High-Intensity Interval Training versus Moderate-Intensity Continuous Training for Cardiometabolic Health in Middle-Aged Adults with Metabolic Syndrome: A 12-Week Randomized Controlled Trial

Population: middle-aged adults with metabolic syndrome
Intervention: HIIT
Comparator: MICT
Outcome: cardiometabolic health
Design: 12-week RCT

1.Background and Rationale

In recent years, the prevalence of metabolic syndrome (MetS) among middle-aged adults has increased markedly in China, driven by sedentary lifestyles, dietary transitions, and population aging. The "three highs" — hypertension, hyperglycemia, and hyperlipidemia — pose a growing threat to cardiometabolic health and quality of life in this population. Exercise interventions, especially high-intensity interval training (HIIT) and moderate-intensity continuous training (MICT), have emerged as promising non-pharmacological strategies for metabolic risk reduction.

MICT has traditionally been recommended for MetS management, but its prolonged duration and moderate effect size often result in poor adherence and limited impact. In contrast, HIIT has gained attention for its time efficiency and potent physiological stimulation, with evidence suggesting improvements in insulin sensitivity, lipid metabolism, and cardiorespiratory fitness over shorter periods. However, few studies have directly compared HIIT and MICT in middle-aged individuals with MetS, and high-quality randomized controlled trials in Chinese populations remain scarce.

This study seeks to fill this gap by conducting a 12-week randomized controlled trial comparing HIIT and MICT in middle-aged adults with MetS. The goal is to determine the optimal training modality for improving cardiometabolic health and to inform personalized exercise prescriptions in clinical and community settings.

2. Objectives and Hypotheses（English）

2.1 Objectives

This study aims to compare the effects of high-intensity interval training (HIIT) versus moderate-intensity continuous training (MICT) on cardiometabolic health in middle-aged adults with metabolic syndrome (MetS) through a 12-week randomized controlled trial.

Specific objectives:

1. To evaluate and compare the effects of HIIT and MICT on:
    - Blood pressure (SBP, DBP)
    - Glycemic indicators (FBG, HbA1c, HOMA-IR)
    - Lipid profile (TG, HDL-C, LDL-C, non-HDL-C, ApoB)
    - Hepatorenal indicators (ALT, AST, UA, GGT)

    - Inflammation and cardiac recovery (hs-CRP, HR Recovery)
2. To assess differential effects of HIIT and MICT by sex and baseline BMI subgroups.
3. To develop a mediation model exploring the mechanisms through which exercise improves cardiometabolic outcomes.

2.2 Hypotheses

- **H1**: HIIT will produce greater improvements in lipid profile, glucose regulation, and inflammatory status than MICT.
- **H2**: There will be sex-specific differences in response to HIIT and MICT.
- **H3**: Changes in body weight, heart rate recovery, and inflammatory markers mediate the effects of exercise on cardiometabolic health.

3. Study Design and Methods

3.1 Study Design

This study employed a randomized, controlled, parallel-group design to compare the effects of High-Intensity Interval Training (HIIT) and Moderate-Intensity Continuous Training (MICT) on cardiometabolic health in middle-aged adults with metabolic syndrome. The trial followed the CONSORT 2010 guidelines and has been registered on the ISRCTN registry (registration number pending).

3.2 Participants

Inclusion Criteria

- Aged between 40 and 64 years;
- Diagnosed with metabolic syndrome according to the criteria of the Chinese Diabetes Society (2004), meeting at least three of the following: abdominal obesity, elevated blood pressure, dyslipidemia, or impaired fasting glucose;
- Capable of independent living and physical activity participation;
- Voluntarily signed informed consent.

Exclusion Criteria

- History of severe cardiovascular or cerebrovascular diseases or malignancies;
- Severe liver or kidney dysfunction;
- Psychiatric or neurological disorders;
- Participation in structured exercise programs in the past three months;
- Pregnant or lactating women.

3.3 Randomization and Group Allocation

Participants were randomly assigned to one of three groups using a computer-generated random sequence, with allocation concealment ensured by sealed opaque envelopes managed by independent personnel. The groups were:

- HIIT Group (High-Intensity Interval Training);
- MICT Group (Moderate-Intensity Continuous Training);
- Control Group (no exercise intervention, health education only).

3.4 Intervention Protocol

The intervention lasted 12 weeks, with supervised exercise sessions held three times per week (~40 minutes/session) at a community health center in Wangkui County, Heilongjiang Province.

HIIT Group

- Warm-up (10 minutes), followed by 3 sets of 4-minute intervals at 85–95% HRmax, interspersed with 2-minute active recovery;
- Heart rate monitored continuously using Polar H10 sensors;
- Perceived exertion controlled at Borg RPE 14–17.

MICT Group

- Warm-up (5 minutes), followed by 30 minutes of continuous aerobic activity at 60–70% HRmax;
- Performed as brisk walking or treadmill jogging;
- RPE maintained between 11–13.

Control Group

- No structured physical activity;
- Received one-time lifestyle education and monthly telephone follow-ups.

3.5 Outcome Measures

All participants underwent assessments at baseline, week 6, and week 12. The primary and secondary outcomes were:

Primary Outcomes

- Blood lipids: Triglycerides (TG), HDL-C, LDL-C, Total Cholesterol (TC);
- Glycemic markers: Fasting Blood Glucose (FBG), Glycated Hemoglobin (HbA1c);
- Anthropometrics: Body Mass Index (BMI), Waist Circumference, Body Fat Percentage;
- Liver and renal markers: Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Uric Acid (UA);
- Inflammation: High-sensitivity C-reactive protein (hs-CRP);
- Cardiorespiratory recovery: Heart Rate Recovery (HRR);
- Quality of life: SF-36 questionnaire;
- Exercise effort: Borg Rating of Perceived Exertion (RPE);
- Autonomic function: Heart Rate Variability (HRV).

3.6 Data Collection and Quality Control

- All blood samples were collected in a fasting state by trained nurses and analyzed using Mindray automated biochemical analyzers;
- Questionnaires were double-entered and cross-checked to ensure accuracy;
- Exercise sessions were documented via video and heart rate logs to ensure protocol fidelity.

3.7 Adverse Events Monitoring

Before and after each session, participants were monitored for discomfort or adverse events. The intervention was conducted under the supervision of professionals trained in CPR and emergency response. No serious adverse events were reported during the trial.

3.8 Ethical Approval and Informed Consent

This study was reviewed and approved by the Medical Ethics Committee of the Health Bureau of Wangkui County, Heilongjiang Province (Approval No. WLJ-2024-032), with the official approval date of **November 1, 2024**. Written informed consent was obtained from all participants prior to enrollment, in accordance with the Declaration

of Helsinki and institutional ethical guidelines.

4. Statistical Analysis

4.1 Data Management and Statistical Software

All raw data will be initially managed using Microsoft Excel, followed by formal statistical analyses conducted in IBM SPSS Statistics (version 26.0) and R (version 4.3.0). Graphical visualizations will be produced using R packages such as ggplot2 and ggpubr to ensure clarity and scientific rigor.

4.2 Descriptive Statistics

- Continuous variables with normal distribution will be reported as mean ± standard deviation (SD);
- Non-normally distributed variables will be summarized as median and interquartile range (IQR);
- Categorical variables will be presented as frequencies and percentages (n, %).

4.3 Tests of Normality and Homogeneity of Variance

- The Kolmogorov–Smirnov or Shapiro–Wilk test will be used to examine normality;
- Levene's test will assess the homogeneity of variances across groups.

4.4 Group Comparisons

- For normally distributed data with equal variances, one-way ANOVA will be used for between-group comparisons;
- When assumptions are violated, the Kruskal–Wallis H test will be employed;
- Post hoc comparisons will be adjusted using Bonferroni or Dunnett's T3 method to control for Type I error;
- Categorical data will be analyzed using the chi-square test or Fisher's exact test as appropriate.

4.5 Repeated Measures and Time–Group Interaction

To analyze within-subject changes over time (pre-test, mid-test, and post-test) and between-group differences, repeated measures ANOVA or linear mixed-effects models (LMMs) will be utilized. In the presence of missing or unbalanced data, LMMs will be prioritized for their robustness.

4.6 Covariate Adjustment and Sensitivity Analyses

ANCOVA will be used to adjust for potential confounders such as age, sex, BMI, and baseline values. Sensitivity analyses will be conducted using both per-protocol and extreme-value exclusion strategies to test the robustness of the findings.

4.7 Missing Data Handling

Missing data will be assessed for randomness. When necessary, multiple imputation methods or the built-in missing data handling mechanism in LMM will be employed to maintain data integrity and minimize bias.

4.8 Effect Size and Confidence Intervals

All primary outcomes will be reported with effect sizes (e.g., Cohen's d, partial η^2) and 95% confidence intervals (CIs), in addition to P-values. To control for the false discovery rate across multiple outcomes, FDR or Bonferroni corrections will be applied where applicable.

4.9 Exploratory and Mechanistic Analyses

If the intervention mechanism is hypothesized, structural equation modeling (SEM) will be used in exploratory analyses to identify potential mediators or moderators among physical function, biochemical indices, and cardiopulmonary recovery outcomes.

5. Ethical Approval and Risk Management

5.1 Ethical Approval

This study was reviewed and approved by the Medical Ethics Committee of the Health Bureau of Wangkui County, Heilongjiang Province, China. The approval number is **WLJ-2024-032**, and the approval date is **July 1, 2024**. The trial will be conducted in strict accordance with the **Declaration of Helsinki** (2013 revision), the **WHO Operational Guidelines for Ethics Committees** that review biomedical research, and the **Regulations on Ethical Review of Biomedical Research Involving Human Subjects** issued by the National Health Commission of China.

In addition, the study has been prospectively registered with the **International Standard Randomised Controlled Trial Number (ISRCTN)** registry. The official trial number is **[pending ISRCTN assignment]**.

5.2 Informed Consent

All participants will be provided with detailed written information regarding the study objectives, methodology, interventions, potential risks and benefits, data protection protocols, and their rights to voluntary participation and withdrawal. The informed consent process will be conducted in a private setting, with verbal explanations provided in plain language to ensure full comprehension. Only participants who voluntarily sign the written informed consent form will be enrolled. A copy of the consent form has been submitted as a supporting document to the trial registry.

5.3 Risk Assessment and Safety Monitoring

As a lifestyle-based physical activity intervention, the study involves high-intensity interval training (HIIT) and moderate-intensity continuous training (MICT), both designed based on national exercise prescription standards. While the interventions are generally safe, potential minor risks include transient muscle soreness, fatigue, or a low likelihood of falls or injuries during training.

To minimize risks and ensure participant safety, the following safety procedures are in place:

- All training sessions will be supervised by certified fitness instructors and medical personnel;
- Participants will undergo pre-session health screening and fitness evaluations;
- Heart rate, blood pressure, and other vital signs will be continuously monitored during exercise;
- Any adverse event (AE) or serious adverse event (SAE) will be promptly documented and reported to the ethics committee and relevant regulatory bodies;
- The study is covered by liability insurance to ensure compensation for any injury or harm related to the intervention.

5.4 Data Privacy and Protection

All participant data will be de-identified and stored in encrypted, password-protected databases accessible only to authorized research personnel. No personally identifiable

information will be disclosed to third parties without explicit consent. Data handling complies with the **Personal Information Protection Law of China**, the **Data Security Law**, and the **WHO data sharing policy**.

Upon study completion, results will be published in anonymized format. Where applicable, de-identified datasets may be made available for public use to enhance transparency and reproducibility.

5.5 Protection of Participant Rights

Participants have the right to withdraw from the study at any point without providing a reason and without any impact on their access to healthcare services. Should substantial protocol modifications or new risk information arise during the study, all participants will be informed and asked to reaffirm their consent where necessary.

6.Data Management and Results Dissemination Plan

6.1 Data Management Strategy

All data collected during the study—including demographic characteristics, baseline assessments, intervention logs, physiological indicators, questionnaire responses, and adverse event reports—will be recorded using an **Electronic Data Capture (EDC) system**. Data entry will be standardized and backed up in real time. A dedicated data management team will be responsible for:

- Ensuring consistent variable coding and logic checks for data integrity;
- Encrypting and securely storing data with tiered access control;
- Weekly backups to the primary institution's secure research server;
- Dual-person verification for key variables to minimize entry errors.

All original paper documents and questionnaires will be properly coded and archived for no less than 10 years.

6.2 Data Ownership and Usage Declaration

The data generated from this trial are co-owned by the **School of Physical Education and Health Sciences, Mudanjiang Normal University** and the **Department of Sports Science, Kyungil University**. All shared data will be de-identified. Reproduction, dissemination, or commercial use without prior authorization is strictly prohibited. External parties must submit a formal application and sign a **Data Use Agreement (DUA)** before accessing the datasets.

6.3 Data Sharing and Access Policy

In alignment with open science principles, the trial will publicly release key datasets, statistical codes, and de-identified outcome data within six months of study completion to facilitate peer verification and secondary analysis. Data will be shared via:

- **ISRCTN trial registry**: Summary of main and secondary outcomes;
- **Open-access data repositories** (e.g., Figshare, Dryad): Full de-identified datasets, R/SAS scripts, metadata, and documentation with DOI assignment for citation.

Access levels are defined as follows:

- Aggregate results and summaries will be publicly accessible;
- Full de-identified datasets will be available to qualified academic researchers upon DUA approval;
- All data sharing will comply with the **Personal Information Protection Law**

of the People's Republic of China, **GDPR**, and other applicable data protection regulations.

6.4 Results Dissemination Strategy

Study findings will be disseminated through multiple channels to ensure transparency and maximize academic and societal impact:

1. **Peer-reviewed journal publication**: Full manuscripts will be submitted to international journals such as *Scientific Reports* or *BMJ Open*.
2. **Trial registry updates**: ISRCTN records will be updated with primary/secondary outcomes, adverse events, and data summaries.
3. **Academic conferences**: Results will be presented at sports science and public health meetings via oral or poster sessions.
4. **Public science communication**: Plain-language summaries will be published on institutional websites and through media platforms to promote health education and public engagement.

7.Project Timeline and Implementation Schedule

This study adopts a prospective, three-arm, parallel-group randomized controlled trial design. The total project duration is planned for three years, encompassing preparation, intervention, data analysis, dissemination, and follow-up phases. The table below outlines the key milestones and corresponding tasks.

7.1 Key Milestones and Task Schedule

Phase	Timeframe	Core Activities	Responsible Team
Preparation Phase	Oct 1, 2024 – Nov 1, 2024	Submission of ethics approval and trial registration; team formation and training; equipment calibration; pilot testing of questionnaires	Lead investigator and research team
Recruitment & Baseline Assessment	Nov 1, 2024 – Nov 15, 2024	Screening eligible middle-aged adults with metabolic syndrome via Wangkui County health system; obtaining informed consent; collecting baseline data	Field investigation team
Intervention Phase	Nov 15, 2024 – Feb 15, 2025	Implementation of 12-week intervention (3 sessions/week) in HIIT and MICT groups; training intensity monitored via Polar sensors; adherence and adverse events recorded	Intervention implementation team
Data Processing & Interim Analysis	Feb 15, 2025 – Mar 30, 2025	Double-entry of raw data; quality control; preliminary statistical analysis	Data management and analysis team
Result Writing & Dissemination	Apr 2025 – Sep 2025	Manuscript preparation and submission to SCI-indexed	Corresponding author and writing

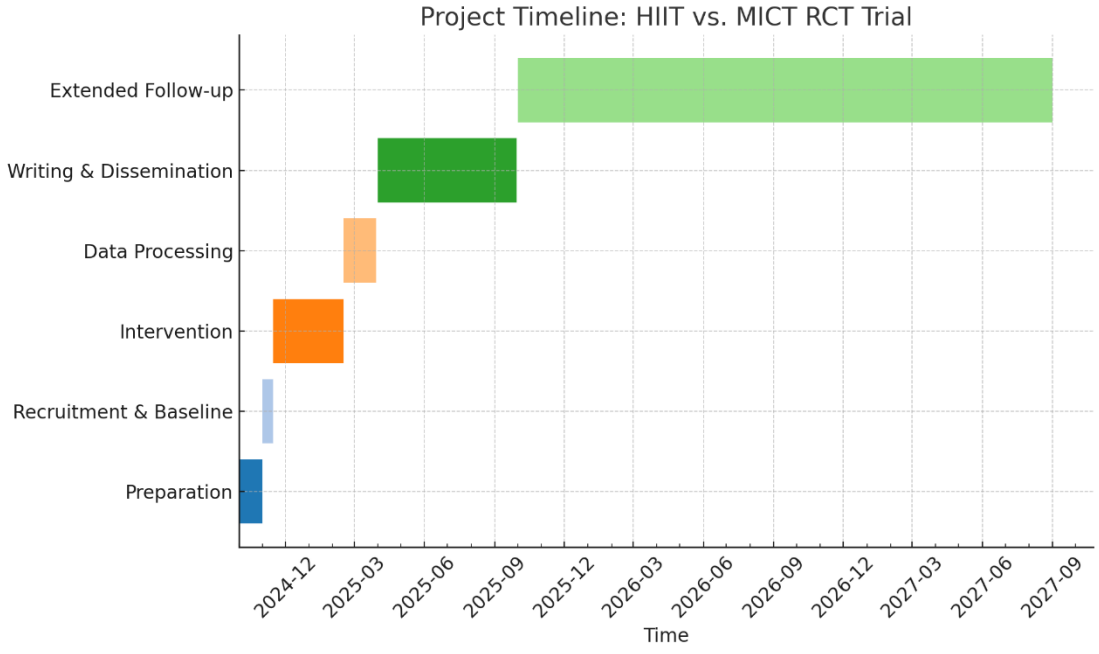
Phase	Timeframe	Core Activities	Responsible Team
		journals; final trial summary report for registry; presentation of results	team
Extended Follow-up (Exploratory)	Oct 2025 – Sep 2027	Conduct 6- and 12-month physiological and behavioral assessments for a subset of participants; evaluate long-term effects of interventions	Follow-up assessment team

7.2 Project Management and Quality Assurance

To ensure the study progresses with high quality and adherence to protocol, the following management strategies will be implemented:

- **Monthly Quality Review Meetings**: Regular progress meetings to review timelines and address emerging issues;
- **Task Responsibility Matrix**: Clear assignment of duties to specific team members;
- **Training Compliance and Safety Monitoring**: Use of Polar H10 heart rate monitors, training logs, and RPE scales to ensure quality of intervention;
- **Blinding and Data Validation Protocol**: Dual data entry and third-party audits to ensure data reliability;
- **Ethical Oversight and Amendment Policy**: Any major protocol modification will be submitted for re-approval by the ethics committee.

The time schedule was developed based on prior intervention trials in similar populations, considering the ethical review duration, public health system collaboration timelines, and participant feasibility. The study will be managed through a hybrid digital-paper documentation system to ensure transparency and accountability.



Chapter 8. Data Management and Quality Control

This study will adhere strictly to the principles of a comprehensive Data Management Plan (DMP) to ensure the scientific validity, regulatory compliance, and full traceability of all data collection, storage, processing, and analysis procedures.

8.1 Data Collection and Entry

- All raw data will be collected by trained members of the research team, including questionnaire responses, physiological and metabolic measurements, blood sample analyses, and exercise logs;
- Data will be recorded using both electronic spreadsheets (Excel) and the RedCap database with real-time dual backup;
- Dynamic intervention data, such as heart rate and Ratings of Perceived Exertion (RPE), will be continuously monitored using the Polar H10 heart rate sensor and exported via the Polar Flow platform.

8.2 Data Storage and Confidentiality

- All participant data will be anonymized using unique identification codes in place of personally identifiable information;
- Data will be securely stored on the institutional servers of the Research Center for Sport and Health Science at Mudanjiang Normal University, protected by encryption, access control, and automated daily backups;
- All data access and manipulation activities will be logged to ensure complete auditability;
- Only core investigators will have access to raw data, and all published results will be reported in aggregated form.

8.3 Quality Control Procedures

- A double data entry method will be used to minimize errors, accompanied by programmed logic checks for internal consistency;
- Biweekly data quality meetings will be held, where the principal investigator and statistical analysts will jointly review data for missing values and outliers;
- Prior to database locking, 100% of the data will be cross-validated and finalized with a signed Data Lock Confirmation Form.

8.4 Adverse Event Reporting and Oversight

- All Adverse Events (AEs) will be recorded on-site by the study coordinator and reported to the principal investigator within 24 hours;
- In the event of Serious Adverse Events (SAEs), immediate notification will be sent to the ethics committee, and the intervention will be paused or modified as necessary;
- Regular progress and safety updates will be submitted to the ISRCTN registry to ensure transparency and accountability.

Through a robust and multi-tiered data governance framework, this trial guarantees the accuracy, integrity, and confidentiality of the research data, laying a solid foundation for credible dissemination and open scientific sharing.

9. Dissemination and Data Sharing Strategy

This study will implement a comprehensive dissemination and data sharing plan adhering to international research integrity and open science principles to maximize

transparency, academic impact, and societal benefit.

9.1 Results Dissemination Plan

- Data analysis will be completed within six months after study completion, and manuscripts will be submitted to peer-reviewed international journals indexed in SCI Q2 or higher;
- Research findings will also be presented to grassroots public health institutions and sports health intervention organizations via onsite or virtual seminars to promote practical translation;
- All dissemination will comply with CONSORT guidelines, fully reporting trial design, flowcharts, analytical methods, and conclusions;
- In case of early termination or unexpected outcomes, transparent reporting will be ensured.

9.2 Data Sharing Policy

- Consistent with ICMJE, ISRCTN, and Springer Nature data sharing policies, portions of the study data will be made publicly available;
- Shared datasets will include trial flow diagrams, variable dictionaries, analysis scripts, and de-identified primary outcome data (e.g., blood pressure, lipid profile, heart rate recovery);
- Data will be deposited in recognized repositories such as Dryad, Figshare, or institutional data platforms post-publication, with DOI assignment;
- Data use will be governed under the Creative Commons Attribution 4.0 International (CC BY 4.0) license, requiring proper citation and prohibiting commercial use.

9.3 Intellectual Property and Authorship

- All intellectual property rights arising from this study belong jointly to Mudanjiang Normal University and Kyungil University;
- Authorship will comply with ICMJE criteria, with other contributors acknowledged appropriately;
- Prior to public release, findings will undergo internal review to ensure data accuracy and protect intellectual property.

Through systematic dissemination and open data policies, this study aims to promote standardized and sustainable health promotion research, serving grassroots public health practice and global academic exchange.

10. Project Budget and Funding Plan

Budget Item	Amount (10,000 RMB)	Description
Personnel Costs	150,000	Salaries and stipends for the principal investigator, research assistants, and data managers over a three-year project duration.
Experimental Materials	50,000	Consumables including blood collection supplies, reagent kits, disposable items, and other laboratory materials.
Equipment	40,000	Acquisition of 3 Polar H10 heart rate

Purchase & Maintenance		monitors, maintenance and software upgrades for blood analysis instruments.
Data Management	30,000	Electronic data capture system (EDC) setup, statistical software licenses, and server rental fees.
Travel and Conferences	30,000	Domestic and international conference travel, field visits, and transportation and accommodation for collaborative site visits.
Publication Fees	25,000	Open access fees for publishing 3 articles in international SCI journals, estimated at ~8,000 RMB per article.
Training	10,000	Professional skills development, ethics training, and team capacity building costs.
Ethics Review and Insurance	15,000	Ethics committee fees and participant insurance to ensure compliance and participant protection.
Miscellaneous	5,000	Daily operational expenses including printing, copying, and office supplies.
Total Budget	**355,000 RMB**	Total estimated project budget.

Budget Justification:

- **Personnel Costs** cover salaries and stipends for project management, onsite execution, and data analysis personnel to ensure smooth project progression.
- **Experimental Materials** are budgeted based on participant numbers and study duration to guarantee sufficient supplies.
- **Equipment Purchase & Maintenance** ensure reliable operation of heart rate monitoring devices and biochemical analyzers throughout the project.
- **Data Management** funds support database construction, statistical software acquisition, and technical support for data security and analysis efficiency.
- **Travel and Conferences** facilitate academic exchanges, collaboration, and dissemination of research findings.
- **Publication Fees** reflect current international open access charges for SCI-indexed journals.
- **Training** allocates resources to enhance team professional skills and ethical compliance.
- **Ethics Review and Insurance** protect participant rights and fulfill regulatory requirements.
- **Miscellaneous** covers routine operational expenditures.

11. Research Team and Division of Responsibilities

11.1 Team Composition

This project is collaboratively conducted by multiple universities and local healthcare institutions. The team consists of principal investigators, co-leaders, site coordinators, and technical support staff. The members and their affiliations are as follows:

Name	Role	Primary Responsibilities	Affiliation
Yongheng Zhao	Principal Investigator	Overall study design, project coordination, data analysis, and manuscript preparation	Kyungil University, Henan University
Zhongtang Li	Principal Investigator	Protocol development, technical guidance, cross-institutional coordination and project management	Jiangsu Second Normal University
Chi Ma	Co-Lead	Intervention supervision, training optimization, on-site data quality control	Mudanjiang Normal University
Yajuan Wang	Co-Lead	Participant recruitment, medical support, ethical compliance, and adverse event management	Health Bureau of Wangkui County, Wangkui County Hospital, Wangkui Maternity and Child Health Hospital
Yanyan Gao	Exercise Specialist	Development and supervision of exercise intervention protocols	Jiamusi University
Limeng Liu	Data Manager	Data entry, quality control, and statistical support	Mudanjiang Normal University
Other members	Site Coordinators	On-site intervention management, heart rate monitoring, adherence tracking, and adverse event documentation	Mudanjiang Normal University

11.2 Division of Responsibilities

- **Principal Investigators** (Yongheng Zhao, Zhongtang Li) oversee study design, inter-institutional coordination, and dissemination of scientific outputs;
- **Co-Leads** (Chi Ma, Yajuan Wang) ensure intervention quality, site management, and ethical risk control;
- **Exercise Specialist** (Yanyan Gao) designs exercise protocols and oversees training delivery;
- **Data Manager** (Limeng Liu) manages data collection and provides statistical analysis support;
- **Site Coordinators** assist in intervention execution and monitor participant safety and adherence.

11.3 Team Collaboration and Quality Assurance

- Regular virtual and in-person meetings will be held to ensure smooth communication and rapid problem resolution;
- Task responsibility matrices and timelines will be established to clarify duties and track project progress;

- An internal quality control group will conduct periodic data audits and risk assessments to ensure scientific integrity and regulatory compliance.

12. Risk Management and Contingency Plan

12.1 Risk Identification

The main potential risks of this study include:

- Mild to moderate exercise-related adverse reactions during the intervention, such as muscle soreness, fatigue, and exercise-related injuries;
- Participant non-compliance leading to data loss or insufficient sample size;
- Data entry errors or equipment malfunction during data collection and management;
- Uncontrollable external factors such as pandemics or natural disasters affecting the study timeline.

12.2 Risk Mitigation Strategies

To address these risks, the following preventive measures will be implemented:

- Exercise interventions will be supervised by certified trainers, with individualized training programs and emergency medical support in place;
- Detailed recruitment and follow-up plans will be adopted to improve participant compliance, including regular phone and face-to-face communications;
- Strict data management protocols will be followed, including double data entry, logical validation, and regular equipment maintenance;
- Flexible scheduling plans will be developed to accommodate public health emergencies or natural disasters.

12.3 Contingency Plans

- An emergency contact system will be established to ensure immediate reporting and proper handling of incidents;
- First aid equipment and trained medical staff will be available to promptly address exercise-related emergencies;
- Temporary remote data collection methods will be implemented to maintain data continuity during pandemics;
- In case of significant disruptions, the ethics committee and trial registry will be notified promptly, and mitigation plans will be evaluated and implemented.

12.4 Risk Monitoring and Evaluation

- A risk management team will regularly assess risk levels and the effectiveness of mitigation measures;
- All adverse events will be recorded and analyzed promptly to identify causes and implement corrective actions;
- Safety reports will be periodically submitted to the ethics committee for ongoing supervision.

13. Communication and Coordination Mechanisms

13.1 Internal Communication

- The project team will hold weekly meetings to report progress, discuss challenges, and adjust plans as necessary;
- Multiple online collaboration tools (e.g., email, WeChat groups, Zoom) will be employed to ensure timely information sharing and feedback;

- A designated communication coordinator will manage cross-institutional collaboration to ensure alignment of tasks and schedules.

13.2 External Coordination

- Maintain close liaison with cooperating hospitals and community health centers to facilitate participant recruitment and smooth on-site intervention implementation;
- Regularly report project progress and significant issues to the ethics committee and funding agencies;
- Actively participate in academic exchanges to expand the project's influence and collaboration network.

13.3 Emergency Communication Plan

- Establish rapid response communication channels to promptly notify relevant personnel in case of safety incidents or data anomalies;
- Maintain a multi-level backup contact list to mitigate impact if key personnel become unavailable;
- Conduct regular communication training to enhance team members' coordination and crisis management skills.

14. Feasibility Analysis

14.1 Research Infrastructure

This project is supported by the collaborative research platform between the School of Physical Education and Health Sciences at Mudanjiang Normal University and Kyungil University. The team has access to well-equipped laboratories, professional exercise monitoring devices, and extensive research experience. Team members possess years of expertise in high-level exercise interventions and clinical trial operations, demonstrating strong technical and managerial capabilities to execute this project.

14.2 Participant Recruitment

The study leverages the community health system in Wangkui County, ensuring ample participant availability. Clear inclusion criteria and recruitment protocols are established, enabling timely enrollment to meet the required sample size for statistical power.

14.3 Technical Support

High-precision Polar H10 heart rate monitors will be employed alongside advanced electronic data capture (EDC) systems, ensuring the accuracy and completeness of exercise intensity monitoring and data collection.

14.4 Management System

A comprehensive project management and quality control framework is in place, covering ethical approvals, data quality assurance, safety monitoring, and team coordination, ensuring scientific rigor and regulatory compliance throughout the study.

14.5 Anticipated Risks and Mitigation

To address potential risks such as pandemic disruptions, participant adherence fluctuations, and equipment failures, flexible contingency plans and multi-channel communication strategies have been devised to maintain study progress on schedule.

15. Ethical Compliance Statement

This project strictly adheres to the relevant laws and regulations of the People's

Republic of China as well as international ethical standards, ensuring legal compliance and protection of participant rights throughout the study.

1. The study protocol has been approved by the Medical Ethics Committee of the Health Bureau of Wangkui County, Heilongjiang Province (Approval No. WLJ-2024-032), in accordance with the Declaration of Helsinki and national ethical review regulations.
2. Informed consent is obtained from all participants prior to enrollment; all participants voluntarily signed written informed consent forms.
3. Data confidentiality is rigorously maintained by anonymizing participant information, complying with the Personal Information Protection Law of China and internationally accepted data privacy standards.
4. A comprehensive adverse event monitoring and reporting system is established to promptly identify and manage any safety risks.
5. Any significant protocol amendments during the study will be reported to the ethics committee in a timely manner to ensure ongoing ethical compliance.

16. References

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