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Chronotype-aligned exercise timing in middle-aged adults at cardiometabolic risk

Submission date	Recruitment status	[_] Prospectively registered
03/02/2026	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
05/02/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/02/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

Contact information

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Study information

Scientific Title
Effects of chronotype-aligned versus chronotype-misaligned aerobic exercise on cardiovascular, metabolic, and sleep outcomes: a randomized controlled trial

Study objectives
To investigate whether aligning exercise timing with chronotype enhances cardiometabolic and sleep-related benefits in sedentary adults with cardiovascular risk factors.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/01/2025, Research ethics committee, The university of Lahore (1-Km Defence Road, near Bhuptian Chowk, Lahore, Lahore, 54000, Pakistan; +92 42 111-865-865; info@uol.edu.pk), ref: REC-UOL-002-01-2025

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Cardiovascular risk factors in sedentary middle-aged adults (40–60 years), including prehypertension, stage 1 hypertension, overweight/obesity, impaired fasting glucose, and family history of premature cardiovascular disease.

Interventions

Participants were randomized using computer-generated permuted blocks of size 4 and 6, stratified by chronotype (morning or evening) and cardiovascular risk level (low, moderate). Block sizes were randomly varied to maintain allocation concealment. Allocation was performed independently using sealed envelopes prepared by staff not involved in outcome assessment.

Chronotype-Aligned Exercise (CAE) Group:
Participants performed moderate-intensity aerobic exercise at a time aligned with their individual chronotype, determined using the Morningness–Eveningness Questionnaire (MEQ).

Morning-type participants exercised in the morning (08:00–11:00)

Evening-type participants exercised in the evening (18:00–21:00)

Chronotype-Misaligned Exercise (CME) Group:
Participants performed the same aerobic exercise protocol at a time not aligned with their chronotype.

Morning-type participants exercised in the evening (18:00–21:00)

Evening-type participants exercised in the morning (08:00–11:00)

Exercise Protocol (Both Groups)

Mode: Brisk walking or treadmill walking

Intensity: Moderate (60–70% of age-predicted maximum heart rate)

Session duration: 40 minutes (5-min warm-up, 30-min aerobic phase, 5-min cool-down)

Frequency: 5 sessions per week

Duration: 12 weeks

Setting: Supervised hospital gym sessions

Monitoring: Heart rate monitored using Polar® H10 sensors

Intervention Type
Behavioural

Primary outcome(s)
1. Systolic and diastolic blood pressure and heart rate variability (RMSSD) were measured using an automated sphygmomanometer, and a 5-minute resting ECG (RMSSD), respectively, at baseline and after 12 weeks of intervention

Key secondary outcome(s))
1. Estimated VO_2 peak and exercise performance (total time and Bruce protocol stage) measured using the Bruce submaximal treadmill protocol with heart-rate monitoring at baseline (Week 0) and after completion of the intervention at Week 12

2. Metabolic markers: Lipid profile (LDL cholesterol), glycemic markers (fasting glucose and HbA1c) measured using standard procedures with fasting blood samples at baseline (Week 0) and after completion of the intervention at Week 12

3. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline (Week 0) and after completion of the intervention at Week 12

4. Exercise adherence measured using supervised attendance logs and the Exercise Adherence Rating Scale (EARS) at baseline (Week 0) and after completion of the intervention at Week 12

Completion date
16/06/2025

Eligibility

Key inclusion criteria
1. Age 40–60 years
2. Sedentary lifestyle (no structured physical activity ≥1 session/week in the past 3 months)
3. At least one cardiovascular risk factor:
4. Prehypertension or stage 1 hypertension
5. Overweight/obesity (BMI ≥ 25 kg/m²)
6. Impaired fasting glucose
7. Family history of premature cardiovascular disease
8. Regular sleep schedules

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
60 years

Sex
All

Total final enrolment
134

Key exclusion criteria
1. Clinically diagnosed cardiovascular or metabolic diseases (e.g., coronary artery disease, diabetes)
2. Night shift workers or irregular sleep schedules
3. Diagnosed sleep disorders (e.g., insomnia, obstructive sleep apnea)
4. Medications affecting cardiovascular or circadian regulation (unless stable ≥6 months)
5. Intermediate chronotype (Morningness-Eveningness Questionnaire score 42–58)

Date of first enrolment
06/01/2025

Date of final enrolment
14/03/2025

Locations

Countries of recruitment
Pakistan

Sponsor information

Organisation
University of Lahore

ROR
https://ror.org/051jrjw38

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			05/02/2026	No	Yes
Protocol file			05/02/2026	No	No
Statistical Analysis Plan			05/02/2026	No	No