Study Protocol and Statistical Analysis Plan

Title: The Effects of Combined Transcranial Direct Current Stimulation and Pneumatic Compression on Selected Recovery Parameters After a 10K Run

NCT Number: Pending

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Objectives and Hypotheses

Research Question:

In this context, the primary research question is:
" How do transcranial direct current stimulation (tDCS), pneumatic compression (PC), and their combined application affect subjective well-being, total quality of recovery (TQR), heart rate variability (HRV), neuromuscular performance (maximal voluntary isometric contraction and vertical jump), and cognitive function (Stroop Test) in master male long-distance runners aged 40–55, immediately before, immediately after a 10-kilometer (10K) run, and following a 20-minute recovery intervention?

Hypotheses:

- **H1:** tDCS application will significantly improve post-run recovery markers, including subjective well-being, TQR, HRV, neuromuscular performance, and cognitive function.
- **H2:** PC application will significantly improve post-run recovery markers, including subjective well-being, TQR, HRV, neuromuscular performance, and cognitive function.
- **H3:** Combined application of tDCS and PC will produce greater improvements in recovery markers compared to either intervention applied individually.

Objective:

The aim of this study is to evaluate the effects of tDCS, PC, and their combined application on physical, physiological, psychological, and cognitive recovery in master male long-distance runners after a 10K run, with the goal of shortening recovery time and preventing performance decline following intensive exercise.

Specific Aims:

- To investigate the effects of tDCS and PC and combined tDCS+PC on post-run muscle fatigue and neuromuscular performance (maximal voluntary isometric contraction and vertical jump).
- To examine changes in subjective well-being and TQR as indicators of psychological recovery.
- To assess cognitive recovery using the Stroop test.
- To analyze physiological responses by evaluating HRV following each intervention.
- To compare the individual and combined contributions of tDCS and PC to overall recovery.

Method

The aim of this study is to investigate the effects of combined tDCS and PC on recovery in master male runners following a 10K run. The study also aims to examine whether these interventions can shorten recovery time and prevent performance decline after prolonged and intense exercise.
This study will be conducted as a randomized, controlled, crossover trial using a mixed experimental design. Each participant will undergo four different recovery protocols in a randomized order, with a one-week interval between sessions. Randomization will be performed using Research Randomizer (https://www.randomizer.org/), assigning participants to one of four sequences (e.g., B–A–D–C). Participants will be identified only by numerical codes to ensure blinding and maintain confidentiality. Each participant will experience all protocols, allowing within-subject comparisons and minimizing order-related bias.

The four recovery protocols are:
(A) tDCS group: transcranial direct current stimulation only
(B) PC group: pneumatic compression only
(C) tDCS + PC group: simultaneous application of both tDCS and PC
(D) Control group: passive rest with no intervention

tDCS and PC interventions represent the independent variables, while dependent variables include WBQ, TQR, HRV, Stroop Test, vertical jump, and MVIC with EMG recordings.

Participants will be 35 male long-distance master runners aged 40–55, residing in Bursa, Turkey, with at least five years of consistent training. They will train five days per week, 90 minutes per day, and must meet aerobic fitness criteria established by the American College of Sports Medicine, completing official 10K race under 50 minutes within last six months and maintain a weekly running volume of 60-80 km. Volunteers will be recruited from the local long-distance running community familiar to the principal investigator, Hilal Oruç Kaya. Participants will be excluded if they have used regular medications within the last six months, consumed stimulants, caffeine, or alcohol within 24 hours prior to testing, smoke, have experienced musculoskeletal injuries in the past six months, are currently undergoing physical therapy, or have neurological conditions such as epilepsy or seizure history, or possess cardiac, brain, or other electronic implants. Additional exclusion criteria include open wounds or dermatological conditions on the head, circulatory disorders such as deep vein thrombosis, peripheral arterial disease, severe varicose veins, or prior exposure to tDCS or PC interventions. Participants may withdraw voluntarily, fail to attend sessions, or be removed if cardiovascular, neurological, or orthopedic complications occur during exercise or interventions, or if they experience excessive discomfort or adverse effects from the tDCS or PC procedures. Written informed consent will be obtained after explaining the study's purpose, procedures, potential risks, and benefits. Sample size was calculated using G*Power 3.1.9.7 for repeated measures ANOVA with within-between interaction, effect size $f = 0.30$, $\alpha = 0.05$, power = 0.80, resulting in $n = 28$. Accounting for potential dropouts, 35 participants will be recruited.

Screening and Familiarization Session:

Participants will undergo anthropometric measurements (weight, body fat, height) using Tanita BC 418 MA and Seca stadiometer. Physical fitness will be evaluated with a 12-minute Cooper Test on a 400 m track under controlled conditions (temperature 20–24°C, relative

humidity 50–70%, wind ≤10 km/h). A 20-minute warm-up including jogging, accelerations, jumps, and stretching will precede testing. Distances will be recorded with a Polar V3 GPS watch.

Participants will also complete a familiarization session with the 10K course, tDCS and PC devices, Stroop Test, MVIC, and vertical jump measurements to ensure procedural understanding.

Experimental Sessions

Pre-run Measurements (T1): Immediately prior to the 10K run, participants will complete the TQR, and the WBQ in the gym. Following this, the Polar Vantage V3 GPS-enabled watch and H10 heart rate strap will be fitted to each participant, and HRV data will be recorded for 5 minutes in a seated position.

After HRV recording, participants will perform the Stroop test under researcher supervision using a computer. Subsequently, vertical jump performance will be assessed. Participants will start from an upright standing position, perform a preliminary downward squat by flexing the knees and hips, and immediately extend the knees and hips to jump vertically. Vertical jump measurements will be performed three times with a 1-minute interval between trials, and the results will be recorded.

Following the jump assessment, participants will be fitted with an EMG device for the MVIC test. EMG signals will be recorded from the Vastus Lateralis, Rectus Femoris, and Vastus Medialis muscles during the test.

10K Run: After Test-1, participants will complete a 10K run on the athletics track at Bursa Uludağ University (BUU). The route begins and ends at the Faculty of Sports Sciences, BUÜ. Participants will have 30 minutes for individual warm-up and preparation.

The run will be performed at 75% intensity, determined using the Karvonen method, based on each participant's maximum heart rate obtained during an on-field Cooper test. Target heart rate zones will be set with a ±5 bpm tolerance. GPS and HRV tracking will be conducted using the Polar Vantage V3 watch. Additionally, perceived exertion will be assessed verbally using the Borg-20 scale at the 5K mark and immediately after completing the run, with responses recorded by the researchers.

Post-run Measurements (T2): Immediately after completing the 10K run, the procedures conducted in Test 1 will be repeated.

Interventions:
Participants will be randomly assigned to one of four protocols:

- **(A) tDCS:** Participants assigned to the tDCS intervention will receive stimulation using the Brain Premier tDCS device. During the application, participants will be positioned in a semi-recumbent posture at approximately 45° recline, and the device will be adjusted accordingly. Anode and cathode electrodes, embedded in 5×5 cm saline-soaked sponge pads, will be placed over the F3 (left dorsolateral prefrontal cortex) and F4 (right dorsolateral prefrontal cortex) locations according to the international 10–20 EEG system. Stimulation will be delivered at a constant current intensity of 2 mA for 20 minutes.

- **(B) Pneumatic Compression (PC):** Participants assigned to the PC intervention will receive lower-limb pneumatic compression using the Normatec device. They will be positioned in a semi-recumbent posture at approximately 45° recline, and the device will be adjusted to match this posture. Compression will last for 20 minute. Specifically, the most distal chamber (cell 1, ankle level) will receive 70 mmHg pulse pressure; the intermediate chambers (cells 2–4) will receive 80 mmHg; and the most proximal chamber (cell 5) will receive 60 mmHg. Each chamber will undergo 30 seconds of pulsed compression followed by 30 seconds of static hold. Chambers will inflate and deflate sequentially from distal to proximal to create a peristaltic compression pattern. This method aims to enhance intramuscular fluid dynamics, promote venous return, and facilitate the removal of metabolic by products.
- **(C) Combined tDCS + PC:** Participants in the combined intervention group will simultaneously receive tDCS and PC for 20 minutes while positioned in a semi-recumbent posture at approximately 45° recline. tDCS will be applied via 5×5 cm saline-soaked sponge electrodes over F3 and F4 regions using the Brain Premier CE-certified device at 2 mA. Electrode contact quality will be monitored via the device interface to ensure safety and adherence to protocol parameters. PC will be applied concurrently using the Normatec device. Distal cell (cell 1) will receive 70 mmHg, intermediate cells (cells 2–4) 80 mmHg, and proximal cell (cell 5) 60 mmHg pulse pressure. Each chamber will follow 30 seconds of pulsed compression and 30 seconds of static hold, proceeding in a distal-to-proximal sequential pattern to create a peristaltic flow. This synchronized intervention aims to provide a holistic recovery effect by targeting both peripheral and central mechanisms of recovery.
- **(D) Control:** Participants in the control group will be positioned in a semi-recumbent posture at approximately 45° recline for 20 minutes without receiving any intervention. During this period, participants will remain passive in a quiet, distraction-free environment. The 45° semi-recumbent posture is consistent with the intervention groups to control for physiological variations arising from body positioning (e.g., blood flow, venous return, postural hemodynamic changes). Active recovery strategies (e.g., walking, stretching) were deliberately excluded to avoid potential confounding effects. This standardized passive rest condition allows for a valid comparison of intervention effects between groups.

Post-intervention Measurements (T3): The procedures conducted in Test 1 will be repeated immediately after the participant completes the assigned intervention protocol.

Outcome Measures:

- Subjective scales: Well-being Questionnaire, Total Quality Recovery
- Heart rate variability (HRV) and GPS
- Cognitive performance via Stroop Test
- Vertical jump height via My Jump app
- MVIC with EMG on quadriceps muscles following SENIAM protocol
- tDCS and PC applied according to standardized protocols

Statistical Analysis

Data will be analyzed with IBM SPSS 29. Normality (Shapiro-Wilk), homogeneity (Levene), and sphericity (Mauchly) will be tested. Two-way repeated measures ANOVA (4 Time × 4 Group) will assess interactions, with Bonferroni post-hoc tests. Effect sizes will be reported using partial eta squared (η_p^2): small (>0.01), medium (>0.06), large (>0.14). Significance threshold $p < 0.05$.

This study will provide comprehensive insight into the effects of tDCS and PC, alone and in combination, on recovery in older endurance athletes, contributing evidence-based recommendations for optimizing performance and minimizing injury risk.