







Protocol

Psychophysiological Data Harmonization for the Sustainability of Outdoor Activities

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Abstract: Prolonged sedentary behavior is considered a risk factor for health throughout the human lifespan. Although outdoor activities, such as walking and hiking, can be effective in reducing sedentary behavior, there is a lack of data harmonization on the psychophysiological characteristics of hiking trails. Therefore, this research protocol aims to provide an innovative and uniform methodology to provide a psychophysiological characterization of hiking. Enrolled subjects will be allocated in groups equally distributed for age, physical activity level (physically active vs. sedentary), and sex (male vs. female). Subjects will perform two treadmill tests in laboratory sessions and two hiking tests in field sessions. The Ruffier test will be performed before each session to assess subjects' exercise capacity. During each session, body mass measurement, cardiometabolic evaluation, heart rate and heart rate variability monitoring, rating of perceived exertion, and physical activity enjoyment rate will be assessed. To measure breath-by-breath ventilation, oxygen consumption, and energy expenditure, subjects will be equipped with a portable gas analyzer during one laboratory session and one field session. Findings from the present study protocol have the potential to fill a gap in assessing hiking-related fitness, promoting physical and mental health, and offering a practical way to evaluate fitness for hiking, encouraging outdoor activity. These findings will have the potential to impact tourism, health, and well-being through outdoor experiences.

Keywords: walking; physical inactivity; sedentary lifestyle; hiking; exercise prescription



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1. Introduction

In recent years, the issue of sustainability has gained attention from the public. A well-known pathway to a sustainable future includes the 17 sustainable development goals, in reference to the United Nations 2030 sustainability agenda [1]. The 17 sustainable development goals are not limited to environmental conservation and economic development, but they also extend to improving the quality of human life. In particular, Sustainable Development Goal (SDG) 3 focuses on ensuring healthy lives and promoting well-being for everyone at all ages [1], emphasizing the critical importance of addressing health-related issues, including the alarming rise in sedentary behavior (SB). SB is defined as any waking behavior characterized by an energy expenditure of 1.5 metabolic equivalent of task (METs) or lower while sitting, reclining, or lying down, such as desk-based office work, driving a car, and watching television [2]. In the 21st century, the rate of a sedentary lifestyle in Italy has reached 35.2% of population, with a tendency to increase [3]. Sedentary lifestyles are considered the fourth leading risk factor for global mortality and are associated with poor health outcomes and deteriorating mental and physical health [2]. The key role of physical activity (PA) in reducing SB is well documented [4], and the beneficial effects of PA in enhancing overall health regardless of age confirm that it may contribute to the

maintenance of general well-being, improving postural control and quality of life in general, as well as having an impact on health maintenance and disease prevention [5]. Moreover, PA is not solely an individual health behavior, but it can positively impact planetary health and sustainable development. The literature shows how engagement in PA relates to the different SDGs and outlines how PA can contribute “to improving malnutrition (SDG 2), health behaviors (SDG 3), education (SDG 4), reducing inequalities (SDG 10), sustainable cities (SDG 12), and peace (SDG 16) and sustainable consumption (SDG 11) and combating climate change (SDG 13)” [1,6,7].

The American College of Sport Medicine (ACSM) and the World Health Organization (WHO) suggest practicing moderate-intensity aerobic PA for at least 150–300 min, higher intensity (vigorous-intensity aerobic PA) for a reduced amount of time (75–150 min), or an equivalent combination of moderate- and vigorous-intensity activity over a 7-day period to have considerable health benefits [2,8]. Moreover, adults should also include strength-based activities involving all major muscle groups on 2 or more days per week at moderate or greater intensity, to provide additional health benefits [2,8]. The suggested amount of activity may be achieved in a single session or accumulated on different days. Thus, PA guidelines specify that time and intensity are important factors to consider for the accurate estimation of activity and to better investigate the health-related effects of PA [9].

Exercise intensity, used to monitor PA, is usually defined as the energy expenditure per minute to perform a certain task [10]. Standard variables used to prescribe exercise intensity are percentages of maximal heart rate (HR_{max}) and maximal oxygen uptake (VO_{2max}) as well as calculated sub-fractions of these variables such as heart rate (HR) reserve (HRR), VO₂ reserve (VO_{2R}), and the peak oxygen uptake (VO_{2peak}). HR_{max} is the highest HR a subject can achieve during an effort to the point of exhaustion, being an important physiological variable for assessing maximal exertion during an exercise. Although it is widely used for prescribing exercise intensity in PA, Tanaka et al. suggested relative HR, normalized for the theoretical HR_{max}, as one of the effective methods for monitoring HR pattern to classify PA [11,12]. VO_{2max} is the maximum amount of oxygen a person can intake, and it is expressed as liters/min as an absolute value or in milliliters/kg/min as a relative value. VO_{2max} is an accurate measurement of cardio-respiratory fitness and is usually measured during a maximal or submaximal incremental test [13]. In addition to HR or VO₂ monitoring, fatigue and satisfaction from the activity are also useful parameters in prescribing exercise [14]. In fact, while exercise intensity was initially determined using relative percentages, recent approaches have emphasized exercise prescription based on threshold and psychophysiological variables such as the assessment of perceived exertion and the talk test. The talk test is commonly used as a surrogate for maximal testing exercises due to its simplicity, validity, and easy determination of exercise intensity in several populations. It is defined as a subjective measure of exercise intensity which has come to be accepted as an alternative to objective measures (%HRR, %VO_{2max}) for exercise evaluation and prescription [12,15]. The rating of perceived exertion (RPE), defined as an alternative method to more technological and physiological measurements, holding some insights into accumulated fatigue is a widely accepted method for measuring intensity during exercise [16]. Enjoyment, described as the process of experiencing joy and reflecting general feelings of pleasure, fun, and happiness, has emerged as an important factor for PA levels, representing a good indicator for PA participation [17,18].

In the context of promoting PA and understanding its importance in countering sedentary behavior, it is essential to consider the positive associations between PA and various physical fitness variables [19]. Physical fitness is defined as a set of measurable health- and skill-related attributes or components, which encompass cardiorespiratory fitness, muscular strength, flexibility, balance, agility, and walking speed [20]. These components play a critical role in determining one’s overall well-being and health status. To gauge these facets of physical fitness accurately, various testing protocols have been established, including the Balke protocol [21], Ruffier test [22], and the talk test [12,15]. A comprehensive assessment of physical fitness parameters provides valuable insights into

the holistic impact of physical activity and outdoor activities like walking on individual health and well-being [23]. Moreover, to better understand the influence of hiking on sedentary behavior, a focus on the relationship between PA and external and environmental factors is also needed.

Over the past few centuries, both PA and various external or environmental factors, including diet, geographical location, availability of green spaces, and climate conditions, have been undergoing significant changes. These changes have contributed to a rising prevalence of non-communicable diseases [24]. Furthermore, there is an increasing body of evidence suggesting that natural environments hold significant potential for preventing diseases and promoting better health [25]. Promoting outdoor PA, especially walking, not only holds substantial potential to enhance human well-being but also aligns with SDG 13, which emphasizes the mitigation of climate change and its associated consequences. By promoting outdoor activities and reducing reliance on environmentally detrimental transportation methods, we can directly ameliorate our environmental footprint and reduce harmful emissions, thereby actively contributing to climate action [1].

Therefore, considering the positive impact of regular outdoor activities on well-being and their role in supporting climate action, promoting outdoor walking could be a good strategy to reduce SB [5,26,27]. Research on how exactly and to what extent outdoor activities can promote human health is currently limited, although increasing evidence regarding the positive effects of outdoor activities on physical [28,29], mental [28–30], and social [28,31] health exists. Moreover, studies have demonstrated that participants, especially sedentary ones, are more encouraged to start practicing outdoor activities than indoor ones [32]. The exposure to nature while exercising can play a crucial role in physiological [23,33–35], psychological [23,36], biochemical [37], and social [36] levels, giving green exercise a useful role in primary and secondary prevention of disease. In addition, the engagement of sedentary individuals in green exercise could be an effective vehicle in driving behavioral change by improving adherence to PA [38].

Among outdoor activities, walking is considered the most accessible for people of all abilities in terms of the limited skills and equipment needed, as well as the ability for individuals to choose the terrain difficulty and the speed at which they walk [39,40]. It is the most natural and common form of PA and can be practiced from childhood to old age, and it is effective in maintaining and improving adherence to an exercise program. Walking significantly enhances human immune function, reduces the levels of stress hormones such as adrenaline and noradrenaline, increases vigor and decreases anxiety, depression, fatigue, confusion, and anger [2,8]. Additionally, walking demonstrates favorable outcomes in reducing both systolic and diastolic blood pressure, establishing it as a protective element in the management and prevention of non-communicable diseases, including sarcopenia, type 2 diabetes, fractures, musculoskeletal disorders, and pulmonary diseases [2,8].

The practice of an outdoor activity such as walking dates back to the 16th and 17th centuries, with the start of the practice of the Via Lauretana, St. Francis Way, and the Camino de Santiago. These were initially used for religious purposes only, although people also started to walk in pre-established hikes for tourism [41]. Culture and tourism have always been inextricably linked. Cultural sights, attractions, and events provide an important motivation for travel, and travel itself generates culture. It is only in recent decades that the link between culture and tourism has been more specifically identified as cultural tourism [42], during which the visitor's essential motivation is to learn, discover, experience, and consume the tangible and intangible cultural attractions/products in a touristic destination, adding all the walking benefits. These attractions/products relate to a set of distinctive material, intellectual, spiritual, and emotional features of a society that encompasses arts and architecture, historical, cultural, and culinary heritage, literature, music, creative industries, and living cultures with their lifestyles, value systems, beliefs, and traditions [43,44].

With the growth of the phenomenon, there is the need to develop hikes based on the “walkability” principle [45]. To make hiking accessible for everyone, intrinsic and extrinsic

factors should be identified, as follows: (1) the presence of necessary services within a walking distance; (2) the attractiveness of the route in terms of architecture and social context; (3) the level of comfort and safety of the route. Although outdoor activities are known to be the starting point of hiking, there is limited research describing hiking utility, the amount and intensity of walking, and motives for using it [46]. Along with the increase in outdoor activities, the development of different types of hikes and their characterization in terms of distance, time, slope, and degree of difficulty is needed. Therefore, the primary aim of this study protocol is to provide a specific methodology to evaluate hiking difficulty in relation to the energy demand based on (1) metabolic equivalent, (2) HRR, (3) fatigue, and (4) satisfaction while practicing pre-established hikes. The secondary aim is to classify the identified hikes as easy, intermediate, or difficult, based on the primary results and physical fitness parameters.

2. Materials and Methods

2.1. Study Design

The research protocol, designed as a cross-sectional study, was approved on 14 April 2022 by the Institutional Review Board of the Department of Human Sciences, Society, and Health of the University of Cassino and Lazio Meridionale (approval number 6663) in accordance with the Declaration of Helsinki. Participants will receive comprehensive information about the research protocol and will have the option to discontinue their involvement in the study at any point, for any reason, without incurring any adverse consequences. They will also be required to provide their informed consent before participating in the study. In accordance with Regulation (EU) 2016/679 of the European Parliament and the Council, dated 27 April 2016, regarding the protection of individuals in relation to the processing and sharing of personal data, while repealing Directive 95/46/EC (known as the General Data Protection Regulation or GDPR), we will guarantee the security and confidentiality of personal data. In particular, each participant will be assigned a unique identification code to ensure anonymity, and the data will be exclusively utilized for statistical purposes. Throughout each phase of the study, the study supervisors will oversee all activities. While physical assessments and the outdoor activity program are generally associated with low personal risk, any adverse events will be observed and documented by the research team.

2.2. Participants

Participants of different ages will be recruited by means of flyers, posters, brochures, advertisements on social networks, and word-of-mouth. The inclusion criteria for the study will be the absence of the following conditions: the presence or a known history of neuromuscular disorders, uncontrolled heart failure or hypertension, multiple sclerosis, significant cognitive impairment, acute rheumatoid arthritis, cardiovascular diseases, use of antihypertensive medication, pulmonary dysfunction, uncontrolled metabolic diseases such as diabetes, a prior diagnosis of osteoporosis, or any injury sustained within the past six months. As suggested by previous studies [47,48], ensuring adherence to PA involves incorporating various approaches known for their effectiveness in promoting PA adherence. These approaches encompass preparing participants with informational, behavioral, social, and environmental aspects. Participants will be informed about the benefits of hiking and the associated cardiovascular changes, in addition to the provision of evaluations within the protocol that can offer insights into participants' current health or fitness levels, thereby encouraging active participation. Furthermore, the study integrates group activity programs and interaction with personal trainers or healthcare professionals to provide opportunities for social engagement that enhances participation. Additionally, it emphasizes the provision of easy access to facilities that promote PA, such as parks, trails, and footpaths, as a fundamental aspect of promoting adherence.

The Italian short version (7 items) of the International Physical Activity Questionnaire (IPAQ) will be administered to assess individual PA levels [49]. According to the IPAQ

Scoring Protocol, participants will be categorized into two groups: the Sedentary Group, including individuals reporting no activity or reporting some activity but not enough to meet the 'Minimally Active' category, and the Physically Active Group, including participants meeting at least one of the 'Minimally Active' criteria: 3 or more days of vigorous activity for at least 20 min per day; 5 or more days of moderate-intensity activity or walking for at least 30 min per day; or 5 or more days of any combination of walking, moderate-intensity, or vigorous-intensity activities achieving a minimum of at least 600 MET·min·week⁻¹.

2.3. Procedures

2.3.1. Preliminary Evaluation

Characteristics and PA levels of participants will be assessed one week prior to the initial session. Body weight and height will be determined using a precision instrument that combines a scale and stadiometer accurate to 0.1 kg and 0.1 cm (Seca, model 709, Vogel & Halke, Hamburg, Germany). Additionally, the body mass index (BMI) will be calculated [50]. Waist circumference will be measured at the narrowest point in the abdominal region. In cases where the narrowest point is not clearly distinguishable, the measurement will be taken midway between the 10th rib and the crest of the pelvic bone. Hip circumference will be measured horizontally at the most prominent points on the posterior, lateral, and anterior sides. The waist-to-hip ratio (WHR) will be subsequently computed. Theoretical HR_{max} will be calculated for each participant, according to the equation: 220-years (age) [51]. Subsequently, participants will have to perform four different testing procedures to complete the study, including two laboratory tests on a treadmill and two hikes. There will be at least 48 h of rest between each testing day.

During the laboratory testing sessions, all participants will undergo two maximal incremental tests on a treadmill. These tests will include the modified Balke-type protocol with a portable gas analyzer and a modified Balke-type protocol without a portable gas analyzer [21]. The modified Balke-type protocol will be conducted on a treadmill, with the initial speed individually chosen to match a comfortable walking pace during the first 2-min stage. Subsequently, each stage will have increments in workload achieved by increasing the treadmill grade by 2%. During the modified Balke-type protocol without a portable gas analyzer, participants will be asked to recite a standard paragraph composed of 40 words during the final 30 s of each exercise stage [52]. Participants will recite the paragraph out loud, and after completing the recitation, they will be asked the question, 'Can you speak comfortably?' with three possible answers: 'yes' (positive), 'not sure' (equivocal), or 'no' (negative). At the end of each stage, participants will also be asked to provide their RPE by placing a value on the Borg scale (0–10) [53]. The test will be stopped if participants reach voluntary exhaustion. The modified Balke-type protocol with a portable gas analyzer will serve to measure VO₂, VO_{2peak}, predict VO_{2max}, and ventilatory thresholds and to calculate energy costs in METs. Respiratory metabolism will be assessed using the VO₂ Master Pro analyzer (version 1.1.1) during the modified Balke-type protocol. The analyzer will be connected to a facemask (7450 V2 series, Hans Rudolph, Shawnee, KS, USA) through the large (L) user piece, with a ventilation display range of 25–250 L/min and an accurate ventilation range of 40–220 L/min. The Flow Sensor will be calibrated using a 3-L syringe. The VO₂ Master will automatically calibrate gas concentrations, ambient temperature, humidity, and barometric pressure to the ambient air upon activation. After gas calibration, the VO₂ Master will be attached to participants, and they will be instructed to take 10–15 deep breaths for flowmeter calibration. The VO₂ Master will transmit data via Bluetooth® to a personal phone, and the GPS Smartwatch (Forerunner® 245 Music, Garmin, Olathe, KS, USA) will be synchronized with the VO₂ Master mobile application for data storage and downloads. Temperature and humidity levels in the laboratory will be recorded during the experimental procedures to ensure consistency between laboratory testing sessions and hikes. These conditions will be maintained within the range of 26–32 °C and 40–65% humidity.

Following the preliminary evaluation, the participants will be divided in groups according to their age, PA level, physical characteristics, cardiorespiratory fitness, and sex.

2.3.2. Route Identification

Hike locations will be determined based on physical-environmental factors and historical-cultural documentation. The main activities will revolve around identifying sites of historical, cultural, and environmental significance, as well as analyzing the connecting and access routes through cartographic analysis. This analysis will involve inspecting potential routes to assess their condition and accessibility. The identification of hikes includes evaluating various parameters such as duration, total length, slope, and energy demand as per the Club Alpino Italiano (CAI) Manual [54]. Subsequently, the trails will be classified into three hiking difficulty levels: easy, intermediate, or difficult, each associated with specific colors (Table 1).

Table 1. Evaluation criteria for classifying hikes based on hiking difficulty.

Hiking Difficulty	Duration	Total Length	Slope	Energy Demand	Color Scale *
Easy	≤2 h	≤500 m	≤100 m	Low	Green path
Intermediate	2–5 h	500–1000 m	100–500 m	Medium	Sky blue path
Difficult	≥5 h	≥1000 m	≥500 m	High	Red path

* Overview of the trail color scale (green, sky blue, and red) and the descriptions associated with each level of difficulty (easy, intermediate, and difficult) provided by the Club Alpino Italiano (CAI) Manual.

2.3.3. Hike Evaluation and Data Collection

At the start of each hiking session, comprehensive data on participant characteristics and weather conditions will be collected to ensure the reliability and accuracy of the study's findings. Prior to, during, and after the hiking activities, participants will undergo an evaluation of various physiological and subjective parameters.

Body Mass Measurement: Participants' body mass (in kilograms) will be measured before and after each hike, accounting for any additional weight, such as water and clothing. The additional weight should not exceed 10% of the individual's baseline body mass, as assessed during a preliminary session.

Cardiometabolic Evaluation: Blood pressure (in millimeters of mercury, mmHg) and blood glucose levels (in milligrams per deciliter, mg/dL) will be measured at various time points: 15 min before the hike, at the conclusion of the hike, and at 15 and 30 min post-hike. This thorough evaluation will allow for the assessment of acute cardiometabolic responses.

Ruffier Test (With and Without Talking): Participants will engage in a standardized protocol that involves performing 30 squats in 45 s [22]. Subsequently, HR will be recorded, and then after a one-minute recovery period, HR will be measured again. The resulting data will be used to calculate the Ruffier index, which serves as an important indicator of participants' effort tolerance, recovery capacity, and cardiovascular response [55]. In the adapted "Talk Test" variation, participants will be further tasked with reciting a standard paragraph of approximately 40 words aloud during the squat exercise. Post-exercise, participants will be asked to express their comfort level with speech, allowing for three possible responses: "yes" (indicating a positive ability to speak comfortably), "not sure" (equivocal), and "no" (indicating discomfort). Additionally, participants will subjectively rate their RPE. This comprehensive assessment of cardiovascular and physiological response will provide insights into participants' fitness levels and their ability to tolerate and recover from physical exertion. The Ruffier test (with and without talking) will be randomly conducted 15 min before each session, contributing to a thorough evaluation of participants' physical fitness and performance capacity.

HR and HR Variability (HRV) Monitoring: Participants will wear Garmin HRM-Pro™ (Garmin International, Kansas City, MO, USA) HR monitors throughout the hiking sessions. These compact modules, measuring 29.4 × 51.4 × 8.5 mm and weighing 59 g, utilize both ANT+® connectivity and Bluetooth® low-energy technology. Positioned just

below the xiphoid process on the chest, they will record real-time HR data and track the coordinates of the hiking route, sampling at a rate of 1 Hz [56,57]. Additionally, continuous HRV monitoring will provide insights into the autonomic nervous system's response to exercise [58].

Spatiotemporal Data Collection: To gather spatiotemporal data during the hike, participants will be equipped with a GPS Smartwatch, specifically the Garmin Forerunner® 245 Music. This smartwatch, measuring 42.3 mm in width, 12.2 mm in thickness, and weighing 38.5 g, will be worn on the left wrist. It will display real-time HR and VO₂ data, which are directly acquired from the Garmin HRM-Pro™ HR belt and VO₂ Master Pro analyzer [57].

Gas Analysis: To measure breath-by-breath ventilation (in liters per minute, L/min), VO₂ (in milliliters per kilogram per minute, mL/kg/min), and energy expenditure (in kilocalories, kcal) for each participant during the hike, a portable gas analyzer (VO₂ Master Pro analyzer, The VO₂ Master Pro, version 1.1.1.) will be utilized. The unit and mask have a combined weight of 0.32 kg and are powered by a single battery. The analyzer will be linked to a Hans Rudolph 7450 V2 over-nose mask using a mask adapter referred to as a 'user piece.' This adapter, which is essentially a plastic tube connecting the analyzer and the mask, includes an exhaust hole for the inflow and outflow of air. To ensure stability, soft headgear will be employed to secure the unit onto the participants' faces. The medium (M) user piece will be used with a ventilation display range of 15–180 L/min and an accurate range of 30–160 L/min. A single-use filter, replaced after each use following the manufacturer's guidelines, will be installed between the user piece and the analyzer. The VO₂ Master unit is equipped with a passive, pump-less gas sampling system, a galvanic fuel cell O₂ sensor, and a differential pressure flow sensor (information obtained through personal communications with the manufacturer). The Flow Sensor will be calibrated using a 3-L syringe. Upon activation, the VO₂ Master will undergo automatic calibration for gas concentrations, ambient temperature, humidity, and barometric pressure. After gas calibration, the VO₂ Master will be affixed to the participants, who will be instructed to perform 10–15 deep breaths to facilitate flowmeter calibration. Data will be transmitted via Bluetooth® to personal smartphones, tablets, and the GPS Smartwatch Garmin Forerunner® 245 Music. These devices are equipped with the VO₂ Master mobile application for the storage and retrieval of data [59,60].

RPE: Participants will subjectively evaluate their effort on a scale from 0 to 10 (AU) before the hike, every 10 min during the hike, at the end of the hike, and 30 min following its conclusion.

Session RPE (sRPE): At the end of each hike, sRPE will be calculated by multiplying the overall hike's RPE by the duration of the hike activity (AU). Participants will be asked, "How intense was your hike today?" and rate their effort on a scale ranging from 0 to 10 (AU). This measurement will not only provide insight into the overall hike intensity but also accumulated fatigue [61,62].

Physical Activity Enjoyment Scale (PACES): After completing the hike, participants will fill out the PACES questionnaire to assess their individual satisfaction with the activity. This questionnaire comprises five items evaluated on a seven-point Likert scale (AU). For items 1 and 4, the score ranges from 1 (completely agree) to 7 (completely disagree), while for items 2, 3, and 5, the score ranges from 1 (completely disagree) to 7 (completely agree) [18].

All devices will be utilized in strict accordance with the manufacturers' guidelines. Participants will be equipped with the necessary devices for the entire duration of the hiking sessions. All data will be collected using specialized formats, which can be accessed via personal phones, tablets, and paper sheets. Each participant will complete the same hike at least two times to ensure data reliability and validity.

2.3.4. Statistical Analysis

In this section, we present the statistical methods and analyses that will be applied to investigate the effects of hiking on various physiological and psychological parameters.

Descriptive Statistics

To gain an initial understanding of the data, descriptive statistics will be used to summarize the characteristics of both the dependent and independent variables. This includes calculating measures such as means, standard deviations (SD), medians, ranges, and percentages for the relevant variables. To calculate means, SD, medians, and ranges for several variables, we will aim for a representative sample. Assuming a medium effect size, a sample size of at least 100 participants should be adequate. Furthermore, since this section involves no hypothesis testing, traditional power calculations will not be applied.

For example, we will provide the following:

- The mean and SD of HR during hiking, as it is a critical physiological response variable (e.g., mean HR during hiking = 125 bpm, SD = 10 bpm).
- Frequency of occurrence expressed in percentage for hikes classified by difficulty to understand the distribution of hikes (e.g., easy hikes: 40%, intermediate hikes: 30%, difficult hikes: 30%).
- Median and range for participants' age and fitness level to capture the central tendency and variability in these demographics (e.g., median age = 35 years, range = 25–50 years).
- Histograms for PACES scores to visualize the distribution of psychological responses.

Normality Testing

Normality assumptions will be assessed to determine whether the data follow a normal distribution. This will guide the selection of appropriate statistical tests. Normality testing does not require specific sample sizes. Similar to descriptive statistics, power calculations are not typically conducted for normality testing. Example:

- The Shapiro–Wilk test will be applied to HR data during hiking to assess their normality (Shapiro–Wilk p -value < 0.05, indicating non-normal distribution).

Internal Consistency and Reliability Analysis

To evaluate the consistency and reliability of the measurements, relevant statistical methods will be applied. This may include Cronbach's alpha for scales or test–retest reliability for repeated measures (e.g., Cronbach's alpha for the PACES questionnaire = 0.85, indicating high internal consistency). The sample size required will depend on the number of items in the scale and the desired level of reliability. For example, for a Cronbach's alpha of 0.85, a sample size of 150 participants may be sufficient. Moreover, power calculations will not be conducted for internal consistency analysis.

Validity Assessment

The validity of measurements will also be examined. For example, we may assess the concurrent validity of the Ruffier "Talk Test" index by comparing it to other accepted measures of cardiovascular response (e.g., Ruffier "Talk Test" index shows a strong correlation with peak HR achieved during hiking, $r = 0.75$). Assuming a moderate correlation (e.g., $r = 0.5$), a sample size of around 80 participants may be needed to detect this correlation with adequate power.

Correlation Analysis

We will explore relationships between variables using various correlation techniques. For correlation analysis, the required sample size depends on the expected effect size and significance level. Assuming a moderate effect size (e.g., $r = 0.4$) and a significance level of 0.05, a sample size of approximately 100 participants might be necessary. A power of 0.80 can be achieved with 100 participants. Example:

- Pearson's correlation will be used to investigate the relationship between hike duration (independent variable) and HR (dependent variable) during the hikes (e.g., Pearson's $r = 0.42$, $p < 0.001$, indicating a moderate positive correlation).

- Spearman's rank correlation will be applied to understand the association between the hike difficulty (independent variable) and HR variability (dependent variable) during the hikes (e.g., Spearman's $\rho = 0.08$, $p = 0.320$, indicating no significant correlation).

Multilevel Mixed-Effect Generalized Linear Model Analysis

To investigate differences in hike classifications and characteristics between groups (e.g., sex, age groups, fitness levels), multilevel mixed-effect generalized linear models will be employed. For instance, we could find that middle-aged participants will be significantly more likely to classify hikes as difficult compared to their younger and older counterparts, after accounting for individual variations within each age group. The multilevel structure will make it possible to examine how these factors influence the likelihood of hike classifications, considering the nested nature of the data with participants belonging to different age groups. This analysis could provide information about how sex, age, and fitness level interact to affect perceptions of hike difficulty among the study participants. The sample size required for multilevel mixed-effect model highly depends on the complexity of the analysis and the anticipated effect sizes. Assuming moderate effects, a sample size of at least 300 participants, considering the nested structure of the data, may be necessary. Furthermore, with the mentioned parameters, a power of 0.80 can be achieved with around 300 participants.

Generalized Estimating Equation Regression Models

Participants' baseline characteristics, fitness levels, hike features (e.g., slope, length), and hike performance (e.g., speed, total time) will be modeled using generalized estimating equation regression models. For example, a strong positive association between baseline fitness levels and hike performance could be identified, indicating that participants with higher fitness levels completed the hikes more quickly. This modeling approach considers the correlated nature of the data, where multiple measurements will be taken from each participant across different hikes, making it ideal for examining the complex interaction between various factors and their influence on hike-related outcomes. Assuming moderate effects, a sample size of around 200 participants may be required with a power of 0.80.

Survival Analysis

For time-dependent variables, such as the time it takes to complete hikes, we will employ Kaplan–Meier survival curves. For instance, this method will be used to assess the time taken by the participants to complete different hikes within the study. Kaplan–Meier curves will make it possible to visualize and analyze the probability of event occurrence over time, such as the likelihood of hike completion at various time points. By employing Kaplan–Meier survival curves, we could have information on how participants' completion times vary across different hikes by highlighting the factors that influence hike duration. For survival analysis, the sample size depends on the expected hazard rates and time-to-event data. Assuming a moderate hazard rate, a sample size of at least 150 participants might be necessary, with a power of 0.80.

Nonlinear Regression Models

Nonlinear regression models will be used to investigate complex relationships. The sample size required for nonlinear regression models depends on the complexity of the model and the expected effect sizes. Assuming moderate effects, a sample size of around 120 participants may be needed (power of 0.80). Example:

- A nonlinear regression model will be applied to assess the relationship between HR (dependent variable) and independent variables such as age and hike duration (e.g., $HR = 160 - 0.5 \times \text{age} + 5 \times \text{hike duration} - 0.2 \times \text{age} \times \text{hike duration}$).

Confounding Variable Management

The statistical analysis encompasses a wide range of methods to ensure the robustness and reliability of the expected research findings. The sample size will range from 100 to 300 participants across different analyses, and, to address other sources of variability, participants will be carefully screened for confounding variables, such as pre-existing medical conditions, medication usage, psychological factors, etc., which might impact the results. Detailed information will be collected on these potential confounders and will be incorporated as covariates in relevant statistical models.

Statistical Software

STATA 18 (StataCorp LP, College Station, TX, USA) will be used for all the statistical analyses mentioned above. By implementing this comprehensive statistical analysis plan, we aim to provide a deeper understanding of the effects of hiking on physiological and psychological responses, while accounting for various factors and relationships within the dataset.

3. Discussion

This study protocol presents a comprehensive approach to evaluating hiking difficulty in relation to energy demand and fitness parameters, with a focus on both physiological and psychological aspects. The primary aims of this research involve assessing metabolic equivalent, relative HR, fatigue, and satisfaction value during pre-established hikes. Additionally, it seeks to classify these hikes into easy, intermediate, or difficult categories based on the obtained data.

The protocol places a strong emphasis on outdoor hiking, which offers numerous advantages. It is an inclusive activity accessible to people of all abilities, requiring minimal skills and equipment, and allowing individuals to set their own walking pace [63]. The synergistic effect of walking in a natural environment makes hiking an ideal pursuit for enhancing overall health and well-being. Regular exposure to nature enriches one's lifestyle by providing an array of benefits, including the inhalation of air rich in beneficial organic compounds, engagement in PA, rejuvenation, and the facilitation of social bonds. Among the benefits of hiking is its impact on cardiovascular health. Hiking demands sustained physical effort, effectively increasing HR and fortifying the cardiovascular system. Engaging in regular hiking can lead to a lowering of blood pressure and enhanced blood circulation [64,65]. These cardiovascular advantages translate into a reduced risk of heart disease, stroke, and other related conditions. Furthermore, hiking serves as an excellent form of aerobic exercise, facilitating weight management and boosting metabolic health. As hikers traverse diverse terrains and elevations, their energy expenditure can significantly increase. Over time, this may result in weight loss or weight maintenance, depending on the duration and intensity of the hike. Additionally, consistent aerobic exercise, such as hiking, has been associated with improved insulin sensitivity, better glucose control, and a reduced risk of developing type 2 diabetes [2,8]. Beyond the physical advantages, hiking also provides a host of mental health benefits. Engaging in outdoor physical activities has been associated with reduced symptoms of stress, anxiety, and depression. The combination of PA, exposure to natural surroundings, and fresh air contributes to a sense of well-being and relaxation.

Hiking provides an opportunity to disconnect from the demands of everyday life and immerse oneself in the beauty of nature, fostering mindfulness and mental revitalization. In modern urban settings, where sedentary lifestyles have become the norm, hiking offers a much-needed respite. Prolonged periods of inactivity, extended periods of sitting, and excessive screen time can result in both physical and mental exhaustion. Hiking offers a rejuvenating solution, inspiring people to be active, inhale fresh air, and connect with the natural world. It offers a shift in pace and an opportunity to reconnect with the senses, offering a break from the monotony of indoor living. Walking and hiking represent cost-effective and accessible forms of exercise suitable for individuals of all ages and abilities [39,66,67].

They are widely regarded as the most inclusive activities, given the minimal requirements in terms of skill and equipment, along with the freedom for individuals to select the terrain difficulty and their preferred walking speed. Research has shown that individuals with disabilities, who are also at an increased risk of experiencing depression, may benefit from engaging in outdoor recreational activities, potentially reducing that risk [67,68]. Hiking is also considered a good strategy for stimulating social interaction and for providing benefits in terms of plasticity (e.g., advanced motor fitness, including coordination, balance, and agility) among children [39]. Therefore, encouraging individuals to engage in green sustainable tourism and health-focused holidays is a key aspect of this study. By providing easily accessible fitness tests that guide participants towards suitable hiking practices, the study protocol contributes to reducing the risk of overexertion. This proactive approach aims to lower the incidence of cardiovascular events during hiking. By promoting awareness of individual fitness levels and providing personalized hiking recommendations, in line with Goal 3 of the 2030 Agenda for Sustainable Development, which aims to ensure a healthy life and promote well-being for all at every age. Furthermore, it contributes to the broader goals of fostering sustainable tourism that takes into consideration both environmental and health aspects [1].

The practical applications of this study protocol are many, as it combines physiological and psychological assessments and the promotion of outdoor activities. The comprehensive evaluation of hiking difficulty and its potential impacts can benefit various stakeholders:

- For individuals interested in hiking, the study protocol provides insights into their fitness levels and helps them understand the difficulty of specific hiking routes. By offering personalized recommendations, it allows hikers to make informed choices and to enjoy their outdoor experiences while minimizing health risks. Moreover, it encourages people to incorporate more outdoor activities into their lives, contributing to overall well-being.
- The tourism industry can use the findings of this study protocol to promote green tourism and health-focused holidays. By guiding travelers toward suitable hiking options based on their fitness levels, tour operators can enhance the overall experience and ensure the safety of their clients. The health sector can benefit from the data by promoting hiking as a cost-effective and accessible means of improving physical and mental health.
- The research community can use the methods outlined in this protocol to further investigate the impact of outdoor activities on various health parameters. The data can be used to develop evidence-based policies and guidelines for promoting outdoor and hiking activities. It can also inform future research on the physiological and psychological effects of spending time in nature.
- Fitness trainers, coaches, and health professionals can incorporate the findings of this study into their practice. By understanding the unique demands of hiking and the benefits it offers, they can provide targeted recommendations to their clients. The data can be used to tailor fitness and training programs, ensuring that individuals are adequately prepared for hiking adventures.

4. Conclusions

This study addresses a gap in the assessment of hiking-specific exercise capacities and offers a holistic approach to promoting both physical and mental health. By providing a valid and practical method for evaluating fitness levels in the context of hiking, it encourages individuals to embrace outdoor activities and gain the numerous benefits they offer. Findings from this research have the potential to influence tourism, health, and fitness practices, and contribute to the broader goal of enhancing well-being through outdoor experiences. We anticipate that the initial concrete outcomes of our study may manifest in the domain of cardiometabolic evaluations, including the measurement of blood pressure and blood glucose levels at various time points during hiking. These initial tangible outcomes in the realm of cardiometabolic assessments may serve as a foundation

for subsequent investigations into the enhancement of physiological parameters such as HR, HRV, and VO₂. This comprehensive evaluation will facilitate the examination of acute cardiometabolic responses, with a focus on the impact of the cardiometabolic aspect of the study.

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