

Title: Personalized Lifestyle Intervention and Weight Control ID:

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NCT04079972

Proposal and Statistical analysis

In this study, we aim to conduct the most efficient analysis possible with limited research funding through appropriate epidemiological research designs and statistical analysis techniques.

1. Randomized Controlled Trial:

- **Subjects:** 53 overweight or obese young adults.
- **Randomization:** Participants were randomly assigned to two groups (experimental and control) using a computer-generated randomization sequence.
- **Experimental group (27 participants):** Participants received their obesity-related genetic test results (including *FTO*, *MC4R*, and *BDNF*) along with genotype-tailored lifestyle recommendations encouraging healthy behaviors such as reducing fat intake, limiting snacking, and avoiding emotional eating.
- **Control group (26 participants):** Participants received genetic test results limited to non-obesity-related traits (e.g., beauty-related genes). No lifestyle recommendations were provided. Obesity-related genetic results were disclosed only after completion of the final follow-up.
- **Follow-up:** Questionnaire surveys and body composition measurements were conducted at baseline, approximately 5 months after randomization, and at study completion (up to 17 months).
- **First Statistical Analysis (Intention to Treat Analysis):**
 - **Causal variable:** Knowledge of obesity-related genetic test results.
 - **Outcome variable:** Changes in body weight and body composition (body fat mass, body fat percentage, and skeletal muscle mass) compared to baseline.
 - **Statistical analysis to observe the correlation between causal and outcome variables:** The association between the causal and outcome variables will be examined using general linear regression and linear mixed models adjusted for baseline body mass index (BMI), physical activity, smoking status, and alcohol consumption.

- **Second Statistical Analysis (As Treated Analysis):**

- Although all participants in the experimental group received obesity-related genetic results and tailored lifestyle recommendations, adherence levels may vary. We will compare characteristics of those who reported behavioral changes after reading their genetic test results (“behavior changers”) with those who did not (“behavior maintainers”).
- **Causal variable:** Causal variable: Degree of self-reported dietary and lifestyle change according to genotype from baseline to approximately 5 months after randomization.
- **Outcome variable:** Changes in body weight and body composition compared to baseline.
- **Statistical analysis:** Linear regression or mixed models will be used to evaluate associations between variables.
- **(Additional Analysis):** Within the experimental group, baseline characteristics of behavior changers and maintainers will be compared using chi-square tests or t-tests.

- **Ethical Issues:** For the control group, only non-obesity-related genetic information was provided during the study period, and obesity-related genetic results were disclosed after the study ended. Therefore, no ethical issues were anticipated.