects of a **fiber jelly product** on:

- Blood glucose response
- Postprandial satiety (feeling of fullness after eating)
- Weight loss outcomes

in **overweight adult women**, within a chrono-nutrition framework.

## Study Product

The study product is a **fiber jelly** made from basil seeds (*Ocimum basilicum*) and roselle calyces (*Hibiscus sabdariffa*). It is a functional food with a high dietary fiber content, designed as a healthy snack to support appetite control and blood glucose regulation.

## **Study Procedures**

If you agree to participate, you will be asked to:

1. Undergo **screening assessments**, including:
  - o Measurement of body weight, height, and body fat composition
  - o Blood glucose measurement
  - o Blood pressure measurement
  - o Review of medical history
2. **Fast overnight** starting from 10:00 p.m. before the study day (only water is allowed).
3. Attend the study visit at **08:00 a.m.** at the Faculty of Sports Science and Health.
4. Consume the fiber jelly product as instructed.
5. Undergo **finger-prick blood sampling** to measure blood glucose levels at minutes **0, 30, 60, 90, and 120.**
6. Complete **Visual Analogue Scale (VAS)** questionnaires to assess satiety at the same time points.
7. Two hours after consuming the fiber jelly, eat until comfortably full and complete additional VAS questionnaires at minutes **180 and 240.**

Blood sampling will be performed by trained personnel using sterile equipment.

## **Duration of Participation**

Your participation in this study will last approximately **2 weeks**, with 2 point (2 days) data collection.

## **Possible Risks and Discomforts**

The risks associated with this study are minimal and may include:

- Mild pain, redness, or discomfort at the fingertip during blood sampling
- Digestive discomfort such as bloating or gastric irritation after consuming fiber jelly
- Rare allergic reactions

All procedures will be conducted following strict hygiene and safety standards. If you experience any adverse effects related to the study, appropriate care will be provided by the research team.

## **Benefits**

You may receive the following benefits:

- Free blood glucose examination

- Free dietary intervention
- Incentives (e.g., e-money) as appreciation for your participation

There may be no direct personal benefit. However, the information gained from this study may help improve nutritional interventions in the future.

### **Alternatives to Participation**

You are free to choose **not to participate** in this study. Refusal to participate will involve **no penalty or loss of benefits**.

### **Confidentiality**

All information collected during this study will be kept confidential. Your data will be identified by a study code rather than your name. Research results may be published, but your identity will not be revealed.

### **Compensation and Costs**

There will be **no cost** to you for participating in this study. All study-related expenses will be covered by the researchers. You will receive compensation as described above.

### **Right to Withdraw**

You may withdraw from the study at any time without giving a reason and without any penalty or loss of benefits to which you are otherwise entitled.

### **Ethical Approval**

This study has been reviewed and approved by:

#### **Health Research Ethics Committee**

Faculty of Medicine, Universitas Negeri Surabaya

Phone: +62 813-3910-5470

Email: [fk@unesa.ac.id](mailto:fk@unesa.ac.id)

### **Questions or Concerns**

If you have any questions about this study, your rights as a participant, or if you experience any problems, you may contact:

**Principal Investigator**

Noor Rohmah Mayasari, Ph.D

## PARTICIPATION APPROVAL SHEET

All these explanations have been submitted to me and all questions have been answered by researchers. I understand that if I need an explanation, I can ask Noor Rohmah Mayasari as principal investigator.

I confirm that:

- I have read and understood the information above.
- I have had the opportunity to ask questions and received satisfactory answers.
- I understand that my participation is voluntary and that I may withdraw at any time without penalty.

By signing below, I freely agree to participate in this research study.

Participant's Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Witness Name: \_\_\_\_\_

Witness Signature: \_\_\_\_\_

Researcher Information:

### **Principal Investigator**

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