Date: 8 May 2025

Dear ClinicalTrials.gov,

We are pleased to submit our protocol entitled “The Effects of Aerobic Exercise on Body Composition in Overweight and Obese Boys Aged 8-12 Years” to ClinicalTrials.gov.

Indonesia is on the verge of a demographic transition that could present substantial economic opportunities by 2045. However, this potential is at risk due to the growing prevalence of malnutrition among children. In our article, we address the urgent need for effective strategies to manage childhood obesity.

This protocol is original, has not been published previously, and is not under consideration for publication elsewhere. All authors have read and approved the protocol, and there are no conflicts of interest to declare.

Thank you for considering our protocol in ClinicalTrials.gov.

On behalf of all co-authors, sincerely,

Moretta Damayanti Fauzi

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Date: 8 May 2025

RESEARCH METHODS

Type of Study

This study is a non-randomised, open-label clinical trial.

Study Setting and Duration

The study was conducted at Muhammadiyah Elementary Schools 6 and 14 in Palembang. Data collection took place from July to October 2024 after obtaining ethical clearance and permission from the local health office.

Population and Sample

Target Population:
The target population consists of children with overweight and obesity in Palembang.

Accessible Population:
Male students with overweight and obesity enrolled in Muhammadiyah Elementary Schools 6 and 14 in Palembang.

Research Sample:
The research subjects were overweight and obese boys aged 8–12 years who met the study criteria.

Inclusion Criteria

- Male children aged 8–12 years
- BMI > 85th percentile based on the CDC 2000 growth chart
- Engaged in light to moderate physical activity
- Parental/guardian signed informed consent

Exclusion Criteria

- Children with medical conditions requiring restricted physical activity
- Children on a special diet

Drop-Out Criteria

- Withdrawal from the study
- Failure to regularly participate in aerobic physical training
- Absence from body composition assessment after intervention

Sample Size

The sample size was calculated using the formula for comparing the means of two independent groups.

$$N = 2\,\delta^2\,(Z_{1-\alpha} + Z_{1-\beta})^2 / (\mu 1 - \mu 2)^2$$

Description:

- **N** = sample size
- $\mathbf{Z_1\text{-}\alpha}$ = 1.96 (standard normal deviate for α = 0.05)
- $\mathbf{Z_1\text{-}\beta}$ = 0.84 (standard normal deviate for β = 0.20)
- $\boldsymbol{\mu_1}$ = Mean of body composition in the intervention group
- $\boldsymbol{\mu_2}$ = Mean of body composition in the control group
- $\boldsymbol{\delta^2} = (n_1\text{-}1)\cdot SD^2 + (n_2\text{-}1)\cdot SD^2 / (n_1\text{-}1) + (n_2\text{-}1)$

Table Sample Size Calculation Based on Body Composition

Body Composition Component	Mean ± SD (Aerobic Group)	Mean ± SD (Control Group)	Total Sample Size Required
Body Fat	31.35 ± 1.48	32.58 ± 0.97	34
Lean Body Mass	51.55 ± 5.03	46.69 ± 5.95	44
Bone Mineral	31.69 ± 5.88	27.33 ± 3.03	76
Body Water	43.9 ± 9.3	35.5 ± 8.5	66

Based on the calculations above, the **bone mineral** component requires the largest sample size (76 subjects). Considering a 10% dropout rate, the **final required sample** is **84 subjects**, equally distributed between the two groups.

Sampling Technique

The intervention group was determined by selecting a school willing to collaborate with the researchers. The sampling technique used was **consecutive sampling**, where all eligible subjects who met the inclusion criteria were enrolled consecutively until the desired sample size was reached. No blinding was applied. The intervention group consisted of students from Muhammadiyah Elementary School 6.

Research Variables

- **Independent Variable:** Aerobic physical exercise

- **Dependent Variable:** Body composition (total body fat, lean body mass, bone mineral content, and total body water)

Operational Definitions

Detailed operational definitions, instruments, measurement methods, results, and data scales are presented in Table 3.2.

Table 3.2 Operational Definitions

No	Variable	Definition	Instrument	Measurement Method	Measurement Result	Scale
1	**Body Composition**	The relative proportion of fat mass and fat-free mass in the body. It includes four main components: total body fat, lean body mass, bone mineral, and body water.	-	-	-	-
a	Total Body Fat	Body fat composed of essential and storage fat, both of which are important for health.	Digital Scale "Tanita InnerScan Body Composition Monitor" BC-545N	The subject is weighed using the specified scale	Percentage	Ratio
b	Lean Body Mass	Fat-free mass, calculated as total body weight minus body fat weight.	Same as above	Same as above	1. Increased2. Decreased	Nominal
c	Bone Mineral Content	The mineral content in bones; bone density refers to the mineral mass per volume unit.	Same as above	Same as above	Grams or g/cm²	Ratio
d	Body Water	The total amount of water content in the human body.	Same as above	Same as above	Kilograms (kg)	Ratio

Materials and Tools

- PAQ-C questionnaire
- Children's sleep habit questionnaire
- Food diary
- Digital scale (Tanita BC-545N)
- OneHealth stadiometer
- Orchidometer

Study Procedure

Prior to research proposal submission, community service activities were conducted at Muhammadiyah Elementary Schools 6 and 14. Screening showed a high prevalence of overweight and obesity in both schools.

Informed consent was obtained from parents/guardians of eligible participants. Interviews and questionnaires on physical activity (PAQ-C), sleep patterns, dietary habits, and pubertal status were conducted. Subjects who had entered puberty were still included in the study.

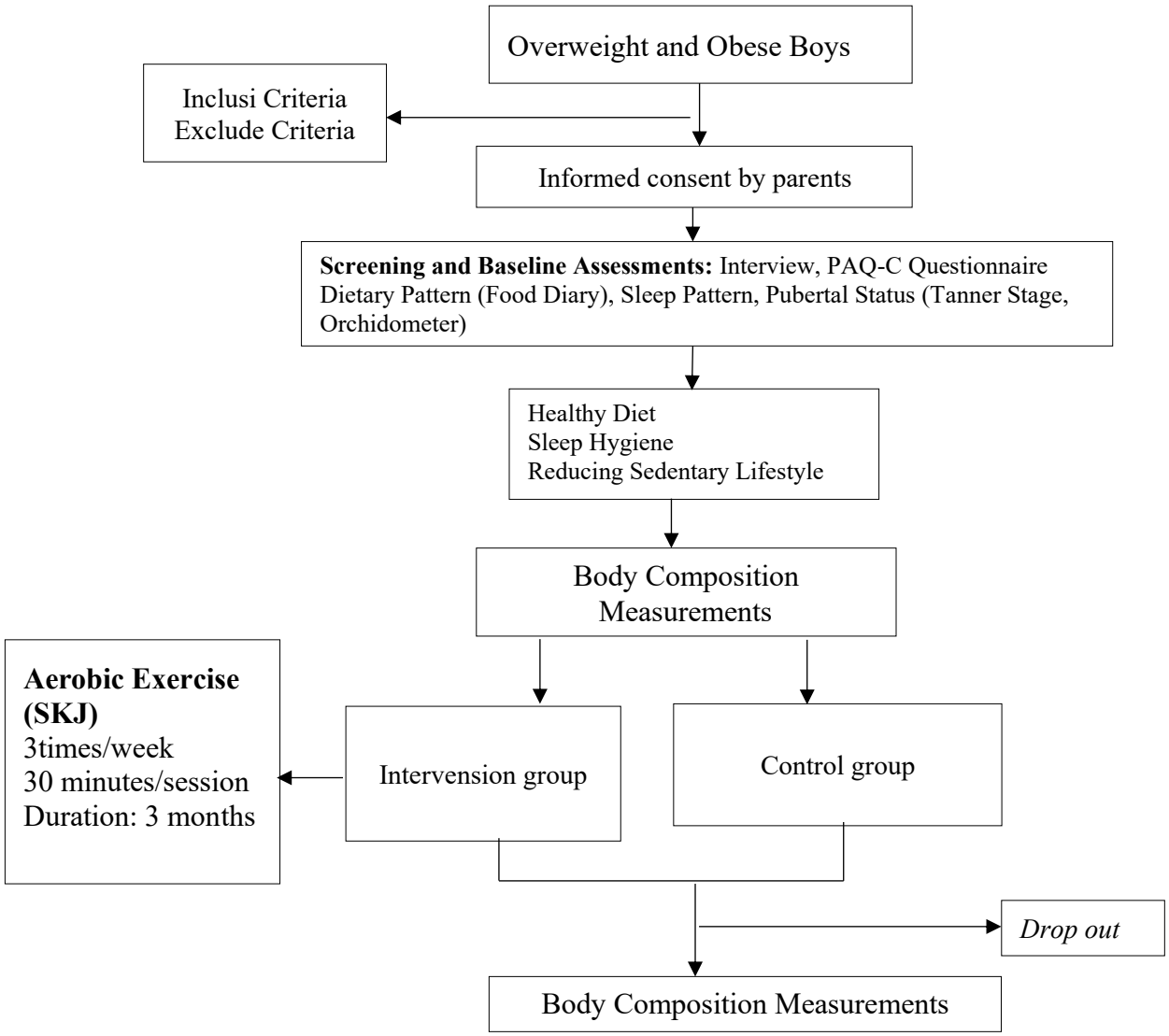
Parents/guardians received health education covering diet, sleep, and physical activity. Baseline measurements of body composition and height were taken using the specified equipment.

The intervention group engaged in **SKJ aerobic exercise** 3 times weekly (Tuesday, Thursday, Friday), 30 minutes per session, for 3 months. Sessions were held before school under supervision of a certified instructor and research team.

Missed sessions were rescheduled. Body composition was re-evaluated monthly during the 3-month intervention.

Research Flow

A diagram of the research flow (Figure 3.1) outlines the inclusion/exclusion process, intervention implementation, follow-ups, and drop-out tracking.



Research Team

Table 3.3 presents names, roles, and responsibilities of all research team members, including the principal investigator, research assistants, instructors, and dietitian.

No	Name	Position	Jobdesk	Start	Finished
1.	dr. Julius Anzar, SpA(K)/dr. Moretta D, SpA(K). M.Kes	Supervisor	Education provider	Agustus 2024	Agustus 2024
2.	dr. Marda Sakinah	Principal investigator	Informed consent, interviews, Explaining filling out questionnaires, Measuring body compotition	Agustus 2024	Desember 2024
3.	Rachmadaniar	Research assistant	Leading and monitoring sample subjects of SKJ aerobic exercise	September 2024	December 2024
4.	Sabda Ibrahim	Research assistant	monitoring sample subjects of SKJ aerobic exercise	September 2024	December 2024
5.	Dwi Agustiningrum, S.Pd	Research assistant	monitoring sample subjects of SKJ aerobic exercise	August 2024	December 2024
5.	dr. Endy Averoselly dan dr. Deva Wulandari	Research assistant	Informed consent, Interviews, Explaining filling out questionnaires, Measuring body compotition	August 2024	December 2024
6.	Retno Tyas Ning Wikan, S.Gz	Dietisien	Dietary pattern interviews, collecting FFQ questionnaires and analyzing	August 2024	December 2024

Data Processing and Statistical Analysis

Data were recorded in case report forms and entered into a database for analysis using SPSS version 23.

- **Univariate analysis:** Frequency distribution tables
- **Bivariate analysis:** Independent t-test, repeated-measures ANOVA, and chi-square tests to compare changes in body composition within and between groups
- **Multivariate analysis:** Pairwise comparison to identify the most significant differences. A p-value < 0.05 with 95% confidence interval was considered statistically significant.

Ethical Clearance

This study was approved by the Health Research Ethics Committee of the Faculty of Medicine, Sriwijaya University/Dr. Mohammad Hoesin Hospital (Approval No. DP.04.03/D.XVIII 6.8/ETIK/104/2024), and permission was granted by the Palembang City Education Office (Letter No. 070/0886/DISDIK/2024).

Informed Consent

I'am, Dr. Marda Sakinah, am a researcher from the Pediatric Department of Dr. Mohammad Hoesin General Hospital Palembang. I hereby invite you to voluntarily participate in a research study entitled:
"The Effect of Aerobic Physical Exercise on Body Composition in Overweight and Obese Boys," with the following explanations:

The purpose of this study is to analyze the relationship between aerobic physical exercise and changes in body composition among overweight and obese children. The study will use a non-randomized, open-label clinical trial design.

Your child is eligible to participate in this study as he is a male aged 8–12 years, classified as overweight or obese, and engages in light to moderate physical activity. Participation in this study is entirely voluntary.

Should you decide not to participate, you may withdraw at any time without any penalty or consequence.

The study will be conducted over a period of three months (July–September) using a non-randomized, open-label clinical trial design.

As compensation, children who participate regularly will receive school supplies and a medal at the end of the study.

Upon completion of the study, you will receive a personalized report on your child's body composition progress.

You will also be informed if your child is found to be in puberty or has a health condition that may hinder participation.

You will be notified of any other relevant findings during data collection.

Participation procedures include filling out questionnaires, attending health education sessions, undergoing body composition measurements, and aerobic exercise sessions outside of regular school physical education time. Although these procedures may be time-consuming, they pose no health risk to you or your child.

Before the intervention begins, you will be asked to fill out the following: a Food Frequency Questionnaire (FFQ), a PAQ-C questionnaire for physical activity, a sleep pattern questionnaire, and to allow measurements of weight, height, body composition, and pubertal status by a male physician, accompanied by a school teacher.

The benefit of participation is gaining knowledge of your child's body composition and strategies to promote a healthy lifestyle.

This study is expected to contribute to scientific literature and serve as a reference for potential therapeutic interventions in children with overweight and obesity.

After the study, no further treatment or health procedures will be necessary.

There will be no medical or clinical risk requiring treatment following the study intervention.

You will be informed of any new findings that may arise.

All collected data, including documentation and video footage of aerobic exercise sessions, will be stored for six months by the research team.

All information you provide will remain confidential.

This is an independent study with no external sponsorship.

The research team is fully responsible for conducting the study. The principal investigator will be responsible for any injury that occurs during the exercise sessions. In case of other risks, medical treatment will be provided under the national health insurance (BPJS).

This research has been approved by the Ethics Committee of Dr. Mohammad Hoesin Hospital, Palembang.

You will be informed if any violations of the study protocol occur. If so, the principal investigator will follow up and provide appropriate compensation.

You have the right to withdraw your data at any time during the study.

This research does not involve genetic testing or the use of genetic/family medical records.

This research does not involve the use of your medical or laboratory records, nor the collection or storage of biological materials.

All participants will receive equal treatment, and additional health information will be provided as needed.

This study is not conducted online and does not use digital tools.

If you agree to participate, please fill in your name and sign below. For further information, please contact Dr. Marda Sakinah at 081373100419.

I agree to participate in this research.

Name: _____
Signature: _____

Thank you for your participation.

Sincerely,

Witness	Investigator
_____	Dr. Marda Sakinah