高强度间歇训练与中等强度持续训练对中年三高人群心代谢健康的干预研究：一项12周随机对照试验

关键词覆盖：
高强度间歇训练、持续训练、三高、中年人群、心代谢、干预、随机对照试验

1.研究背景与意义

近年来，随着生活方式的变化和老龄化的加剧，我国中年人群中代谢综合征（Metabolic Syndrome, MetS）患病率显著上升。“三高”问题（高血压、高血糖、高血脂）已成为危害中年人群心血管健康和生活质量的主要公共卫生挑战。运动干预，特别是高强度间歇训练(High-Intensity Interval Training, HIIT)和中等强度持续训练（Moderate-Intensity Continuous Training, MICT），被广泛认为是非药物改善代谢风险因素的重要手段。

尽管MICT长期被应用于代谢综合征管理中，但其干预周期长、依从性差，效果缓慢。相比之下，HIIT 因其时间效率高、代谢激活强度大，逐渐受到关注，已有部分研究显示其可在较短周期内显著改善胰岛素敏感性、脂质代谢与心肺功能。但针对“三高”合并症中年人群的直接对比研究仍较少，尤其是在中国人群中缺乏高质量的随机对照试验证据。

因此，本研究旨在通过为期12周的HIIT与MICT干预，系统比较两种训练模式对中年MetS人群心代谢健康的改善效果，为制定个体化、精准化运动干预策略提供科学依据。

2.研究目标与假设

2.1 研究目标

本研究旨在通过为期12周的随机对照试验，比较高强度间歇训练（HIIT）与中等强度持续训练(MICT)对中年代谢综合征(MetS)人群心代谢健康指标的影响，探索其干预效果的优劣及机制差异。

具体目标包括：

1. 比较HIIT与MICT对以下指标的改善程度：
    - 血压（SBP、DBP）
    - 血糖（FBG、HbA1c、HOMA-IR）
    - 血脂（TG、HDL-C、LDL-C、non-HDL-C、ApoB）
    - 肝肾代谢指标（ALT、AST、UA、GGT）
    - 炎症与心肺恢复能力（hs-CRP、HR Recovery）
2. 探讨HIIT和MICT在不同性别、基线BMI水平下的干预差异。
3. 构建运动干预对心代谢健康的影响路径模型，明确关键中介变量。

2.2 研究假设

- 假设一：HIIT 在改善中年 MetS 人群的血脂、血糖与炎症水平方面优于MICT。
- 假设二：两种训练对不同性别人群的干预效果存在交互差异。
- 假设三：体重变化、心率恢复能力与炎症因子在训练干预效果中起中介作用。

研究设计与方法（中文）

3.1 研究设计

本研究采用随机、对照、平行分组设计，旨在比较高强度间歇训练（HIIT）与中

等强度持续训练（MICT）对中年代谢综合征人群的心代谢健康影响。研究设计遵循 CONSORT 2010 声明，已在国际临床试验注册平台 ISRCTN 完成注册（编号申请中）。

3.2 研究对象

研究对象为居住在黑龙江省望奎县社区的中年“三高”人群，符合以下标准：

纳入标准：

- 年龄为 40－64 岁；
- 诊断为代谢综合征（依据中华医学会 2004 年标准，包括腹型肥胖、血压升高、空腹血糖异常、血脂异常等至少满足三项）；
- 生活自理能力良好，可参与运动干预；
- 在签署知情同意书后自愿参加研究。

排除标准：

- 既往诊断严重心脑血管疾病、恶性肿瘤；
- 合并严重肝肾功能异常；
- 精神或神经系统疾病；
- 近 3 个月参与系统运动干预；
- 妊娠或哺乳女性。

3.3 随机化与分组

本研究使用计算机生成的随机数字表进行分组，并由非研究人员采用封闭编号信封进行分配，确保随机过程的隐蔽性。最终将参与者随机分为三个组：

- HIIT 组（高强度间歇训练）
- MICT 组（中等强度持续训练）
- 对照组（无运动干预，仅接受健康宣教）

3.4 干预方案

干预周期为 12 周，每组每周进行 3 次运动干预，每次约 40 分钟，均由专业教练指导，干预场地为望奎县社区健康中心指定运动室。

HIIT 组：

- 热身 10 分钟，3 组间歇运动，每组 4 分钟@85－95%HRmax，间歇恢复 2 分钟；
- 监控指标：Polar H10 心率带实时监测；
- 配合简易阻力训练动作，控制 RPE 14－17。

MICT 组：

- 热身 5 分钟，持续运动 30 分钟@60－70%HRmax；
- 使用步态跑台或场地快走；
- 强度控制在 RPE 11－13 之间。

对照组：

- 不进行运动干预，仅接受一次基础健康教育；
- 每月进行一次随访提醒。

3.5 测量指标

所有参与者在干预前、第 6 周与第 12 周分别接受指标测量，内容包括：

主要指标：

- 三酯（TG）、HDL-C、LDL-C、总胆固醇（TC）；
- 空腹血糖（FBG）、糖化血红蛋白（HbA1c）；
- 体质指标：BMI、腰围、体脂率；

- 肝酶（ALT、AST）、尿酸（UA）；
- 炎症因子：高敏 C 反应蛋白（hs-CRP）；
- 心率恢复能力（HR Recovery）；
- 生活质量量表：SF-36；
- 运动负荷感知：Borg RPE 量表；
- 心率变异性（HRV）。

3.6 数据收集与质量控制

- 所有检测数据在早晨空腹状态下由专业护士与检验师完成采样；
- 抽血样本使用迈瑞血液生化分析仪检测，控制采集与分析误差；
- 问卷调查与运动记录表由双人核对输入，采用双重录入避免偏差；
- 所有干预过程使用视频与心率仪器进行留档，确保干预一致性。

3.7 不良事件监测

在每次运动前后监测参与者主观不适、突发事件或医疗使用记录。研究团队配备心肺复苏技能人员，研究期间未发生严重不良事件。

3.8 伦理审查与知情同意

本研究已通过黑龙江省望奎县卫生健康局医学伦理委员会审查，伦理批准编号为：WLJ-2024-032，批准日期为 2024 年 11 月 1 日。

所有研究对象均已签署《知情同意书》，并获得其知情参与许可。

4. 统计分析方法

4.1 数据管理与分析软件

所有数据将使用 Microsoft Excel 进行原始录入与初步数据清理，随后导入 IBM SPSS Statistics 26.0 和 R 4.3.0 进行统计分析。图表可视化将采用 R 语言中的 ggplot2 与 ggpubr 等包实现，以增强数据表达的直观性和科学性。

4.2 描述性统计

- 对于正态分布的连续变量，采用均值 ± 标准差（Mean ± SD）表示；
- 对于非正态分布的变量，采用中位数（四分位间距）表示；
- 分类变量以频数与百分比（n, %）表示。

4.3 正态性与方差齐性检验

- 连续变量的正态性检验采用 Kolmogorov-Smirnov 检验或 Shapiro-Wilk 检验；
- 方差齐性通过 Levene 检验评估，以判断后续方差分析适用性。

4.4 组间比较方法

- 若数据符合正态性与方差齐性，采用单因素方差分析（One-way ANOVA）比较三组间差异；
- 若不符合正态性或方差齐性，采用 Kruskal－Wallis H 检验；
- 配对比较采用 Bonferroni 或 Dunnett T3 校正方法控制第Ⅰ类错误率（Type I error）；
- 类别变量比较使用卡方检验或 Fisher 确切概率法。

4.5 重复测量与时间效应分析

采用重复测量方差分析（Repeated Measures ANOVA）或线性混合模型（Linear Mixed Models），分析时间（前测-中测-后测）与组别之间的交互效应；若存在缺失值或数据不平衡，则优先采用线性混合效应模型以增强稳健性。

4.6 协变量调整与敏感性分析

为控制混杂因素影响，将年龄、性别、BMI、基础水平等变量作为协变量纳入协

方差分析（ANCOVA）模型中；
主要结局变量将进行敏感性分析，采用极端值排除法与完整性分析法双重检验干预效应的稳健性。
4.7 缺失值处理策略
缺失数据将评估其随机性，并在必要时采用多重插补（Multiple Imputation）或 LMM 内建缺失值建模机制进行处理，确保数据完整性不影响结论可靠性。
4.8 效应量与置信区间报告
所有统计结果除 P 值外，均报告效应量（Cohen’s d、Partial η^2）与 95%置信区间(CI)，以增强结果解释力和比较性。多重结局分析中将控制假阳性率，采用 FDR 或 Bonferroni 方法校正。
4.9 路径机制与探索性分析（如适用）
若研究假设涉及干预机制，将进一步构建结构方程模型（Structural Equation Modeling, SEM)，探索身体功能、生化指标与心肺恢复等变量之间的中介或调节路径，以揭示训练效果产生机制。
5.伦理审查与风险控制
5.1 伦理审批情况
本研究已获得黑龙江省望奎县卫生健康局医学伦理委员会的正式批准，伦理批准编号为 WLJ-2024-032，批准日期为 2024 年 7 月 1 日。研究将严格遵循《赫尔辛基宣言》(2013 年修订版)、世界卫生组织《人体生物医学研究伦理审查操作指南》以及中国国家卫生健康委员会《涉及人的生物医学研究伦理审查办法》等相关国际国内伦理法规实施。
本研究亦已在国际临床试验注册平台 ISRCTN（International Standard Randomised Controlled Trial Number）登记，注册号为：ISRCTN 待补充。
5.2 知情同意程序
所有参与者将在研究正式开始前，接受由研究人员提供的详细说明，内容包括研究目的、方法、干预措施、潜在风险与预期获益、隐私保护政策、参与及退出权利等。研究人员将采用通俗易懂的语言进行面对面解释，确保受试者充分理解，并自愿签署书面知情同意书。此过程将在保证私密性与安全性的独立环境中进行，知情同意书样本文件亦已提交至注册平台备查。
5.3 风险评估与应对机制
本研究为以运动干预为主的生活方式研究，干预方案包括高强度间歇训练(HIIT)与中等强度持续训练（MICT)，均基于国家运动处方标准设计，并由具备资质的体能教练与医务人员全程指导与监测。研究中可能出现的风险主要包括肌肉酸痛、疲劳、训练中跌倒等轻至中度可控性风险。
为保障受试者安全，研究团队制定了以下风险应对机制：

- 干预期间全程配备急救设备与医务人员；
- 每次训练前进行健康筛查与身体状态评估；
- 实施心率、血压等生命体征动态监测；
- 一旦出现不良事件（Adverse Event, AE）或严重不良事件（Serious Adverse Event, SAE)，将立即启动应急响应程序，并按规定上报伦理委员会与相关管理机构；
- 已为本研究投保相关研究责任险，确保参与者在干预过程中如遇身体伤害可获得合理补偿。

5.4 数据隐私与保护策略

所有研究数据将在去标识化处理后存储于受密码保护的数据平台，仅供授权研究人员访问。参与者个人信息将严格保密，未经本人许可不得向第三方披露。本研究数据管理与处理符合《个人信息保护法》《数据安全法》及 WHO 数据共享政策。

研究结束后，研究结果将以匿名化方式公开发表，必要时原始数据将在不侵犯隐私前提下开放获取。

5.5 受试者权益保障

受试者可在研究任一阶段无须说明理由自主退出，其正常医疗权利与待遇不受任何影响。如研究方案在实施过程中发生重大调整或发现新风险信息，将及时通知参与者并更新知情同意。

6.研究数据管理与结果公开计划

6.1 数据管理策略

本研究采集的所有数据，包括人口学特征、基线检测、干预记录、生理指标、问卷反馈和不良事件信息，均通过**电子数据采集系统（EDC）**标准化录入，并实时备份。研究团队设立独立数据管理小组，具体职责如下：

- 统一变量编码与逻辑核查，保障数据质量；
- 数据加密存储、访问权限分级管理；
- 每周定期备份至主研单位科研服务器；
- 核心变量采用双人复核制，增强准确性。

所有纸质原始记录与问卷将妥善编号保存，存档时间不少于 10 年。

6.2 数据所有权与使用声明

研究数据归牡丹江师范学院体育与健康科学学院与庆一大学体育学科联合研究团队共同所有。所有共享数据均已脱敏，禁止擅自复制、传播或用于商业用途。外部单位需提交正式申请并签署数据使用协议（DUA）方可使用。

6.3 数据共享与访问政策

本研究遵循开放科学原则，研究完成后 6 个月内公开数据摘要、分析代码与核心去标识化数据集，支持同行验证与再分析。具体共享方式包括：

- ISRCTN 注册平台：同步发布关键结果摘要；
- 开放数据平台（如 Figshare、Dryad）：提供完整数据集、分析脚本及说明文档，分配 DOI 供引用。

数据访问权限说明如下：

- 汇总数据与结果摘要向公众开放；
- 完整去标识化数据开放给学术研究者，需签署数据使用协议；
- 所有数据严格遵守《中华人民共和国个人信息保护法》与 GDPR 等国际数据保护标准。

6.4 结果公开与传播计划

研究完成后，结果将通过以下方式对外公开：

1. SCI 期刊投稿：计划向《Scientific Reports》《BMJ Open》等国际期刊提交全文；
2. 注册平台同步更新：在 ISRCTN 平台公布主要/次要结局、不良事件和数据摘要；
3. 学术会议报告：参加运动医学与公共健康会议做口头/海报报告；
4. 公众科普传播：撰写简洁通俗报告，通过高校网站、媒体平台传播科学运动知识，增强健康教育效果。

7.项目进度与实施时间表

本研究采用前瞻性、三组平行对照的随机对照试验设计，整个项目周期预定为三年，涵盖干预准备、正式实施、数据整理、结果发布及远期随访等阶段。下表为主要时间节点与任务安排：

7.1 项目主要时间节点安排表

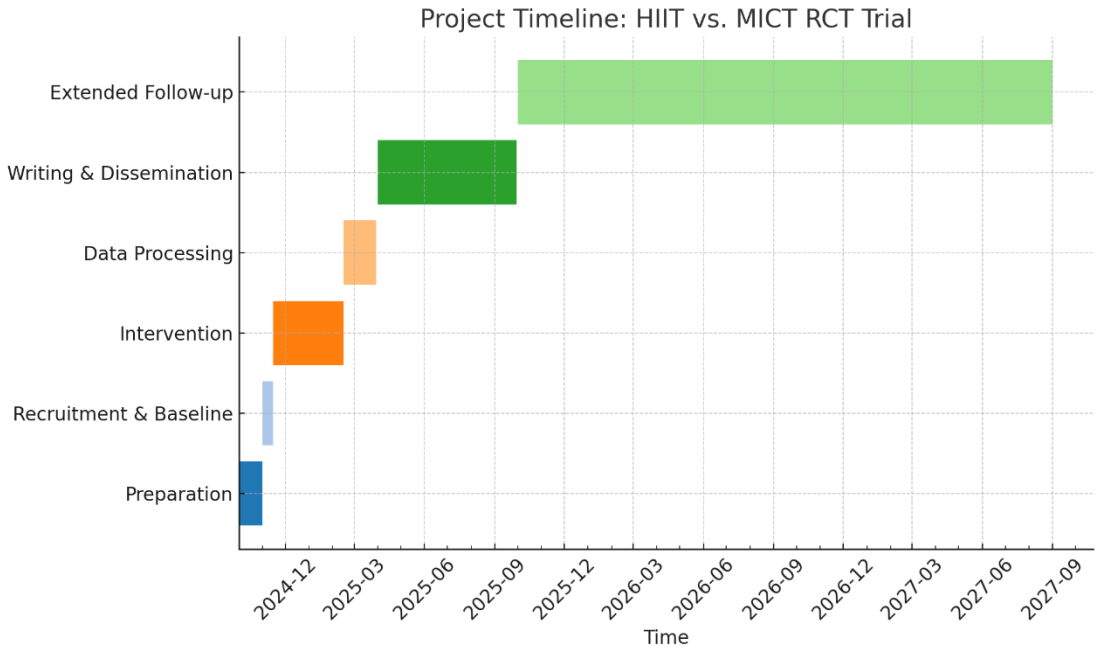
阶段	时间范围	核心任务	负责人/单位
准备阶段	2024年10月1日 — 2024年11月1日	提交伦理申请与注册材料；组建研究团队；研究人员培训；设备校准与问卷预试	第一作者及研究小组
招募与基线测量	2024年11月1日 — 2024年11月15日	通过望奎县社区卫生系统筛选符合标准的三高人群；签署知情同意书；采集基线数据	现场调查团队
干预实施阶段	2024年11月15日 — 2025年2月15日	HIIT组与MICT组分别开展每周3次训练，共持续12周；使用Polar监测训练强度，定期回访；记录依从性与不良事件	干预执行组
数据整理与中期分析	2025年2月15日 — 2025年3月30日	数据双录入、质量核查；完成初步统计分析	数据管理与统计分析组
结果撰写与成果发布	2025年4月 — 2025年9月	撰写学术论文并投稿SCI期刊；完成试验总结报告并提交注册平台；开展成果汇报会	通讯作者及撰稿组
远期随访阶段(探索性)	2025年10月 — 2027年9月	针对部分受试者进行6月/12月生理与生活方式评估；评估干预远期维持效果	跟踪评估组

7.2 时间管理与质量保障机制

为确保研究各阶段高质量推进，设立如下保障机制：

- 月度质控会议机制：每月召开一次项目推进会，审查进度与问题；
- 任务责任矩阵机制：明确每项任务负责人，分工到人；
- 依从性与安全监测机制：使用Polar H10心率带、训练日志、运动感知量表（RPE）监控干预质量；
- 盲法与数据核查机制：数据双录入与第三方抽检审核，保证数据信度；
- 伦理审查与修订机制：若研究计划发生重大调整，将即时报请伦理委员会复审。

本项目时间安排参考既往同类人群干预周期设定，考虑伦理审批、公卫系统合作与受试者日常干预接受度，设定科学、可控的节点节奏。研究全过程将结合电子管理系统与纸质文档双重监管，确保高效执行与合规透明。



8.数据管理与质量控制

本研究将严格遵循数据管理计划（Data Management Plan, DMP）的各项要求，确保数据采集、存储、处理与分析过程的科学性、合规性与可追溯性。

8.1 数据采集与录入

- 所有原始数据由经过培训的研究团队成员采集，包括问卷调查、生理与代谢指标测量、血样分析及运动日志记录；
- 数据采集将采用电子表格（Excel）与 RedCap 数据库双重录入，并实时备份；
- 干预期间的动态数据（如心率、主观疲劳评分 RPE）将通过 Polar H10 心率监测仪和 Polar Flow 平台进行连续记录与导出。

8.2 数据存储与保密机制

- 所有参与者信息将进行去标识化处理，采用唯一编号替代个人身份信息；
- 数据存储于牡丹江师范学院体育健康研究中心内部服务器，配备多重加密、权限设定与自动备份功能；
- 所有数据访问与操作行为均将日志化记录，确保全过程审计追溯；
- 原始数据仅限核心研究人员访问，公开发表仅基于聚合数据。

8.3 数据质量控制流程

- 数据录入采用“双人双录”法（double data entry），并通过逻辑校验程序进行一致性核查；
- 项目组每两周召开一次数据质量评估会议，由统计分析专家与项目负责人联合审核，及时修正缺失值与异常值；
- 数据锁定（data locking）前，完成 100%数据核查与交叉验证，并签署《数据锁定确认书》。

8.4 不良事件记录与上报机制

- 所有不良事件（Adverse Events, AEs）将由研究协调员在现场第一时间记录，并在 24 小时内提交项目负责人；
- 若出现严重不良事件（Serious Adverse Events, SAEs），将立即向伦理委员会通报，并根据情况暂停或调整干预计划；

- 定期向 ISRCTN 注册平台提交进展报告与安全性更新，确保透明公开。

通过全流程的数据管理体系与高标准质量控制措施，本研究确保研究数据的科学性、完整性与安全性，为后续结果发布与数据共享奠定坚实基础。

9. 结果发布与数据共享策略

本研究将按照国际科研诚信与开放科学（Open Science）原则，制定系统的结果发布与数据共享计划，以提升研究透明度、学术价值与社会影响力。

9.1 结果发布计划

- 本研究结果将在研究结束后 6 个月内完成分析，并撰写英文稿件投稿至 SCI 二区及以上水平的国际同行评审期刊；
- 研究成果亦将面向基层公共卫生单位、体育健康干预机构组织线下或线上报告会，促进成果落地转化；
- 所有结果发布将遵循 CONSORT 指南，完整呈现实验设计、流图、数据分析流程与结论；
- 若出现提前中止或结果显著偏离预期的情况，亦将如实报告，确保透明性。

9.2 数据共享政策

- 本研究将根据 ICMJE、ISRCTN 和 Springer Nature 的数据共享政策，向公众开放部分研究数据；
- 可共享的数据集将包括：研究流程图、变量字典、分析代码、去标识化后的主要指标数据（如血压、血脂、HRR 等）；
- 数据将在研究成果正式发表后，上传至 Dryad、Figshare 或机构数据平台，并标明 DOI 链接；
- 数据使用须遵守 CC BY 4.0 协议，用户需注明数据来源并不得用于商业用途。

9.3 知识产权与成果署名

- 本研究所有知识产权归属牡丹江师范学院与庆一大学联合所有；
- 所有署名作者需符合 ICMJE 作者标准，其他贡献者将列入“致谢”部分；
- 研究成果公开前将提交内部审核，确保数据准确性与知识产权保护。

通过系统性的信息发布与数据开放策略，本研究将推动健康促进干预研究的规范化与可持续发展，服务基层公共卫生实践与全球学术交流。

10.项目预算与资金使用计划

预算项目	预算金额（万元）	说明
人员经费	15.0	包括项目负责人、研究助理、数据管理员等人员工资及劳务补贴，项目周期三年，按比例分配。
实验材料费	5.0	涉及采血管、试剂盒、一次性耗材、血液分析相关消耗品等。
设备购置与维护	4.0	心率监测仪（如 Polar H10）购置 3 套，血液分析设备维护和软件升级费用。
数据管理费	3.0	包括电子数据采集系统（EDC）、统计软件授权及服务器租赁费用。
差旅与会议费	3.0	国内外学术会议差旅费、实地调研及合作单位访问所需的交通及住宿费用。
论文发表费	2.5	预计发表 3 篇国际开放获取 SCI 期刊，按每篇约 8000 元人民币开放获取费预算。

培训费	1.0	涵盖专业技能培训、伦理培训及团队能力建设相关费用。
伦理审查费及保险	1.5	包含伦理审查费用和受试者保险费用，用于保障研究安全与合法合规。
其他杂费	0.5	日常办公、资料复印、打印等相关费用。
预算总计	**35.5**	预算总金额为人民币 35.5 万元。

预算说明：

- **人员经费**覆盖项目核心人员的工资与劳务补助，包括项目管理、现场执行及数据分析人员，确保项目顺利推进。
- **实验材料费**依据受试者数量和试验周期，充分保障实验所需物资供应。
- **设备购置与维护**保障运动监测设备和生化分析设备的正常运行与维护。
- **数据管理费**覆盖数据库建设、统计软件购买及技术支持，确保数据安全与分析效率。
- **差旅与会议费**支持团队参加学术交流，促进科研合作与成果传播。
- **论文发表费**基于目前国际 SCI 期刊开放获取标准估算。
- **培训费**确保团队具备必要的专业技能和伦理知识。
- **伦理审查费及保险**保障受试者权益，符合科研伦理规范。
- **其他杂费**满足项目运行中产生的日常支出。

11.研究团队及分工

11.1 研究团队组成

本项目由多所高校与地方医疗卫生机构联合承担，团队成员涵盖项目负责人、联合负责人、现场协调员及技术支持人员。具体成员及所属单位如下：

姓名	职务	主要职责	所属单位
赵永恒	项目负责人	研究设计、项目整体协调、数据分析与成果撰写	庆一大学、河南大学
李忠堂	项目负责人	方案制定、技术指导、跨校协调与进度管理	江苏第二师范学院
马驰	联合负责人	干预实施监督、训练方案优化、现场数据质量控制	牡丹江师范学院
王亚娟	联合负责人	受试者招募、医疗支持、伦理合规及不良事件管理	望奎县卫生健康局、望奎县中医院、望奎县妇幼保健院
高妍	运动指导专家	训练方案制定与运动干预指导	佳木斯大学
刘力萌	数据管理员	数据录入、质量控制与统计协助	牡丹江师范学院
其他成员	现场协调员	现场执行管理、心率监测、依从性跟踪与不良事件记录	牡丹江师范学院

11.2 分工协作机制

- **项目负责人**（赵永恒、李忠堂）负责整体方案设计、跨机构协调及科研成果输出；
- **联合负责人**（马驰、王亚娟）负责干预执行质量保障、现场管理及伦理风险管控；

- **运动指导专家**（高妍）制定运动干预方案，监督训练实施；
- **数据管理员**（刘力萌）负责数据管理与统计分析支持；
- **现场协调员**协助干预执行，监测运动负荷和安全。

11.3 团队合作保障

- 定期召开视频与线下会议，保障信息畅通与问题快速响应；
- 设立任务责任清单，明确分工与时间节点，定期评估项目进度与质量；
- 成立内部质控小组，定期进行数据审核与风险评估，确保研究科学性与合规性。

12.风险管理与应急预案

12.1 风险识别

本研究可能面临的主要风险包括：

- 运动干预过程中可能出现的轻度或中度运动相关不良反应，如肌肉酸痛、疲劳、运动损伤等；
- 受试者依从性不足导致数据缺失或样本量不足；
- 数据采集或管理过程中可能出现的信息录入错误或设备故障；
- 疫情或自然灾害等不可抗力因素对研究进度的影响。

12.2 风险预防措施

针对上述风险，制定以下预防策略：

- 运动干预由专业教练指导，制定个体化训练方案，并设有应急预案和医疗支持；
- 采用详细的受试者招募及随访计划，提高依从性，定期进行电话及面对面沟通；
- 严格执行数据管理规范，实施双人双录、逻辑校验和设备维护；
- 制定灵活的研究时间调整计划，应对突发公共卫生事件或自然灾害。

12.3 应急预案

- 建立应急联络机制，确保突发事件第一时间上报并妥善处理；
- 配备急救设备和训练有素的医护人员，及时应对运动相关意外；
- 设立临时远程数据采集方案，保障疫情期间数据采集连续性；
- 若研究受到严重干扰，将及时通知伦理委员会及注册机构，并评估调整方案。

12.4 风险监控与评估

- 设立风险管理小组，定期评估风险等级与防控效果；
- 所有不良事件均按规定记录，及时分析原因并采取相应措施；
- 定期向伦理委员会提交安全性报告，接受监督检查。

13. 沟通与协调机制

13.1 内部沟通机制

- 项目团队定期召开周例会，汇报研究进展、解决问题及调整方案；
- 采用多种线上协作工具（如邮件、微信群、Zoom 会议等），保障信息及时共享和反馈；
- 设立专项沟通负责人，协调跨单位合作，确保任务分工与进度同步。

13.2 外部协调机制

- 与合作医院、社区卫生服务中心保持密切联系，确保受试者招募和现场干预顺利开展；
- 定期向伦理委员会和资助机构报告项目进展及重大事项；

- 积极参与学术交流活动，扩大项目影响力和合作网络。

13.3 应急沟通预案

- 建立突发事件快速响应通道，确保在发生安全或数据异常时第一时间通知相关人员；
- 设立多层次备份联系人名单，防止关键人员无法联系时影响项目推进；
- 定期组织沟通培训，提升团队成员的协调和应对能力。

14. 项目可行性分析

14.1 研究基础

本课题依托牡丹江师范学院体育与健康科学学院与韩国庆一大学的联合科研平台，拥有成熟的实验室设备、专业的运动监测仪器及丰富的科研经验。团队成员具有多年的高水平运动干预和临床试验操作经验，具备开展本项目的技术与管理能力。

14.2 受试者来源

项目依托望奎县社区卫生系统，受试者来源充足，筛选标准明确，预计可在短时间内完成招募目标，确保样本量满足统计学要求。

14.3 技术保障

配备高精度 **Polar H10** 心率监测设备，配合先进的电子数据采集系统（**EDC**），确保运动干预强度与数据采集的准确性与完整性。

14.4 管理机制

完善的项目管理和质量控制体系，涵盖伦理审批、数据质量、安全监控和团队协调，保障项目科学规范开展。

14.5 预期风险与应对

针对可能的疫情影响、受试者依从性波动及设备故障，项目制定了灵活的应急预案和多渠道沟通方案，确保研究按计划推进。

15. 项目伦理合规声明

本项目严格遵守中华人民共和国相关法律法规及国际伦理规范，确保研究全过程的合法合规与受试者权益保护。

1. 项目已获得黑龙江省望奎县卫生健康局医学伦理委员会批准，伦理编号 **WLJ-2024-032**，遵循《赫尔辛基宣言》及国家伦理审查规定。
2. 研究全程执行知情同意制度，所有受试者均签署书面知情同意书，自愿参与。
3. 研究数据严格保密，采用匿名化处理，符合《中华人民共和国个人信息保护法》及国际通用的数据隐私标准。
4. 项目设立不良事件监测与报告机制，确保及时发现和处理安全风险。
5. 若项目执行过程中发生重大变更，将及时报告伦理委员会，确保持续伦理合规。

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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

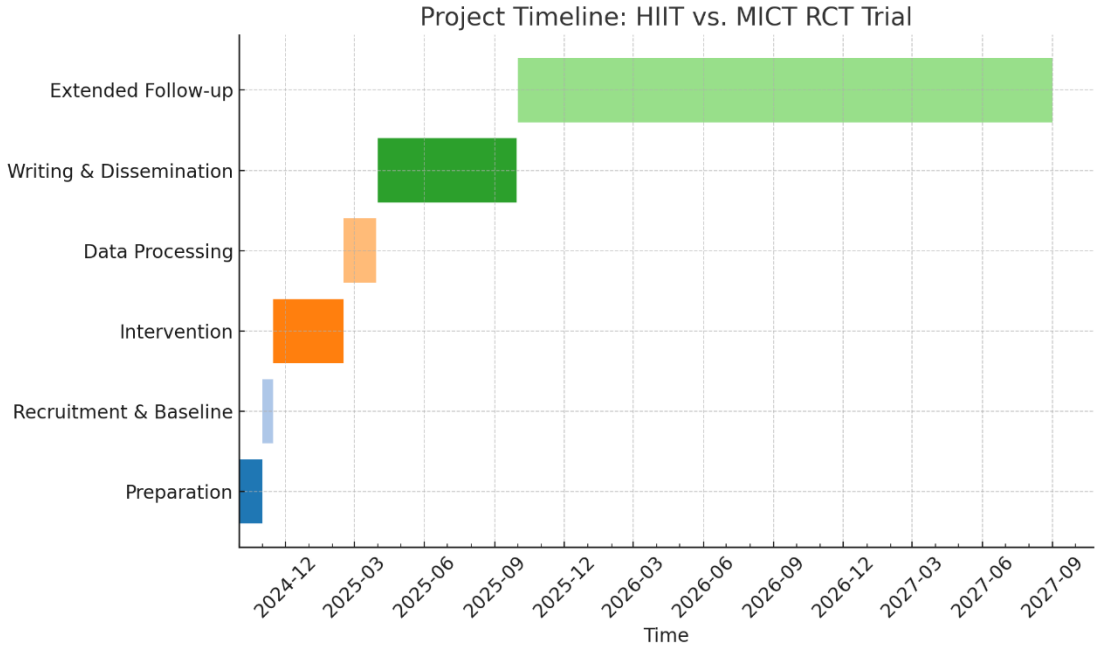
Phase	Timeframe	Core Activities	Responsible Team
		journals; final trial summary report for registry; presentation of results	team
Extended Follow-up (Exploratory)	Oct 2025 – Sep 2027	Conduct 6- and 12-month physiological and behavioral assessments for a subset of participants; evaluate long-term effects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

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